ORAL ARGUMENT NOT YET SCHEDULED

NO. 18-5004

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Plaintiffs-Appellants,

v.

ALEX M. AZAR II, in his official capacity, *et al.*,
Defendants-Appellees,

On Appeal from a Final Judgment of the
U.S. District Court for the District of Columbia,
(Honorable Rudolph Contreras)

BRIEF OF PLAINTIFFS-APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1)(A), Appellants American Hospital Association ("AHA"), Association of American Medical Colleges ("AAMC"), America's Essential Hospitals ("AEH"), Eastern Maine Healthcare Systems ("EMHS"), Henry Ford Health System ("Henry Ford") and Fletcher Hospital, Inc., d/b/a/ Park Ridge Health ("Park Ridge") state as follows:

(1) Parties and *Amici*.

AHA, AAMC, AEH, EMHS, Henry Ford, and Park Ridge were Plaintiffs before the District Court and are Appellants in this Court.

Eric D. Hargan, in his official capacity as the then-Acting Secretary of Health and Human Services, and the Department of Health and Human Services were Defendants before the District Court. Alex M. Azar II, in his official capacity as the Secretary of Health and Human Services, and HHS are Appellees in this Court.

Before the District Court, the following 32 state and regional hospital associations submitted a brief as amici curiae:

Arkansas Hospital Association, California Hospital Association, Colorado Hospital Association, Georgia Hospital Association, Illinois Health and Hospital Association, Kansas Hospital Association, Louisiana Hospital Association, Maine Hospital Association, Massachusetts Health and Hospital Association, Michigan

Health and Hospital Association, Minnesota Hospital Association, Mississippi Hospital Association, Missouri Hospital Association, New Hampshire Hospital Association, New Jersey Hospital Association, New Mexico Hospital Association, Healthcare Association of New York State, Greater New York Hospital Association, Iroquois Healthcare Association, Rochester Regional Healthcare Association, Suburban Hospital Alliance of New York State, Western New York Healthcare Association, North Carolina Hospital Association, Ohio Hospital Association, Oregon Association of Hospitals and Health Systems, Hospital and Healthsystem Association of Pennsylvania, South Dakota Association of Healthcare Organizations, Tennessee Hospital Association, Texas Hospital Association, Virginia Hospital and Healthcare Association, West Virginia Hospital Association, and Wisconsin Hospital Association.

(2) Rulings Under Review

Appellants seek review of the District Court's order and opinion issued December 29, 2017, in *American Hospital Association v. Hargan*, No. 1:17-CV-02447-RC (D.D.C.) JA527-43. *See* 2017 U.S. Dist. LEXIS 213027 (Dec. 29, 2017).

(3) Related Cases

Appellants are not aware of any case related to this appeal.

/s/ Carlos T. Angulo
Carlos T. Angulo
Attorney for Plaintiffs-Appellants

CORPORATE DISCLOSURE STATEMENT

Pursuant to D.C. Circuit Rule 26.1, Appellants AHA, AAMC, AEH, EMHS, Henry Ford, and Park Ridge state as follows:

Appellant AHA is not-for-profit association headquartered in Washington, D.C. It represents and serves nearly 5,000 hospitals, healthcare systems, and networks, plus 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, health systems, and other related organizations that are accountable to the community and committed to health improvement.

Appellant AAMC is not-for-profit association headquartered in Washington, D.C. Its membership consists of all 149 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. AAMC is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research.

Appellant AEH is non-for-profit association headquartered in Washington, D.C. It represents 325 hospital members that are vital to their communities, providing primary care through trauma care, disaster response, health professional training, research, public health programs, and other services. AEH is a champion

for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable.

Appellant EMHS is a not-for-profit integrated health care system headquartered in Brewer, Maine. The system provides a broad range of health care and related services in Northern, Eastern and Southern Maine through its subsidiaries and affiliated entities, including to poor and vulnerable persons in those communities.

Appellant Henry Ford is a not-for-profit health care system headquartered in Detroit, Michigan. The system provides a broad range of health care and related services to the people of southeastern and southcentral Michigan, including poor and vulnerable persons in those communities.

Appellant Park Ridge is a not-for-profit health care system headquartered in Hendersonville, North Carolina. It is a member of the Adventist Health System, a faith-based not-for-profit health care system that provides health care services to communities in nine states. Park Ridge in particular provides health care and related services at 30 locations across Henderson, Buncombe, and Haywood Counties in North Carolina, including poor and vulnerable persons in those communities.

No publicly held corporation has a 10 percent or greater ownership interest in any Appellant.

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GLOSSARY

HHS	U.S. Department of Health and Human Services
340B	Section 340B of the Public Health Service Act (42 U.S.C. § 256b)
AHA	Plaintiff-Appellant American Hospital Association
AAMC	Plaintiff-Appellant Association of American Medical Colleges
AEH	Plaintiff-Appellant America's Essential Hospitals
EMHS	Plaintiff-Appellant Eastern Maine Health Systems
ASP	Average Sales Price
OPPS	Outpatient Prospective Payment System
CMS	Centers for Medicare and Medicaid Services (division of HHS)
MedPAC	Medicare Payment Advisory Commission
HRSA	Health Resources Services Administration (division of HHS)
GAO	U.S. Government Accountability Office

STATEMENT OF JURISDICTION

This is an appeal from the District Court's December 29, 2017 order dismissing Plaintiffs-Appellants' complaint and denying as moot their motion for preliminary injunction seeking to suspend a portion of the Final Rule published at 82 Fed. Reg. 52,356 (Nov. 13, 2017). Plaintiffs filed a timely notice of appeal on January 9, 2018. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1291 and 1292(a)(1).

LIST OF STATUTES AND REGULATIONS

The pertinent statutes and regulations are:

- 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-(II)
- 42 U.S.C. § 1395*l*(t)(14)(E)
- 42 U.S.C. § 405(g)
- 42 C.F.R. § 405.1063
- 82 Fed. Reg. 52,356, 52,493-52,511 (Nov. 13, 2017)

These statutes and regulations are reprinted in the addendum to this brief.

INTRODUCTION

Three hospital trade associations (the "Association Plaintiffs")[1] and three hospital systems (the "Hospital Plaintiffs")[2] (collectively, "Plaintiffs") seek to enjoin a regulation issued in November 2017 by the Defendant Department of Health and Human Services ("HHS"). The regulation reduces by nearly 30% Medicare payments to certain public and non-profit hospitals for outpatient drugs purchased by those hospitals under section 340B of the Public Health Service Act ("the 340B Program"). The 340B Program helps hospitals and clinics that serve a disproportionate share of persons unable to pay their medical bills to provide critical healthcare programs and services to their communities, including underserved populations in those communities. The part of the regulation Plaintiffs challenge became effective on January 1, 2018, and unless enjoined will reduce reimbursements to 340B hospitals by $1.6 billion annually. The regulation is causing irreparable injury to the Hospital Plaintiffs by jeopardizing essential programs and services provided to their communities and the vulnerable, poor and

[1] The associations are the American Hospital Association ("AHA"), the Association of American Medical Colleges ("AAMC"), and America's Essential Hospitals ("AEH").

[2] The hospital systems are Eastern Maine Healthcare Systems ("EMHS"), Henry Ford Health System ("Henry Ford") and Fletcher Hospital, Inc., d/b/a/ Park Ridge Health ("Park Ridge").

other underserved populations, such as oncology, dialysis, and immediate stroke treatment services.

Although the District Court dismissed this case on the ground that Plaintiffs had not "presented" their claim to HHS as required by the Social Security Act, in fact Plaintiffs did so in extensive comments supporting their claim that the proposed regulation was unlawful – a claim the Secretary expressly addressed and rejected. This was the only meaningful forum for presenting Plaintiffs' position because once HHS issued the final regulation, no agency official could give Plaintiffs relief from the new reimbursement rate.

On the merits, the Secretary's near-30% rate reduction reflects an improper exercise of his statutory rate-setting authority. Under that authority, HHS must base the rate on acquisition costs if it has certain data specifically identified in the statute. If it lacks that data, the statute provides that the reimbursement rate is the average sales price of the drug ("ASP") plus 6% to account for overhead and related costs – a rate the statute authorizes the Secretary to "adjust[] as necessary for purposes of this paragraph." Here HHS acknowledged that it lacked the data required to use acquisition cost, but attempted to end-run the statutory requirement by adopting an acquisition-cost based rate in the guise of an "adjustment" to the ASP plus 6% statutory rate. The result of the new methodology was not an "adjustment" of anything; it was a near-30% cut in reimbursements for 340B

hospitals based on improper reliance on acquisition cost. Moreover the Secretary's authority to adjust the ASP or overhead cannot be used to make significant changes to the 340B Program, which is not part of the OPPS system and therefore not the proper subject of an "adjustment as necessary" under that system.

ISSUES PRESENTED FOR REVIEW

1. Did Plaintiffs satisfy the jurisdictional presentment and exhaustion requirements of the Social Security Act where: (1) they submitted detailed comments to a proposed regulation challenging, as a matter of law, HHS's statutory authority to adopt a near-30% reduction for Medicare 340B drug reimbursements for most hospitals participating in the 340B Program; (2) HHS explicitly addressed and rejected Plaintiffs' legal challenge and adopted a final, binding regulation incorporating the challenged rate; and (3) Plaintiffs could not and cannot obtain relief anywhere in the administrative process from operation of the illegal regulation because it is binding on all agency decision-makers?

2. If the District Court erred in dismissing Plaintiffs' complaint, should this Court enter a preliminary injunction suspending further application of the challenged rate reduction pending resolution of this litigation?

STATEMENT OF THE CASE

I. STATUTORY FRAMEWORK

A. The Outpatient Prospective Payment System

The Medicare drug reimbursements at issue are authorized by the Outpatient Prospective Payment System ("OPPS") adopted by Congress in 1997 and implemented by HHS through its Centers for Medicare and Medicaid Services ("CMS"). Through the OPPS, which CMS updates annually, CMS determines Medicare reimbursement rates for hospital outpatient services. The part of the OPPS that is relevant here, 42 U.S.C. § 1395*l*(t)(14), was enacted by Congress in 2003. It requires CMS to set Medicare rates for outpatient drugs that are used and reimbursed separately and are not bundled with outpatient services. This statutory framework provides precise direction to guide CMS's rate-setting authority starting in 2006.[3]

Under the statute, the rate-setting methodology CMS may use depends on the information available to it. Under Subclause (I) of section 1395*l*(t)(14)(A)(iii), CMS *must* set rates based on drugs' actual acquisition costs *if, but only if,* it possesses the acquisition cost data specifically identified in the statute. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) (requiring the use of "hospital acquisition cost survey data

[3] The statute set forth different rates for these outpatient drugs for 2004 and 2005 that are not relevant here. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(i), (ii) (setting 2004 and 2005 rates, respectively).

under [§ 1395*l*(t)(14)(D)]"). It is undisputed that CMS has never had this data. Where, as here, the specified acquisition cost data are not available, Subclause II requires CMS to use a mandatory default rate based on average sales price ("ASP"). 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). That rate is ASP plus 6%. *Id.* (referring to 42 U.S.C. § 1395w-3a, which sets the payment rate at 106% of "the volume-weighted average of the average sales prices" for drugs and biologics). Subclause II also provides that this ASP plus 6% default rate may be "calculated and adjusted [by HHS] as necessary for purposes of this paragraph." *Id.* The meaning and limits of this "adjustment" authority and its limits are central in this case.

The term "adjust" also appears in the OPPS drug reimbursement provisions where Congress specifies that post-2006 rate determinations under Subclause I or Subclause II are "subject to subparagraph (E)." 42 U.S.C. § 1395*l*(t)(14)(A)(iii). That subparagraph directs the Medicare Payment Advisory Commission ("MedPAC")[4] to report on "adjustment" of payment rates to "take into account overhead and related expenses." 42 U.S.C. § 1395*l*(t)(14)(E)(i). It also authorizes

[4] MedPAC is an independent federal commission comprised of experts in the financing and delivery of healthcare services that advises Congress on issues affecting the administration of the Medicare program. *See* About MedPAC, http://www.medpac.gov/-about-medpac- (last visited Feb. 13, 2018).

HHS to "adjust" the rates "to take into account" any recommendations made in this report regarding these expenses. 42 U.S.C. § 1395*l*(t)(14)(E)(ii).

From 2006-2011, CMS applied a reimbursement formula of ASP plus a small fixed percentage, generally 4-6%. *See* 77 Fed. Reg. 68,210, 68,383-68,386 (Nov. 15, 2012). CMS's variations from "ASP plus 6%" were generally intended to reflect overhead costs for providing the drugs. *Id.* In 2012, CMS formally adopted the Subclause II default rate of ASP plus 6%, acknowledging the "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost" and expressing concern that deviating from the default rate "may not appropriately account for average acquisition and pharmacy overhead cost . . . ." *Id*. at 68,386. From 2012 until its adoption of the near-30% rate reduction at issue in this case, CMS consistently applied the ASP plus 6% statutory rate.

B. The 340B Program

Congress created the 340B Program in 1992 to provide certain hospitals and federally-funded clinics servicing low-income patients (under the statute, "covered entities") with outpatient drug discounts comparable to those available to state Medicaid agencies. Under the 340B Program, private prescription drug manufacturers, as a condition of having their outpatient drugs covered through Medicaid, are required to offer 340B hospitals and clinics outpatient drugs at or below an applicable, discounted, statutorily-determined ceiling price. Section

340B of the Public Health Service Act, 42 U.S.C. § 256b(a)(1). Drugs purchased under the 340B Program include drugs that are reimbursed under the OPPS outpatient drug reimbursement system.

Congress enacted the 340B Program "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. NO. 102-384(II), at 12 (1992); *see* OPPS Rule, 82 Fed. Reg. at 52,493 & n.18 (acknowledging this legislative intent and quoting House Report). As explained by the Health Resources and Services Administration ("HRSA"), the HHS agency responsible for administering the 340B Program, the Program furthers this legislative purpose by "lower[ing] the cost of acquiring covered outpatient drugs" from drug manufacturers, thereby generating additional resources from "health insurance reimbursements" − including reimbursements under Medicare − that are "maintained or not reduced as much as the 340B discounts or rebates."[5] In other words, under the Program, 340B hospitals receive insurance reimbursements, including from Medicare, that exceed the discounted price paid by these hospitals to drug manufacturers. These increased resources, in turn, enable 340B hospitals

[5] HRSA, HEMOPHILIA TREATMENT CENTER MANUAL FOR PARTICIPATING IN THE DRUG PRICING PROGRAM ESTABLISHED BY SECTION 340B OF THE PUBLIC HEALTH SERVICE ACT 14 (July 2005) ("2005 HRSA Manual") (emphasis added), https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/hemophiliatreatmentcenter340bmanual.pdf.

to deliver programs and services to serve their communities, including vulnerable populations in those communities.

Since the 340B Program was first implemented, and consistent with the statutory design, 340B hospitals and clinics have retained savings generated by the Program. Recognizing the importance of financial flexibility to the operation of covered entities, Congress did not specify how funds generated through the Program must be used, *see* 42 U.S.C. § 256b, although it anticipated that participation in the Program would enable 340B hospitals and clinics to provide additional healthcare services to communities with vulnerable populations. A 2011 report from the U.S. Government Accountability Office ("GAO") found that this is exactly what happened and that covered entities have used the additional resources to provide critical healthcare services to communities with underserved populations that could not otherwise afford these services − for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services.[6]

Recognizing the value of the 340B Program, Congress has increased the categories of "covered entities" over time. Originally, "covered entities" included federally-funded health centers and clinics providing services such as family

[6] U.S. Gov't Accountability Off., GAO-11-836, MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT 17-18 (2011), http://www.gao.gov/assets/330/323702.pdf.

planning, AIDS intervention, and hemophilia treatment, as well as public and certain not-for-profit hospitals serving a large proportion of low-income or uninsured populations. H.R. REP. NO. 102-384(II), at 13; 42 U.S.C. §§ 256b(a)(4)(A)-(L). In 2010, as a part of the Affordable Care Act, Congress expanded "covered entities" to include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. 42 U.S.C. § 256b(a)(4)(M)-(O).

II. PROCEDURAL HISTORY

A. The Proposed Rule

On July 13, 2017, CMS issued its annual Proposed OPPS Rule for Calendar Year 2018. 82 Fed. Reg. 33,558 (July 20, 2017). CMS proposed changing the reimbursement rate for 340B hospitals for outpatient drugs whose reimbursement is not bundled with medical procedures from the longstanding rate of ASP plus 6% to ASP minus 22.5% – a 28.5 percentage point reduction.[7] *Id.* at 33,634. The Proposed Rule retained the ASP plus 6% rate for separately payable outpatient drugs purchased by non-340B hospitals (and drugs purchased by 340B hospitals outside the 340B Program).

[7] Because the baseline is 106% (ASP plus 6%), the 28.5 percentage point decrease (from "plus 6%" to "minus 22.5%") is a 27% decrease in the payment rate (28.5/106).

CMS based its targeted rate change on MedPAC estimates that 340B hospitals "receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS]," 82 Fed. Reg. at 33,632 (internal quotation omitted), concluding that an ASP minus 22.5% rate "better represents the average acquisition cost for these drugs and biologicals." *Id.* at 33,634. CMS acknowledged, however, that it (and MedPAC) lacked the data required under the statute to permit the use of acquisition cost as the measurement for reimbursement under Subclause I of the statute. *E.g.*, *id.* (noting that "the confidentiality of ceiling and subceiling prices limits our ability to precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug"). Instead, relying on MedPAC average acquisition cost estimates, CMS invoked HHS's authority under Subclause II to "adjust" the ASP plus 6% rate "as necessary for purposes of this paragraph." 82 Fed. Reg. at 33,634. In other words, although CMS was not allowed under the statute to use average acquisition cost to set the rate, it effectively adopted the MedPAC acquisition cost estimates in the guise of an alleged "adjustment" to the ASP plus 6% default rate. Far from adjusting the ASP rate, HHS used MedPAC's acquisition cost estimates to effect an unprecedented, near-30% cut to the reimbursement rate.

CMS justified its rate reduction on policy grounds, stating – inaccurately– that the 340B Program was responsible for "unnecessary utilization and potential

overutilization of separately payable drugs"[8] (*id.* at 33,633) and that, because of the "inextricable link" between the Medicare payment rate and Medicare beneficiaries' 20% cost-sharing obligation, lowering the rate would "allow Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program."[9] *Id.* at 33,634.

CMS proposed this near-30% reduction without consulting the Advisory Panel on Hospital Outpatient Payment, even though the Medicare law requires

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[8] CMS relied on a 2015 GAO study, *see* 82 Fed. Reg. at 52,494-52,495, but failed to mention that HHS's response to the study questioned the study's methodology and its characterization of "spending on [340B drugs] as 'more . . . than necessary to treat Medicare Part B beneficiaries.'" HHS pointed out that the GAO study "did not examine any patient differences in terms of outcomes or quality" and did not sufficiently account for the health status of the populations served by 340B hospitals. U.S. Gov't Accountability Off., GAO-15-442, MEDICARE PART B DRUGS: ACTION NEEDED TO REDUCE FINANCIAL INCENTIVES TO PRESCRIBE 340B DRUGS AT PARTICIPATING HOSPITALS 38 (June 2015) ("2015 GAO Report"), https://www.gao.gov/assets/680/670676.pdf (reproducing HHS response). Indeed, an analysis of the cumulative payment for Part B drugs ranked by percentage of total drug payments shows that 340B and non-340B hospitals utilize the same drugs at the same rates, and that the skyrocketing cost of pharmaceuticals is the main driver of Part B drug expenditure increases. JA364-67 (AHA comments); *see also* JA394-97 (AAMC comments); JA144-45 (AEH comments); JA183 (Adventist/Park Ridge comments).

[9] Most Medicare beneficiaries have supplemental coverage (including Medicaid for those with the lowest incomes) that reduce or entirely cover their copayments, limiting the potential benefit from any copayment reduction. The Final Rule may cause some beneficiaries increases in out-of-pocket costs for other non-drug OPPS services. JA364 (AHA comments); JA143-44 (AEH comments); JA172 (Henry Ford comments).

such consultation with respect to matters relating to payment rates. 42 U.S.C. § 1395*l*(t)(9)(A). Indeed, when that Advisory Panel reviewed the rate change at its annual meeting in August 2017, after the proposed rule had been issued, it advised CMS not to adopt the change, recommending instead that CMS collect additional data "on the potential impact of revising the payment rate," including the "potential impact on 340B hospitals."[10]

Numerous stakeholders − including Plaintiffs − submitted comments opposing the Proposed Rule. JA353-89 (AHA comments); JA391-418 (AAMC comments); JA135-65 (AEH comments); JA167-69 (EMHS comments); JA171-79 (Henry Ford comments); JA181-90 (Adventist/Park Ridge[11] comments). These comments addressed the incorrectness of CMS's policy justifications for the rate reduction[12] and the devastating impact of the reduction on 340B covered entities' ability to provide critical healthcare programs to their communities, including

[10] CMS, Advisory Panel on Hospital Outpatient Payment: Recommendations 2 (Aug. 21, 2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2017-08-21-Panel-Recommendations.pdf.

[11] Park Ridge is a member of the Adventist system.

[12] *E.g.*, JA364-69 (AHA comments); JA393-97 (AAMC comments); JA144-46 (AEH comments); JA172 (Henry Ford comments); JA182-83 (Adventist/Park Ridge comments).

underserved patients.[13] These comments also presented detailed arguments that HHS lacked statutory authority to adopt the proposed reduction because:

- The proposed reduction was an impermissible departure from the ASP plus 6% statutory default rate under Subclause II of section 1395*l*(t)(14)(A)(iii);
- The proposed reduction improperly relied on acquisition costs of 340B drugs despite CMS's acknowledgment that it lacked the data required under Subclause I of section 1395*l*(t)(14)(A)(iii) in order for CMS to base the reimbursement rate on acquisition cost; and
- The proposed reduction severely undermined the 340B Program and was inconsistent with Congress's purposes in enacting that Program.

E.g., JA358-63 (AHA comments); JA405-13 (attached memorandum to AAMC comments); JA137-41 (AEH comments); JA172-73 (Henry Ford comments); JA182-83 (Adventist/Park Ridge comments).

B. The Final Rule

On November 1, 2017, CMS adopted the near-30% reduction as part of the Final OPPS Rule, applying it to 340B hospitals other than certain rural 340B hospitals. 82 Fed. Reg. 52,356, 52,493-52,511 (Nov. 13, 2017). In its Final Rule, CMS increased to $1.6 billion its estimate of the reduction's total impact on 340B hospitals. *Id.* at 52,623.

[13] *E.g.*, JA361-64 (AHA comments); JA392-93 (AAMC comments); JA142-44 (AEH comments); JA167-68 (EMHS comments); JA171-72 (Henry Ford comments); JA182-83 (Adventist/Park Ridge comments).

CMS defended its legal authority to adopt the rate reduction and expressly rejected the arguments to the contrary made in Plaintiffs' comments. HHS devoted five pages of its 13-page response on the rate reduction issue to explain why it had the statutory authority Plaintiffs claimed it lacked. As in the Proposed Rule, CMS acknowledged it lacked the statutorily required acquisition cost data needed to trigger the use of the Subclause I acquisition cost methodology (*id.* at 52,501), but asserted it had "broad discretion" (*id.* at 52,499) under the Subclause II sales price methodology to "calculate and adjust rates as necessary in the absence of acquisition cost." *Id.* at 52,499, 52,501. Tellingly, however, CMS acknowledged that its purpose in adopting the rate reduction was to "better align [payments to hospitals for 340B drugs] *with hospital acquisition costs*." *Id.* at 52,498 (emphasis added). CMS also reiterated its policy arguments for the reduction, claiming that the 340B Program had led to increased drug utilization and costs and that the reduction would lessen financial burdens on Medicare beneficiaries. *Id.*

C. Proceedings Below

On November 13, 2017, the day the final OPPS Rule was published in the Federal Register, the Association Plaintiffs and Hospital Plaintiffs filed this case against the Appellees HHS and its then-Acting Secretary (hereafter, "the Government"). Plaintiffs' claim was that the near-30% rate reduction exceeded HHS' statutory authority – the same claim presented by Plaintiffs and others

during the rulemaking process and expressly rejected by HHS in the Final Rule. *E.g.*, JA19-21 (Compl. ¶¶ 44-49). The complaint sought a declaratory judgment that the reduction was "an unlawful exercise of [the Government's'] authority" and an order directing HHS to apply the ASP plus 6% statutory default rate to 340B hospitals in 2018. JA21-22. Plaintiffs simultaneously filed a motion for a preliminary injunction suspending the rate reduction before its January 1, 2018, effective date. JA25-53. The motion asserted that Plaintiffs satisfied each of the four factors courts generally consider in connection with requests for interim relief. *See* JA39.

The Government moved to dismiss, arguing that Plaintiffs' claim was precluded from judicial review, that Plaintiffs' claim was unreviewable under the Administrative Procedure Act, and that the court lacked subject matter jurisdiction because Plaintiffs had not yet (1) presented their claim to the agency or (2) exhausted administrative remedies, as required by the Social Security Act, 42 U.S.C. § 405(g) (Section 405(g)). JA243-44. The Government also argued that Plaintiffs failed to state a claim. Several of these arguments relied on the Government's position that its rate reduction was a proper exercise of its sales price adjustment authority under Subclause II. *See* JA245-59.

Opposing Plaintiffs' motion for preliminary injunction, the Government argued that Plaintiffs had not satisfied any of the four preliminary injunction

requirements, including that Plaintiffs had not demonstrated a likelihood of success on the merits. *See* JA259-65.

On December 29, 2017, after an earlier hearing, the District Court dismissed Plaintiffs' complaint. The court addressed only presentment under Section 405(g) of the Social Security Act, holding that Plaintiffs had not met this requirement because they had not "yet presented any specific claim for reimbursement to the Secretary upon which the Secretary might make a final decision." JA537. The District Court rejected Plaintiffs' argument that submission of detailed comments during rulemaking proceedings met the presentment requirement because in its view those comments did not involve a "concrete" claim for reimbursement, JA538, although there was no dispute below about the mandate within HHS that the Final Rule's reimbursement reduction be accepted as lawful and automatically applied to reimbursement claims. *See* 42 C.F.R. § 405.1063(a). The Court then denied the preliminary injunction motion as moot.

D. The Hospital Plaintiffs' Post-Dismissal Claims for Reimbursement.

The near-30% rate reduction went into effect as scheduled on January 1, 2018. Since then, all of the three Hospital Plaintiffs (and other 340B hospitals) have submitted reimbursement claims subject to the new ASP minus 22.5% rate, and two Hospital Plaintiffs have been paid according to this rate pursuant to determinations by Medicare Administrative Contractors, who are responsible for

initial claims determinations. *See* 42 C.F.R. § 405.922. Having received these reimbursements in the amounts required by the regulation they are challenging, one of the Hospital Plaintiffs has sought redetermination by the Medicare contractors on the ground that the payments were based on an unlawful reimbursement rate, for the reasons set forth in the comments rejected by HHS during the rulemaking process. The other two Hospital Plaintiffs will seek redetermination of their claims. This is the process that CMS regulations outline for the review of a payment (42 C.F.R. § 405.942(a)), and the Medicare Administrative Contractor has 60 calendar days from the date of receipt to decide the request. 42 C.F.R. § 405.950(a).

Once CMS adopts a reimbursement rate by regulation, the Agency and its contractors are required to apply that rate, notwithstanding any claim of illegality. *See* 42 C.F.R. § 405.1063(a). CMS regulations provide for further review of reimbursement decisions by "Qualified Independent Contractors" and Administrative Law Judges. 42 C.F.R. §§ 405.970(a), 405.990(a)-(b). But at these review stages as well, which in the aggregate can take several months, the decision-makers must apply the new regulation and have no authority to consider whether it exceeds HHS's statutory authority as a matter of law.

The Association Plaintiffs have also sent a letter to HHS challenging, as they did in their comments, the legality of the reduced rate. The letter requests that the

Secretary and CMS Administrator direct contractors to expedite review of the Hospital Plaintiffs' claims for reimbursement since they raise a purely legal issue which HHS cannot address while the regulation challenged here remains in effect.

SUMMARY OF ARGUMENT

I. The District Court's dismissal of the complaint on the ground that Plaintiffs had not presented a claim to HHS as required by section 405(g) of the Social Security Act was contrary to Circuit precedent. In *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010), this Court held that a letter from plaintiffs' counsel to the Commissioner of the Social Security Administration challenging as a violation of statutory authority the agency's procedures governing recovery of mistaken Medicare overpayments satisfied the section 405(g) presentment requirement. That ruling was consistent with *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976), which held that a Social Security recipient satisfied the presentment requirement when she completed an agency questionnaire and sent a letter to the agency contesting termination of benefits, but did not file a more formal challenge to the termination. *Action Alliance* and *Mathews* make clear that, contrary to the District Court's conclusion in this case, presentment can be achieved without resort to formal agency claims administration processes. The District Court declined to follow this Court's presentment holding in *Action Alliance* on the ground that the presentment issue was not fully briefed by the

parties in that case. That was not an appropriate reason to disregard the decision and in any event was incorrect because the issue in fact had been fully briefed during an earlier phase of the litigation.

Plaintiffs submitted comments during rulemaking proceedings directly challenging HHS's statutory authority to reduce Medicare reimbursements for 340B drugs by nearly 30%. As was true for the letter submitted in *Action Alliance* explaining the legal basis of the claims in that case, Plaintiffs' comments here fulfilled the purposes of the presentment requirement. These purposes are to "assur[e] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). Plaintiffs' comments during rulemaking proceedings afforded HHS an opportunity to consider their claim, and in fact HHS considered and explicitly rejected Plaintiffs' claim when it adopted the Final Rule. The rulemaking process was Plaintiffs' *only* opportunity to obtain relief, and HHS's *only* opportunity to address Plaintiffs' claims. Once the rule became final on January 1, 2018, it became binding on all HHS officials and requires them to reimburse for 340B drugs at the deeply reduced rates to which Plaintiffs objected. 42 C.F.R. § 405.1063. Nowhere in HHS's process for contesting reimbursement amounts is there authority to undo what the Secretary did in the Final Rule, to deem the new regulation unlawful, or to avoid the reimbursement formula the Rule dictates. The

District Court's requirement that Plaintiffs administratively challenge the legality of the new regulation turns presentment into a meaningless exercise.

Although the District Court did not decide whether Plaintiffs had exhausted administrative remedies, Circuit precedent demonstrates Plaintiffs have satisfied this requirement as well. In *Tataranowicz v. Sullivan*, 959 F.2d 268 (D.C. Cir. 1992), this Court held that exhaustion was not necessary to obtain judicial review of the denial of certain Medicare reimbursements where it would be futile, and that futility exists where "judicial resolution of the statutory issue (1) will not interfere with the agency's efficient functioning; (2) will not thwart any effort at self-correction; (3) will not deny the court or parties the benefit of the agency's experience or expertise; and (4) will not curtail development of a record useful for judicial review." *Id.* at 275. That is exactly the case here because the challenge to the new regulation is purely legal and concerns the authority of the Secretary of HHS, a matter that cannot be reevaluated in the administrative process.

II. If this Court determines that dismissal for lack of presentment was erroneous, then it should grant the preliminary injunction Plaintiffs sought below. As this Court held in *League of Women Voters v. Newby*, 838 F.3d 1, 7 (D.C. Cir. 2016), its consideration of a request for a preliminary injunction is especially appropriate where, as here, the "court has a full record, both in the district court and on appeal, the parties amply and ably briefed and litigated all four factors of

the preliminary injunction test," and there is no "need for any additional information concerning the equities and the public interest." All these considerations are present here. *See also Mendoza v. Perez*, 754 F.3d 1002, 1020 (D.C. Cir. 2014) (considering the merits after reversing the district court dismissal of Administrative Procedure Act claims because of lack of standing).

There is a strong likelihood Plaintiffs will succeed on the merits. The statutory authority the Secretary relied on to set the new reimbursement rate for 340B drugs sets the rate at average sales price plus 6%, but gives the Secretary the authority to "adjust[] as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The Secretary's position that this adjustment authority is unlimited, which it would have to be to permit a near-30% reduction in the statutory rate, was rejected in *Amgen Inc. v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004). It also is contrary to the Supreme Court's interpretation of the similar word "modify" in *MCI Telecommunications Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994), which this Court in *Amgen* relied on to limit the meaning of "adjust." Dictionary definitions of "adjust" confirm *Amgen*'s understanding of the limits inherent in that term – limits which preclude the HHS's vastly expansive invocation of adjustment authority here.

The Secretary's rate reduction is also inconsistent with the statutory structure governing drug reimbursement rates (42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-

(II)) for the additional reason that Subclause I of the statute provides that the Secretary may use acquisition cost as a basis for drug reimbursements only if HHS has acquisition cost data based on surveys that meet specified criteria. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) & (t)(14)(D). HHS concedes it lacked this data, but nevertheless sought to use acquisition cost data not permitted by Subclause I – *i.e.*, mere estimates of average acquisition costs for 340B drugs − to "adjust" the statutory default rate of ASP plus 6% under Subclause II. This was an impermissible end-run of the statute's limitation on the use of acquisition costs. The agency knew it did not have the data required by statute to use acquisition costs to determine reimbursement levels, so it paid lip service to the statute's ASP plus 6% sales price approach and then "adjusted" it in a drastic and unprecedented way to establish, in fact, reimbursement based on estimates of acquisition costs. This approach necessarily ignored HHS's historical practice of limiting adjustments to minor modifications to more accurately estimate overhead and related costs, resulting in a reimbursement rate that is neither a refinement of average sales price nor of overhead and related costs.

HHS justified its decision to "align" amounts paid by 340B hospitals for 340B drugs and reimbursements to those hospitals by invoking disputed policy concerns regarding the effects of the 340B Program on drug utilization and Medicare beneficiaries. But HHS itself has recognized that the 340B Program

envisions that eligible hospitals and clinics – which serve a disproportionately large share of persons who cannot afford to pay medical bills – will receive insurance reimbursements for drugs, including from Medicare, in excess of the drug price discounts from pharmaceutical companies created by the 340B Program. Even if HHS's policy concerns about the 340B Program were well-founded, and they are not, "[a]n agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms." *Utility Air Regulatory Grp. v. EPA*, __ U.S. __, 134 S. Ct. 2427, 2445 (2014).

The near-30% reduction will cause irreparable harm to the Hospital Plaintiffs, other members of the Association Plaintiffs, and, most important, the patients they serve. It will threaten programs and services that have been made possible by the funds created by the 340B Program, including oncology, dialysis, and immediate stroke treatment services. Even if Plaintiffs ultimately prevail and 340B hospitals are repaid funds to which they are entitled under the ASP plus 6% rate, temporary denial of those services to hospitals' patients during that interim period will cause harm that cannot be remedied by hospitals' ability to offer those services at a later time. *See Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 243 (D.D.C. 2014); *Children's Hosp. of the King's Daughters, Inc. v. Price*, 258 F. Supp. 3d 672, 692 (E.D. Va. 2017).

Because of the harms that the unlawfully reduced reimbursement rates will cause patients and their communities, and the minor harm (if any) the Government will suffer from an injunction, the balance of equities and the public interest also favor this Court's entry of an injunction.

ARGUMENT

I. PLAINTIFFS SATISFIED BOTH THE PRESENTMENT AND EXHAUSTION REQUIREMENTS OF SECTION 405(g).[14]

A. Plaintiffs Presented Their Claim When They Challenged HHS's Legal Authority to Adopt the Near-30% Reduction During Rulemaking Proceedings, Which Afforded Plaintiffs Their Only Opportunity for Administrative Relief.

Section 405(g), as incorporated into Medicare law by 42 U.S.C. § 1395ii through 42 U.S.C. § 405(h), authorizes federal courts to review Medicare claims that have received a "final decision" from the Secretary. *Action Alliance of Senior Citizens v. Leavitt*, 483 F.3d 852, 856 (D.C. Cir. 2007) ("*Action Alliance I*"). This requirement has two components: a "nonwaivable element . . . that a claim for benefits shall have been presented to the Secretary;" and a "waivable element . . . that the administrative remedies prescribed by the Secretary be exhausted."

[14] As discussed above at pages 17-19, since the effective date of the new OPPS near-30% rate reduction, all three Hospital Plaintiffs have submitted claims for 340B drug reimbursements, two have been paid under the new rate, and one has sought redetermination of the payment based on the alleged illegality of the new rate. Even if Plaintiffs failed to satisfy section 405(g) jurisdictional requirements before filing their lawsuit, under any reading of the relevant standards, they will satisfy these requirements during the pendency of this appeal.

Mathews, 424 U.S. at 328. The District Court dismissed the complaint in this case on the ground that Plaintiffs had "not yet presented any specific claim for reimbursement to the Secretary upon which the Secretary might make a final decision." JA537. The Court held that Plaintiffs' submission of detailed comments challenging the Secretary's authority to adopt the near-30% rate reduction during rulemaking proceedings, and the Secretary's rejection of that challenge in the Final Rule, did not satisfy the presentment requirement. JA538-40. That limited and formalistic interpretation of this requirement was erroneous.[15]

As the District Court noted, the presentment requirement means "virtually all" legal challenges related to decisions under the Medicare program must be "channel[ed] . . . through the agency." JA536 (quoting *Ill. Council*, 529 U.S. at 12). Plaintiffs' claim that HHS lacked statutory authority as a matter of law to adopt the rate reduction was, of course, "channeled" through HHS, through comments to the agency during rulemaking proceedings. The District Court did not cite, and we are not aware of, any case in which an appellate court has specifically held that comments submitted during rulemaking proceedings challenging HHS's statutory authority to enact a regulation cannot be "presented" for Section 405(g) purposes through rulemaking proceedings, or that such a

[15] This Court reviews de novo the dismissal of a complaint for lack of jurisdiction. *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1208 (D.C. Cir. 2011).

challenge *must* take place within the formal Medicare administrative claims process even if relief cannot be obtained there.

Courts of appeals have held the presentment requirement should be interpreted "liberally." *Lopez v. Heckler*, 725 F.2d 1489, 1503 (9th Cir. 1984), *vacated on other grounds by* 489 U.S. 1082 (1984); *Linquist v. Bowen*, 813 F.2d 884, 887 (8th Cir. 1987). Consistent with this approach, this Court has ruled that presentment is satisfied by (1) a letter to HHS, *outside the formal Medicare administrative claims process*, asserting a purely legal objection to agency action and (2) the agency's rejection, again outside the formal claims process, of that objection. *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010) ("*Action Alliance II*") (letter from counsel for plaintiff advocacy group to HHS demanding it comply with certain procedural requirements under the Medicare law in connection with agency efforts to recover overpayments from senior citizens and agency's rejection of this claim constituted presentment); *see Mathews*, 424 U.S. at 328 (social security recipient satisfied presentment by completing agency questionnaire and sending letter, but without filing a formal claim challenging benefits termination); *City of New York v. Heckler*, 742 F.2d 729, 735 (2d Cir. 1984) (beneficiary satisfied presentment, without submitting a claim through the administrative process, by "complet[ing] a Social Security

questionnaire indicating in writing that [they] remained disabled and desired benefits" before benefits were terminated).

In this case, as in *Action Alliance II*, Plaintiffs presented a specific legal objection to agency-wide action that was expressly considered and rejected by HHS. Plaintiffs satisfied the presentment requirement by fully and unsuccessfully engaging the agency in the only way that could produce administrative relief. Only a rigid formalism would require this futile pursuit of relief from the agency before allowing judicial review of the allegedly unlawful regulation.

The District Court in this case questioned the precedential value of *Action Alliance II*. JA540-42 Adopting the view of Judge Lamberth in *American Orthotic & Prosthetic Ass'n v. Sebelius*, 62 F. Supp. 3d 114, 123 (D.D.C. 2014), the District Court determined that the *Action Alliance II* Court's statement that plaintiffs had "cured the jurisdictional defect" (607 F.3d at 862 n.1) by submitting a letter of objection to the agency outside the formal claims administration process was not explained by the Court and also lacked the benefit of full briefing by the parties, and was therefore of "limited support" to Plaintiffs. JA540-42.

Both the District Court in this case and in *American Orthotic* inappropriately discounted the precedential value of this Court's *Action Alliance II* presentment ruling and also ignored the informative context and history underpinning that ruling. In an earlier version of that case, this Court had considered the presentment

issue *sua sponte* and after receiving briefing on that issue had held that plaintiffs' objection to agency action was *not* sufficiently specific to constitute presentment. *See Action Alliance I*, 483 F.3d at 861. After plaintiffs had submitted a more detailed letter to HHS, the district court held plaintiffs satisfied the presentment requirement**,** *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33, 40 (D.D.C. 2009), and HHS did not raise the issue on appeal. Thus, this Court's holding that plaintiffs had "cured the jurisdictional defect" was clearly informed by the Court's previous consideration of the presentment issue and the parties' earlier briefing. In any event, it is for this Court to consider the precedential force of its decisions, not the lower courts.

The District Court's holding that presentment requires a specific request for reimbursement under the Medicare law's formal administrative claims process is not only inconsistent with this Court's cases and with other circuits' precedents. It also loses sight of *why* challenges under the Medicare law must be "channel[ed] . . . through the agency" (JA536 (quoting *Ill. Council*, 529 U.S. at 12)) and how these goals can be, and in this case were, met by a legal challenge to HHS's exercise of statutory authority that is "channeled" through rulemaking proceedings.

As the District Court noted, the purpose of requiring presentment (and exhaustion) under Section 405(g) is to "prevent[] premature interference with agency processes, so that the agency may function efficiently and so that it may

have the opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." JA537 (*quoting Weinberger v. Salfi*, 422 U.S. 749, 765 (1975)). *See also Ill. Council*, 529 U.S. at 13 (noting presentment requirement "assur[es] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes.") Put another way, presentment ensures that a court that eventually considers a challenge under the Medicare law is addressing a concrete, specific agency decision that HHS has had the chance to fully consider and reconsider (on the basis, if necessary, of a factual record).

In this case, Plaintiffs presented extensive comments to HHS during rulemaking proceedings claiming the rate reduction exceeded the Secretary's statutory authority as a matter of law. *E.g.*, JA358-63 (AHA comments); JA405-13 (attached memorandum to AAMC comments); JA137-41 (AEH comments); JA172-73 (Henry Ford comments); JA182-83 (Adventist/Park Ridge comments). And HHS, in the Final Rule, addressed this claim in detail and expressly rejected it in a final decision that binds the agency in the absence of a new rulemaking, an act of Congress, or a court order. *See* 82 Fed. Reg. at 52,499-52,502. Further, the Government argued vigorously below for the legality of the new regulation, adopting HHS's "adjustment" rationale. JA245-59. The Government has signaled no intention of abandoning that view unless an injunction requires it to do so.

Moreover, and critically as a legal and practical matter, in this case the rulemaking process was the *only* agency forum for Plaintiffs to present their purely legal challenge to the near-30% reduction and for the agency to consider that challenge. Now that the reduction has taken effect, the Medicare Administrative Contractors, the Qualified Independent Contractors and Administrative Law Judges that review OPPS reimbursement claims are bound to apply the new rate. 42 C.F.R. § 405.1063. Telling them that the regulation is unlawful is pointless. The District Court's conclusion that Plaintiffs could *not* fulfill the statutory presentment requirement by presenting their claim during the rulemaking process, and its converse conclusion that they could *only* present through the formal administrative claims reimbursement process governed by the new rule would turn the presentment requirement into an empty and meaningless exercise. It would require legal challenges to be brought before administrative decision-makers who have no power to consider, much less act on, these challenges and deems legally irrelevant action before an agency that might actually make a difference. This Court should reject this upside down, formalistic reading of the presentment requirement, which causes damaging delay without any possible benefit.

Heckler v. Ringer, 466 U.S. 602 (1984), on which the District Court heavily relied (*see* JA537-38), is fully consistent with the proposition that Plaintiffs' challenge during rulemaking proceedings constituted presentment. There, the

Supreme Court found no presentment when the plaintiff asserted a claim regarding Medicare coverage for a particular medical procedure that he had not yet undergone. *Ringer*, 466 U.S. at 610, 620, 627. The Court's holding rested largely on its concern that judicial review of a coverage issue based on the claims of someone who had not undergone the allegedly covered procedure would result in the impermissible issuance of advisory opinions, "open[ing] the doors of the federal courts in the first instance to everyone . . . who thinks that he might be eligible to participate in the Medicare program, who thinks that someday he might wish to have some kind of surgery, and who thinks that this surgery might somehow be affected by a rule that the Secretary has promulgated." *Id.* at 621-22, 624-25. There is no such threat here.

As established through their comments, and as the Government does not dispute, Plaintiffs are, or have members who are, hospitals that participate in the 340B Program and continually submit claims for reimbursement of 340B drugs to Medicare. At the time of the District Court's decision, it was clear that they would be doing so in January 2018 and, in the absence of judicial relief, would be subject to CMS's reduced rate, causing these hospitals and their patients substantial harm. Indeed, all three Hospital Plaintiffs have now submitted claims for 340B drugs, and two of them have received reimbursements based on the new rate. There is no danger whatsoever that by allowing these hospitals or hospital associations to seek

judicial review after extensively participating in rulemaking proceedings, the District Court would have "open[ed] the doors of the federal courts" to claimants with potentially only a speculative interest in the agency's action.[16]

B. Plaintiffs Satisfied the Section 405(g) Exhaustion Requirement Because Further Pursuit of Their Claim Through Administrative Channels Is Futile.

Because the District Court dismissed Plaintiffs' claims for lack of presentment, it did not consider the Section 405(g) exhaustion requirement. Under established precedents, Plaintiffs are excused from complying with this waivable element.

The leading case on this issue in this Circuit is *Tataranowicz v. Sullivan*, 959 F.2d 268 (D.C. Cir. 1992). Under *Tataranowicz*, a strong showing that pursuit of the administrative process would be futile excuses the exhaustion requirement. *Id.* at 273-75. The plaintiffs in *Tataranowicz*, like Plaintiffs here, sought a declaration invalidating the Secretary's interpretation of a statutory provision and an injunction against denial of certain Medicare reimbursements for beneficiaries "who would be eligible once the allegedly erroneous interpretation is swept away." *Id.* at 274.

[16] The unpublished opinion in *Three Lower Counties Community Health Services, Inc. v. HHS*, 317 Fed. Appx. 1 (D.C. Cir. Feb. 2, 2009), does not support the District Court's decision. The cost limits challenged there were not issued pursuant to a rulemaking process in which the plaintiff participated, and this Court thus had no occasion to consider whether a submission of comments during such a process could constitute presentment for purposes of Section 405(g). *See id.*, 317 Fed. Appx. at *1-2.

This Court noted that "[i]t is hard to see how any factual disputes might stand in the way of that relief" and that "the Secretary gives no reason to believe that the agency machinery might accede to plaintiffs' claims," *id*., noting that "[o]n this record, it seems wholly formalistic not to regard further appeals as completely futile." The Court concluded by pointing out that "dispensing with further administrative process is consistent with the purposes of exhaustion" because "judicial resolution of the statutory issue (1) will not interfere with the agency's efficient functioning; (2) will not thwart any effort at self-correction; (3) will not deny the court or parties the benefit of the agency's experience or expertise; and (4) will not curtail development of a record useful for judicial review." *Id*. at 275.

Here, likewise, further pursuit of the 340B Hospitals' statutory claim through agency administrative processes after rulemaking proceedings are complete would have been (and still would be) entirely futile. The near-30% reduction regulation is now final and went into effect on January 1, 2018. No HHS administrative review body, following issuance of the final rule, has the authority to alter or deviate from the rate reduction unless and until it is repealed by the agency or enjoined by a court. Simply put, agency personnel cannot undo what the Secretary has done in a final regulation. *See* 42 C.F.R. § 405.1063(a); *Tataranowicz*, 959 F.2d at 274 (noting that the Secretary "does not argue that ALJs

are free to disregard his ruling").[17] In these circumstances, as in *Tataranowicz*, a futility determination is fully consistent with the purposes of the exhaustion doctrine. *See also Liberty Alliance of the Blind v. Califano*, 568 F.2d 333, 346 (3d Cir. 1977) (exhaustion waived where the only issue in dispute is the proper interpretation of a statute and "the Secretary has taken a final position on that issue").[18]

II. PLAINTIFFS HAVE MET THE REQUIREMENTS FOR A PRELIMINARY INJUNCTION.

Because the District Court dismissed Plaintiffs' complaint for lack of subject matter jurisdiction, it dismissed as moot their motion for a preliminary injunction. This Court should grant Plaintiffs' request for interim relief and enter an order suspending implementation of the near-30% rate reduction pending final resolution of the merits by the District Court on remand.

A. This Court Can Consider the Preliminary Injunction Motion.

This Court can grant a preliminary injunction if it determines that Plaintiffs have met the applicable requirements. *Newby*, 838 F.3d at 7 (citation omitted). These factors are whether (1) the movant is likely to succeed on the merits of its

[17] The argument for futility is actually stronger here than in *Tataranowicz*. Here, the challenge is to a formally promulgated regulation, whereas in *Tataranowicz*, the challenge was to an agency pronouncement that could be changed without a formal rulemaking.

[18] To the extent that a showing of irreparable harm from delay caused by pursuit of administrative remedies factors into this analysis, *Tataronowicz*, 959 F.2d at 275, Plaintiffs have made this showing as well. *See infra* at pages 49-54.

claim; (2) the movant is likely to suffer irreparable harm in the absence of an injunction; (3) the balance of equities between the parties favors an injunction; and (4) the public interest favors an injunction. *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008). This Court's consideration of a preliminary injunction motion is especially appropriate where, as here, "this [C]ourt has a full record, both in the district court and on appeal, the parties amply and ably briefed and litigated all four factors of the preliminary injunction test," and there is no "need for any additional information concerning the equities and the public interest." *Newby*, 838 F.3d at 7. The fact that this Court, as in *Newby*, put this appeal on an expedited schedule, mindful of the need for prompt resolution, also weighs in favor of it deciding Plaintiffs' preliminary injunction motion. *Id.* *See also Mendoza*, 754 F.3d at 1020 (considering the merits after reversing the district court dismissal of Administrative Procedure Act claims because of lack of standing, and holding that because the district court had no "comparative advantage" over this Court in considering the merits, remand would be a "waste of judicial resources.")

B. Each of the Four Preliminary Injunction Factors Favors Granting Plaintiffs' Motion.[19]

1. Plaintiffs Are Likely to Succeed on the Merits.

The central question in this case is whether the near-30% reduction from the ASP plus 6% statutory default rate qualifies as an "adjustment" to the statutory average sales price rate under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The Government has taken the position that the Secretary's "adjustment" authority gives him unlimited authority to depart from the ASP statutory default rate, including to adopt the near-30% reimbursement rate reduction, and that their interpretation is a permissible reading of the statute under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *See, e.g.*, JA241 (arguing that the Secretary's adjustment authority is "not subject to any express statutory limitation"); JA242 ("The statute imposes no limitation on the Secretary's 'adjust[ment]' of the payment rate . . . ."). The Government is wrong because (1)

[19] Historically, this Court used a "sliding scale" to evaluate whether a movant satisfies the four-factor preliminary injunction test, "allow[ing] . . . a strong showing on one factor [to] make up for a weaker showing on another." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011) (explaining past use of the "sliding scale" approach). In recent years, it has questioned whether the "sliding scale" approach remains available after the Supreme Court's decision in *Winter*, *supra*. *See Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1292 (D.C. Cir. 2009) (noting that *Winter* "could be read to create a more demanding burden" than the sliding scale analysis, and to require a clear showing on each of the four PI factors). This remains an "open question," *Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014), that need not be answered here because each of the four factors favors granting Plaintiffs' motion. *See Newby*, 838 F.3d at 7.

such a large reduction is not an "adjustment" within the bounds of the average sales price methodology; (2) the agency used its "adjustment" authority to implement an average acquisition cost methodology that it was not allowed to implement because it lacked the data required under the statute as a requirement of relying on acquisition cost; and (3) the rate reduction improperly targeted and undermined the 340B Program.[20]

a. This Court Rejected CMS's Reading of "Adjust" in Amgen v. Smith.

An agency's authority to interpret statutory language is circumscribed by the plain and ordinary meaning of the language. *Roberts v. Sea-Land Servs.*, 566 U.S. 93, 100 (2012). The Government's reading of "adjust" to justify its near-30% rate reduction is contrary to that term's plain meaning. In *Amgen v. Smith*, this Court held that the Secretary's authority to "make . . . adjustments" to payments to providers under a different part of the OPPS system, 42 U.S.C. § 1395*l*(t)(2)(E),

[20] In the District Court, the Government also argued that exercise of "adjustment" authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) is precluded from judicial review by the express terms of the Medicare law and under the doctrine barring review of agency actions that are "committed to agency discretion by law." JA235-42. Both arguments fail. The Medicare law's terms do not preclude courts from reviewing "adjustments" under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). And even if they did, as discussed below, the reduction at issue in this case was not an "adjustment" and therefore would prevent application of preclusion. *See Amgen*, 357 F.3d at 117 (noting that modifications to payment rates that are beyond the scope of Secretary's adjustment authority under a separate OPPS provision are not precluded from review). This Court's interpretation of the bounds of the Secretary's analogous OPPS adjustment authority in *Amgen* (*id.*) makes clear that this issue is not committed to agency discretion by law.

was constrained by the "limitations" that "inhere" in the word "adjustment." *Amgen*, 357 F.3d at 117. This Court found those "inhere[nt]" "limitations" to be similar to those the U.S. Supreme Court placed on the word "modify" in *MCI Telecommunications Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994).

In *MCI*, the Supreme Court held that "'modify' . . . has a connotation of *increment or limitation*," 512 U.S. at 225 (emphasis added), and that "every dictionary we are aware of says that 'to modify' means to *change moderately or in minor fashion*." *Id.* (emphasis added) (citing dictionary definitions of modify). *See also id.* at 227-28 ("'Modify', in our view, connotes moderate change."). This Court's reading of "adjustment" in *Amgen* − through the lens of the Supreme Court's reading of "modify" in *MCI* and in connection with the same general statutory scheme at issue in this case − disposes of the Government's claim that its "adjustment" authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) is unlimited. *See also Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it appears."). Dictionary definitions of "adjust" confirm *Amgen*'s understanding of the limits inherent in the word.[21]

[21] *Adjust*, Oxford Dictionaries, https://en.oxforddictionaries.com/definition/adjust (last visited Feb. 13, 2018) (defining "adjust" to mean "alter or move (something) *slightly* in order to achieve the desired fit, appearance, or result." (emphasis added); *Adjust*, Cambridge Dictionary, https://dictionary.cambridge.org/dictionary/english/adjust (last visited Feb. 13,

The near-30% rate reduction at issue here is a dramatic departure from the ASP plus 6% statutory rate that cannot possibly be viewed as a "moderate," "minor," or "limited" change. CMS's past use of the adjustment authority supports this point. From 2006 until 2011, CMS annually adjusted the ASP plus 6% rate by one or two percentage points (77 Fed. Reg. at 68,383-68,386) and from 2012 until adoption of the near-30% reduction did not adjust that rate at all. CMS's past use of the adjustment authority preserved the basic statutory formula, ASP plus 6%, but tweaked the 6% portion of the formula to better estimate overhead and related costs. *Id.* at 68,383. The near-30% reduction, by contrast, is such a dramatic departure from the statutory sales price rate that it bears no conceptual or numerical relationship to, and is completely untethered from, that rate. As this Court noted in *Amgen* in a separate but analogous OPPS context:

> The statutory requirement that the Secretary "shall" develop certain aspects of the payment system is qualified by the Secretary's authority to "adjust[]" those payment amounts, but *a more substantial departure from*

2018) ("to change something *slightly*, especially to make it more correct, effective, or suitable") (emphasis added); *Adjust*, Collins English Dictionary (12th ed. 2014) ("to alter *slightly*, esp to achieve accuracy; regulate") (emphasis added); *Adjust*, Longman Dictionary, https://www.ldoceonline.com/dictionary/adjust (last visited Feb. 13, 2018) ("to gradually become familiar with a new situation;" "to change or move something *slightly* to improve it or make it more suitable for a particular purpose") (emphasis added); *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust (last visited Feb. 13, 2018) (defining "adjust" for English language learners to mean "to change (something) *in a minor way* so that it works better.") (emphasis added).

> *the default amounts would, at some point, violate the Secretary's obligation to make such payments and cease to be an "adjustment[]."*

357 F.3d at 117 (emphasis added). The near 30% reduction is not an adjustment of the average sales price (for example, to more accurately reflect that price) or of the additional 6% that is supposed to reflect overhead and similar costs. Rather, it is such a "substantial departure" from the ASP plus 6% "default amount" that it plainly exceeds the Secretary's "adjustment" authority.

b. The Secretary's Statutory Authority to Adjust Cannot Be Used to Set a Reimbursement Rule Based on Estimates of Acquisition Cost.

Instead of using his authority to make an adjustment to the statutory formula of ASP plus 6%, the Secretary used it to promulgate a regulation requiring reimbursement for separately payable drugs based on acquisition cost – specifically, the estimate of average acquisition costs for 340B drugs compiled by MedPAC. 82 Fed. Reg. at 52,496. This is flatly inconsistent with the structure of the OPPS reimbursement system set forth in 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-(II), which permits an acquisition cost methodology only if HHS has acquisition cost data that it admits it lacked here and otherwise requires HHS to use a specified sales price methodology, with only minor "adjustments" permitted. *See Amgen*, 357 F.3d at 117 (noting in the context of 42 U.S.C. § 1395*l*(t)(2)(E) that a

modification that causes "severe restructuring of the statutory scheme" is not an "adjustment").

As discussed above at pages 5-6, under Subclause I of section 1395*l*(t)(14)(A)(iii), the Secretary may rely on acquisition costs in setting reimbursement rates *if and only if* it has specific, statutorily defined acquisition cost data (*i.e.*, "the hospital acquisition cost survey data under subparagraph (D)"). But if the Secretary lacks this data, as HHS admits he did here (82 Fed. Reg. at 52,496), the statute requires it to use the sales price methodology in Subclause II, namely ASP plus 6% rate, as "adjusted" by the Secretary. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

HHS's near-30% rate reduction plainly circumvents and undermines the requirements of *both* Subclause I *and* Subclause II. In other words, HHS has paid lip service to the required sales price methodology but actually uses acquisition cost methodology that, absent the data it lacks here, it is not permitted to use. Indeed, CMS acknowledged this effort and the intent behind it when it explained that its objective in reducing payments on 340B purchased drugs was to "better align" those payments "with hospital *acquisition* costs," 82 Fed. Reg. at 52,498 (emphasis added). Indeed, CMS then proceeded to rely not even on the *actual* acquisition cost data required under Subclause I, but on *estimates* of *average*

acquisition costs compiled by MedPAC, formulating a new rate conceptually unrelated to, and completely untethered from, the ASP plus 6% statutory rate.[22]

In short, CMS's approach fundamentally restructures the congressionally-established system of reimbursing hospitals for separately payable drugs under the OPPS, by effectively eliminating both the requirement in Subclause I that CMS use specific data if it is to base reimbursement rates on acquisition costs *and* the Subclause II requirement that, in the absence of such data, the rate be based on the ASP plus 6% formula. This approach, if upheld, would essentially and paradoxically give CMS broad discretion to ignore express statutory requirements – including, as here, to serve disputed and unrelated policy goals.

Indeed, if Congress had intended for CMS to use whatever acquisition cost data it chose and to deviate from the ASP plus 6% rate as much as it wanted, it would not have enacted either the Subclause I data requirement or the Subclause II ASP plus 6% benchmark. Rather, it could have simply given CMS flexibility to use reliable data (including any acquisition cost data) to arrive at a rate reasonably derived from the data. It quite clearly did no such thing.

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[22] MedPAC admitted that this estimate was based on approximations of other metrics, such as average manufacturer price and best price, that were admittedly unknown to MedPAC. *See* MedPAC, OVERVIEW OF THE 340B DRUG PRICING PROGRAM, at App. A (May 2015), http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0.

The Government Accountability Office has concluded that the Secretary's adjustment authority does not allow HHS to establish reimbursement rates based on acquisition costs under Subclause II. GAO noted in a 2015 report that "Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, *regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs*." 2015 GAO Report, *supra* note 8, at 29 (emphasis added). The near-30% rate reduction flies in the face of this limitation.

Given that alterations based on acquisition costs are impermissible when using the sales price methodology under Subclause II, it is reasonable to ask what types of modifications *are* proper "adjustments" under the statutory structure. The provisions in section 1395*l*(t)(14) provide helpful guidance on this issue, stating that the reimbursement formula is "subject to subparagraph (E)." 42 U.S.C. § 1395*l*(t)(14)(A)(iii). "Subparagraph (E)" directs MedPAC to prepare "a report on *adjustment* of payment [related to drugs reimbursed under Paragraph 14] to take into account *overhead and related expenses, such as pharmacy services and handling costs*" and then authorizes the Secretary to "adjust [such payments] to take into account" the report's recommendations. 42 U.S.C. § 1395*l*(t)(14)(E)(i)-(ii) (emphasis added). This statutory language demonstrates that "adjustments" are appropriate to better account for outside factors such as "overhead" and "pharmacy services and handling costs" if the ASP plus 6% formula does not adequately

address those costs. And indeed, all past adjustments to the ASP plus 6% rate were made expressly to account for estimates of overhead, according to HHS at the time. *See* 77 Fed. Reg. at 68,383-68,386. That type of incremental modification, which is tethered to the ASP plus 6% rate and is designed to make it more accurately reflect cost factors not captured by ASP alone, is an appropriate "adjustment" given the text and structure of the statute. A dramatic change replacing ASP plus 6% with an estimate of acquisition cost to change the rate by almost 30% is not.

c. The Authority to Adjust Average Sales Price May Not Be Used to Target and Undermine the 340B Program.

In addition to improperly using its Subclause II average sales price adjustment authority to circumvent the Subclause I prohibition on actual cost reimbursement absent specified data, HHS also abused its adjustment authority by targeting a specific set of hospitals – *i.e.*, non-exempt 340B hospitals, which provide critical care to disproportionately large numbers of persons who cannot afford to pay their medical bills. The methodology in Subclause II (ASP plus 6%) allows HHS to establish a single price that applies to *all* hospitals; it does not allow for a methodology (here, ASP minus 22.5%) to be applied only to a subset of hospitals. Yet HHS in this case expressly purported to "adjust" the reimbursement rate to "align[] [Medicare payments] with resources expended *by hospitals to acquire [340B] drugs*." 82 Fed. Reg. at 52,495 (emphasis added). For non-340B hospitals (and exempted 340B hospitals), HHS has left the ASP plus 6% statutory

default rate undisturbed, regardless of acquisition costs. Nothing in the statute allows for this differential treatment under Subclause II.

The problem of HHS's selective targeting of 340B hospitals is compounded because the reduced rate that is applicable only to these hospitals undermines the basic purposes of the 340B Program. That Program envisioned that eligible hospitals and clinics – *i.e.*, those that served a disproportionately large share of persons who cannot afford to pay medical bills – would receive drug price discounts from pharmaceutical companies. As the Health Resources Services Administration, the HHS agency responsible for the 340B Program, has recognized, the Program's purpose was for insurance reimbursements for those drugs (which necessarily includes reimbursements from Medicare, a government insurance program) to generate additional resources that these hospitals could use to serve their communities, including underserved populations in those communities. 2005 HRSA Manual, *supra* note 5, at 14 (noting that the Program furthers its legislative purpose by "lower[ing] the cost of acquiring covered outpatient drugs" from drug manufacturers, thereby generating additional resources from "health insurance reimbursements" that are "maintained or not reduced as much as the 340B discounts or rebates"). Nothing in the text, structure, or legislative history of the OPPS drug reimbursement provisions, or in HHS's interpretation of those provisions between 2003 and 2017, suggests that Congress

intended to give HHS authority through the OPPS system to "align" 340B drug prices with Medicare reimbursements for those drugs, as HHS seeks to do in this case. *Cf. Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001) ("Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.")

Thus, HHS's rate reduction amounts to an impermissible attempt by the Secretary "to reconfigure" both Congress's statutory 340B scheme *and* the OPPS drug reimbursement scheme. *Howard v. Pritzker*, 775 F.3d 430, 432 (D.C. Cir. 2015). *See also Can-Am Plumbing, Inc. v. NLRB*, 321 F.3d 145, 154 (D.C. Cir. 2003) (holding that an agency must apply a statute "insofar as possible, in a manner that minimizes the impact of its actions on the policies of . . . [an]other statute") (citation omitted).

HHS has justified its efforts to "align" 340B drug prices and reimbursements to 340B hospitals by invoking its policy concerns regarding the effects of the 340B Program on drug utilization and Medicare beneficiaries. Even if those concerns were well-founded, and they are not, "[a]n agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms." *Utility Air Regulatory Grp.*, 134 S. Ct. at 2445. *See also Pettibone Corp. v. United States*, 34 F.3d 536, 541 (7th Cir. 1994) (an agency's authority to interpret a statute "must not be confused with a power to rewrite."). The OPPS law says nothing

about using HHS's adjustment authority to target perceived problems with the 340B Program or to close a gap between drug prices and reimbursements that is at the heart of that Program, and HHS's use of its authority for these ends is unlawful.

Once again, the GAO has agreed that HHS lacks statutory authority in this regard, considering in its 2015 report whether HHS could "limit[] hospitals' Medicare Part B reimbursement for 340B discounted drugs" and concluding that "CMS and HRSA are unable to take such action[] *because they do not have the statutory authority to do so*." 2015 GAO Report, *supra* note 8, at 30 (emphasis added). *See also* HHS Office of Inspector General, PART B PAYMENTS FOR 340B-PURCHASED DRUGS 13 (Nov. 2015) (examining "payment scenarios that show how Medicare could share in 340B discounts" and concluding that this "is not possible under the current design of the 340B Program and Part B payment rules").[23]

Finally, Congress's intent in the OPPS law to leave operation of the 340B Program undisturbed was confirmed by its decision in the Affordable Care Act to significantly expand the number of 340B hospitals. *See* 42 U.S.C. § 256b(a)(4)(M)-(O) (adding certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals to the list of "covered entities"). This endorsement of the 340B Program is inconsistent with the conclusion that Congress intended to allow HHS to dramatically cut the

[23] *Available at* https://oig.hhs.gov/oei/reports/oei-12-14-00030.asp.

Program back through the kind of dramatic reimbursement rate reduction at issue here.

2. Plaintiffs Will Suffer, and Are Suffering, Irreparable Harm as a Result of the Near-30% Reduction, Which Would Jeopardize Critical Programs.

A party seeking a preliminary injunction "must establish that . . . he is likely to suffer irreparable harm in the absence of preliminary relief . . . ." *Winter*, 555 U.S. at 20 (citations omitted). This likely harm must be (1) "actual and not theoretical, and so imminent that there is a clear and present need for equitable relief to prevent irreparable harm"; and (2) beyond remediation. *Newby*, 838 F.3d at 8 (citations, internal quotation marks omitted).

Each Hospital Plaintiff submitted an affidavit below to describe the likely damage from the near-30% reduction to the vital programs and services it provides to its community, including underserved populations.[24] This reduction would result in dramatic and automatic lost savings for these hospitals, placing at risk their ability to provide the care the 340B Program was designed to make possible. *E.g.*, JA194 (EMHS Aff. ¶ 12) (estimating EMHS's net loss from 340B Provisions of the OPPS Rule to be $2.86 million); JA200 (Henry Ford Aff. ¶ 14) (estimating

[24] The affidavits were submitted, respectively, by (1) Tony Filer, Chief Financial Officer of Hospital Plaintiff EMHS (JA192-96, "EMHS Aff."); (2) Mary Whitbread, Vice-President of Finance for Hospital Plaintiff Henry Ford (JA198-202, "Henry Ford Aff."); and (3) Wendi Barber, Chief Financial Officer of Hospital Plaintiff Park Ridge (JA204-08, "Park Ridge Aff.").

Henry Ford's total net loss across its system from 340B Provisions to be $9.3 million); JA206 (Park Ridge Aff. ¶ 14) (estimating Park Ridge's net loss from 340B Provisions to be $3.3 million); *see* 82 Fed. Reg. 52,623 (estimating total lost savings to hospitals from payment reduction to be $1.6 billion).[25]

Now that non-exempt 340B hospitals are submitting claims that are subject to the ASP minus 22.5% rate, and for as long as the new rate remains in effect, the effect of the reduced rate is, and will continue to be, to threaten the programs and services that have been made possible by the savings caused by the differential between the prices 340B hospitals have paid for drugs and the amounts they have been reimbursed for those same drugs – a differential that the rate reduction is expressly designed to close. *E.g.*, JA194-95 (EMHS Aff. ¶ 13-17); JA200-02 (Henry Ford Aff. ¶¶ 15-20); JA206-07 (Park Ridge Aff. ¶¶ 15-19). The effect of the reduction, if not suspended, is (1) actual and not theoretical and (2) imminent.

Nor is there any doubt that the harms caused by the reduction are beyond remediation. As noted above, the loss of funds caused by the reduction threatens critical programs and services offered by the Hospital Plaintiffs (as well as other members of the Association Plaintiffs). *E.g.*, JA194-95 (EMHS Aff. ¶¶ 14-17)

[25] HHS's rule redistributes the $1.6 billion in reduced 340B drug reimbursements across all hospitals receiving Medicare Part B payments, including the 340B hospitals that are subject to the reimbursement reduction. 82 Fed. Reg. at 52,398. The losses estimated in the Hospital Plaintiffs' affidavits take into account any redistribution to those hospitals. JA 194, 200, 206.

(noting at ¶ 15 that EMHS' "oncology services," including specifically its Cancer Care of Maine program, as well as "dialysis services, services for immediate stroke treatment, osteoporosis services, and blood factor services" would "likely be impacted by [the near-30% rate reduction], to at least some degree"); JA207 (Park Ridge Aff. ¶¶ 18-19) (noting at ¶ 18 that the reduction would "threaten the continued health, or even the existence," of Park Ridge's four infusion centers and geriatric psychiatric program). JA201-02 (Henry Ford Aff. ¶¶ 16-20) (noting at ¶ 19 that the reduction would "threaten [Henry Ford] programs" aimed at reducing expensive treatments for uninsured patients, including school-based and community health programs).

Even if the near-30% rate reduction is reversed, and 340B hospitals are repaid funds they would have received under the ASP plus 6% rate, any temporary suspension and denial of services to hospitals' patients in the interim cause harm that cannot be remedied by hospitals' ability to offer the services at a later time. *See Tex. Children's Hosp.*, 76 F. Supp. 3d at 243 (granting preliminary injunction and finding irreparable harm where plaintiff hospitals would be subject to recoupment of Medicaid payments by CMS and noting that "[p]laintiffs . . . are not for-profit entities facing the loss of profit; rather, they are non-profits for whom lost funds would mean reducing hospital services to children . . . "); *Children's Hosp. of the King's Daughters*, 258 F. Supp. 3d at 689-90 (granting preliminary

injunction in same circumstances as in *Texas Children's Hospital* and noting that "[t]he nature of the Plaintiff's enterprise means that financial hardship will cause enduring damage to the Plaintiff's short-term and long-term ability to provide care, and will cause irreversible harm to its patients and their families.").

The courts have recognized that a healthcare provider is not the same as a for-profit business that can restore its financial position by recouping lost profits at a later time, and that is especially true for 340B hospitals and their patients, including underserved populations in their communities. A hospital's entire reason for being is to treat sick patients; even temporary constraints on their ability to fulfill this mission – even if funds unlawfully withheld can later be recovered – constitutes irreparable harm, both by denying the hospital the ability to do its work *and* the reputational injury associated with cuts in programs and services. *E.g.*, *Tex. Children's Hosp.*, 76 F. Supp. 3d at 244 and n.7 (noting that loss of funds threatening non-profit healthcare providers' essential services is "different in kind from economic loss suffered by a for-profit entity" and that the fact that hospital *programs* "*may* be" driven out of business – even temporarily – establishes irreparable harm even if the hospital as a whole will survive (emphasis added)); *Children's Hosp. of the King's Daughters*, 258 F. Supp. 3d at 689 ("Disrupting the Plaintiff's ability to provide medical treatment cannot be likened to interrupting a typical business's ability to turn a profit. The typical business can catch up on lost

profits in the future, but a hospital cannot retroactively treat its patients."). *See also Stuller, Inc. v. Steak N Shake Enters., Inc.*, 695 F.3d 676, 680 (7th Cir. 2012) (franchisee would suffer irreparable harm if forced to implement new pricing policy, because even if it later prevails, "it would be difficult to reestablish its previous business model without a loss of goodwill and reputation"). Put simply, a hospital denied funds to provide services on Day 1 is not made whole by the restoration of funds enabling it to provide the same services on Day 2.[26]

In addition to its effect on specific programs and services, the loss of funds caused by the rate reduction also affects the Hospital Plaintiffs' (and other Association Plaintiffs' members') financial and budgeting operations, including their loan covenants and other arrangements that allow these entities to provide essential health care to their communities. *E.g.*, JA196 (EMHS Aff. ¶ 19).

Thus, Plaintiffs have amply demonstrated irreparable harm in the absence of the requested injunction.

3. The Balance of Equities Favors an Injunction.

The balance of equities factor requires comparison of the hardship that would befall the movant(s) if the requested injunction were not awarded with the

[26] In the district court, 32 State hospital associations sought leave to file an *amicus curiae* brief attesting to the irreparable harm caused by the rate reduction on 340B hospitals. JA268-311. The district court denied the motion for leave to file the *amicus* brief as moot in light of its dismissal of the complaint. Because that dismissal was in error, however, this Court should consider the points made by *amici* below.

harm that would befall other parties if the injunction were awarded. *Newby*, 838 F.3d at 12.

In this case, the non-moving parties are government agencies and officials that would suffer no direct harms if the requested injunction suspending the rate reduction were granted. In short, the effects of the requested injunction on the Government pale in comparison to the direct and substantial harms – outlined above − that Plaintiffs would suffer absent the injunction. *See Children's Hosp. of the King's Daughters*, 258 F. Supp. 3d at 692 ("The potential harm caused to the [government] Defendants by the injunction is less severe and more remote than the immediate and lasting harm the Plaintiff will suffer without an injunction.") The balance of equities therefore favors granting Plaintiffs' request.

4. The Public Interest Favors an Injunction.

The public interest favors the preliminary injunction for two reasons. First, the effect of the new reduction will be to deprive 340B hospitals, including the Hospital Plaintiffs and other members of the Association Plaintiffs, of hundreds of millions of dollars currently used for care in those hospitals' communities. It is not only in the interest of hospitals, but also in the interest of these communities, and particularly their vulnerable patients, for these critical services to continue. *See id.* (noting that "[w]ithout an injunction, the Plaintiff's ability to offer lifesaving medical care may be diminished or delayed, the effects of which will fall on a

particularly vulnerable set of the general public" and that "[t]he harm to the members of the public whose quality of care is diminished . . . cannot be undone.").

Second, it is in the public interest for government agencies to lawfully implement the statutes they administer. *Newby*, 838 F.3d at 12 ("There is generally no public interest in the perpetuation of unlawful agency action.") (citations omitted)). As demonstrated above, the near-30% reduction is clearly contrary to law, and the public interest lies in remedying that unlawful agency action. *Id.* (noting that "appellants' extremely high likelihood of success on the merits is a strong indicator that a preliminary injunction would serve the public interest.").

CONCLUSION

This Court should reverse the District Court's dismissal of the complaint, grant the requested preliminary injunction, and remand the case to the District Court for further proceedings.

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 12,841 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ Carlos T. Angulo
Carlos T. Angulo
Attorney for Plaintiffs-Appellants

CERTIFICATE OF SERVICE

Pursuant to D.C. Circuit Local Rule 25(c), I hereby certify that on February 15, 2018, I caused the foregoing Brief of Plaintiffs-Appellants to be electronically filed with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ Carlos T. Angulo
Carlos T. Angulo
Attorney for Plaintiffs-Appellants

ADDENDUM OF STATUTES AND REGULATIONS

TABLE OF CONTENTS

42 U.S.C.A. § 1395*l*

§ 1395*l*. Payment of benefits

(t) Prospective payment system for hospital outpatient department services

(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)--

(iii) in a subsequent year [to 2005], 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.

* * *

(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).

42 U.S.C.A. § 405

§ 405. Evidence, procedure, and certification for payments

(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact

and decision, and, in any case in which the Commissioner has not made a decision fully favorable to the individual, a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

42 C.F.R. § 405.1063

§ 405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414, 416, and 419

[CMS–1678–FC]

RIN 0938–AT03

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2018 to implement changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

DATES:

Effective date: This final rule with comment period is effective on January 1, 2018, unless otherwise noted.

Comment period: To be assured consideration, comments on the payment classifications assigned to HCPCS codes identified in Addenda B, AA, and BB with the comment indicator ''NI'' and on other areas specified throughout this final rule with comment period must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 31, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1678–FC when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1678–FC, P.O. Box 8013, Baltimore, MD 21244–1850.

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

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1678–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: (We note that public comments must be submitted through one of the four channels outlined in the **ADDRESSES** section above. Comments may not be submitted via email.)

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Elisabeth Daniel via email *Elisabeth.Daniel1@cms.hhs.gov* or at 410–786–0237.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Blood and Blood Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* at 410–786–9732.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

Care Management Services, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

CPT Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov* or at 410–786–6719.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Comprehensive APCs (C–APCs), contact Lela Strong via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Inpatient Only (IPO) Procedures List, contact Lela Strong via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email *Erick.Chuang@cms.hhs.gov* or at 410–786–1816 or Elisabeth Daniel via email *Elisabeth.Daniel1@cms.hhs.gov* or at 410–786–0237.

physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2017 updated furnishing fee was $0.209 per unit.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we were not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

Comment: Commenters' supported CMS' proposal to continue to pay for a blood clotting factor furnishing fee in the hospital outpatient department.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS Web site.

6. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

In the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to continue to use the same payment policy as in CY 2017 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2018 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data was listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site.

Comment: One commenter, the manufacturer of Mylotarg®, requested that CMS change the dose descriptor for HCPCS code J9300 from ''Injection, gemtuzumab ozogamicin, 5 mg'' to ''Injection, gemtuzumab ozogamicin, 0.1 mg,'' to accommodate the new 4.5 mg vial size for Mylotarg®. The commenter noted that HCPCS code J9300 was inactive for a period of time because the prior version of gemtuzumab ozogamicin was removed from the market. As such, HCPCS code J9300 is assigned status indicator ''E2 (items and services for which pricing information and claims data are not available).'' The commenter also requested that CMS change the status indicator from ''E2'' to a payable status indicator.

Response: This comment is outside of the scope of the proposed rule. Requests for changes to Level II Alphanumeric HCPCS codes should be submitted to the CMS HCPCS Workgroup using CMS' standard procedures. Information on the Level II HCPCS code process is available via the Internet on the CMS Web site, which is publicly available at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS.html.*

After consideration of the public comments we received, we are finalizing our CY 2018 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2018 if pricing information becomes available. The CY 2018 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

7. Alternative Payment Methodology for Drugs Purchased Under the 340B Program

a. Background

The 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within HHS. The 340B Program allows participating hospitals and other health care providers to purchase certain ''covered outpatient drugs'' (as defined under section 1927(k) of the Act and interpreted by HRSA through various guidance documents) at discounted prices from drug manufacturers. The statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive.[18]

The 340B statute defines which health care providers are eligible to participate in the program (''covered entities''). In addition to Federal health care grant recipients, covered entities include hospitals with a Medicare disproportionate share hospital (DSH) percentage above 11.75 percent. However, under Public Law 111–148, section 7101 expanded eligibility to critical access hospitals (CAHs), children's hospitals with a DSH adjustment greater than 11.75 percent, sole community hospitals (SCHs) with a DSH adjustment percentage of 8.0 percent or higher, rural referral centers (RRCs) with a DSH adjustment percentage of 8.0 percent or higher, and freestanding cancer hospitals with a DSH adjustment percentage above 11.75 percent. In accordance with section 340B(a)(4)(L)(i) of the Public Health Service Act, all participating hospital types must also meet other criteria.

HRSA calculates the ceiling price for each covered outpatient drug. The ceiling price is the drug's average manufacturer price (AMP) minus the unit rebate amount (URA), which is a

[18] The House report that accompanied the authorizing legislation for the 340B Program stated: ''In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'' (H.R. Rept. No. 102–384(II), at 12 (1992)).

statutory formula that varies depending on whether the drug is an innovator single source drug (no generic available), an innovator multiple source drug (a brand drug with available generic(s)), or a non-innovator multiple source (generic) drug.[19] The ceiling price represents the maximum price a participating drug manufacturer can charge a covered entity for the drug. However, covered entities also have the option to participate in HRSA's Prime Vendor Program (PVP), under which the prime vendor can negotiate even deeper discounts (known as ''subceiling prices'') on some covered outpatient drugs. By the end of FY 2015, the PVP had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price.[20]

As we discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33632 and 33633), several recent studies and reports on Medicare Part B payments for 340B purchased drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost.[21] [22] [23] Links to the full reports referenced in this section can be found in the cited footnotes.

In its May 2015 Report to Congress, MedPAC analyzed Medicare hospital outpatient claims (excluding CAHs) along with information from HRSA on which hospitals participate in the 340B Program. MedPAC included data on all separately payable drugs under the OPPS except for vaccines and orphan drugs provided by freestanding cancer hospitals, RRCs, and SCHs. To estimate costs that 340B hospitals incur to acquire drugs covered under the OPPS, MedPAC generally used the formula for calculating the 340B ceiling price: (AMP)—unit rebate amount (URA) × drug package size. The URA is determined by law and depends upon whether a drug is classified as single source, innovator multiple source, non-innovator multiple source, a clotting factor drug, or an exclusively pediatric drug. CMS provides this URA information to States as a courtesy. However, drug manufacturers remain responsible for correctly calculating the URA for their covered outpatient drugs. More information on the URA calculation and the Medicaid Drug Rebate Program may be found on the Web site at: *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.*

Because MedPAC did not have access to AMP data, it used each drug's ASP as a proxy for AMP. MedPAC noted that ASP is typically slightly lower than AMP. The AMP is defined under section 1927(k)(1) of the Act as the average price paid to the manufacturer by wholesalers in the United States for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts. Manufacturers participating in Medicaid are required to report AMP data quarterly to the Secretary, and these prices are confidential. As described under section 1847A of the Act, the ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts. Certain sales are exempt from the calculation of ASP, including sales at a nominal charge and 340B discounts.

In addition, MedPAC noted that, due to data limitations, its estimates of ceiling prices are conservative and likely higher (possibly much higher) than actual ceiling prices. Further details on the methodology used to calculate the average minimum discount for separately payable drugs can be found in Appendix A of MedPAC's May 2015 Report to Congress. In this report, MedPAC estimated that, on average, hospitals in the 340B Program ''receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS].''

In its March 2016 Report to Congress (page 79), MedPAC noted that another report, which MedPAC attributed to the Office of the Inspector General (OIG), recently estimated that discounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs. According to the U.S. Government Accountability Office (GAO) report, the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid to purchase the drug. In addition, participation in the PVP often results in a covered entity paying a subceiling price on some covered outpatient drugs (estimated to be approximately 10 percent below the ceiling price) (U.S. Department of Health and Human Services, HRSA FY 2018 Budget Justification). Participation in the PVP is voluntary and free.

As noted in the CY 2018 OPPS/ASC proposed rule, with respect to chemotherapy drugs and drug administration services, MedPAC examined Medicare Part B spending for 340B and non-340B hospitals for a 5-year period from 2008 to 2012 and found that ''Medicare spending grew faster among hospitals that participated in the 340B Program for all five years than among hospitals that did not participate in the 340B Program at any time during [the study] period'' (MedPAC May 2015 Report to Congress, page 14). This is just one example of drug spending increases that are correlated with participation in the 340B Program and calls into question whether Medicare's current policy to pay for separately payable drugs at ASP+6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs.

Further, GAO found that ''in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals.'' According to the GAO report, this indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status (GAO Report 15–442, page 20).

Under the OPPS, all hospitals (other than CAHs, which are paid based on 101 percent of reasonable costs as required by section 1834(g) of the Act) are currently paid the same rate for separately payable drugs (ASP+6

[19] 42 U.S.C. 256b(a)(1–2). Occasionally, a drug's URA is equal to its AMP, resulting in a 340B ceiling price of $0. In these instances, HRSA has advised manufacturers to charge covered entities $0.01 per unit.

[20] Department of Health and Human Services. 2017. Fiscal Year 2018 Health Resources and Services Administration justification of estimates for appropriations committees. Washington, DC: HHS. Available at: *https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf.*

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

[22] Medicare Payment Advisory Commission. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015. Available at: *http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0.*

[23] Government Accountability Office. ''Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals GAO–15–442''. June 2015. Available at: *https://www.gao.gov/assets/680/670676.pdf.*

percent), regardless of whether the hospital purchased the drug at a discount through the 340B Program. Medicare beneficiaries are liable for a copayment that is equal to 20 percent of the OPPS payment rate, which is currently ASP+6 percent (regardless of the 340B purchase price for the drug). Based on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the OIG found that, for 35 drugs, the ''difference between the Part B [payment] amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug'' (OIG November 2015, Report OEI–12–14–00030, page 9).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68655), we requested comments regarding the drug costs of hospitals that participate in the 340B Program and whether we should consider an alternative drug payment methodology for participating 340B hospitals. As noted above, in the time since that comment solicitation, access to the 340B Program was expanded under section 7101 of Public Law 111–148, which amended section 340B(a)(4) of the Public Health Service Act to expand the types of covered entities eligible to participate in the 340B Program. It is estimated that covered entities saved $3.8 billion on outpatient drugs purchased through the 340B Program in 2013.[24] In addition, the number of hospitals participating in the program has grown from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014 (MedPAC May 2015 Report to Congress). In its November 2015 report entitled ''Part B Payments for 340B-Purchased Drugs,'' the OIG found that Part B payments were 58 percent more than 340B ceiling prices, which allowed covered entities to retain approximately $1.3 billion in 2013 (OEI–12–14–00030, page 8). Given the growth in the number of providers participating in the 340B Program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, we stated in the CY 2018 OPPS/ASC proposed rule that we believe it is timely to reexamine the appropriateness of continuing to apply the current OPPS methodology of ASP+6 percent to hospitals that have acquired those drugs under the 340B Program at significantly discounted rates.

MedPAC and OIG have recommended alternative drug payment methodologies for hospitals that participate in the 340B Program. In its March 2016 Report to Congress, MedPAC recommended a legislative proposal related to payment for Part B drugs furnished by 340B hospitals under which Medicare would reduce payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the ASP and direct the program savings from reducing Part B drug payment rates to the Medicare funded uncompensated care pool.[25] In its November 2015 report, the OIG described three options under which both the Medicare program and Medicare beneficiaries would be able to share in the program savings realized by hospitals and other covered entities that participate in the 340B Program (OEI–12–14–00030, pages 11–12). These options included: (1) Paying ASP with no additional add-on percentage; (2) paying ASP minus 14.4 percent; and (3) making payment based on the 340B ceiling price plus 6 percent of ASP for each 340B purchased drug (OEI–12–14–00030, page 11). Analysis in several of these reports notes limitations in estimating 340B-purchased drugs' acquisition costs; the inability to identify which drugs were purchased through the 340B Program within Medicare claims data was one of those limitations.

b. OPPS Payment Rate for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33633 through 33634), we proposed changes to our current Medicare Part B drug payment methodology for 340B hospitals that we believe would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow the Medicare program and Medicare beneficiaries to pay less for drugs when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program.

Our goal is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Medicare expenditures on Part B drugs have been rising and are projected to continue to rise faster than overall health spending, thereby increasing this sector's share of health care spending due to a number of underlying factors such as new higher price drugs and price increases for existing drugs.[26] [27] While we recognize the intent of the 340B Program, we believe it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs. We believe that any payment changes we adopt should be limited to separately payable drugs under the OPPS, with some additional exclusions. As a point of further clarity, CAHs are not included in this 340B policy change because they are paid under section 1834(g) of the Act. As stated in the CY 2018 OPPS/ASC proposed rule, these exclusions are for: (1) Drugs on pass-through payment status, which are required to be paid based on the ASP methodology, and (2) vaccines, which are excluded from the 340B Program. In addition, we solicited public comments on whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment.

Data limitations inhibit our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the proposed rule that we intended to provide further details about this modifier in this CY

[24] U.S. Department of Health and Human Services, HRSA FY 2015 Budget Justification, p. 342.

[25] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at: *http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report-.pdf?sfvrsn=0.*

[26] Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Medicare Part B Drugs: Pricing and Incentives. 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf.*

[27] Department of Health and Human Services: Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Observations on Trends in Prescription Drug Spending. March 8, 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.*

2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program.

A summary of public comments received and our responses pertaining to the modifier are included later in this section. As described in detail later in this section, we are implementing the modifier such that it is required for drugs that were acquired under the 340B Program instead of requiring its use on drugs that were *not* acquired under the 340B Program. In addition, we are establishing an informational modifier for use by certain providers who will be excepted from the 340B payment reduction.

Further, we note that the confidentiality of ceiling and subceiling prices limits our ability to precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug. We recognize that each separately payable OPPS drug will have a different ceiling price (or subceiling price when applicable). Accordingly, we stated in the proposed rule that we believe using an average discounted price was appropriate for our proposal. Therefore, for CY 2018, we proposed to apply an average discounted price of 22.5 percent of the ASP for nonpass-through separately payable drugs purchased under the 340B Program, as estimated by MedPAC (MedPAC's May 2015 Report to Congress, page 7).

In the near-term, we believe that the estimated average minimum discount MedPAC calculated—22.5 percent of the ASP—adequately represents the average minimum discount that a 340B participating hospital receives for separately payable drugs under the OPPS. Given the limitations in calculating a precise discount for each OPPS separately payable drug, we did not attempt to do so for the proposed rule. Instead, we stated that we believed that using the analysis from the MedPAC report is appropriate and noted that the analysis is spelled out in detail and can be replicated by interested parties. As MedPAC noted, its estimate was conservative and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent of the ASP. As GAO mentioned, discounts under the 340B Program range from 20 to 50 percent of the ASP (GAO–11–836, page 2). We believe that such reduced payment would meet the requirements under section 1833(t)(14)(A)(iii)(II) of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary. We do not have hospital acquisition cost data for 340B drugs and, therefore, proposed to continue to pay for these drugs under our authority at section 1833(t)(14)(A)(iii)(II) of the Act at ASP, and then to adjust that amount by applying a reduction of 22.5 percent, which, as explained throughout this section, is the adjustment we believe is necessary for drugs acquired under the 340B Program.

Specifically, in the CY 2018 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. However, we proposed to exercise the Secretary's authority to adjust the applicable payment rate as necessary and, for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program, we proposed to adjust the rate to ASP minus 22.5 percent, which we believe better represents the average acquisition cost for these drugs and biologicals.

As indicated earlier, because ceiling prices are confidential, we are unable to publicly disclose those prices or set payment rates in a way that would allow the public to determine the ceiling price for a particular drug. We believe that the MedPAC analysis that found the average minimum discount of 22.5 percent of ASP adequately reflects the average minimum discount that 340B hospitals paid under the OPPS receive. In addition, we believe that using an average discount to set payment rates for OPPS separately payable drugs would achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs, and (2) protecting the confidential nature of discounts applied to a specific drug. Moreover, we do not believe that Medicare beneficiaries should be liable for a copayment rate that is tied to the current methodology of ASP+6 percent when the actual cost to the hospital to purchase the drug under the 340B Program is much lower than the ASP for the drug.

We note that MedPAC excluded vaccines from its analysis because vaccines are not covered under the 340B Program, but it did not exclude drugs with pass-through payment status. Further, because data used to calculate ceiling prices are not publicly available, MedPAC instead estimated ''the lower bound of the average discount received by 340B hospitals for drugs paid under the [OPPS]'' (MedPAC May 2015 Report to Congress, page 6). Accordingly, it is likely that the average discount is higher, potentially significantly higher, than the average minimum of 22.5 percent that MedPAC found through its analysis. In the proposed rule, we encouraged the public to analyze the analysis presented in Appendix A of MedPAC's May 2015 Report to Congress.

As noted earlier, we believe that the discount amount of 22.5 percent below the ASP reflects the average minimum discount that 340B participating hospitals receive for drugs acquired under the 340B Program, and in many cases, the average discount may be higher for some covered outpatient drugs due to hospital participation in the PVP, substitution of ASP (which includes additional rebates) for AMP, and that drugs with pass-through payment status were included rather than excluded from the MedPAC analysis. We believe that a payment rate of ASP+6 percent does not sufficiently recognize the significantly lower acquisition costs of such drugs incurred by a 340B-participating hospital. Accordingly, as noted earlier, we proposed to reduce payment for separately payable drugs, excluding drugs on pass-through payment status and vaccines, that were acquired under the 340B Program by 22.5 percent of ASP for all drugs for which a hospital does not append on the claim the modifier mentioned in the proposed rule and discussed further in this final rule with comment period. (As detailed later in this section, we are instead requiring hospitals to append the applicable modifier on the claim line with any drugs that were acquired under the 340B Program.)

Finally, as detailed in the impact analysis section (section XIX.A.5.a.2) of the proposed rule, we also proposed that the reduced payments for separately payable drugs and biologicals purchased under the 340B Program are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals purchased under the 340B Program. In that section, we also solicited public comments on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018,

rather than simply increasing the conversion factor. In particular, we requested public comments on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. In addition, we requested public comments on whether savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act. More information on the impact estimate associated with this proposal was included in section XIX.A.5.a.2. of the proposed rule. A summary of the public comments received on the impact estimate, along with our responses to those comments and our estimate of this provision for this final rule with comment period, are included in section XVIII.A.5. of this final rule with comment period.

c. Summaries of Public Comments Received and Our Responses

(1) Overall Comments

Comment: Several commenters, including organizations representing physician oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, and several individual Medicare beneficiaries, supported the proposal. Some of these commenters commended CMS for its proposal, which they believed would help address the growth of the 340B Program, stem physician practice consolidation with hospitals, and preserve patient access to community-based care.

One of these commenters stated that the proposals would reduce drug costs for seniors by an estimated $180 million a year; help to stop hospital ''abuses'' of the 340B program; and help reverse the ''perverse incentives'' that have driven the closure and consolidation of the nation's community cancer care system.

Another commenter, representing a large network of community-based oncology practices, noted that since 2008, 609 community cancer practices have been acquired or become affiliated with hospitals, with 75 percent of those community cancer practices acquired by 340B-participating hospitals. The commenter stated that the consolidation in oncology care has resulted in a 30 percent shift in the site of service for chemotherapy administration from the physician office setting to the more costly hospital outpatient setting.

One commenter, an organization representing community oncology practices, cited several issues that the proposal would help address, including that only a small minority of 340B participating hospitals are using the program to benefit patients in need; cancer patients in need are being denied care at 340B participating hospitals or placed on wait lists; and hospitals are making extreme profits on expensive cancer drugs and are consolidating the nation's cancer care system, reducing patient choice and access and shifting care away from the private, physician-owned community oncology clinics into the more expensive 340B hospital setting, which is increasing costs for Medicare and its beneficiaries. In addition, this commenter stated that the increasing scope and magnitude of required 340B discounts are increasing drug prices to record-breaking levels as manufacturers factor these discounts into pricing decisions. The commenter also cited a report that it recently released that suggests, and provides anecdotal evidence supporting, that some 340B hospitals offered little charity care and turned away some patients in need because those patients were uninsured.[28]

With respect to the magnitude of the proposed payment reduction of ASP minus 22.5 percent, one commenter noted that although the proposed decrease in payment may seem ''severe,'' ASP minus 22.5 percent is the minimum discount that hospitals in the 340B Program receive. The commenter further noted that, with 340B discounts on brand drugs approaching, and even exceeding, 50 percent, there is still substantial savings—on the order of 50 percent drug margins—for hospitals to use to provide direct and indirect patient benefits. The commenter also noted that this proposal would result in cost-sharing savings to Medicare beneficiaries, for whom drug cost is an important component of overall outpatient cancer care costs.

Some commenters urged HHS, specifically CMS and HRSA, to work with Congress to reform the 340B Program. One commenter requested greater transparency and accountability on how 340B savings are being used, as well as a specific definition of the ''340B patient,'' which the commenter noted would require a legislative change.

Response: We thank the commenters for their support. As mentioned in the proposed rule, we share the commenters' concern that current Medicare payments for drugs acquired under the 340B Program are well in excess of the overhead and acquisition costs for drugs purchased under the 340B Program. We continue to believe that our proposal would better align Medicare payment for separately payable drugs acquired under the 340B Program with the actual resources expended to acquire such drugs. Importantly, we continue to believe that Medicare beneficiaries should be able to share in the savings on drugs acquired through the 340B Program at a significant discount. We also appreciate the comments supporting the proposed payment amount for drugs acquired under the 340B Program of ASP minus 22.5 percent, which we believe, like several commenters, is an amount that allows hospitals to retain a profit on these drugs for use in the care of low-income and uninsured patients. As detailed later in this section, we are finalizing our proposal, with modifications, in response to public comments.

As previously stated, CMS does not administer the 340B Program. Accordingly, feedback related to eligibility for the 340B Program as well as 340B Program policies are outside the scope of the proposed rule and are not addressed in this final rule with comment period.

Comment: Several commenters expressed concern with the rising cost of drugs and the impact on beneficiaries and taxpayers. These commenters offered varied opinions on whether the proposal would achieve CMS' goal of lowering drug prices and reducing beneficiary out-of-pocket costs. Some commenters stated that the proposal has the potential to alleviate the financial burden that high-cost drugs place on patients. Other commenters stated that, because the proposal does not address the issue of expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs, especially oncology drugs, CMS should not finalize the proposal.

One commenter, an individual who supported the proposal, stated that although the majority of patients with Medicare Part B coverage have supplemental coverage to pay their coinsurance, significant numbers do not have this additional protection. The commenter noted that, for a drug that is paid at $10,000 per month, the price reduction would save a beneficiary approximately $500 a month, which may be the difference between getting treatment and foregoing treatment due to financial reasons.

Another commenter, a large organization with many members who

[28] Community Oncology Alliance. Report: ''How Abuse of the 340B Program is Hurting Patients'' September 2017. Available at: *https://www.communityoncology.org/wp-content/uploads/2017/09/COA_340B-PatientStories_FINAL.pdf.*

are Medicare beneficiaries, stated that the proposal would provide a measure of price relief to the 16 percent of Medicare beneficiaries without supplemental coverage. The commenter also expressed concern that the proposal would have serious health implications for beneficiaries in safety-net hospitals. The commenter urged HHS to develop proposals that will lower underlying drug prices, but did not provide any specific examples of such proposals. Another commenter stated that the cost of drugs is becoming unsustainable and applying the proposed policy is a decent ''baby step'' in controlling a situation that is ''grossly'' unfair to American taxpayers, especially when the development of new drugs is frequently funded to a large extent by taxpayers through Federal grants.

In addition, one commenter, a large organization representing its physician and medical student members, commented that it shares the Administration's interest in addressing the rising costs of drugs and biologicals. The commenter appreciated that the proposal would address a longstanding concern: That the current payment policy for Part B drugs creates strong incentives to move Medicare beneficiary care from lower cost sites of care (such as physician offices) to higher cost sites of care (such as hospital outpatient departments). The commenter noted that many smaller physician practices have had to refer cancer and other patients who need chemotherapy and other expensive drugs to the hospital outpatient setting because the ASP+6 percent payment does not always cover a physician's acquisition cost, thereby undermining continuity of care and creating burdens for frail and medically compromised patients.

This commenter also stated that, given the 340B Program's focus on low-income patients, it is imperative to ensure that an across-the-board reduction actually reflects the size of the 340B discount to avoid creating barriers to access, should both physician practices and the hospital outpatient departments be unable to cover actual acquisition costs. Further, the commenter noted that it is essential that ''a bright line policy does not inadvertently deleteriously impact patient access in all sites of care.'' Finally, the commenter stated that, while the proposed policy alters the relative disparity between payments for some hospital outpatient departments and physician practices, it still does not address the persistent challenges physician practices face in obtaining payment that covers acquisition costs.

Response: We thank the commenters' for their feedback and share their concern about the high cost of drugs and their effect on Medicare beneficiaries. As discussed in detail later in this section, we are finalizing a change to the payment rate for certain Medicare Part B drugs purchased by hospitals through the 340B Program in order to lower the cost of drugs for seniors and ensure that they benefit from the discounts provided through the program. We look forward to working with Congress to provide HHS additional 340B programmatic flexibility, which could include tools to provide additional considerations for safety net hospitals, which play a critical role in serving our most vulnerable populations.

As a general matter, we note that, even though many beneficiaries have supplemental coverage, beneficiaries often pay a premium for such supplemental coverage and those plans make coinsurance payments for the beneficiary. Thus, to the extent Medicare would be lessening the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans to decrease or otherwise reflect these lower costs in the future, thereby lowering the amount that beneficiaries pay for supplemental plan coverage. Further, for those Medicare beneficiaries who do not have supplemental coverage at all or who have a supplemental plan that does not cover all of a beneficiary's cost-sharing obligation, the proposed policy would directly lower out-of-pocket spending for 340B-acquired drugs for those beneficiaries.

In addition, we note that in the hospital setting, not only are beneficiaries liable for cost-sharing for drugs they receive, but they also incur a ''facility fee'' solely because the drug was furnished in the hospital setting. As described in section II.A.3.b. of this final rule with comment period, for CY 2018, we are adopting a policy to conditionally package Level 1 and Level 2 Drug Administration services and believe that these steps, taken together, may help encourage site-neutral care in that beneficiaries may receive the same drugs and drug administration services at the physician office setting without a significant difference in their financial liability between settings.

As previously stated, we believe that ASP minus 22.5 percent is a lower bound estimate of the average discount given to hospitals participating in the 340B Program. Accordingly, we disagree that this proposal represents a ''bright-line'' policy that would hinder safety-net hospitals' ability to treat patients.

While the commenter's request that HHS develop proposals to lower underlying drug prices is outside the scope of the proposals made in the proposed rule, we note that lowering the price of pharmaceuticals is a top priority, and we are committed to finding ways for Medicare payment policy not to incentivize use of overpriced drugs. With respect to Medicare Part B drug payment under the OPPS, we believe that reducing payments on 340B purchased drugs to better align with hospital acquisition costs directly lowers drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital by reducing their copayments. Further, to the extent that studies have found that 340B participating hospitals tend to use more high cost drugs, we believe that this proposal helps address the incentive for hospitals to utilize these drugs in this manner solely for financial reasons.

The expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs are outside the authority conferred by section 1833(t) of the Act (and, thus, are outside the scope of the proposed rule), and we see no reason to withdraw the proposal solely on account of these issues not being addressed by the proposal. Likewise, we note that the public comments on Medicare Part B drug payment in the physician office setting are also outside the scope of the proposed rule, and, therefore, are not addressed in this final rule with comment period.

Comment: Several commenters, including organizations representing 340B-eligible safety-net hospitals in urban and rural areas and teaching hospitals, were generally opposed to the proposed changes and urged CMS to withdraw the proposal from consideration. As detailed further below, these commenters believed that the Secretary lacks statutory authority to impose such a large reduction in the payment rate for 340B drugs, and contended that such change would effectively eviscerate the 340B Program. The commenters further noted that Medicare payment cuts of this magnitude would greatly ''undermine 340B hospitals' ability to continue programs designed to improve access to services—the very goal of the 340B Program.''

These commenters urged that, rather than ''punitively targeting'' 340B safety-net hospitals serving vulnerable patients, including those in rural areas, CMS instead redirect its efforts to halt the ''unchecked, unsustainable increases'' in the price of drugs.

Response: We do not believe that our proposed policy ''punitively'' targets safety-net hospitals. The current OPPS payment rate of ASP+6 percent significantly exceeds the discounts received for covered outpatient drugs by hospitals enrolled in the 340B Program, which can be as much as 50 percent below ASP (or higher through the PVP). As stated throughout this section, ASP minus 22.5 percent represents the average minimum discount that 340B enrolled hospitals paid under the OPPS receive. We also have noted that 340B participation does not appear to be well-aligned with the provision of uncompensated care, as some commenters suggested. As stated earlier in this section, while the commenter's request that HHS develop proposals to lower underlying drug prices is outside the scope of the proposals made in the proposed rule, we note that lowering the price of pharmaceuticals is a top priority.

(2) Comments on the Statutory Authority for the 340B Payment Proposal

Many commenters challenged the statutory authority of various aspects of the proposal. These comments are summarized into the broad categories below. For the reasons stated below, we disagree with these comments and believe that our proposal is within our statutory authority to promulgate.

- *Secretary's Authority To Calculate and Adjust 340B-Acquired Drug Payment Rates*

Comment: Commenters asserted that section 1833(t)(14)(A)(iii)(II) of the Act does not authorize CMS to ''calculate and adjust'' the payment rate in a manner that would ''eviscerate'' the 340B Program as it applies to 340B hospitals. Some commenters asserted that the plain and ordinary meaning of the terms ''calculate'' and ''adjust'' express a limited and circumscribed authority to set the payment rate. The commenters noted that the Oxford Dictionaries define ''calculate'' as ''determine (the amount or number of something) mathematically;'' likewise, to ''adjust'' is to ''alter or move (something) slightly in order to achieve the desired fit, appearance, or result.'' Consequently, the commenters asserted that section 1833(t)(14)(A)(iii)(II) of the Act restricts the agency to mathematically determining ''an appropriate, slight alteration.'' Further, they posited that the law does not convey the power to adopt what they referred to as a novel, sweeping change to the payment rate that is a significant numerical departure from the previous rate and that would result in a reduction in payment to 340B hospitals of at least $900 million, according to the agency's own estimates, or $1.65 billion, according to the commenter's estimates.

Another commenter stated that the Secretary's limited adjustment authority under section 1833(t)(14)(A)(iii)(II) of the Act does not ''extend so far as to gut'' what it referred to as an ''explicit statutory directive''. For example, the commenter referred the agency to *Pettibone Corp.* v. *United States,* 34 F.3d 536, 541 (7th Cir. 1994) (an agency's authority to interpret a statute ''must not be confused with a power to rewrite'').

Some commenters, including an organization representing over 1,300 providers enrolled in the 340B Program, argued that the proposal would take away almost the entire 340B discount for many 340B drugs, especially brand name drugs (which they asserted were many of the drugs affected by the proposal). These commenters asserted that the Secretary does not have the authority to calculate and adjust 340B-acquired drug rates in this manner and noted that the standard 340B ceiling price for a brand name drug is AMP minus 23.1 percent, although the price can be lower if the drug's best price is lower or if the manufacturer increases the price of the drug more quickly than the rate of inflation. In addition, the commenters asserted that if a brand name drug's 340B ceiling price was based on the standard formula, the proposal would strip the hospital of nearly all its 340B savings because ''AMP has been found to be close to ASP.'' Thus, the commenters asserted, the proposed payment rate of ASP minus 22.5 percent is nearly identical to AMP minus 23.1 percent, leaving the hospital with ''virtually no 340B savings.''

Some commenters stated that the proposal mistakenly assumes that 340B hospitals purchase most 340B drugs at subceiling prices negotiated by the PVP. These commenters noted that some hospitals estimate that less than 10 percent of the drugs affected by the proposal are available at a subceiling price.

In addition, some commenters contended that subclause (I) of section 1833(t)(14)((A)(iii) establishes that the payment rate for subsequent years be set to the average acquisition cost of the drug taking into account hospital acquisition costs survey data collected through surveys meeting precise statutory requirements, and that such subclause does not provide adjustment authority for the agency. They stated that subclause (II) of section 1833(t)(14)((A)(iii) of the Act directs CMS, where acquisition cost data are not available, to set payment rates by reference to ASP provisions. Considered in context, the commenters stated that the statute reflects Congress's intent to limit CMS' authority to set payment rates and, consequently, is consistent with adjustment authority under subclause (II)—to convey only limited authority for any agency to adjust the payment rate. The commenters referred to *Roberts* v. *Sea-Land Servs., Inc.,* 566 U.S. 93, 101 (2012) (Statutory provisions ''. . . cannot be construed in a vacuum. It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme'') to support their conclusions, although the commenters did not elaborate on the particular relevance of this case.

Finally, some commenters raised concern over the Secretary's use of the May 2015 MedPAC estimate as support for the 340B payment proposal. These commenters stated that the Secretary did not conduct his own independent analysis to support the payment proposal nor did he provide justification for use of MedPAC's analysis. One commenter stated that the Secretary cannot implement a payment cut of the magnitude proposed without providing a sufficient and replicable methodology that supports the proposal and that relying on a MedPAC analysis does not suffice for this ''important fiduciary, and legal, requirement.''

Response: We believe our authority under section 1833(t)(14)(A)(iii)(II) of the Act to ''calculate and adjust'' drug payments ''as necessary for purposes of this paragraph'' gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount. We disagree that this Medicare payment policy would effectively eviscerate the 340B Program and note that this proposal solely applies to applicable drug payments under the Medicare program; it does not change a hospital's eligibility for the 340B program. Further, under our proposal, we anticipate that the Medicare payment rate would continue to exceed the discounted 340B price the hospital received under the 340B program.

As previously stated, MedPAC's estimate of ASP minus 22.5 percent represents a lower bound estimate of the average minimum discount and the actual discount is likely much higher—up to 50 percent higher, according to some estimates, for certain drugs. In

some cases, beneficiary coinsurance alone exceeds the amount the hospital paid to acquire the drug under the 340B Program (OIG November 2015, Report OEI–12–14–00030, page 9). We did not receive public comments suggesting an alternative minimum discount off the ASP that would better reflect the hospital acquisition costs for 340B-acquired drugs. We believe this is notable because hospitals have their own data regarding their own acquisition costs, as well as data regarding OPPS payment rates for drugs. The fact that hospitals did not submit comments suggesting an alternative minimum discount that would be a better, more accurate reflection of the discount at issue is instructive for two reasons. One, it gives us confidence that our suggested payment of ASP minus 22.5 percent is, in fact, the low bound of the estimate and keeps Medicare payment within the range where hospitals will not be underpaid for their acquisition costs of such drugs. Two, it gives us confidence that the affected hospital community does not believe there is some other number, such as ASP minus 24 percent or ASP minus 17 percent, that would be a better, more accurate measure of what Medicare Part B should pay for drugs acquired at a discount through the 340B Program. Given the limitations in calculating a precise discount for each OPPS separately payable drug, we did not attempt to do so for the proposed rule. Instead, we stated that we believed that using the analysis from the MedPAC report is appropriate because MedPAC's estimate is based on all drugs separately paid under the OPPS except for vaccines, which are not eligible for 340B prices. Furthermore, the analysis is publicly available and can be replicated by interested parties.

With respect to the comments about the PVP, as previously stated, by the end of FY 2015, the PVP had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price. Participation in the PVP is voluntary and free, and we are aware of no reason that an eligible entity would not participate.

Furthermore, we disagree that the Secretary's authority under section 1834(t)(14)(A)(iii)(II) of the Act to calculate and adjust drugs rates as necessary is limited to what some might consider minor changes and find no evidence in the statute to support that position. As previously stated, we believe that ASP minus 22.5 percent represents the average minimum discount that hospitals paid under the OPPS received for drugs acquired under the 340B Program and reiterate that, in many instances, the discount is much higher. Thus, we are using this authority to apply a downward adjustment that is necessary to better reflect acquisition costs of those drugs.

• *Authority To Vary Payment by Hospital Group*

Comment: Some commenters asserted that only subparagraph (I), and not subparagraph (II), of section 1833(t)(14)(A)(iii) of the Act permits CMS to vary payment ''by hospital group.'' These commenters suggested that, by including ''by hospital group'' in subparagraph (I) and omitting it in subparagraph (II), Congress expressed its intent that CMS may not vary prices by hospital group under subparagraph (II). They further commented that the subparagraph (II) methodology must apply to ''the drug,'' and CMS may not vary payment for the same drug based upon the type of hospital.

Response: We disagree with the commenters who argue that the proposed policy would exceed the Secretary's authority under the statute by inappropriately varying payments for drugs by ''hospital group'' because we rely on section 1833(t)(14)(A)(iii)(II) of the Act, even though the explicit authority to vary payment rates by hospital group is in subclause (I) of section 1833(t)(14)(A)(iii) of the Act, not subclause (II). As noted above, we believe our authority under section 1833(t)(14)(A)(iii)(II) of the Act to ''calculate and adjust'' drug payments ''as necessary for purposes of this paragraph'' gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust payment rates according to whether or not certain drugs are acquired at a significant discount for Medicare beneficiaries. Although we acknowledge that hospitals are eligible to receive drugs at discounted rates under the 340B Program if they qualify as a ''covered entity'' for purposes of the 340B Program, not all drugs for which a covered entity submits a claim for payment under the OPPS are necessarily acquired under the 340B Program. The OPPS payment for those drugs not acquired under the 340B Program would continue to be paid at ASP+6 percent.

We also note generally that the OPPS statute authorized the Secretary to establish appropriate Medicare OPPS payment rates for covered outpatient drugs. After specifically setting forth the payment methodology for 2004 and 2005, Congress provided that the Secretary could set OPPS drug prices in one of two ways: Using the average acquisition cost for the drug for that year, or using the average price for that drug in the year. However, in either case, prices set using either benchmark may be adjusted by the Secretary. Such adjustments may occur under section 1833(t)(14)(A)(iii)(II) of the Act if the Secretary determines they are ''necessary for purposes of'' section 1833(t)(14) of the Act, and this paragraph of the Medicare OPPS statute repeatedly discusses terms like ''hospital acquisition cost'' and ''variation in hospital acquisition costs'', and specifically notes in one section that it is within the Secretary's authority to determine that the payment rate for one drug ''may vary by hospital group.'' It would be odd for Congress to have a significant delegation of authority to the Secretary, use these specific terms and considerations throughout section 1833(t)(14) of the Act, and then assume the Secretary is foreclosed from taking into account those considerations in adjusting ASP ''as necessary for purposes'' of section 1833(t)(14) of the Act. The Secretary is generally empowered to adjust drug prices ''as necessary'' for the overall purposes of section 1833(t)(14) of the Act, and there is nothing in section 1833(t)(14) of the Act to indicate the Secretary is foreclosed from varying Medicare OPPS payment for a drug, depending on whether a 340B hospital acquired that drug at such a substantially lower acquisition cost.

• *Authority To Establish Payment Rates in the Absence of Acquisition Cost Survey Data and Authority To Base Payment on an Average Discount*

Comment: Some commenters, including a commenter representing teaching hospitals, stated that the Secretary ignored the statutory directive in section 1833(t)(14) of the Act to set payment rates at the average acquisition cost for specific drugs and not to use averages for all drugs. In addition, the commenters stated that section 1833(t)(14) of the Act requires the Secretary to rely on an average of acquisition cost data and sales prices for a given drug, not an average discount that is applied to all drugs acquired under the 340B Program.

One commenter stated that the Secretary impermissibly conflates the two alternative methods for setting payment rates, ''essentially discarding Congress' requirement that any survey data used in setting payment rates must be derived from statistically rigorous surveys.'' This commenter asserted that the Secretary is using MedPAC's estimate of average discounts as a proxy

or replacement for the surveys required under subsection (iii)(I).

Response: We disagree that section 1833(t)(14)(A)(iii)(II) of the Act requires use of survey data and note that, unlike subclause (I) of this section, subclause (II) does not require taking survey data into account for determining average price for the drug in the year. We continue to believe that section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary the authority to calculate and adjust rates as necessary in the absence of acquisition cost. Moreover, under section 1833(t)(14)(A) of the Act, there still will be one starting, baseline price for an applicable drug, that is, the rate that applies under 1842(o), 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary. For drugs not acquired under the 340B Program, we will continue to utilize that price (ASP+6 percent), which as we have explained ''requires no further adjustment'' because it ''represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.'' However, for drugs acquired through the 340B Program, we are adjusting that price downward (ASP minus 22.5 percent) to more closely align with the hospital acquisition cost for a drug when purchased at a discounted price under the 340B Program. In the absence of acquisition costs from hospitals that purchase drugs through the 340B Program, we believe it is appropriate to exercise our authority to adjust the average price for 340B-acquired drugs, which are estimated to be acquired at an average minimum discount of ASP minus 22.5 percent. Importantly, because we are not using authority under section 1833(t)(14)(A)(iii)(I) of the Act (as the commenter suggested), we disagree with the commenter's suggestion that the Secretary is using the MedPAC analysis to stand in the place of the survey requirement under subclause (I).

- *Current Agency View Contrasts With Longstanding Practice*

Comment: Some commenters contended that the proposal contrasts sharply with the agency's previous view and longstanding practice of applying the statutory scheme of section 1833(t)(14) of the Act. These commenters noted that since CMS began relying on subclause (II) in 2012 to set the payment rate, the agency has never invoked the discretionary authority. The commenters stated that, instead, CMS stated that the statutory default of ASP+6 percent ''requires no further adjustment'' because it ''represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.'' Moreover, the commenters added, CMS has applied the statutory default rate without further adjustment in each subsequent year. They asserted that the CY 2018 proposal, in contrast, departs dramatically from longstanding prior practice and adopts a substantially reduced payment rate of ASP minus 22.5 percent for drugs acquired under a 340B Program.

Response: As discussed in the earlier background section, section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary authority to adjust, as necessary for purposes of paragraph (14) of section 1833(t) of the Act, the applicable payment rate for separately payable covered outpatient drugs under the OPPS. Specifically, we believe that the proposed reduced payment for 340B-acquired drugs would meet the requirements under section 1833(t)(14)(A)(iii)(II) of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph* (paragraph (14) of section 1833(t) of the Act) (emphasis added). We do not have hospital acquisition cost data for 340B drugs and, therefore, we proposed to continue to pay for these drugs under the methodology in our authority at section 1833(t)(14)(A)(iii)(II) of the Act which we determined to be ASP, and then to adjust that amount by applying a reduction of 22.5 percent to that payment methodology, which, as explained throughout this section, is the adjustment we believe is necessary to more closely align with the acquisition costs for drugs acquired under the 340B Program.

As previously stated, we believe that using an average discount to set payment rates for separately payable 340B-acquired drugs will achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs and (2) protecting the confidential nature of discounts applied to a specific drug. Furthermore, our proposed and finalized policy will lower OPPS payment rates for Medicare beneficiaries who receive drugs at hospitals subject to the 340B payment reduction.

In addition, we do not believe that the fact that we have not historically utilized our adjustment authority under section 1833(t)(14)(A)(iii)(II) of the Act to adjust payment amounts for separately payable 340B-acquired drugs means we are permanently barred from adjusting these payments where, as here, we have provided a reasoned explanation for doing so. We continue to believe, as the commenter noted, that ASP+6 percent requires no further adjustment for drugs that are not acquired under the 340B Program because, at this time, we have not found similar evidence of the difference between the statutory benchmark (ASP+6 percent) and average hospital acquisition costs for such drugs. However, that is not the case for 340B-acquired drugs. As explained in detail throughout this section, we believe that a payment amount of ASP minus 22.5 percent for drugs acquired under the 340B Program is better aligned to hospitals' acquisition costs and thus this adjustment, for drugs acquired under the 340B Program, is necessary for Medicare OPPS payment policy.

- *Violation of Section 340B of the Public Health Service Act*

Comment: Some commenters stated that the proposed payment reduction would violate the 340B statute, which expressly defines the types of hospitals that may receive the benefits of 340B discounts. One commenter asserted that the payment proposal would ''hijack Congress' carefully crafted statutory scheme by seizing 340B discounts from hospitals and transferring the funds to providers that Congress excluded from the 340B Program,'' thereby violating section 340B of the Public Health Service Act. The commenter further noted that discounts under the 340B Program are only available to ''covered entities'' that are defined by law and that Congress thus intended the benefits of the program to accrue to these providers only. The commenter contended that Congress' reference to Medicare definitions when describing covered entities demonstrates that it considered the Medicare program when it adopted the 340B Program and decided not to grant discounts to all Medicare hospitals. Rather, the commenter believed that Congress made a deliberate decision to limit the benefits of the 340B Program only to Medicare hospitals that serve large numbers of low-income or other underprivileged patients. In addition, the commenter stated that when Congress has intended Federal health care programs to intrude upon the 340B Program, it has been crystal clear.

In contrast, commenters asserted that Congress has been wholly silent on the relationship between 340B and Medicare Part B, which indicates Congress's intent that Medicare should not ''encroach'' upon the 340B Program

by ''redistributing [340B] discounts to non-340B providers.'' The commenters noted that the 340B statute and Medicare have coexisted for several years and that Congress has had ample opportunity to amend the Medicare statute governing Part B payments and/or the 340B statute to expressly permit CMS to reduce Medicare payments to 340B hospitals, but has not done so. As an example, the commenters cited legislation enacted in 2010, in which Congress amended both the 340B and the Medicare statutes, but did not authorize CMS to redistribute 340B savings to non-340B hospitals or to Part B generally.

Commenters further asserted that the proposed cut to 340B hospitals is also contrary to Congress's intent for the 340B Program to enable safety-net providers to reach more patients and furnish more comprehensive services and would undermine this purpose by preventing the operation of the 340B statute. These commenters suggested that, although manufacturers would still have to give 340B discounts, 340B participating hospitals would receive no benefit from those discounts; thus, the statutory purpose of 340B would be fatally undermined.

Response: We do not believe that this proposal under section 1833(t) of the Act is in conflict with section 340B of the Public Health Service Act. Section 1833(t) of the Act governs Medicare payment policies for covered hospital outpatient department services paid under the OPPS, while section 340B of the Public Health Service Act governs eligibility and program rules for participation in the 340B Program. There are no references in either section of law to each other. In fact, the failure of either statute to reference the other proves the opposite—that each statute stands on its own and neither is hindered or rendered null and void by the other. There is no requirement in the Public Health Service Act that the 340B Program ''guarantee'' or provide a certain profit from the Medicare program. Likewise, there is no requirement in section 1833(t) of the Act to pay a particular rate for a hospital enrolled in the 340B Program. We agree with the commenters that Congress was aware of both the 340B Program and the OPPS and of the programs' relationships to one another. However, we believe that the silence of each statute with respect to the other should not be viewed as a constraint on the broad authority conferred to the Secretary under section 1833(t) of the Act to establish payment rates under the OPPS.

Furthermore, we are unaware of legislative history or other evidence to corroborate the commenters' belief that Congress' silence on the relationship between 340B and Medicare Part B OPPS payments should be viewed as constraining the Secretary's ability under section 1833(t)(14) of the Act as to how to calculate payment rates for drugs acquired under the 340B Program under the OPPS. While legislative silence can be difficult to interpret, we note that Congress' silence regarding the 340B Program in enacting Medicare OPPS payment for certain drugs would create the opposite inference. The 340B Program existed well before Congress enacted the Medicare OPPS and payment for certain drugs. If Congress wanted to exempt 340B drugs or entities with a 340B agreement from Medicare OPPS payment for drugs generally, it easily could have done so. Instead, Congress provided for Medicare OPPS drug payments ''as calculated and adjusted by the Secretary as necessary,'' without any mention of, or restriction regarding, the already existent 340B Program.

We also disagree with commenters who believe that implementing the OPPS payment methodology for 340B-acquired drugs as proposed will ''eviscerate'' or ''gut'' the 340B Program. As discussed earlier in the background section, the findings from several 340B studies conducted by the GAO, OIG, and MedPAC show a wide range of discounts that are afforded to 340B hospitals, with some reports finding discounts of up to 50 percent. As stated in the proposed rule, we believe ASP minus 22.5 percent is a conservative estimate of the discount for 340B-acquired drugs and that even with the reduced payment, hospitals will continue to receive savings that can be directed at programs and services to carry out the intent of the 340B Program.

With respect to the comment that the proposal would frustrate the intent of the 340B Program and redirect Medicare payments to other hospitals that do not participate in the 340B Program, we reiterate that we proposed to redistribute the savings in an equal and offsetting manner to all hospitals paid under the OPPS, including those in the 340B Program, in accordance with the budget neutrality requirements under section 1833(t)(9)(B) of the Act. However, we remain interested in exploring ways to better target the offsetting amount to those hospitals that serve low-income and uninsured patients, as measured by uncompensated care. Details on the redistribution of funds are included in section XVIII. of this final rule with comment period.

- Proposal Is Procedurally Defective and Inconsistent With Advisory Panel Recommendations

Comment: Some commenters contended that the proposal is procedurally defective under the OPPS statute. The commenters asserted that the Secretary's justification for the proposed reduced rate rests, in part, on intertwined issues related to clinical use and hospital cost of drugs. The commenters objected to CMS' reference to studies suggesting that 340B hospitals may be unnecessarily prescribing more drugs and/or more expensive drugs relative to non-340B hospitals as support for proposing a payment rate that eliminates the differential between acquisition cost and Medicare payment. These commenters cited other studies in an effort to refute the evidence presented in the proposed rule.[29] [30] The commenters believed that CMS should have asked the HOP Panel to consider the intertwined issues of drug cost and clinical use prior to making a proposal to reduce payment for 340B-acquired drugs, and the Secretary should have consulted with the HOP Panel in accordance with section 1833(t)(9)(A) of the Act, as part of the process of review and revision of the payment groups for covered outpatient department services and the relative payment weights for the groups. The commenters argued that, because the Secretary did not consult with the HOP Panel before publishing its 340B payment proposal, the Secretary acted contrary to the statute. The commenters noted that at the August 21, 2017 meeting of the HOP Panel that occurred after publication of the proposed rule, the Panel urged that CMS not finalize the proposed payment reduction.

At the August 21, 2017 meeting of the HOP Panel, the Panel made the following recommendations with respect to the proposed policy for OPPS payment for drugs acquired under the 340B Program:

The Panel recommended that CMS:

- Not finalize its proposal to revise the payment rate for drugs purchased under the 340B Program;
- Collect data from public comments and other sources, such as State

[29] Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016). Available at: *http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf.*

[30] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017). Available at: *http://www.340bhealth.org/files/LowIncomeOncology.pdf*;

Medicaid programs in Texas and New York, on the potential impact of revising the payment rate, implementing a modifier code, and the effects of possible mechanisms for redistributing the savings that result from changing the payment rate; and

- Assess the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved.

In addition, one commenter suggested that the proposal was ''procedurally defective'' because the proposal was solely articulated through preamble and did not propose to amend the Code of Federal Regulations (CFR). The commenter asserted that the proposal cannot be implemented without a change to the Medicare regulations and stated that the Medicare statute requires CMS to issue regulations when altering the substantive standards for payment.[31] The commenter stated that the proposal falls squarely within this requirement because it would change the substantive legal standard governing payments to 340B hospitals for separately payable drugs.

Another commenter stated that CMS' proposal also violates section 1833(t)(2)(E) of the Act because the agency is not authorized and did not offer a reasoned basis for applying savings achieved as a result of its proposal to reduce significantly payments to 340B hospitals to Part B services generally. Likewise, a few commenters stated that the Administrative Procedure Act (APA) requires the Secretary to offer a ''reasoned basis'' for proposing to take an unprecedented action. The commenters suggested that, as a matter of longstanding policy and practice, the Secretary has never applied such a sweeping change to drug rates nor has it ever applied savings from OPPS outside of the OPPS.

Response: We remind the commenters that our proposal was based on findings that ASP minus 22.5 percent reflects the minimum average discount that hospitals in the 340B Program receive. We are familiar with the reports the commenters referenced in their comments. However, we continue to believe, based on numerous studies and reports, that 340B participation is not well correlated to the provision of uncompensated care and is associated with differences in prescribing patterns and drug costs. For example, as noted earlier in this section, GAO found that ''in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals,'' thus indicating that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis.

With respect to the HOP Panel, we believe that this comment reflects a misunderstanding of the Panel's role in advising the Secretary. Section 1833(t)(9)(A) of the Act provides that 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.

The provisions described under section 1833(t)(9)(A) of the Act do not impose an obligation on the Secretary to consult with the HOP Panel *prior* to issuing a notice of proposed rulemaking nor do they require the Secretary to adopt the Panel's recommendation(s). Rather, the statute provides that the Secretary shall consult with the Panel on policies affecting the clinical integrity of the ambulatory payment classifications and their associated weights under the OPPS. The Secretary met the requirement of section 1833(t)(9)(A) of the Act at the HOP Panel August 21, 2017 meeting in which the Panel made recommendations on this very proposed policy. The HOP Panel's recommendations, along with public comments to the proposed rule, have all been taken into consideration in the development of this final rule with comment period.

While we are not accepting the HOP Panel's recommendation not to finalize the payment reduction for drugs purchased under the 340B Program, as discussed later in this section, we are modifying our position on the modifier in an effort to ease administrative burden on providers, taking into account the way in which the modifier is used in several State Medicaid programs, as the Panel recommended. In addition, we have collected data from public comments on the potential impact of revising the payment rate, implementing a modifier, and the effects of possible mechanisms for redistributing the ''savings'' (or the dollars that result) from changing the payment rate and have assessed the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved, all of which were steps the HOP Panel recommended we take.

Regarding the comments asserting that the Secretary is out of compliance with procedures used to promulgate regulations as described under section 1871 of the Act (42 U.S.C. 1395hh), we note that we have received public comments on our interpretation of the Medicare statute, and we respond to those comments above. We further note that we did not establish in the Code of Federal Regulations the rates for separately payable, nonpass-through drugs and biologicals in past rulemakings. Because we have not adopted regulation text that prescribes the specific payment amounts for separately payable, nonpass-through drugs and biologicals, there was no regulation text to amend to include our proposed payment methodology for drugs acquired under the 340B Program. However, this does not mean that payment rates for separately payable drugs were not available to the public. That information is available in Addendum B to this final rule with comment period, which lists the national payment rates for services paid under the OPPS, including the payment rates for separately payable drugs and biologicals based on ASP+6 percent. We note that we have not provided the reduced payment rates for separately payable drugs and biologicals acquired under the 340B Program in Addendum B, but hospitals can arrive at those rates using the ASP+6 percent rate that is included in Addendum B. Finally, with respect to comments on redistribution of the dollars that result from the 340B payment policy, we are finalizing our proposal to achieve budget neutrality for the payment reduction for 340B-acquired drugs through an increase in the conversion factor. We disagree that our proposal to apply budget neutrality in accordance with section 1833(t)(9)(B) of the Act violates the APA or statutory authority. Further, we note that if we decide to take a different approach with respect to the redistribution of funds for budget neutrality in the future, we will consider such approach in future rulemaking.

- Impact on Medicare Beneficiary Cost-Sharing

Comment: Some commenters noted that Medicare beneficiaries, including dual-eligible Medicare beneficiaries,

[31] ''No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation. . . .'' Section 1871 of the Social Security Act (42 U.S.C. 1395hh).

would not directly benefit from a lowered drug copayment amount. The commenters noted that many beneficiaries have supplemental insurance that covers their out-of-pocket drug costs, in whole or in part. These commenters asserted that the proposal would actually increase their out-of-pocket costs for other Part B benefits.

Response: The cost-sharing obligation for Medicare beneficiaries is generally 20 percent of the Medicare payment rate. While many Medicare beneficiaries may have supplemental coverage that covers some or all of their out-of-pocket expenses, not all beneficiaries have such coverage. This policy will lower both the amount that a beneficiary is responsible to pay as well as the amount that any supplemental insurance, including the Medicaid program, will pay on behalf of the beneficiary. While we are implementing this policy in a budget neutral manner equally across the OPPS for CY 2018 for non-drug items and services, we may revisit how any savings from the lowered drug payment rate for 340B drugs may be allocated in the future and continue to be interested in ways to better target the savings to hospitals that serve the uninsured and low-income populations or that provide a disproportionate share of uncompensated care.

In addition, as noted earlier in this section, in the hospital setting, not only are beneficiaries liable for cost-sharing for drugs they receive, but they also incur a ''facility fee'' solely because the drug was furnished in the hospital setting. As described in section II.A.3.b. of this final rule with comment period, for CY 2018, we are adopting a policy to conditionally package Level 1 and Level 2 drug administration services and believe that these steps taken together may help encourage site-neutral care in that beneficiaries may receive the same drugs and drug administration services at the physician office setting without a significant difference in their financial liability between settings.

• *Calculation of Savings*

Comment: Commenters disagreed with CMS' impact estimate and a few commenters provided their own analysis of the 340B drug payment proposal. One commenter believed that even if CMS implements the policy as proposed, in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, payments for non-drug APCs would increase across hospitals by approximately 3.7 percent (in contrast to CMS' estimate of 1.4 percent). According to the commenter, this redistribution would result in a net decrease in payments to 340B hospitals of approximately 2.6 percent, or approximately $800 million. The commenter asserted that CMS' proposal would remove $800 million intended to support what it referred to as the congressionally mandated mission of 340B hospitals from these already vulnerable facilities and redistribute these dollars to other hospitals that do not participate in the 340B Program. Likewise, the commenter challenged CMS' suggested alternative approaches to achieving budget neutrality, such as applying offsetting savings to specific services within the OPPS or outside of the OPPS to Part B generally (such as to physician services under the Medicare Physician Fee Schedule), which the commenter believed would similarly penalize these most vulnerable hospitals and inhibit their efforts to carry out the purpose of the 340B Program. Finally, other commenters noted that implementing the proposed policy in a non-budget neutral manner would effectively ''gut'' the 340B Program.

Response: With respect to comments on the proposed distribution of savings, we refer readers to section XVIII. of this 2018 OPPS/ASC final rule with comment for discussion on the redistribution of savings that result from the estimated impact of the 340B policy as well as calculation of budget neutrality. Briefly, for CY 2018, we are implementing the alternative payment methodology for drugs purchased under the 340B Program in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor for nondrug services. Therefore, the resulting savings from the 340B payment policy will be redistributed pro rata through an increase in rates for non-drug items and services under the OPPS. We have already addressed comments relating to the assertion that our proposal would ''gut'' or ''eviscerate'' the 340B Program. Likewise, we have addressed the interaction between our authority under section 1833(t)(14)(A) of the Act relative to section 340B of the Public Health Service Act in our responses above.

(3) Other Areas

Comment: MedPAC commented reiterating its recommendations to Congress in its March 2016 Report to the Congress. Specifically, MedPAC commented that it recommended that payment rates for all separately payable drugs provided in a 340B hospital should be reduced to 10 percent of the ASP rate (resulting in ASP minus 5.3 percent after taking application of the sequester into account). MedPAC noted that its March 2016 report also included a recommendation to the Congress that savings from the reduced payment rates be directed to the Medicare-funded uncompensated care pool, which would target hospitals providing the most care to the uninsured, and in that way benefit indigent patients, and that payments be distributed in proportion to the amount of uncompensated care that hospitals provide. MedPAC believed that legislation would be needed to direct drug payment savings to the uncompensated care pool and noted that current law requires the savings to be retained with the OPPS to make the payment system budget neutral. MedPAC encouraged the Secretary to work with Congress to enact legislation necessary to allow MedPAC's recommendation to be implemented, if such recommendation could not be implemented administratively. MedPAC further noted that legislation would also allow Medicare to apply the policy to all OPPS separately payable drugs, including those on pass-through payment status.

Response: We thank MedPAC for its comments and for its clarification that its recommendation that ''[t]he Congress should direct the Secretary of the Department of Health and Human Services to reduce Medicare payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the average sales price (ASP)'' was intended to be 10 percent lower than the current Medicare rate of ASP+6 percent and would result in a final OPPS payment of ASP minus 5.3 percent when taking the sequester into account. However, we do not believe that reducing the Medicare payment rate by only 10 percentage points below the current payment rate of ASP+6 percent (that is, ASP minus 4 percent) would better reflect the acquisition costs incurred by 340B participating hospitals. In its May 2015 Report to the Congress, MedPAC estimated that the average minimum discount for a 340B hospital paid under the OPPS was ASP minus 22.5 percent, which it noted was a conservative, ''lower bound'' estimate. Further, in its March 2016 Report to the Congress, MedPAC stated that, ''[i]n aggregate, the Office of Inspector General (OIG) estimates that discounts across all 340B providers (hospitals and certain clinics) average 34 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs (MedPAC March 2016 Report to Congress, page 76). MedPAC further noted the estimate of the aggregate discount was based on all covered entities (hospitals and certain clinics).

Because 340B hospitals accounted for 91 percent of Part B drug spending for all covered entities in 2013, it is reasonable to assume that 340B hospitals received a discount similar to 33.6 percent of ASP (MedPAC March 2016 Report to Congress, page 79).

Further, as we stated in the proposed rule, the GAO reported that the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid to purchase the drug. In addition, voluntary participation in the PVP results in a covered entity paying a subceiling price on certain covered outpatient drugs (estimated to be approximately 10 percent below the ceiling price). (U.S. Department of Health and Human Services, HRSA FY 2018 Budget Justification)

Accordingly, we continue to believe that ASP minus 22.5 percent represents a conservative estimate of the average minimum discount that 340B-enrolled hospitals paid under the OPPS receive for drugs purchased with a 340B Program discount and that hospitals likely receive an even steeper discount on many drugs, especially brand name drugs. We also continue to believe that section 1833(t)(14)(A)(iii)(II) of the Act allows the Secretary to make adjustments, if hospital acquisition cost data is not available, as necessary, so that the Medicare payment rate better represents the acquisition cost for drugs and biologicals that have been acquired with a 340B discount.

With respect to MedPAC's comment regarding targeting the savings to uncompensated care, we refer readers to section XVIII.A.5. of this final rule with comment period.

- Comments Regarding Rural Hospitals

Comment: Commenters representing rural hospitals, particularly RRCs and SCHs, expressed opposition to the proposal, noting that it could be especially harmful to rural hospitals in light of the ''hospital closure crisis.'' One commenter cited a report from a health analytics company and noted that since 2010, 80 rural hospitals have closed and that one-third of remaining rural hospitals are vulnerable to closure, with 41 percent of rural hospitals operating at a financial loss.

Commenters noted that rural hospitals enrolled in the 340B Program depend on the drug discounts to provide access to expensive, necessary care such as labor and delivery and oncology infusions. The commenters stated that rural Americans are more likely to be older, sicker, and poorer than their urban counterparts. The commenter gave examples of rural hospitals that have used profit margins on 340B-acquired drugs to offset uncompensated care and staff emergency departments. In addition, the commenters stated that a portion of rural hospitals are excluded from purchasing orphan drugs through the 340B Program. Therefore, the commenters stated, these hospitals often use their 340B savings to offset the expense of purchasing orphan drugs, which they note comprise a growing number of new drug approvals.

In addition, a commenter representing several 340B-enrolled hospitals stated that multiple hospitals report that the 340B Program is the reason the hospital can provide oncology infusions in their local community and that the chemotherapy infusion centers tend to be small with variation in patients served based on the needs of the community. The commenter stated that, without the 340B Program, many rural hospitals would likely need to stop providing many of the outpatient infusions, thereby forcing patients to either travel 35 miles (in the case of SCHs which must generally be located at least 35 miles from the nearest like hospital) to another facility or receive care in a hospital inpatient setting, which is a more costly care setting. Another commenter, a member of Congress representing a district in the State of Ohio, commented that while the 340B Program is in need of reform, the program remains an important safety net for rural hospitals in Ohio and around the country. The commenter stated that 340B hospitals offer safety-net programs to their communities, including opioid treatment programs, behavioral health science programs, and others. The commenter further stated that the 340B drug payment proposal did not address broader structural issues with the 340B Program itself, including lack of oversight and clear guidance and definitions, and that the proposal could harm the hospitals that the 340B Program was intended to help. In addition, the commenter noted that ''arbitrary cuts'' to the 340B Program for safety-net hospitals could have detrimental impacts on the economic growth and opportunities in the communities those hospitals serve and that the proposal does not advance the larger goals of 340B Program reform.

One commenter noted that SCHs face 47.5 percent higher levels of bad debt and 55 percent lower profit margins. Thus, even with 340B discounts, the commenter argued that rural hospitals like rural SCHs are financially threatened. Commenters also noted that rural hospitals are typically located in lower income economic areas and are not able to absorb the proposed reduction in drug payment for 340B purchased drugs. Moreover, commenters suggested that the proposal disproportionately impacts rural hospitals compared to its effect on urban hospitals.

Finally, commenters requested that, if CMS finalizes the policy as proposed, CMS exempt hospitals with a RRC or SCH designation from the alternative 340B drug payment policy. The commenters asserted that RRCs and SCHs are rural safety-net hospitals that provide localized care for Medicare beneficiaries and also serve as ''economic engines'' for many rural communities.

Response: We share commenters' concerns about access to care, especially in rural areas where access issues may be even more pronounced than in other areas of the country. We note our proposal would not alter covered entities' access to the 340B Program. The alternative 340B drug payment methodology solely changes Medicare payment for 340B-acquired drugs.

Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

In the CY 2018 OPPS/ASC proposed rule, we sought public comment for future policy refinements on whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPS payments for drugs acquired under the 340B program. Taking into consideration the comments

regarding rural hospitals, we believe further study on the effect of the 340B drug payment policy is warranted for classes of hospitals that receive statutory payment adjustments under the OPPS. In particular, given challenges such as low patient volume, it is important that we take a closer look at the effect of an ASP minus 22.5 percent payment on rural SCHs.

With respect to RRCs, we note that there is no special payment designation for RRCs under the OPPS. By definition, RRCs must have at least 275 beds and therefore are larger relative to rural SCHs. In addition, RRCs are not subject to a distance requirement from other hospitals. Accordingly, at this time, we are not exempting RRCs from the 340B payment adjustment.

For CY 2018, we are excluding rural SCHs (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes) from this policy. We may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction, in the CY 2019 OPPS rulemaking.

• Children's and PPS-Exempt Cancer Hospitals

Comment: Commenters representing children's hospitals (''children's'') raised objections to the proposal because of the potential impact on the approximate 8,000 children with end-stage renal disease (ESRD) who are eligible for Medicare. One commenter cited that currently 48 children's hospitals participate in the 340B Program and rely on the savings the program provides to enhance care for vulnerable children. According to the commenter, pediatric ESRD patients require high levels of care and rely on life-saving pharmaceuticals that often come at a high cost. Therefore, the commenters posited that it is because children's patients are more expensive to treat and not because of inappropriate drug use that 340B hospitals incur higher drug expenditures. In addition, the commenters expressed concern with the effect the 340B drug payment policy may have on State Medicaid programs, considering Medicaid is the predominant payer type for children's hospitals. The commenters requested that, unless CMS is able to examine the impact on pediatric Medicare beneficiaries, CMS should exempt children's hospitals from the alternative 340B drug payment methodology.

An organization representing PPS-exempt cancer hospitals commented that CMS' proposal would severely harm the hospitals that treat the most vulnerable and underserved patients and communities, undermining these hospitals' ability to continue providing programs designed to improve access to services. The commenter believed that assumptions alluded to in the CY 2018 OPPS/ASC proposed rule, which suggested that providers are abusing the savings generated from the 340B Program or potentially creating incentives to over utilize drugs, are inaccurate and that clinicians provide the care that is necessary to treat a patient's disease. The commenter suggested that CMS work with, or defer to, HRSA to first conduct a complete analysis of how the 340B Program is utilized for the benefit of patients prior to proposing any changes to Medicare payment for drugs purchased through the program.

Response: We share the commenters' views on protecting access to high quality care for all Medicare beneficiaries, including those treated in children's or PPS-exempt cancer hospitals. Further, because of how these classes of hospitals are paid under the OPPS, we recognize that the 340B drug payment proposal may not result in reduced payments for these hospitals in the aggregate.

Specifically, in accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. That is, these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure.

Accordingly, we believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology for CY 2018. Therefore, for CY 2018, we are excluding children's and PPS-exempt cancer hospitals from the alternative 340B drug payment policy. As discussed in a later section in this final rule with comment period, because we are redistributing the dollars in a budget neutral manner within the OPPS through an offsetting increase to the conversion factor, children's hospitals and PPS-exempt cancer hospitals will receive a higher payment when providing a non-drug service.

In summary, we are adopting for CY 2018 an exemption for rural SCHs, children's hospitals, and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology. These three types of hospitals will not be subject to a reduced drug payment for drugs that are purchased under the 340B Program in CY 2018. We may revisit the specific types of hospitals excluded, if any, from the 340B payment policy in CY 2019 rulemaking. However, as discussed in more detail below, it remains important to collect information on which drugs being billed to Medicare were acquired under the 340B Program. Accordingly, these three types of hospitals will still be required to report an informational modifier ''TB'' for tracking and monitoring purposes. We may revisit this 340B drug payment policy, including whether these types of hospitals should continue to be excepted from the reduced Medicare payment rate, in future rulemaking.

• Biosimilar Biological Products

Comment: Some commenters expressed opposing views about applying the proposed 340B payment methodology to biosimilar biological products. One pharmaceutical manufacturer recommended that the Secretary use his equitable adjustment authority at section 1833(t)(2)(E) of the Act to apply a narrow equitable adjustment to biosimilar biological products with pass-through payment status to pay for these drugs at ASP minus 22.5 percent of the reference product rather than ASP+6 percent of the reference product. The commenter asserted that excluding biosimilar biological products from the alternative 340B payment methodology would result in a significant payment differential between biosimilar biological products and reference products which may cause providers to switch patients to different products for financial reasons, rather than clinical factors. The commenter stated that, if the policy is implemented as proposed, the competitive biosimilar marketplace would significantly change because Medicare would pay more for the biosimilar biological product with pass-through payment status and weaken market forces. The commenter estimated that if the 340B drug policy is implemented as proposed, up to $50 million of any savings could be lost due to hospitals switching to the biosimilar biological product on pass-through payment status (that will be paid at ASP+6 percent of the reference product). Moreover, the commenter pointed out that CMS' policy to only provide pass-through payments for the

first eligible biosimilar biological product of any reference biological would also create a similar payment disadvantage for any subsequent biosimilar biological product, which would be ineligible for pass-through payment under CMS' policy.

Another commenter, a different pharmaceutical manufacturer, requested that CMS exclude biosimilar biological products from the proposed payment adjustment until such time as the biosimilar biological product market is better established. The commenter indicated that while a biosimilar biological product is less expensive to the Medicare program, hospitals are incented by the 340B Program to purchase the originator product because of ''the spread'' or payment differential with respect to the originator product. Moreover, the commenter stated that applying the proposed adjustment to payment for biosimilar biological products in certain hospitals will retain market share for the more expensive reference product that is further compounded by market practices of volume-based rebates and exclusionary contracts for the reference product.

Response: We understand the commenters' concerns. As discussed in section V.B.2. of this CY 2018 OPPS/ASC final rule with comment period, we are adopting the biosimilar biological products HCPCS coding established under the CY 2018 MPFS final rule. Briefly, we adopted a final policy to establish separate HCPCS codes for each biosimilar biological product for a particular reference product beginning January 1, 2018. In addition, we also stated in section V.B.2. of this CY 2018 OPPS/ASC final rule with comment period that we are making a conforming amendment to our pass-through payment policy for biosimilar biological products such that each FDA-approved biosimilar biological product will be eligible for transitional pass-through payment instead of only the first biosimilar for a particular reference product.

Therefore, given the policy changes affecting coding and payment for biosimilar biological products that we are adopting in the CY 2018 MPFS final rule and this CY 2018 OPPS/ASC final rule with comment period, we disagree with the commenters that we should exclude biosimilar biological products from the 340B payment policy or use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to adjust payment to ASP minus 22.5 percent of the reference product for biosimilar biological products with pass-through payment status. We believe the statutory provision on transitional drug pass-through payment under section 1833(t)(6)(D)(i) of the Act provides for an explicit payment for drugs eligible for pass-through payment. Therefore, we are unable to accept the commenter's request to pay a biosimilar biological product on pass-through payment status the reduced 340B payment rate. We are adopting a policy that any biosimilar biological product with pass-through payment status will be exempt from the alternative payment methodology for 340B drugs and will continue to be paid at ASP+6 percent of the reference product. Biosimilar biological products that are not on pass-through payment status will be paid ASP minus 22.5 percent of the reference product. We believe it is appropriate to pay this amount for biosimilar biological products as it is consistent with the amount paid for non-340B-acquired biosimilar biological products, which is ASP+6 percent of the reference product. Currently, there are two biosimilar biological products available on the market and both are on pass-through payment status for the entirety of CY 2018. Therefore, no biosimilar biological products currently available will be affected by the alternative payment methodology for 340B-acquired drugs for CY 2018. We recognize the concerns about paying different rates for similar drugs and biologicals and continue to assess the feasibility and practicality of an alternative 340B payment adjustment for biosimilar biological products in the future.

- Nonexcepted Off-Campus Hospital Outpatient Departments

Comment: A few commenters noted that CMS' proposed alternative payment methodology for 340B purchased drugs would not apply to nonexcepted off-campus provider-based departments (PBDs) of a hospital and could result in behavioral changes that may undermine CMS' policy goals of reducing beneficiary cost-sharing liability and undercut the goals of section 603 of the Bipartisan Budget Act of 2015. Commenters recommended that, if CMS adopts a final policy to establish an alternative payment methodology for 340B drugs in CY 2018, CMS also apply the same adjustment to payment rates for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs are acquired under the 340B Program. In addition, the commenters believed that because CMS did not propose to limit the expansion of services or volume increases at excepted off-campus PBDs, CMS will create financial incentives for hospitals to shift or reallocate services to the site of care that pays the highest rate for an item or service.

Response: We appreciate the commenter's concerns about potential unintended consequences of our proposal. We will continue to monitor the billing patterns of claims submitted by nonexcepted off-campus outpatient PBDs as we continue to explore whether to pursue future rulemaking on the issues of clinical service line expansion or volume increases, and other related section 603 implementation policies.

In the CY 2017 OPPS/ASC final rule with comment period, we discussed the provision of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 144–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered outpatient department services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met (81 FR 79699). We issued an interim final rule with comment period along with the CY 2017 OPPS/ASC final rule with comment period to establish the MPFS as the ''applicable payment system,'' which will apply in most cases, and payment rates under the MPFS for non-excepted items and services furnished by nonexcepted off-campus outpatient provider based departments (PBDs) (81 FR 79720). (Other payment systems, such as the Clinical Laboratory Fee Schedule, continue to apply in appropriate cases.) That is, items and services furnished by nonexcepted off-campus outpatient PBDs, are nonexcepted items and services that are not covered outpatient services, and thus, are not payable under the OPPS. Rather, these nonexcepted items and services are paid ''under the applicable payment system,'' which, in this case, is generally the MPFS.

As we discussed in the CY 2017 OPPS/ASC interim final with comment period (81 FR 79718) and reiterated in the CY 2018 MPFS final rule, payment for Part B drugs that would be separately payable under the OPPS (assigned status indicator ''K'') but are not payable under the OPPS because they are furnished by nonexcepted off-campus outpatient PBDs will be paid in accordance with section 1847A of the Act (generally, ASP+6 percent),

consistent with Part B drug payment policy in the physician office. We did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018 but may consider adopting such a policy in CY 2019 notice-and-comment rulemaking.

• Data Collection and Modifier

Comment: The vast majority of commenters objected to CMS' intention to require hospitals that *do not* purchase a drug or biological through the 340B program to apply a modifier to avoid a reduced drug payment. A few commenters supported the modifier proposal. The commenters who disagreed with proposal stated that it would place an unnecessary administrative and financial burden on hospitals that do not participate or are not eligible to participate in the 340B Program. Similarly, the commenters stated that the modifier requirement as described in the proposed rule would put a financial and administrative strain on hospitals with fewer resources. In addition, the commenters contended that a requirement for hospitals to report a modifier for drugs that were not acquired under the 340B Program would place hospitals at significant risk for noncompliance if not implemented correctly, which many commenters believe is nearly impossible to do. As an alternative approach, numerous commenters recommended that CMS require hospitals that *do* purchase a drug under the 340B Program to report the modifier, rather than those that do not.

Regarding a January 1, 2018, implementation date for the modifier, some commenters expressed concern and doubted their ability to implement the modifier as described in the proposed rule accurately. The commenters indicated that additional time would be needed to adapt billing systems, allow for testing of claims reported with the modifier, and educate staff. Based on discussion of how the modifier would work in the proposed rule, the commenters stated that hospitals would either have to append the modifier to the claim at the time the drug is furnished, or retroactively apply the modifier, thus delaying claims submission to Medicare.

The commenters provided detailed descriptions on hospital pharmacy set up, including information on software tools to support inventory management of drugs dispensed to 340B and non-340B patients (based on HRSA definition of an eligible patient). One commenter indicated that the drug supply system used for purchasing covered outpatient drugs is completely separate from—and does not necessarily communicate with—the hospital's pharmacy drug dispensing and patient billing systems. While these software tools enable split-billing to distinguish 340B and non-340B patients, the commenters noted that this patient determination is typically not done in real time when a drug is administered. Commenters noted that 340B hospitals that use split-billing software do not receive information on 340B patient status on a daily basis and the proposal could result in delayed billing. The commenters stated that hospitals typically make these determinations retrospectively and it may be 3 to 10 days post-dispensing before the hospital knows whether a drug was replenished under 340B or at regular pricing. The commenters noted that, under this ''replenishment model,'' hospitals track how many 340B-eligible drugs are used, and once enough drugs are dispensed to complete a package, they will replenish the drug at the 340B rate. As such, the commenters argued that hospitals do not know when the drug is dispensed whether it will cost them the 340B rate or the wholesale acquisition cost (WAC). Therefore, the commenters expressed concern that the modifier requirement as described in the proposed rule would result in billing delays and, for some hospitals, may cause a short-term interruption in cash flow.

In addition, the commenters requested that, while the payment reduction would apply to nonpass-through separately payable drugs purchased with a 340B discount, CMS accept the modifier when reported with drug HCPCS codes that are packaged (and for which no separate payment will be made) to reduce or prevent operational burden that may be caused if affected providers have to determine on a claim-by-claim basis whether a drug is eligible for separate payment.

With respect to State Medicaid programs that also require a modifier to identify 340B-purchased drugs on outpatient claims, the commenters noted that CMS' proposal would be counter to Medicaid requirements and would create confusion and add complexity for providers who treat Medicaid recipients in multiple states. The commenters reported that many State Medicaid programs require a modifier to identify drugs that were purchased under 340B to administer their Medicaid drug rebate programs to prevent duplicate discounts on 340B drugs. The commenters suggested that if CMS reversed its position on application of the modifier, it would ensure crossover claims (claims transferred from Medicare to Medicaid) are correctly interpreted by State Medicaid programs so that they can appropriately request manufacturer rebates on drugs not purchased under the 340B Program. Moreover, some commenters believed that if CMS required the modifier to be reported for 340B-purchased drugs, State Medicaid programs would also adopt the modifier, leading to national uniformity in reporting of 340B drugs.

Finally, in the event that CMS required the modifier on claims for 340B drugs, rather than non-340B drugs, commenters sought clarity on whether the modifier applies only to drugs purchased under the 340B Program which are subject to a ceiling price payment from the manufacturer or if the modifier would also apply to drugs purchased by a 340B-registered facility, but purchased under the Prime Vendor Program for which only 340B facilities are eligible. One commenter asked that CMS emphasize that 340B pricing is not available on drugs furnished to hospital inpatients.

Response: We appreciate the detailed comments that were submitted. As noted in the proposed rule, we did not propose to establish the modifier but rather noted our intent to establish the modifier, regardless of whether we adopted the alternative payment methodology for drugs acquired through the 340B Program. However, we are responding to some of the comments submitted in this final rule with comment period with information on this modifier that we believe is important to communicate as soon as possible. We will consider whether additional details will need to be communicated through a subregulatory process, such as information posted to the CMS Web site.

After considering the administrative and financial challenges associated with providers reporting the modifier as described in the CY 2018 OPPS/ASC proposed rule, and in order to reduce regulatory burden, we are reversing our position on how the modifier will be used by providers to effectuate the payment adjustment for 340B-purchased drugs.

Specifically, beginning January 1, 2018, providers who are not excepted from the 340B payment adjustment will report modifier ''JG'' (Drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug *was* acquired under the 340B Program. This requirement is aligned with the modifier requirement already mandated in several States under their Medicaid programs. Therefore, we believe that this option will pose less of an administrative burden. Further, having

consistent application of the modifier being required for a drug that was purchased under the 340B Program instead of a drug not purchased under the 340B Program will help improve program integrity by helping ensure that hospitals are not receiving ''duplicate discounts'' through both the Medicaid rebate program and the 340B Program. The phrase ''acquired under the 340B Program'' is inclusive of all drugs acquired under the 340B Program or PVP, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program should not be reported with the modifier ''JG''. For separately payable drugs (status indicator ''K''), application of modifier ''JG'' will trigger a payment adjustment such that the 340B-acquired drug is paid at ASP minus 22.5 percent. In response to the commenters' request that we allow the 340B modifier to be reported with status indicator ''N'' drugs (that is, drugs that are always packaged), we will accept modifier ''JG'' or ''TB'' to be reported with a packaged drug (although such modifier will not result in a payment adjustment).

In addition, beginning January 1, 2018, providers that are excepted from the 340B drug payment policy for CY 2018, which include rural SCHs, children's hospitals, and PPS-exempt cancer hospitals, should not report modifier ''JG''. Instead, these excepted providers should report the informational modifier ''TB'' (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount. The informational modifier ''TB'' will facilitate the collection and tracking of 340B claims data for OPPS providers that are excepted from the payment adjustment in CY 2018. However, use of modifier ''TB'' will not trigger a payment adjustment and these providers will receive ASP+6 percent for separately payable drugs furnished in CY 2018, even if such drugs were acquired under the 340B Program.

For drugs administered to dual-eligible beneficiaries (that is, beneficiaries covered under both Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program, the State Medicaid programs should be aware of modifier ''JG'' to help further prevent inappropriate billing of manufacturer rebates.

With respect to comments about timing to operationalize a modifier, we note that hospitals have been on notice since the proposed rule went on display at the Office of the Federal Register on July 13, 2017 that we intended to establish a modifier to implement the policy for payment of drugs acquired under the 340B Program, if finalized. In addition, the modifier will not be required until January 1, 2018, which after display of this final rule with comment period will give hospitals two additional months to operationalize the modifier. Under section 1835(a) of the Act, providers have 12 months after the date of service to timely file a claim for payment. Therefore, for those hospitals that may need more time to ensure that they are in compliance with the modifier requirements, they have 12 months from the date of service to do so.

Further, to the extent many hospitals already report a modifier through their State Medicaid program, we believe that also requiring the modifier on outpatient claims for 340B-acquired drugs paid for under the OPPS would not be a significant administrative burden and would promote consistency between the two programs. With respect to providers in States that are not currently required to report a modifier under the Medicaid program, we note that providers are nonetheless responsible for ensuring that drugs are furnished to ''covered patients'' under the 340B Program and, therefore, should already have a tracking mechanism in place to ensure that they are in compliance with this requirement. Furthermore, modifiers are commonly used for payment purposes; in this case, the presence of the modifier will enable us to pay the applicable 340B drug rate of ASP minus 22.5 percent and track these claims in the Medicare data (in the case of ''JG'' modifier) and will allow us to track other drugs billed on claims that are not subject to the payment reduction (modifier ''TB''). In addition, the presence of the both modifiers will enable Medicare and other entities to conduct research on 340B-acquired drugs in the future.

We remind readers that our 340B payment policy applies to only OPPS separately payable drugs (status indicator ''K'') and does not apply to vaccines (status indicator ''L'' or ''M''), or drugs with transitional pass-through payment status (status indicator ''G'').

Finally, Federal law permits Medicare to recover its erroneous payments. Medicare requires the return of any payment it erroneously paid as the primary payer. Medicare can also fine providers for knowingly, willfully, and repeatedly billing incorrectly coded claims. Providers are required to submit accurate claims, maintain current knowledge of Medicare billing policies, and ensure all documentation required to support the validity of the services reported on the claim is available upon request.

d. Summary of Final Policies for CY 2018

In summary, for CY 2018, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, separately payable Part B drugs (assigned status indicator ''K''), other than vaccines and drugs on pass-through payment status, that meet the definition of ''covered outpatient drug'' as defined in the section 1927(k) of the Act, that are acquired through the 340B Program or through the 340B PVP at or below the 340B ceiling price will be paid at the ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator ''L'' or ''M'') and drugs with OPPS transitional pass-through payment status (assigned status indicator ''G''). Medicare will continue to pay drugs that were not purchased with a 340B discount at ASP+6 percent.

Effective January 1, 2018, biosimilar biological products not on pass-through payment status that are purchased through the 340B program or through the 340B PVP will be paid at ASP minus 22.5 percent of the reference product's ASP, while biosimilar biological products on drug pass-through payment status will continue to be paid ASP+6 percent of the reference product.

To effectuate the payment adjustment for 340B-acquired drugs, CMS is implementing modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or those hospitals paid under the Maryland waiver) or excepted from the 340B drug payment policy for CY 2018, are required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural SCHs, children's hospitals and PPS-exempt cancer hospitals will be excepted from the 340B payment adjustment. These hospitals will be required to report informational modifier ''TB'' for 340B-acquired drugs, and will continue to be paid ASP+6 percent.

To maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final alternative 340B drug payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under

the OPPS for CY 2018. Specifically, the redistributed dollars will increase the conversion factor across non-drug rates by 3.2 percent for CY 2018.

We may revisit the alternative 340B drug payment methodology in CY 2019 rulemaking.

e. Comment Solicitation on Additional 340B Considerations

As discussed above, we recognize there are data limitations in estimating the average discount for 340B drugs. In the CY 2018 OPPS/ASC proposed rule (82 FR 33634 through 33635), we welcomed stakeholder input with regard to MedPAC's May 2015 analysis and the resulting estimate of ASP minus 22.5 percent as the proposed payment rate for separately payable, nonpass-through OPPS drugs purchased under the 340B Program in CY 2018. We also requested comment on whether we should adopt a different payment rate to account for the average minimum discount of OPPS drugs purchased under the 340B Program. Also, we sought comment on whether the proposal to pay ASP minus 22.5 percent for 340B-acquired drugs should be phased in over time (such as over a period of 2 to 3 years).

In addition, we recognize that the acquisition costs for drugs may vary among hospitals, depending on a number of factors such as size, patient volume, labor market area and case-mix. Accordingly, in the longer term, we are interested in exploring ways to more closely align the actual acquisition costs that hospitals incur rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals. In the proposed rule, we requested public comment on whether, as a longer term option, Medicare should require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim. Having the acquisition cost on a drug-specific basis would enable us to pay a rate under the OPPS that is directly tied to the acquisition costs for each separately payable drug. To the extent that the acquisition costs for some drugs may equal the ceiling price for a drug, we recognize that there may be challenges with keeping the ceiling price confidential as required by section 1927(b)(3)(D) of the Act and we sought comment on this point.

Lastly, for consideration for future policy refinements, we requested public comment on (1) whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPS payments to 340B participating hospitals (if so, describe how adjusted rates for drugs purchased under the 340B Program would disproportionately affect access in these provider settings); (2) whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment; and (3) whether hospital-owned or affiliated ASCs have access to 340B discounted drugs.

We received feedback on a variety of issues in response to the comment solicitation on additional future considerations. These comments are summarized below.

Comment: One commenter recommended that CMS establish an exemption mechanism for use by stakeholders to request exemptions for certain groups of hospitals. The commenters urged CMS to propose and seek comment on specific guidelines that outline procedures for stakeholders to request an exemption and the criteria CMS would use to determine whether to grant an exception.

Response: We appreciate the comment. As we stated in the summary of final policies, we may revisit the 340B drug payment policy in the CY 2019 rulemaking. For CY 2018, as stated earlier in this section, rural SCHs, children's hospitals and PPS-exempt cancer hospitals will be excepted from the alternative 340B drug payment methodology being adopted in this final rule with comment period. However, each of these excepted providers will report informational modifier ''TB'' on the same claim line as the HCPCS code for their 340B-acquired drugs.

Comment: In response to the solicitation of comments on whether CMS should exclude certain types of drugs from the proposed alternative 340B drug payment methodology, manufacturers of blood clotting factors and radiopharmaceuticals recommended that CMS continue to pay these drug types at ASP+6 percent. With respect to blood clotting factors, the commenters stated that individuals with bleeding disorders have unique needs and are expensive to treat such that the proposed reduced payment could threaten access and/or create unnecessary treatment delays for these patients. With respect to radiopharmaceuticals, the commenters stated that they do not believe that these products are covered outpatient drugs (because it is not possible for the manufacturer to accurately report final dose and pricing information), and therefore these drugs should be excluded as a category of drugs included in the covered drug definition for the 340B Program.

In addition, one commenter recommended that CMS develop a process for stakeholders to request exemptions from the alternative 340B payment methodology that CMS would evaluate using objective patient guidelines designed to ensure patient access.

Response: We appreciate the comments. To the extent that blood clotting factors and radiopharmaceuticals are covered outpatient drugs purchased under the 340B Program, we believe that the OPPS payment rate for these drugs should account for the discounted rate under which they were purchased. Therefore, for CY 2018, OPPS payment for separately payable, nonpass-through drugs, biologicals, and radiopharmaceuticals, including blood clotting factors and radiopharmaceuticals, if purchased through the 340B Program, will be paid at ASP minus 22.5 percent. As we stated in the summary of final policies, we may revisit the 340B drug payment policy in the CY 2019 rulemaking. We will consider these requests for exceptions for certain drug classes in development of the CY 2019 OPPS/ASC proposed rule.

It is unclear to us whether the commenter meant that radiopharmaceuticals are not considered covered outpatient drugs under the OPPS or not considered a covered outpatient drug for purposes of the 340B Program. We assume the commenter was referring to the definition of covered outpatient drug for purposes of the 340B Program and, as such, these comments are outside the scope of the CY 2018 OPPS/ASC proposed rule. We refer commenters to HRSA with questions related to the 340B Program.

Comment: One commenter representing community oncology practices urged CMS not to ''reduce the size of the reimbursement reduction'' or to phase in the adjustment over 2 to 3 years because the commenter believed that hospitals would use that time to ''aggressively strong-arm independent community oncology practices to sell out to them.''

Response: As stated earlier in this section, we are finalizing our proposal to pay ASP minus 22.5 percent for separately payable nonpass-through drugs (other than vaccines). In addition, we agree that it is not necessary to phase in the payment reduction and are implementing the full adjustment for CY 2018.

Comment: Commenters expressed concern about the challenges and costs of implementing acquisition cost billing.

The commenters reported that hospital charge masters are not designed to bill drugs to one payer at a different rate than other payers. The commenters cited a survey response from hospitals that revealed acquisition cost billing would require investment in expensive software upgrades, obtaining a second charge master, or devising burdensome manual workarounds. One commenter stated that hospital cost reports already reflect the 340B acquisition cost based on expenses reported in the pharmacy cost center. The commenter further stated that these lower costs are already reflected in the drug CCR, which will likely be lower because the cost to acquire these drugs is lower. Thus, the commenter asserted, the OPPS ratesetting process already reflects a blend of discounting/lower expenses with respect to 340B drug acquisition in the annual application of CCRs to pharmacy charges.

Response: We thank the commenters for their feedback and will take these comments into consideration for future policymaking. We note that several State Medicaid programs require reporting of actual acquisition cost (AAC) for 340B drugs so the magnitude of the challenges to implement may be less than the commenter suggests.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2018 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2018. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2017 or beginning in CY 2018. The sum of the CY 2018 pass-through spending estimates for these two groups of device categories equals the total CY 2018 pass-through spending estimate for device categories with pass-through payment status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the CY 2018 OPPS/ASC proposed rule (82 FR 33635), we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2018, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, 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) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we proposed to pay for most nonpass-through separately payable drugs and biologicals under the CY 2018 OPPS at ASP+6 percent, and because we proposed to pay for CY 2018 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of the proposed rule, our estimate of drug and biological pass-through payment for CY 2018 for this group of items was $0, as discussed below. In the proposed rule, we noted that our estimate did not reflect the proposed payment policy for drugs purchased through the 340B program, as we discussed in section V.A. of the proposed rule.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of the proposed rule and this final rule with comment period. In the CY 2018 OPPS/ASC proposed rule (82 FR 33635 through 33636), we proposed that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2018. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2018 was not $0, as discussed below. In section V.A.5. of the proposed rule, we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs