UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, 800 Tenth Street, NW, Suite 400 Washington, DC 20001, *et al.*, *Plaintiffs,* –v– ERIC D. HARGAN, in his official capacity as the Acting Secretary of Health and Human Services, 200 Independence Avenue, SW Washington, DC 20201, *et al.*, *Defendants.*	**Case No. _____**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES AND RULES

OTHER AUTHORITIES

Plaintiffs American Hospital Association ("AHA"), Association of American Medical Colleges ("AAMC"), America's Essential Hospitals ("AEH"), Eastern Maine Healthcare Systems, Henry Ford Health System, and Fletcher Hospital, Inc. d/b/a Park Ridge Health ("Park Ridge") (collectively, "Plaintiffs") respectfully submit this memorandum of law in support of their motion for a preliminary injunction. The requested injunction would direct the Department of Health and Human Services ("HHS") and its Acting Secretary Eric D. Hargan (collectively "Defendants") not to implement, pending resolution of this lawsuit, certain provisions of a final rule issued by the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS, on November 1, 2017. The final rule concerns the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. 82 Fed. Reg. 52,356 (Nov. 13, 2017). The provisions of the final CMS Rule that Plaintiffs are challenging in this lawsuit will hereafter be referred to as the "340B Provisions of the OPPS Rule" and are included as Exhibit A to this memorandum. *See also* 82 Fed. Reg. at 52,493-52,511, 52,622-52,625. Absent the requested injunction, the 340B Provisions of the OPPS Rule will take effect on January 1, 2018.

INTRODUCTION

Plaintiffs in this case are three hospital associations (the AHA, AAMC, and AEH, collectively the "Association Plaintiffs") and three of their member hospitals (Eastern Maine Healthcare Systems ("EMHS"), Henry Ford Health System ("Henry Ford"), and Park Ridge Health ("Park Ridge") (collectively the "Hospital Plaintiffs").[1] The 340B Provisions of the OPPS Rule, promulgated despite the recommendations of the advisory panel with whom CMS by statute must consult on these matters, would reduce by nearly 30% Medicare payments to

[1] All three Hospital Plaintiffs are members of AHA. Henry Ford is also a member of AAMC and AEH.

certain public and non-profit hospitals, including the Hospital Plaintiffs and other members of the Association Plaintiffs, for outpatient drugs purchased by those hospitals under section 340B of the Public Health Service Act (hereafter, "the 340B Program" or "the Program").

As explained below, the 340B Provisions of the OPPS Rule violate the Social Security Act and consequently should be set aside under the Administrative Procedure Act as unlawful and in excess of the Secretary's statutory authority. 5 U.S.C. §§ 706(2)(A), (C). If those provisions were to take effect as planned on January 1, 2018, they would cause the Hospital Plaintiffs and other members of the Association Plaintiffs irreparable harm by jeopardizing the many types of essential health programs that are currently funded by the differential between government Medicare drug reimbursements to hospitals and the discounted prices the hospitals pay for those drugs under the 340B program – an approximately $1.6 billion (by CMS's own estimate) total differential that the 340B Provisions of the OPPS Rule's nearly 30% reimbursement reduction is expressly designed to eliminate. A preliminary injunction suspending the effective date of the 340B Provisions of the OPPS Rule and maintaining essential medical programs pending resolution of Plaintiffs' legal challenge would avoid this irreparable harm, preserve the *status quo*, cause no harm to the Defendant government agencies and officials that have no direct economic or other tangible stake in the 340B Provisions of the OPPS Rule, and is in the public interest. Thus, Plaintiffs satisfy each of the four factors courts consider when deciding whether to grant a preliminary injunction.

STATUTORY AND REGULATORY BACKGROUND

A. The 340B Program

Congress created the 340B Program in 1992 to provide publicly-funded and certain not-for-profit hospitals and federally-funded clinics that service low-income patients (collectively, "covered entities") with outpatient drug discounts comparable to those available to state

Medicaid agencies. Under the 340B Program, codified at 42 U.S.C. § 256b, private prescription drug manufacturers, as a condition of having their outpatient drugs covered through state Medicaid programs, are required to offer covered entities outpatient drugs at or below an applicable, discounted ceiling price calculated pursuant to a statutory formula.[2] 42 U.S.C. § 256b(a)(1). CMS, relying on estimates contained in a 2015 Report to Congress by the Medicare Payment Advisory Commission ("MedPAC"),[3] estimates in its final rule that on average hospitals participating in the Medicare program receive a 22.5% discount on drugs and biologics purchased under the Program. 82 Fed. Reg. at 52,494.

Congress's intent in enacting the 340B program was "to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive." H.R. REP. NO. 102-384(II), at 12 (1992). CMS in the 340B Provisions of the OPPS Rule acknowledged this legislative intent. *See* 82 Fed. Reg. at 52,493 & n.18 (citing and quoting House Report). As explained by the Health Resources and Services Administration ("HRSA"), the agency within HHS responsible for administering the 340B Program, the Program furthers this recognized legislative purpose by "lower[ing] the cost of acquiring covered outpatient drugs," thereby creating a differential between the discounted acquisition costs of the drugs and the "revenue from grants or health insurance reimbursements"—*including reimbursements under Medicare*—that are "maintained or not reduced as much as the 340B discounts or rebates." HRSA, HEMOPHILIA TREATMENT CENTER MANUAL FOR PARTICIPATING IN THE DRUG PRICING PROGRAM ESTABLISHED BY SECTION 340B OF THE PUBLIC HEALTH SERVICE

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[2] The relevant statutory provisions are included in Exhibit B to this memorandum.

[3] 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 accessed Nov. 11, 2017).

ACT 14 (2005).[4] This differential, in turn, creates additional resources for covered entities to use to serve their communities, including the vulnerable populations in those communities. Thus, as HRSA has also noted, the 340B Program "permits HHS programs to provide additional financial capacity to assisted health care providers without increasing the Federal budget for the grant or other assistance programs that confer eligibility for the discounts." *Id.*

Since the 340B Program was first implemented more than 20 years ago, consistent with the design of the Program and congressional intent, covered entities have retained all savings generated through the Program. In recognition of the importance of financial flexibility to the operation of these covered entities, Congress did not specify how funds generated through the Program must be used, *see* 42 U.S.C. § 256b, although as discussed above it anticipated that participation in the 340B Program would enable covered entities to provide additional healthcare services to communities with vulnerable populations. A 2011 report from the U.S. Government Accountability Office ("GAO") found this is exactly what has 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. U.S. Gov't Accountability Off., GAO-11-836, MANUFACTURER DISCOUNT IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT 17-18 (2011) ("2011 GAO Report").[5] As noted by the Chairman of the House Committee on Energy and Commerce at an October 11, 2017, subcommittee hearing on the

[4] *Available at* https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/hemophiliatreatmentcenter340bmanual.pdf.

[5] *Available at* http://www.gao.gov/assets/330/323702.pdf.

340B Program, the Program over the years has in fact enabled these entities "to extend care to underserved populations, to create programs that serve specific community needs, and to provide life-saving drugs at discounted prices to the populations that need them the most." Hearing before the Subcomm. on Oversight, 115th Cong. 2 (2017) (statement of U.S. Rep. Greg Walden).[6]

Recognizing the value of the 340B Program, Congress has increased the categories of "covered entities" since it originally enacted the 340B Program in 1992. Originally, "covered entities" included federally-funded health centers and clinics providing services such as family 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)-(E), (G), (L). In 2010, as a part of the Affordable Care Act, Congress expanded "covered entities" to include several additional categories of hospitals, specifically certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals. *See* 42 U.S.C. § 256b(a)(4)(M).

B. The Medicare Outpatient Prospective Payment System

As part of the Balanced Budget Act of 1997, and to control Medicare expenditures for outpatient services, Congress directed CMS to develop a hospital Outpatient Prospective Payment System ("OPPS") for Medicare to pay for services offered by hospitals' outpatient departments (*e.g.*, rehabilitation services). H.R. CONF. REP. NO. 105-217, at 783 (1997). CMS

[6] *Available at* http://docs.house.gov/meetings/IF/IF02/20171011/106498/HHRG-115-IF02-MState-W000791-20171011.pdf. At this hearing, 12 additional members of the Subcommittee explicitly recognized that the purpose of the 340B Program is to benefit covered entities. Even though the hearing postdated issuance of the 340B Provisions of the OPPS Rule, not a single member of the subcommittee expressed support for those provisions. *See* Prelim. Oct. 17, 2017 Hr'g Tr. at 60-61, 82, 89, *available at* http://docs.house.gov/meetings/IF/IF02/20171011/106498/HHRG-115-IF02-Transcript-20171011.pdf.

updates the OPPS rates annually and is required to do so in consultation with an expert outside advisory panel, the Advisory Panel on Hospital Outpatient Payment ("OPPS Advisory Panel"). 42 U.S.C. § 1395*l*(t)(9)(A).

In 2003, Congress amended the Social Security Act ("SSA") to require CMS, starting in 2004, to set Medicare payment rates for separately payable drugs, *i.e.*, covered outpatient drugs that are not bundled with other outpatient services, which includes some of the outpatient drugs purchased by hospitals under the 340B Program. 42 U.S.C. § 1395*l*(t)(14)(A)(i). *See also* 82 Fed. Reg. at 52,493-52,494. The SSA provides CMS with two methods of setting Medicare payment rates for separately payable drugs starting in 2006. CMS must set rates based on the acquisition costs of these drugs, if statistically sound survey data on acquisition cost are available. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("Reimbursement Option I"). If acquisition cost data are not available, CMS must use a mandatory default rate based on average sales price ("ASP"). 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("Reimbursement Option II"). That statutory default rate is ASP plus 6% (although as explained below Congress gave CMS limited authority to adjust the rate). *See 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).

During 2006-2011, CMS applied a formula of ASP plus an add-on, fixed percentage intended to reflect the applicable overhead costs for providing the drugs. 77 Fed. Reg. 68,210, 68,385-68,386 (Nov. 15, 2012). CMS utilized this formula because it could not obtain sufficiently reliable data on actual acquisition and overhead costs and thus chose to "us[e] the ASP as a proxy for average acquisition cost" and to estimate the add-on percentage based on the limited overhead cost data that were available. *Id.*; *see also* 80 Fed. Reg. 70,298, 70,439 (Nov. 13, 2015) (noting the "continuing uncertainty about the full cost of pharmacy overhead and

acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs" between 2006 and 2012). During this 2006-2011 period, the add-on percentage ranged between 4% and 6%. *See* 77 Fed. Reg. at 68,383-68,386.

In 2012, CMS formally adopted the statutory default payment rate of ASP plus 6% for all separately payable drugs, finding that this rate is appropriate because it "yields increased predictability in payment," is "consistent with payment amounts yielded by [its] drug payment methodologies over the past 7 years," and "requires no further adjustment" because it "represents the combined acquisition and pharmacy overhead payment for drugs and biologicals." *Id.* at 68386. From 2012 onward, until its adoption of the 340B Provisions of the OPPS Rule, CMS applied this statutory default rate without further adjustment. *See* 80 Fed. Reg. at 70,439.

C. CMS's Proposed and Final Rule to Reduce Payment Rate for 340B Drugs

On July 13, 2017, CMS issued its annual proposed rule on OPPS (and other subjects not at issue here) for the Calendar Year 2018. 82 Fed. Reg. 33,558 (July 20, 2017). In addition to generally updating OPPS with 2018 rates, CMS proposed to change how Medicare pays hospitals for separately payable drugs that are acquired from private pharmaceutical companies at discounted prices under the 340B Program. *Id.* at 33,634. Specifically, this change proposed to lower the payment rate for such drugs from the current rate of ASP plus 6% to ASP minus 22.5% – a 28.5 percentage point (or 27 percent) reduction in the reimbursement rate. *Id.*[7]

CMS made no attempt to reconcile this proposed reduction with the purpose and design of the 340B Program or to tie the proposed new rate to the statutory default rate of ASP plus 6%. Instead, based on estimates by MedPAC that hospitals in the 340B Program "receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS]," *id.* at 33,632, CMS took

[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).

the position in its proposed rule that the proposed rate of ASP minus 22.5% "better represents the average acquisition cost for these drugs and biologicals." *Id.* at 33,634. CMS originally estimated that OPPS payments for separately payable drugs "could decrease by as much as $900 million" as a result of this new payment rate. *Id.* at 33,711.

CMS made this drastic reduction of nearly 30% without consulting the OPPS Advisory Panel, even though the SSA requires it to do so with respect to matters relating to payment rates. 42 U.S.C. § 1395*l*(t)(9)(A). Indeed, when the OPPS Advisory Panel reviewed the 340B Provisions of the OPPS Proposed Rule at its annual meeting on August 21, 2017, it advised CMS not to adopt those provisions, recommending instead that CMS collect additional data "on the potential impact of revising the payment rate," including the "potential impact on 340B hospitals."[8]

Each of the Association Plaintiffs in this case, as well as Hospital Plaintiff EMHS, Hospital Plaintiff Henry Ford, and Adventist Hospitals (of which Hospital Plaintiff Park Ridge is a member) submitted comments opposing the 340B Provisions of the OPPS Proposed Rule. *See* Ex. C (AHA comments); Ex. D (AAMC comments); Ex. E (AEH comments); Ex. F (EHMS comments); Ex. G (Henry Ford comments); Ex. H (Adventist comments). These comments addressed, among other things, both the lack of legal authority for these provisions and the devastating impact of the proposed nearly-30% Medicare payment reduction on covered entities' ability to provide critical healthcare programs to their communities, including underserved patients.

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

On November 1, 2017, CMS adopted the nearly-30% reduction in the final OPPS Rule. 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017). While the 340B Provisions of the OPPS Final Rule exempted certain rural and other 340B-eligible hospitals, the reduction applies to a significant number of hospitals that participate in the 340B Program. *See id.* at 52,505-52,506. In its final rule, CMS revised upwards by nearly 80% its original $900 million estimate of the cost to 340B hospitals of the reduction in Medicare payments – concluding instead that the reduction would cost those hospitals approximately $1.6 billion. *Id.* at 52,623.

In the 340B Provisions of the OPPS Final Rule, CMS, as in the proposed rule, adopted the nearly-30% payment reduction based on its purported authority under Reimbursement Option II. *Id.* at 52,496. However, as in the proposed rule, CMS in the final rule based its revised rate not on the statutory default rate of ASP plus 6% that applies when Reimbursement Option II is used, but rather on MedPAC's *estimates* of drug acquisition costs – even though acquisition cost is only allowed as the benchmark under Reimbursement Option I, and only when CMS has gathered and can rely on statistically sound acquisition cost data (which CMS concededly lacks here). *See id.* at 52,496, 52,501. As authority for its use of acquisition cost estimates under Reimbursement Option II, CMS invoked the provisions in Reimbursement Option II allowing the Secretary to "calculate[] and adjust[]" the statutory default rate on which Reimbursement Option II is based (42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)), claiming that this language gives the Secretary "broad discretion" under Option II to adjust the payment rate according to acquisition cost. *Id.* at 52,499.

Absent a preliminary injunction from this Court, the new ASP minus 22.5% rate would go into effect on January 1, 2018, and thereafter immediately and significantly reduce Medicare payments to most covered entities for 340B drugs, eliminating the corresponding source of

savings that the Hospital Plaintiffs and members of the Association Plaintiffs rely on to provide vital health services to their communities, including underserved populations in those communities.

ARGUMENT

A party seeking a preliminary injunction must show that four factors, taken together, warrant relief: (1) the movant can demonstrate likely success on the merits; (2) the movant will likely suffer irreparable harm absent the injunction; (3) the balance of hardship as between the parties favors awarding the injunction; and (4) the injunction is in accord with the public interest. *League of Women Voters v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016). In this case, the four factors, taken together and each individually, require granting Plaintiffs' requested relief.[9]

A. Plaintiffs Are Likely to Succeed on the Merits.

Plaintiffs are likely to succeed in demonstrating that the nearly-30% Medicare payment reduction in the 340B Provisions of the OPPS Rule violates the Social Security Act and therefore should be set aside under the APA as not in accordance with law and in excess of the Secretary's statutory authority. 5 U.S.C. § 706(2)(A), (C).

[9] Historically, the D.C. Circuit has 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, however, this Circuit has questioned whether the "sliding scale" approach remains available after the Supreme Court's decision in *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). *See Davis v. Pension Ben. 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 preliminary injunction factors). It remains an "open question" in this Circuit whether the "sliding scale" approach is acceptable (*Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014)), but the question need not be answered here because in this case each of the four preliminary factors independently favors granting Plaintiffs' requested relief.

1. The 340B Provisions of the OPPS Rule Exceed the Secretary's Authority to Calculate and Adjust the Payment Rate Under Section 1395*l*(t)(14)(A)(iii)(II).

As described above, section 1395*l*(t)(14)(A) of Title 42 establishes how payment rates can be set for separately payable drugs (including the 340B drugs at issue in this case) under OPPS. Section 1395*l*(t)(14)(A)(iii)(I) and (II), respectively, provide two methods for setting this amount (starting in 2006), namely that the payment amount:

> shall be equal, subject to subparagraph (E) [concerning MedPAC's 2005 report on overhead and related expenses]—
>
> (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.

42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) and (II). Thus, under subclause (I), the Secretary must set the payment rate equal to the average acquisition cost for the drug for that year *if* survey data on hospital acquisition cost—which must meet certain statistical significance and other statutory requirements—are available ("Reimbursement Option I"). Subclause (II) provides that if the data required for use of subclause (I) are not available, the Secretary "shall" use the statutory default rate of ASP plus 6%, which is based on the average sales price for the drug. Under this provision, the Secretary has the authority to "calculate[] and adjust[]" the statutory default rate "as necessary for purposes of this paragraph." As noted above, CMS has formally relied on subclause (II) since 2012, and including in the 340B Provisions of the OPPS Rule, to set

Medicare payment rates (and even before 2012 used average sales price plus a small (4-6%) adjustment for overhead to set its rate).

The ASP minus 22.5% rate set in the 340B Provisions of the OPPS Rule is a dramatic departure from the ASP plus 6% statutory default rate mandated under subclause (II) − and, indeed, from any payment rate set by CMS since the two-method system went into effect in 2006. Defendants invoke as the statutory basis for this dramatic departure the Secretary's authority under subclause (II) to "calculate[] and adjust[] . . . as necessary for purposes of this paragraph" the average sales price formula. Specifically, CMS states in defense of the 340B Provisions of the OPPS Rule that this "calculate[] and adjust[]" authority "gives the Secretary broad discretion to adjust payment 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." 82 Fed. Reg. at 52,499; *see also id.* at 52,500 (noting that CMS is "using this ['calculate[] and adjust[]'] authority to better reflect acquisition costs of [340B] drugs."). The Secretary's "calculate[] and adjust[]" authority, however, cannot support the nearly 30% reduction set forth in the 340B Provisions of the OPPS Rule.

The Secretary's authority to "calculate[] and adjust[]" the statutory default rate is circumscribed, in the first instance, by the plain and ordinary meaning of those terms. *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 100 (2012). The plain and ordinary meaning of "calculate" is to "determine (the amount or number of something) *mathematically*"[10] while "adjust" is to "alter or move (something) *slightly* in order to achieve the desired fit, appearance, or result." [11] Thus, CMS's authority under subclause (II) to "calculate[] and adjust[] . . . as necessary" is a limited

[10] *Calculate*, Oxford Dictionaries, https://en.oxforddictionaries.com/definition/calculate (emphasis added).

[11] *Adjust*, Oxford Dictionaries, https://en.oxforddictionaries.com/definition/adjust (emphasis added).

authority to determine mathematically any appropriate, slight alterations that should be applied to the ASP plus 6% statutory default rate in a given year.

The OPPS Rule's nearly-30% reduction of the statutory default rate is neither slight nor mathematically derived from any calculation of ASP. Rather, the new rate is based on a completely different measurement not mentioned in subclause (II) – *i.e.*, CMS' adoption of MedPAC's estimate (which did not include the statistically significant data required under subclause (I)) of average acquisition costs for 340B drugs – and dramatically departs from the statutorily-mandated "ASP plus 6%" measurement. CMS's new proposed payment rate thus reflects a significant numerical and conceptual deviation from the statutory default rate and indeed embodies an entirely different formula that is neither a "calculation" *nor* an "adjustment" related to average sales price. The proposed new rate far exceeds CMS's limited authority to make fine-tuned modifications under the plain language of subclause (II) and therefore should be set aside under the APA.

This limited reading of subclause (II) is not only supported by the plain and ordinary meaning of "calculate" and "adjust," but also by the statutory scheme of section 1395*l*(t)(14)(A) overall. *See Roberts*, 566 U.S. at 101 (holding that statutory provisions "cannot be construed in a vacuum" and that "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"). Section 1395*l*(t)(14)(A)(iii) requires that CMS's determination of (post-2005) payment rates under either subclause (I) or subclause (II) be made "subject to subparagraph (E)," *i.e.*, 42 U.S.C. § 1395*l*(t)(14)(E). Subparagraph (E)(i), in turn, directs MedPAC to submit a 2005 report that analyzes "*adjustment[s]* of payment [for outpatient drugs] *to take into account overhead and related expenses*, such as pharmacy services and handling costs" and provides recommendations

as to whether and how to make such adjustments. 42 U.S.C. § 1395*l*(t)(14)(E) (emphasis added). Subparagraph (E)(ii), in turn, authorizes CMS to make adjustments that take into account MedPAC's recommendations from that 2005 report. 42 U.S.C. § 1395*l*(t)(14)(E)(ii). Thus, in subparagraph (E), Congress used the term "adjustment" to take into consideration "overhead and related expenses." The use of the related term "adjusted" in section 1395*l*(t)(14)(A)(iii)(II), and that section's cross-reference to subparagraph (E), makes clear that "adjusted" as used in subparagraph (A)(iii)(II) is similarly limited to alterations for "overhead and related expenses" – a limitation that precludes the dramatic payment reductions set forth in the 340B Provisions of the OPPS Rule. *See 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.").

Importantly, this limited interpretation of the "calculate and adjust" authority is also consistent with CMS's own historical practice and understanding of subclause (II). From 2006-2011, CMS applied as the payment rate ASP plus an add-on, fixed percentage between 4-6% that was intended to reflect the applicable overhead cost for administering the drugs.[12] *See* 77 Fed. Reg. at 68,383-68,386. Thereafter, between 2012 and issuance of the 340 Provisions of the OPPS Rule challenged in this case, CMS did not invoke subclause (II)'s "calculate and adjust" authority. *Id.* at 68,386. Instead, CMS found that the statutory default rate of ASP plus 6% "requires *no further adjustment*" because it "represents the combined acquisition and pharmacy *overhead payment* for drugs and biologicals." *Id.* (emphasis added). Thus, until the rule at issue

[12] During each year of this 2006-2012 period, CMS purported to rely on subclause (I) as authority for setting a payment rate. In fact, however, CMS had no authority to invoke subclause (I) because, as it admitted, it could not obtain the requisite survey data on average acquisition cost because of administrative burden; instead, CMS "us[ed] the ASP as a proxy for average acquisition cost." 77 Fed. Reg. at 68,385-68,386. Thus, even during this period, CMS should have used its authority under subclause (II) to set rates in the absence of hospital acquisition cost data, and the adjustments it made to the add-on percentage based on overhead cost reflect precisely the type of fine-tuned adjustment permitted under subclause (II).

here, CMS never once deviated from the statutory default rate by more than 2%, and its adjustments, if any, were limited to modifications to address overhead costs. Put another way, until now, permissible changes under the "calculate and adjust" authority were understood by CMS to be limited to changes to overhead and similar expense calculations.[13]

2. Subclause (I) Demonstrates that the Secretary Exceeded His Authority Under Subclause (II) in Issuing the 340B Provisions of the OPPS Rule.

The structure of section 1395*l*(t)(14)(A)(iii), as discussed above, offers the Secretary a binary choice in setting payment rates: the Secretary must under subclause (I) set reimbursement rates on acquisition cost if there are statistically sound surveys of acquisition cost data to support that rate; or, in the absence of such cost data, he must, under subclause (II), set reimbursement rates based on the average sales price of the drug. The Secretary has no authority to use a third, hybrid method of his own design for setting payment rates, in lieu of the statutory alternatives. *See, e.g.*, *Utility Air Regulatory Group v. EPA*, 134 S. Ct. 2427, 2445 (2014) ("An agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms."); *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").[14]

Yet that is exactly what the Secretary did in the 340B Provisions of the OPPS Rule. The Rule's ASP minus 22.5% rate is based on MedPAC's *estimate* of the *average* aggregate discount

[13] Indeed, the overall statutory scheme of subparagraph (A) reflects a congressional intent to carefully constrain CMS's authority with respect to setting payment rates. Sections 1395*l*(t)(14)(A)(i) and (ii) of Title 42 specify the payment rate for 2004 and 2005, respectively, for each drug type (*e.g.*, single-source, innovator multiple source, non-innovator multiple source), without providing CMS with *any* adjustment authority. For each subsequent year, CMS had to either set rates based on specific acquisition cost data that met statutory requirements or use the statutory default formula discussed above.

[14] As we explain in Section A.3, below, the Secretary also had no authority under *either* subclause (I) or subclause (II) to promulgate the 340B Provisions of the OPPS Rule, because the OPPS reduction undermines the purpose and design of the 340B Program.

on 340B drugs and attempts to align the payment rate with these estimated average acquisition costs. *See* 82 Fed. Reg. at 52,500 (noting that the rate of ASP minus 22.5% "is necessary to better reflect acquisition costs" of 340B drugs). But subclause (II), the payment authority relied on by the Secretary, mandates payment based on *average sales price,* not acquisition cost.

The Secretary's conceded reason for not simply relying on subclause (I), which provides for rate-setting based on acquisition cost, is that CMS lacks the statistically sound acquisition cost data required under that subclause. *See, e.g.*, 77 Fed. Reg. at 68,383-68,386; 80 Fed. Reg. at 70,439; 82 Fed. Reg. at 52501 ("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 [subclause (II)], and then to adjust that amount by applying a reduction of 22.5% . . . ."). Because CMS did not collect data from "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for *each* . . . drug," § 1395*l*(t)(14)(D)(iii) (emphasis added), as required by subclause (I), it improperly used MedPAC's *estimate* of the average *aggregate* discounts for 340B drugs. *See* 82 Fed. Reg. at 52,494. In short, the Secretary's hybrid approach impermissibly sought to rely on acquisition cost under subclause (II), but without the requisite statistically significant acquisition cost data required under subclause (I). The SSA does not give the Secretary this option.

It is also important to note that the GAO agrees with this limited view of CMS's authority, noting in its 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 cost*." GAO, GAO-15-442, MEDICARE PART B DRUGS:

ACTIONS NEEDED TO REDUCE FINANCIAL INCENTIVES TO PRESCRIBE 340B DRUGS AT PARTICIPATING HOSPITALS 29 (June 2015) ("2015 GAO Report").[15]

3. The 340B Provisions of the OPPS Rule Exceed the Secretary's Authority Because They Undermine the Statutorily Created Section 340B Program.

The 340B Provisions of the OPPS Rule undermine the 340B Program as it applies to hospitals. CMS has admitted that the Rule's nearly-30% payment reduction is intended to "align[] [Medicare payments] with resources expended by hospitals to acquire [340B] drugs." 82 Fed. Reg. at 52,495. The reduced rate is thus expressly designed to close the gap between (i) the cost to hospitals of acquiring 340B drugs and (ii) Medicare payments to those hospitals, and thereby to cut off those hospitals' ability to use the savings caused by that gap as Congress envisioned when it created the 340B program – *i.e.*, to offer vital health care services to their communities, including the vulnerable populations within those communities.

The 340B Provisions of the OPPS Rule thus amount to an impermissible attempt by the Secretary "to reconfigure Congress's statutory scheme" and are contrary to law. *Howard v. Pritzker*, 775 F.3d 430, 432 (D.C. Cir. 2015). In interpreting statutes, the "task is to fit, if possible, all parts into a harmonious whole." *Roberts*, 566 U.S. at 100. The Secretary's authority to "calculate[] and adjust[] . . . as necessary" the statutory default rate under subclause (II) therefore must be read in light of the entire statutory scheme relating to outpatient drug payment, taking into account the "balance of interests . . . chosen by Congress." *Howard*, 775 F.3d at 432-33. Where "Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions," an agency has no authority to undo that congressional scheme by invoking some general authority found elsewhere in the statute. *Id.* at

[15] *Available at* https://www.gao.gov/assets/680/670676.pdf.

438 (quoting *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012)). Instead, "the more specific statute applies." *Id.*

Here, the 340B Program and SSA section 1395*l*(t)(14)(A)(iii) are interrelated statutes that regulate hospital outpatient drug pricing and payments. In enacting the 340B Program, Congress sought to solve a specific problem: to find a way for covered entities "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; *see also* 82 Fed. Reg. at 52,493 & n.18 (citing House report). As HRSA and other agencies have consistently recognized, the 340B Program solved this problem by providing covered entities with access to discounted outpatient drugs, thereby allowing them to benefit from the significant differential between the prices paid *by* these entities for those drugs and government reimbursements *to* the entities for those drugs under 42 U.S.C. § 1395*l*(t)(14)(A)(iii).[16] Consistent with the purpose of the 340B Program, covered entities have used—and relied on—the existing reimbursement structure to maintain this differential and thereby to generate funds for vital health services to their communities. *See, e.g.*, 2011 GAO Report at 17-18 (finding that studied covered entities used the savings generated from the Program to provide additional services at more locations, patient education programs, and translation and transportation services that the entities otherwise could not afford). Put another way, the clear purpose of the 340B Program is to separate – the *opposite* of the "aligning" that takes place under the 340B Provisions of the OPPS Rule – hospitals' costs of purchasing 340B prescription drugs and Medicare payments to those hospitals for those prescription drugs.

[16] This benefit may extend to all patients of a covered entity, regardless of coverage. The intent of the 340B program was to provide hospitals that (1) served communities with underserved populations and (2) had limited resources with additional savings, so that they could continue to serve these communities and populations and expand those services with the additional resources created by 340B savings.

In light of this well-recognized, specific purpose of the 340B Program, and regardless of the breadth of the Secretary's authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) to "calculate[] and adjust[]" Medicare payment rates, this authority cannot be exercised in a way that so severely undermines the Program as it applies to hospitals. That is especially the case since Congress emphasized the importance of the Program in 2010 in the Affordable Care Act by increasing the categories of "covered entities." *See* 42 U.S.C. § 256b(a)(1)(M)-(O) (adding certain children's hospitals, free-standing cancer hospitals, critical access hospitals, and sole community hospitals to the list of "covered entities"). Congress's clear and conscious expansion of the 340B Program reflects its recognition that the Program should continue to be implemented to allow covered entities to leverage discounts received under the Program into additional resources to provide more comprehensive services to patients they serve. The 340B Provisions of the OPPS Rule dramatically undercut this congressional goal.

Once again, the GAO has agreed. In its 2015 report, GAO considered whether HHS could "limit[] hospitals' Medicare Part B reimbursement for 340B discounted drugs" and concluded that "CMS and HRSA are unable to take such action[] *because they do not have the statutory authority to do so*." 2015 GAO Report 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").[17]

In short, the 340B Provisions of the OPPS Rule are inconsistent with and completely undermine the 340B scheme. They therefore exceed the Secretary's legal authority and should be set aside under the APA.

[17] *Available at* https://oig.hhs.gov/oei-12-14-00030.pdf

B. Plaintiffs Will Suffer Irreparable Harm in the Absence of the Requested Preliminary Injunction.

A showing of irreparable harm has two components. First, the claimed harm must be "certain and great, actual and not theoretical, and so imminent that there is a clear and present need for equitable relief to prevent irreparable harm." *Newby*, 838 F.3d at 8 (citations, internal quotation marks omitted). Second, the harm must be beyond remediation. *Id*. (citation, internal quotation marks omitted).

Plaintiffs in this case easily satisfy both these components.

The harms alleged by Plaintiffs in this case are undoubtedly certain and imminent. As set forth in the affidavits attached hereto as Exhibits I-K,[18] the 340B Provisions of the OPPS Rule, if implemented, would result in dramatic and automatic lost savings for each of the Hospital Plaintiffs (which are each a member of one or more of the Association Plaintiffs). *E.g.*, EMHS Aff. ¶ 12 (estimating EMHS's net loss from 340B Provisions of the OPPS Rule to be $2.86 million); Henry Ford Aff. ¶ 14 (estimating Henry Ford's total net loss across its system from 340B Provisions to be $9.3 million); Park Ridge Aff. ¶ 14 (estimating Park Ridge's net loss from 340B Provisions to be $3.3 million). *See also* 82 Fed. Reg. 52,623 (estimating total lost savings to hospitals from payment reduction to be $1.6 billion). If the 340B Provisions of the OPPS Rule were to take place on January 1, 2018, as scheduled, the new payment rate causing these losses would be locked in immediately. The margin between acquisition costs and Medicare reimbursement rates created by the 340B Program has helped the Hospital Plaintiffs (as well as other members of the Association Plaintiffs) provide critical services to their communities,

[18] These affidavits are submitted, respectively, by (1) Tony Filer, Chief Financial Officer of Hospital Plaintiff EMHS (Exh. I, "EMHS Aff."); (2) Mary Whitbread, Vice-President of Finance for Hospital Plaintiff Henry Ford (Exh. J, "Henry Ford Aff."); and (3) Wendi Barber, Chief Financial Officer of Hospital Plaintiff Park Ridge (Exh. K, "Park Ridge Aff.").

including underserved populations in those communities. *E.g.*, EMHS Aff. ¶ 13; Henry Ford Aff. ¶¶ 15-17; Park Ridge Aff. ¶¶ 15-17. The closing of that margin through the 340B Provisions of the OPPS Rule threatens these critical services. *E.g.*, EMHS Aff. ¶¶ 14-17; Henry Ford Aff. ¶¶ 18-20; Park Ridge Aff. ¶¶ 18-19. Thus, the effect of these provisions, if implemented, on Plaintiffs would be certain, immediate, and dramatic.

Nor is there any doubt that the harms caused by the 340B Provisions of the OPPS Rule are beyond remediation. As noted above, the loss of funds caused by the nearly 30% reimbursement reduction would threaten critical programs and services offered by the Hospital Plaintiffs (as well as other members of the Association Plaintiffs). *E.g.*, EMHS Aff. ¶¶ 14-17; Henry Ford Aff. ¶¶ 18-20; Park Ridge Aff. ¶¶ 18-19. Even if these payment reductions could theoretically be reversed, any temporary suspension of services, and denial of those services to hospitals' patients during that temporary period, would cause harm that would not be remedied by hospitals' ability to offer those services at a later time. *See Texas Children's Hospital v. Burwell*, 76 F. Supp. 3d 224, 243 (D.D.C. 2014) (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 for children . . . ."). 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. *Cf. id.* at 242-43.

C. Plaintiffs Would Face Far Greater Harm from Failure to Grant the Injunction Than Defendants Would Face from the Grant of an Injunction.

The balance of hardships prong requires a court to compare the hardship that would befall the movant(s) if the requested injunction were not awarded with the harm that would befall other

parties if the injunction were awarded. *Newby*, 838 F.3d at 12 (holding that the balance of equities in that case favored the movant because the requested preliminary injunction would not substantially injure other interested parties).

In this case, the non-moving parties are government agencies and officials that would suffer no economic or other direct harms if the requested injunction suspending the 340B Provisions of the OPPS Rule were granted. Moreover, the requested injunction would merely preserve the *status quo* by preventing defendants from implementing, through the OPPS Rule, changes to the 340B program as it currently operates. *See Sherley v. Sebelius*, 644 F.3d at 398 (finding that the balance of equities favored the defendant because the injunction would "upend the status quo"); *Tyndale House Publishers, Inc. v. Sebelius*, 904 F.Supp. 2d 106, 129-130 (D.D.C. 2012) (finding that the balance of equities favored the plaintiffs because denial of the injunction would "upend the status quo" (citing *Sherley*)); *Aamer v. Obama*, 742 F.3d at 1043 ("The primary purpose of a preliminary injunction is to preserve the object of the controversy in its then existing condition – to preserve the status quo.") (citation, internal quotation marks omitted)). Even in the unlikely event that Defendants were to prevail on the merits, they would suffer no harm if the 340B Provisions of the OPPS Rule were held in abeyance until the courts have had an opportunity to determine their legality.

In short, the effects of the requested injunction on defendants pale in comparison to the direct and substantial harms – outlined in subsection B, above − that Plaintiffs would suffer absent the injunction. The balance of equities therefore favors granting Plaintiffs' request.

D. The Preliminary Injunction Is in the Public Interest.

The public interest favors the preliminary injunction for two reasons. First, it is generally in the public interest for government agencies to lawfully implement the statutes they administer. *Jacksonville Port Auth. v. Adams*, 556 F.2d 52, 59 (D.C. Cir. 1977) ("[T]here is an overriding

public interest . . . in the general importance of an agency's faithful adherence to its statutory mandate."); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (holding that the public interest lies in the "faithful application of the laws"); *Newby*, 838 F.3d at 12 ("There is generally no public interest in the perpetuation of unlawful agency action.") (citations omitted)). As alleged in the complaint, and as Plaintiffs are likely to successfully show, the 340B Provisions of the OPPS Rule are contrary to law and in violation of the APA, and the public interest lies in remedying that unlawful agency action.

Second, and specific to this case, the effect of the 340B Provisions of the OPPS rule would be to deprive hospitals participating in the Medicare program, including members of the Association Plaintiffs (including the Hospital Plaintiffs) of $1.6 billion (CMS' final estimate) used for care in those hospitals' communities. It is not only in the interest of hospitals, but also in the interests of these communities, particularly their vulnerable patients, for the critical services made possible by the 340B program as currently implemented to continue. At minimum, it is clearly in the public interest for the *status quo* to be maintained – and for individuals in need of the critical care made possible through the current 340B program to receive that care − until the legality of the payment reductions envisioned by the 340B Provisions of the OPPS rule can be determined by the courts.

CONCLUSION

For the foregoing reasons, this Court should grant the requested preliminary injunction suspending the effective date of the 340B Provisions of the OPPS Rule pending resolution of this action, including any appeal.

Dated: November 13, 2017

Respectfully submitted,

/s/ Carlos T. Angulo

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001, *et al.*,

Plaintiffs,

–v–

ERIC D. HARGAN, in his official capacity as the Acting Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. _____

EXHIBITS TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Exhibit A – 340B provisions of the OPPS Rule (final rule) (82 Fed. Reg. 52,356, 52,493-52,511, 52,622-52,625 (November 13, 2017))

Exhibit B- relevant statutory provisions

Exhibit B-1 – 42 U.S.C. § 256b

Exhibit B-2 – 42 U.S.C.§ 1395l(t)

Exhibit C- comments of Plaintiff American Hospital Association to the proposed 340B Provisions of the OPPS Rule, 82 Fed. Reg. 33,558 (July 20, 2017)

Exhibit D- comments of Plaintiff Association of American Medical Colleges to the proposed 340B Provisions of the OPPS Rule

Exhibit E – comments of Plaintiff America's Essential Hospitals to the proposed 340B Provisions of the OPPS Rule

Exhibit F – comments of Plaintiff Eastern Maine Healthcare Systems ("EMHS") to the proposed 340B Provisions of the OPPS Rule

Exhibit G – comments of Plaintiff Henry Ford Health System ("Henry Ford") to the proposed 340B Provisions of the OPPS Rule

Exhibit H - comments of Adventist Health Policy Association to the proposed 340B Provisions of the OPPS Rule

Exhibit I – Affidavit of Tony Filer, Chief Financial Officer, Eastern Maine Healthcare Systems

Exhibit J – Affidavit of Mary Whitbread, Vice-President of Finance, Henry Ford Health System

Exhibit K – Affidavit of Wendi Barber, Chief Financial Officer, Park Ridge Health

Exhibit A

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.

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(HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2018. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. 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.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2018, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.35 percent. This increase factor is based on the hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.6 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2018 is approximately $70 billion, an increase of approximately $5.8 billion compared to estimated CY 2017 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

- *High Cost/Low Cost Threshold for Packaged Skin Substitutes:* As we did for CY 2017, we are assigning skin substitutes with a geometric mean unit cost (MUC) or a per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, for CY 2018, we are establishing that a skin substitute product that does not exceed either the CY 2018 MUC or PDC threshold for CY 2018, but was assigned to the high cost group for CY 2017, is assigned to the high cost group for CY 2018. The goal of our policy is to maintain similar levels of payment for skin substitute products for CY 2018 while we study our current skin substitute payment methodology to determine whether refinements to our existing methodologies may be warranted.
- *Supervision of Hospital Outpatient Therapeutic Services:* In the CY 2009 and CY 2010 OPPS/ASC proposed rules and final rules with comment period, we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals, CAHs, and in provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPPS final rule with comment period. For several years, there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium on enforcement expiring on December 31, 2016. In this final rule with comment period, as we proposed, we are reinstating the nonenforcement policy for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds and reinstating our enforcement instruction for CY 2018 and CY 2019.
- *340B Drug Pricing:* We are changing our current Medicare Part B drug payment methodology for 340B hospitals that we believe will better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. These changes will lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program. For CY 2018, we are exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excluded from this payment adjustment in CY 2018. In addition, in this final rule with comment period, we are establishing two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program—one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction but that acquire drugs under the 340B Program.
- *Device Pass-Through Payment Applications:* For CY 2018, we evaluated five devices for eligibility to receive pass through payments and sought public comments in the CY 2018 proposed rule on whether each of these items meet the criteria for device pass-through payment status. None of the applications were approved for device pass-through payments for CY 2018.
- *Rural Adjustment:* We are continuing the adjustment of 7.1 percent to the OPPS payments to certain rural SCHs, including essential access community hospitals (EACHs). This adjustment will apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.
- *Cancer Hospital Payment Adjustment:* For CY 2018, we are continuing to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, beginning CY 2018, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a target PCR of 0.88 will be used to determine the CY 2018 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.
- *Changes to the Inpatient Only List:* For CY 2018, we are finalizing our proposal to remove total knee arthroplasty (TKA) from the inpatient only list. In addition, we are precluding the Recovery Audit Contractors from reviewing TKA procedures for ''patient status'' (that is, site of service) for a period of 2 years. We note that we will monitor changes in site of service to determine whether changes may be necessary to certain CMS Innovation Center models. In addition, we are removing five other procedures from the inpatient only list and adding one procedure to the list.
- *Comprehensive APCs:* For CY 2018, we did not propose to create any new C–APCs or make any extensive changes to the already established methodology used for C–APCs. There will be a total

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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

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ability, presents the costs and benefits of this portion of this final rule with comment period. Table 89 and 90 of this final rule with comment period display the redistributive impact of the CY 2018 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule with comment period, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this final rule with comment period. In the CY 2018 OPPS/ASC proposed rule (82 FR 33711), we welcomed any comments on the approach in estimating the number of entities that will review the proposed rule. However, we did not receive any comments on our approach.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule with comment period, and therefore for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. In the CY 2018 OPPS/ASC proposed rule, we also sought public comments on this assumption, but we did not receive any comments.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/2016/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of this final rule with comment period. For each facility that reviews the rule, the estimated cost is $841.28 (8 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $2,851,939 ($841.28 × 3,390 reviewers).

5. Detailed Economic Analyses

a. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2018 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2018 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1678–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 88 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters.

In the CY 2018 OPPS/ASC proposed rule, we solicited public comment and information about the anticipated effects of the proposed changes included in the proposed rule on providers and our methodology for estimating them. Any public comments that we receive are addressed in the applicable sections of this final rule with comment period that discuss the specific policies.

(2) Estimated Effects of OPPS Changes to Part B Drug Payment on 340B Eligible Hospitals Paid Under the OPPS

In section V.B.7. of this final rule with comment period, we discuss our finalized policies to reduce the payment for nonpass-through, separately payable drugs purchased by certain 340B-participating hospitals through the 340B Program. Rural SCHs, children's hospitals, and PPS-exempt cancer hospitals are excepted from this payment policy in CY 2018. Specifically, in this final rule with comment period, for CY 2018, for hospitals paid under the OPPS (other than those that are excepted for CY 2018), we are paying for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent instead of ASP+6 percent. For context, based on CY 2016 claims data, the total OPPS Part B drug payment is approximately $10.2 billion.

We recognize that it may be difficult to determine precisely what the impact on Medicare spending will be because OPPS claims data do not currently indicate if the drug being provided was purchased with a 340B discount. Furthermore, a list of outpatient drugs covered under the 340B program is not publicly available. Accordingly, for purposes of estimating the impact for this final rule with comment period, as we did in the CY 2018 OPPS/ASC proposed rule, we assumed that all applicable drugs purchased by hospitals eligible to participate in the 340B Program were purchased at a discounted price under the 340B program. While we recognize that certain newly covered entities do not have access to 340B drug pricing for designated orphan drugs, we believe that our CY 2018 policy to except newly covered entity types such as rural SCHs, PPS-exempt cancer hospitals, and children's hospitals, largely mitigates the 340B drug spend attributable to orphan drugs and therefore does not dramatically affect our final estimate. In addition, for this final rule with comment period, we utilized the HRSA covered entity database to identify 340B participating hospitals and cross-checked these providers with the CY 2018 OPPS facility impact public use file to determine which 340B hospitals are paid under the OPPS. The HRSA covered entity database is available via the Internet at *https://340bopais.hrsa.gov/coveredentitysearch*. Using this database, we found 1,338 OPPS hospitals in the 340B program (compared to the 954 estimated for the proposed rule). Of these, 270 were rural SCHs, 47 were children's hospitals, and 3 were PPS-exempt cancer hospitals. We did not assume changes in the quantity of 340B purchased drugs provided by hospitals participating in the 340B program (thereby affecting unit volume) or changes in the number of hospitals

participating in the 340B program that may occur due to the payment reduction.

While we acknowledge that there are some limitations in Medicare's ability to prospectively calculate a precise estimate for purposes of this final rule with comment period, we note that each hospital has the ability to calculate how this policy will change its Medicare payments for separately payable drugs in CY 2018. Specifically, each hospital that is not participating in the 340B program or that is excepted from the policy to pay for drugs acquired under the 340B Program at ASP minus 22.5 percent in CY 2018 will know that its Medicare payments for drugs will be unaffected by this finalized policy; whereas each hospital participating in the 340B Program has access to 340B ceiling prices (and subceiling prices if it participates in the Prime Vendor Program), knows the volume of 340B drugs that it has historically billed to Medicare, and can generally project the specific covered 340B drugs (and volume thereof) for which it expects to bill Medicare in CY 2018. Accordingly, a hospital participating in the 340B Program is able to estimate the difference in payment that it will receive if Medicare pays ASP minus 22.5 percent instead of ASP+6 percent for 340B drugs.

Using the list of participating 340B providers (derived from the HRSA database) and updated CY 2016 claims data available for this final rule with comment period for the applicable separately payable drugs and biologicals, excluding those on pass-through payment status and vaccines, billed by hospitals eligible to participate in the 340B Program, except for those hospital types that are excepted from this policy in CY 2018, we estimate that OPPS payments for separately payable drugs, including beneficiary copayments, will decrease by approximately $1.6 billion under this finalized policy, which reflects an additional estimated reduction of $700 million over the proposed rule estimate of $900 million. If PPS-exempt cancer hospitals, children's hospitals, and rural SCHs had *not* been excluded from the reduced drug payment in CY 2018, drug payments to PPS-exempt cancer hospitals would have been reduced by approximately $29 million, to children's hospitals by approximately $2 million, and to rural SCHs by approximately $199 million—this would have resulted in a total savings estimate of approximately $1.8 billion. Because we are implementing this payment reduction in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B Program will increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount.

Because data on drugs that are purchased with a 340B discount are not publicly available, we do not believe it is possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting amount of the adjustment that is necessary to ensure budget neutrality through higher payment rates for other services. Furthermore, there are potential offsetting factors, including possible changes in provider behavior and overall market changes that would likely lower the impact of the payment reduction. As a result, we may need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount within the OPPS, similar to the adjustment we made for clinical diagnostic laboratory test packaging policy in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70352 through 70357).

In this final rule, we project that reducing payment for 340B drugs to ASP minus 22.5 percent will increase OPPS payment rates for non-drug items and services by approximately 3.2 percent in CY 2018. The estimated impacts of this policy are displayed in Table 88 below. We note that the payment rates included in Addendum A and Addendum B of this final rule with comment period do not reflect the reduced payments for drugs purchased under the 340B Program; however, they do include the increase to payments rates for non-drug items and services due to the corresponding increase in the conversion factor. In the proposed rule (82 FR 33712), we reminded commenters that this estimate could change in the final rule based on a number of factors, including other policies that are adopted in the final rule and the availability of updated data and/or method of assessing the impact in the final rule. We sought public comment on our estimate and stated that we were especially interested in whether commenters believe there are other publicly available data sources or proxies that can be used for determining which drugs billed by hospitals paid under the OPPS were acquired under the 340B Program.

We proposed that the reduced payments for separately payable drugs and biologicals purchased under the 340B Program would be 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 would not be applied in determining payments for these separately paid drugs and biologicals purchased under the 340B Program.

In addition, we solicited public comment 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 sought public comment 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. Finally, we sought public comment on whether the redistribution of savings associated with the 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.

Comment: Several commenters stated that if the 340B drug payment policy was finalized, the funds should be redistributed across the OPPS, as has been the case for the application of budget neutrality in the past. One commenter supported CMS' proposal to implement the savings attributed to the 340B payment reduction in a budget neutral manner within the OPPS. Commenters noted that the budget neutrality requirement upon which CMS relied in the proposed rule at section 1833(t)(9)(B) of the Act has historically been interpreted by CMS as requiring budget neutrality within the OPPS. Commenters strongly urged CMS to follow its longstanding interpretation of section 1833(t)(9)(B) of the Act and offset the full amount of the aggregate 340B payment reduction through offsetting payment increases within the OPPS.

MedPAC reiterated its March 2016 recommendation that that payments be distributed in proportion to the amount of uncompensated care that hospitals provide, ''to make sure that dollars in the uncompensated care pool actually go to the hospitals providing the most uncompensated care.'' MedPAC commented that the 340B Program is not well targeted to hospitals that provide high levels of uncompensated care and noted that 40 percent of 340B hospitals provide less than the median level of uncompensated care. MedPAC stated that it believed that legislation would be needed to direct the savings to the uncompensated care pool because current law would require that the savings be retained within the OPPS to make it budget neutral. However,

MedPAC encouraged CMS to request that Congress enact the legislation necessary to allow CMS to implement its recommendation. MedPAC further noted that legislation would also allow CMS to apply the policy to all separately payable drugs, including those that are separately payable as a result of their pass-through status.

Response: We thank the commenters for their feedback. After consideration of the public comments we received, we are finalizing our proposal to fully redistribute the savings associated with adoption of the alternative payment methodology for drugs acquired under the 340B Program within the OPPS to non-drug items and services. That is, we will redistribute $1.6 billion dollars in estimated lower payment for OPPS drugs by increasing the conversion factor for all OPPS non-drug items and services by 3.2 percent. We may revisit how the funds should be targeted in the future.

Comment: Some commenters challenged the accuracy of the $900 million estimate CMS calculated in the proposed rule. According to these commenters, their analysis of the proposal would have an estimated impact in the range of $1.2 billion to $1.65 billion. As a result, these commenters asserted that if the proposed payment reductions are applied in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, their analysis showed that payments for non-drug APCs would increase across hospitals by about 3.7 percent (in contrast to CMS's estimate of 1.4 percent) based on the proposed rule data. Moreover, based on their analysis, the commenters believed the redistribution of the savings would result in a net decrease in payments to 340B hospitals of approximately 2.6 percent, or approximately $800 million—funding that they stated was intended to support the congressionally-mandated mission of 340B hospitals—not be redistributed to other hospitals that do not participate in the 340B Program.

Response: We stated in the proposed rule that the estimate of the 340B payment reductions would likely change in the final rule based on updated data, revised assumptions, and final policies. For this final rule with comment period, as discussed in detail earlier, we used updated CY 2016 claims data and an updated list of 340B eligible providers to calculate an estimated impact of $1.6 billion based on the final policy. As shown in Table 88 below this reflects a reduction of about $1.5 billion to urban hospitals and $86 million to rural hospitals. We are redistributing the savings from this payment reduction in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor. This increase to the conversion factor increases all OPPS non-drug payment rates to all providers under the OPPS by 3.2 percent. With respect to comments on the redistribution of the 340B savings to non-340B participating hospitals, we note that 340B hospitals will also receive the conversion factor increase.

Comment: In response to the comment solicitation on whether the savings generated by the reduced payment on 340B drugs should be used to increase payments for specific services paid under the OPPS or under Part B generally in CY 2018, commenters generally objected to the notion that CMS has authority to redistribute savings outside of OPPS. One commenter stated that CMS did not provide any analysis or justification to support a reading that section 1833(t)(9)(B) of the Act establishes a budget neutrality concept for the Medicare Part B Trust Fund. Another commenter stated that CMS should not redistribute the savings gained by the 340B proposal based on Medicare DSH metrics (that is, insured low-income days) because such metrics are not well correlated with uncompensated care costs. This commenter also expressed concern regarding the suitability of using uncompensated care as a metric ''to identify hospitals that provide the most help to needy patients because it includes bad debt as well as charity care.'' The commenter stated that bad debt is the amount that hospitals billed but did not collect, and therefore is not a measure of hospital assistance to the poor. Several commenters challenged the logic of reducing 340B payments to participating 340B hospitals, only to return the savings to the very same hospitals.

Response: We appreciate the feedback. Because the OPPS is a budget neutral payment system, historically CMS has maintained budget neutrality through offsetting estimated payment decreases/increases within the OPPS, such as by increasing/decreasing the conversion factor by an equal offsetting amount. We have articulated the policy justification for reducing drug payment to ASP minus 22.5 percent for 340B-acquired drugs in section V.B.7. of this final rule with comment period and are redistributing the resulting dollars within the OPPS to maintain budget neutrality for CY 2018. Therefore, we are finalizing our proposal to redistribute the estimated reduction in payment for 340B-acquired drugs and biologicals by increasing the conversion factor, and we are not targeting the savings to specific services paid under the OPPS or under Part B generally. We continue to be interested in exploring ways that funds from a subsequent proposal could be targeted in future years to hospitals that serve a high share of low-income or uninsured patients.

Comment: Many commenters noted that CMS' proposal to redistribute the savings that result from the 340B reduction in a budget neutral manner within the OPPS would increase beneficiary copayments on non-drug services. Accordingly, the commenters stated that most patients would not directly receive the benefit of the 340B copayment reduction even if reduced payments for 340B drugs lower coinsurance amounts for these drugs. The commenters stated the proposal will likely increase costs for uninsured patients because 340B hospitals provide a disproportionate amount of care to that population and participating 340B hospitals may no longer be able to provide ''discounts to low-income patients'' or other uncompensated care. One commenter suggested that CMS, with stakeholder input, develop an outpatient hospital charity care metric that could be used to redistribute the 340B savings based on the level of outpatient charity care provided by the hospital.

Response: We appreciate the stakeholders' concerns. 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. Further, to the extent that studies have found that 340B participating hospitals tend to use more high costs drugs, we believe that this 340B payment policy helps address drug pricing in the hospital outpatient setting by lessening the incentive for unnecessary utilization of costly drugs. In addition, even though many beneficiaries have supplemental coverage, those plans make coinsurance payments on behalf of beneficiaries. Thus, to the extent this policy lessens the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans could decrease or otherwise reflect these lower costs in the future.

In summary, to maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final 340B payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the

OPPS through increasing the payment rates by 3.2 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018.

(3) Estimated Effects of OPPS Changes on Hospitals

Table 88 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 88, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2018, we are paying CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs), and we are paying hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this final rule with comment period. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2018 is 2.7 percent (82 FR 38177). Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.6 percentage point for FY 2018 (which is also the MFP adjustment for FY 2018 in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38177 through 38178)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the OPD fee schedule increase factor of 1.35 percent. We are using the OPD fee schedule increase factor of 1.35 percent in the calculation of the CY 2018 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2018 estimates in Table 88.

To illustrate the impact of the CY 2018 changes, our analysis begins with a baseline simulation model that uses the CY 2017 relative payment weights, the FY 2017 final IPPS wage indexes that include reclassifications, and the final CY 2017 conversion factor. Table 88 shows the estimated redistribution of the increase or decrease in payments for CY 2018 over CY 2017 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2017 and CY 2018 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 1.35 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all payments for CY 2018 relative to all payments for CY 2017, including the impact of changes in estimated outlier payments, the frontier State wage adjustment, and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2018. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2018 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2017 and CY 2018 by various groups of hospitals, which CMS cannot forecast.

In CY 2016, we excluded all molecular pathology laboratory tests from our packaging policy, and in CY 2017, we expanded the laboratory packaging exception to apply to all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. For CY 2018, we sought public comments on whether laboratories (instead of hospitals) should be permitted to bill Medicare directly for molecular pathology tests and ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act (and are granted ADLT status by CMS), that are ordered less than 14 days following the date of a hospital outpatient's discharge from the hospital outpatient department.

The laboratory date of service (DOS) issue is discussed in section X.F. of this final rule with comment period. Because there are currently no laboratory tests designated as ADLTs and because the payment rate for laboratory tests excluded from our packaging policy billed by a hospital would have been the applicable rate for the laboratory test under the CLFS, any aspect of this discussion that is finalized in this final rule with comment period will not result in a net costs or savings to the program. Accordingly, section X.F. of this final rule with comment period is not included in the impact table in the regulatory impact analysis.

Overall, we estimate that the rates for CY 2018 will increase Medicare OPPS payments by an estimated 1.4 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.5 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 88 shows the total number of facilities (3,878), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2016 hospital outpatient and CMHC claims data to model CY 2017 and CY 2018 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2017 or CY 2018 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State

Exhibit B-1

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or PreemptedNegative Treatment Reconsidered by Florida ex rel. Atty. Gen. v. U.S. Dept. of Health and Human Services, 11th Cir.(Fla.), Aug. 12, 2011
KeyCite Yellow Flag - Negative TreatmentProposed Legislation

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 6A. Public Health Service (Refs & Annos)
Subchapter II. General Powers and Duties
Part D. Primary Health Care
Subpart VII. Drug Pricing Agreements

42 U.S.C.A. § 256b

§ 256b. Limitation on prices of drugs purchased by covered entities

Currentness

(a) Requirements for agreement with Secretary

(1) In general

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

(2) Rebate percentage defined

(A) In general

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

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

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

(B) Over the counter drugs

(i) In general

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

(ii) Over the counter drug defined

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

(3) Drugs provided under State Medicaid plans

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

(4) Covered entity defined

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

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

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

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

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

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

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

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C.A. § 701(a)(2)].

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

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

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

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

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

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

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

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

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

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

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

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C.A. § 1396d(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C.A. § 1396r-8].

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act [42 U.S.C.A. § 1396r-8(a)(5)(C)] shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[1] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

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

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act [42 U.S.C.A. § 1396a(a)(5)] of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions--

(1) In general

In this section, the terms “average manufacturer price”, “covered outpatient drug”, and “manufacturer” have the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C.A. § 1396r-8(k)].

(2) Covered drug

In this section, the term “covered drug”--

(A) means a covered outpatient drug (as defined in section 1927(k) (2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub.L. 111-152, Title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which--

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which--

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the

information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an

administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[2] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall--

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.

CREDIT(S)

(July 1, 1944, c. 373, Title III, § 340B, as added Pub.L. 102-585, Title VI, § 602(a), Nov. 4, 1992, 106 Stat. 4967; amended Pub.L. 103-43, Title XX, § 2008(i)(1)(A), June 10, 1993, 107 Stat. 212; Pub.L. 111-148, Title II, § 2501(f)(1), Title VII, §§ 7101(a) to (d), 7102, Mar. 23, 2010, 124 Stat. 309, 821, 823; Pub.L. 111-152, Title II, § 2302, Mar. 30, 2010, 124 Stat. 1082; Pub.L. 111-309, Title II, § 204(a)(1), Dec. 15, 2010, 124 Stat. 3289.)

Notes of Decisions (3)

Footnotes

1 So in original. Probably should be "subparagraph".

2 So in original. Probably should be "subsection".

42 U.S.C.A. § 256b, 42 USCA § 256b
Current through P.L. 115-68. Also includes P.L. 115-72. Title 26 current through 115-73.

End of Document

Exhibit B-2

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 7. Social Security (Refs & Annos)
Subchapter XVIII. Health Insurance for Aged and Disabled (Refs & Annos)
Part B. Supplementary Medical Insurance Benefits for Aged and Disabled (Refs & Annos)

42 U.S.C.A. § 1395*l*

§ 1395*l*. Payment of benefits

Currentness

(t)Prospective payment system for hospital outpatient department services

(1)Amount of payment

(A)In general

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

(B)Definition of covered OPD services

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

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

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

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

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1395m(k) of this title or section 1395m(l) of this title and does not include screening mammography (as defined in section 1395x(jj) of this title), diagnostic mammography, personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), or preventive services described in subparagraphs (A) and (B) of section 1395x(ddd)(3) of this title that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population; and

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

(2)System requirements

Under the payment system--

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

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

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

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

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

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

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

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

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

(3)Calculation of base amounts

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

The Secretary shall estimate the sum of--

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

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

(B)Unadjusted copayment amount

(i)In general

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

period.

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

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

(iii)Rules for new services

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

(C)Calculation of conversion factors

(i)For 1999

(I)In general

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

(II)Product described

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

(ii)Subsequent years

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

(iii)Adjustment for service mix changes

Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv)OPD fee schedule increase factor

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

(D)Calculation of medicare OPD fee schedule amounts

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

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

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

(E)Pre-deductible payment percentage

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

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

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

(F)Productivity and other adjustment

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

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

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

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

(G)Other adjustment

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

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

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

(iii) for 2014, 0.3 percentage point;

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

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

(4)Medicare payment amount

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

(A)Fee schedule adjustments

The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B)Subtract applicable deductible

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

(C)Apply payment proportion to remainder

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

(5)Outlier adjustment

(A)In general

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

(i) a fixed multiple of the sum of--

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

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

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

(B)Amount of adjustment

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

(C)Limit on aggregate outlier adjustments

(i)In general

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

(ii)Applicable percentage

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

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

(II) for 2004 and thereafter, 3.0 percent.

(D)Transitional authority

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

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

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

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

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

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

(A)In general

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

(i)Current orphan drugs

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

(ii)Current cancer therapy drugs and biologicals and brachytherapy

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

(iii)Current radiopharmaceutical drugs and biological products

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

(iv)New medical devices, drugs, and biologicals

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

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

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

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

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

(i)Establishment of initial categories

(I)In general

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

(II)Authorization of implementation other than through regulations

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

(ii)Establishing criteria for additional categories

(I)In general

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

period).

(II)Standard

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

(III)Deadline

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

(IV)Adding categories

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

(iii)Period for which category is in effect

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

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

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

(iv)Requirements treated as met

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

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

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

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

(C)Limited period of payment

(i)Drugs and biologicals

The payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins--

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

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

(ii)Medical devices

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

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

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

(D)Amount of additional payment

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

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

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

(E)Limit on aggregate annual adjustment

(i)In general

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

(ii)Applicable percentage

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

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

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

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

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

(F)Limitation of application of functional equivalence standard

(i)In general

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

(ii)Application

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

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

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

(iii)Rule of construction

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

(7)Transitional adjustment to limit decline in payment

(A)Before 2002

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

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

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

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

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

(B)2002

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

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

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

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

(C)2003

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

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection

shall be increased by 60 percent of the amount of such difference; or

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

(D)Hold harmless provisions

(i)Temporary treatment for certain rural hospitals

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

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

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

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

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

(E)PPS amount defined

In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this

subchapter for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1895cc(a)(2)(A)(ii) of this title, and the deductible under subsection (b).

(F)Pre-BBA amount defined

(i)In general

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

(ii)Base payment-to-cost ratio defined

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

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

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

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

(G)Interim payments

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

(H)No effect on copayments

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

(I)Application without regard to budget neutrality

The additional payments made under this paragraph--

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

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

(8)Copayment amount

(A)In general

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

(B)Election to offer reduced copayment amount

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

(C)Limitation on copayment amount

(i)To inpatient hospital deductible amount

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

(ii)To specified percentage

The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted

basis) for that service in the year does not exceed the following percentage:

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

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

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

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

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

(D)No impact on deductibles

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

(E)Computation ignoring outlier and pass-through adjustments

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

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

(A)Periodic review

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

(B)Budget neutrality adjustment

If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C)Update factor

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

(10)Special rule for ambulance services

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

(11)Special rules for certain hospitals

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

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

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

(12)Limitation on review

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

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

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

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

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

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

(13)Authorization of adjustment for rural hospitals

(A)Study

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

(B)Authorization of adjustment

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

(14)Drug APC payment rates

(A)In general

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

(i) in 2004, in the case of--

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

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

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

(ii) in 2005, in the case of--

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

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

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

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

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

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

(B)Specified covered outpatient drug defined

(i)In general

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

(I) a radiopharmaceutical; or

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

(ii)Exception

Such term does not include--

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

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

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

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

The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D)Acquisition cost survey for hospital outpatient drugs

(i)Annual GAO surveys in 2004 and 2005

(I)In general

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

(II)Recommendations

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

(ii)Subsequent secretarial surveys

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

(iii)Survey requirements

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

(iv)Differentiation in cost

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

(v)Comment on proposed rates

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

(E)Adjustment in payment rates for overhead costs

(i)MedPAC report on drug APC design

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

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

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

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

(ii)Adjustment authorized

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

(F)Classes of drugs

For purposes of this paragraph:

(i)Sole source drugs

The term “sole source drug” means--

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

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

(ii)Innovator multiple source drugs

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

(iii)Noninnovator multiple source drugs

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

(G)Reference average wholesale price

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

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

Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

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

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

(16)Miscellaneous provisions

(A)Application of reclassification of certain hospitals

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

(B)Threshold for establishment of separate APCs for drugs

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

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

Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D)Special payment rule

(i)In general

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

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

(II) the payment rate that would otherwise apply under this section for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

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

(ii)Hospital described

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

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

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

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

(iii)Not budget neutral

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

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

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

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

Notwithstanding the previous provisions of this subsection:

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

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

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

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

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection)

for such year shall be reduced by 7 percent; and

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

(iii)Application without regard to budget neutrality

The reductions made under this subparagraph--

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

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

(iv)Implementation

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

(17)Quality reporting

(A)Reduction in update for failure to report

(i)In general

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

(ii)Non-cumulative application

A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take

into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B)Form and manner of submission

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

(C)Development of outpatient measures

(i)In general

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

(ii)Construction

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

(D)Replacement of measures

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

(E)Availability of data

The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18)Authorization of adjustment for cancer hospitals

(A)Study

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

(B)Authorization of adjustment

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

(C)Target PCR adjustment

In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1395ww(d)(1)(B)(v) of this title. In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

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

(A)In general

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

(B)Limitation

This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related

share adjustment under section 1395ww(d)(5)(H) of this title.

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

The Secretary shall not take into account the reduced expenditures that result from the application of section 1395m(p) of this title in making any budget neutrality adjustments this[12] subsection.

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

(A)Applicable items and services

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

(B)Off-campus outpatient department of a provider

(i)In general

For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of November 2, 2015) that is not located--

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

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

(ii)Exception

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

(iii)Deemed treatment for 2017

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

(iv)Alternative exception beginning with 2018

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

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

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

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

(v)Mid-build requirement described

The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi)Exclusion for certain cancer hospitals

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

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

(II) in the case of a department that meets such requirements after December 13, 2016, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii)Audit

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

(viii)Implementation

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

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

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

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until expended.

(C)Availability of payment under other payment systems

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

(D)Information needed for implementation

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

(E)Limitations

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

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

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

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

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

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XVIII, § 1833, as added Pub.L. 89-97, Title I, § 102(a), July 30, 1965, 79 Stat. 302; amended Pub.L. 90-248, Title I, §§ 129(c)(7), (8), 131(a), (b), 132(b), 135(c), Jan. 2, 1968, 81 Stat. 848 to 850, 853; Pub.L. 92-603, Title II, §§ 204(a), 211(c)(4), 226(c)(2), 233(b), 245(d), 251(a)(2), (3), 279, 299K(a), Oct. 30, 1972, 86 Stat. 1377, 1384, 1404, 1411, 1424, 1445, 1454, 1464; Pub.L. 95-142, § 16(a), Oct. 25, 1977, 91 Stat. 1200; Pub.L. 95-210, § 1(b), Dec. 13, 1977, 91 Stat. 1485; Pub.L. 95-292, § 4(b), (c), June 13, 1978, 92 Stat. 315; Pub.L. 96-473, § 6(j), Oct. 19, 1980, 94 Stat. 2266; Pub.L. 96-499, Title IX, §§ 918(a)(4), 930(h), 932(a)(1), 934(b), (d)(1), (3), 935(a), 942, 943(a), Dec. 5, 1980, 94 Stat. 2626, 2631, 2634, 2637, 2639, 2641; Pub.L. 96-611, § 1(b)(1), (2), Dec. 28, 1980, 94 Stat. 3566; Pub.L. 97-35, Title XXI, §§ 2106(a), 2133(a), 2134(a), Aug. 13, 1981, 95 Stat. 792, 797; Pub.L. 97-248, Title I, §§ 101(c)(2), 112(a), (b), 117(a)(2), 148(d), Sept. 3, 1982, 96 Stat. 336, 340, 355, 394; Pub. L. 98-369, Div. B, Title III, §§ 2303(a) to (d), 2305(a) to (d), 2308(b)(2)(B), 2321(b), (d)(4)(A), 2323(b)(1), (2), (4), 2354(b)(5), (7), July 18, 1984, 98 Stat. 1064, 1069, 1070, 1074, 1084 to 1086, 1100; Pub.L. 98-617, § 3(b)(2), (3), Nov. 8, 1984, 98 Stat. 3295; Pub.L. 99-272, Title IX, §§ 9303(a)(1), (b)(1) to (3), 9401(b)(1), (2)(A) to (E), Apr. 7, 1986, 100 Stat. 188, 189, 198, 199; Pub.L. 99-509, Title IX, §§ 9320(e)(1), (2), 9337(b), 9339(a)(1), (b)(1), (2), (c)(1), 9343(a), (b), (e)(2), Oct. 21, 1986, 100 Stat. 2014, 2033, 2036, 2039 to 2041; Pub.L.

100-203, Title IV, §§ 4042(b)(2)(B), 4043(a), 4045(c)(2)(A), 4049(a)(1), 4055(a) [formerly 4054(a)], 4062(d)(3)(A), 4063(b), 4063(e)(1), 4064(a), (b), (c)(1) [formerly (c)], 4066(a), (b), 4067(a), 4068(a), 4070(a), (b)(4), 4072(b), 4073(b)(1), (2) [formerly 4073(b)(2), (3)], 4077(b)(2), (3) [formerly 4077(b)(3), (4)], 4084(a), (c)(2), 4085(b)(1), (i)(1) to (3), (21)(D)(i), (22)(B), (23), Dec. 22, 1987, 101 Stat. 1330-88, 1330-109 to 1330-115, 1330-117, 1330-129 to 1330-133; Pub.L. 100-360, Title I, § 104(d)(7), Title II, §§ 201(a), 202(b)(1) to (3), 203(c)(1)(A) to (E), 204(d)(1), 205(c), 212(c)(2), Title IV, § 411(f)(2)(D), (8)(B)(i), (C), (12), (14), (g)(1)(E), (2)(E), (3)(A) to (F), (4)(C), (5), (h)(1)(A), (3)(B), (4)(B), (C), (7)(C), (D), (F), (i)(3), (4)(B), (C)(i), (ii), (iv), (vi), July 1, 1988, 102 Stat. 700, 704, 722, 728, 730, 741, 777, 779, 781 to 789; Pub.L. 100-485, Title VI, §§ 608(d)(3)(G), (4), (22)(B), (D), (23)(A), Oct. 13, 1988, 102 Stat. 2414, 2420, 2421; Pub.L. 100-647, Title VIII, §§ 8421(a), 8422(a), Nov. 10, 1988, 102 Stat. 3802; Pub.L. 101-234, Title II, §§ 201(a)(1), 202(a), Dec. 13, 1989, 103 Stat. 1981; Pub.L. 101-239, Title VI, §§ 6003(e)(2)(A), (g)(3)(D)(vii), 6102(c)(1), (e)(1), (5), (6)(A), (7), (f)(2), 6111(a), (b)(1), 6113(b)(3), (d), 6116(b)(1), 6131(a)(1), (b), 6133(a), 6204(b), Dec. 19, 1989, 103 Stat. 2143, 2153, 2184, 2187, 2188, 2189, 2213, 2214, 2217, 2219, 2221, 2222, 2241; Pub.L. 101-508, Title IV, §§ 4008(m)(2)(C), 4104(b)(1), 4118(f)(2)(D), 4151(c)(1), (2), 4153(a)(2)(B), (C), 4154(a) to (c)(1), (e)(1), 4155(b)(2), (3), 4160, 4161(a)(3)(B), 4163(d)(1), 4206(b)(2), 4302, Nov. 5, 1990, 104 Stat. 1388-53, 1388-59, 1388-70, 1388-73, 1388-83 to 1388-85, 1388-86, 1388-87, 1388-91, 1388-93, 1388-100, 1388-116, 1388-125; Pub.L. 101-597, Title IV, § 401(c)(2), Nov. 16, 1990, 104 Stat. 3035; Pub.L. 103-66, Title XIII, §§ 13516(b), 13532(a), 13544(b)(2), 13551, 13555(a), Aug. 10, 1993, 107 Stat. 584, 586, 590 to 592; Pub.L. 103-432, Title I, §§ 123(b)(2)(A), (e), 141(a), (c)(1), 147(a), (d), (e)(2), (3), (f)(6)(C), (D), 156(a)(2)(B), 160(d)(1), Oct. 31, 1994, 108 Stat. 4411, 4412, 4424, 4425, 4429, 4430, 4432, 4440, 4443; Pub.L. 105-33, Title IV, §§ 4002(j)(1)(A), 4101(b), 4102(b), 4103(b), 4104(c)(1), (2), 4201(c)(1), 4205(a)(1)(A), (2), 4315(b), 4432(b)(5)(C), 4511(b), 4512(b)(1), 4521(a), (b), 4523(a), (d)(1)(A)(i), (1)(B), (2), (3), 4531(b)(1), 4541(a)(1), (c), (d)(1), 4553(a), (b), 4555, 4556(b), 4603(c)(2)(A), Aug. 5, 1997, 111 Stat. 330, 360 to 362, 365, 373, 376, 390, 421, 442 to 445, 449, 450, 454, 456, 460, 462, 463, 470; Pub.L. 106-113, Div. B, § 1000(a)(6) [Title II, §§ 201(a) to (d), (e)(1), (f), (g), (h)(1), (i), (j), 202(a), 204(a), (b), 221(a)(1), 224(a), Title III, § 321(g)(2), (k)(2), Title IV, §§ 401(b)(1), 403(e)(1)], Nov. 29, 1999, 113 Stat. 1536, 1501A-336 to 1501A-342, 1501A-345, 1501A-351, 1501A-353, 1501A-366, 1501A-369; Pub.L. 106-554, § 1(a)(6) [Title I, §§ 105(c), 111(a)(1), Title II, §§ 201(b)(1), 205(b), 223(c), 224(a), Title IV, §§ 401(a), (b)(1), 402(a), (b), 403(a), 405(a), 406(a), 421(a), 430(a), Title V, § 531(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A-472, 2763A-481, 2763A-483, 2763A-489, 2763A-490, 2763A-502, 2763A-503, 2763A-505, 2763A-506, 2763A-507, 2763A-508, 2763A-516, 2763A-524, 2763A-547; Pub.L. 108-173, Title II, § 237(a), Title III, §§ 302(b)(2), 303(i)(3)(A), Title IV, §§ 411(a)(1), (b), 413(a), (b)(1), Title VI, §§ 614(a), (b), 621(a)(1) to (5), (b)(1), (2), 622, 624(a)(1), 626(a) to (c), 627(a)(1), 628, 629, 642(b), Title VII, § 736(b)(1), (2), Title IX, § 942(b), Dec. 8, 2003, 117 Stat. 2212, 2229, 2254, 2274, 2275, 2277, 2306 to 2311, 2317 to 2321, 2322, 2355, 2421; Pub.L. 109-171, Title V, §§ 5103, 5105, 5107(a)(1), 5112(e), 5113(a), Feb. 8, 2006, 120 Stat. 40, 41, 42, 44; Pub.L. 109-432, Div. B, Title I, §§ 107(a), (b)(1), 109(a)(1), (b), Title II, § 201, Dec. 20, 2006, 120 Stat. 2983 to 2986; Pub.L. 110-173, Title I, §§ 102, 105, 106, 113, Dec. 29, 2007, 121 Stat. 2495, 2496, 2501; Pub.L. 110-275, Title I, §§ 101(a)(2), (b)(2), 102, 141, 142, 143(b)(2), (3), 145(a)(2), (b), 147, 151, 184, July 15, 2008, 122 Stat. 2497, 2498, 2542, 2547, 2548, 2550, 2587; Pub.L. 111-144, § 6, Mar. 2, 2010, 124 Stat. 46; Pub.L. 111-148, Title III, §§ 3103, 3114, 3121, 3138, 3401(i), (k), (l), Title IV, §§ 4103(c)(1), (3)(A), (B), (4), 4104(b), (c), Title V, § 5501(a)(1), (b)(1), Title X, §§ 10221(a), 10221(b)(4), 10319(g), 10324(b), 10406, 10501(i)(3)(B), (C), Mar. 23, 2010, 124 Stat. 417, 423, 439, 485, 486, 556, 557, 652, 653, 935, 936, 949, 960, 975, 998; Pub.L. 111-152, Title I, § 1105(e), Mar. 30, 2010, 124 Stat. 1049; Pub.L. 111-309, Title I, §§ 104, 108, Dec. 15, 2010, 124 Stat. 3287, 3288; Pub.L. 112-78, Title III, §§ 304, 308, Dec. 23, 2011, 125 Stat. 1284, 1285; Pub.L. 112-96, Title III, §§ 3002(a), 3005(a), (b), 3202, Feb. 22, 2012, 126 Stat. 186, 187, 193; Pub.L. 112-240, Title VI, § 603(a) to (c), 634, Jan. 2, 2013, 126 Stat. 2347, 2355; Pub.L. 113-67, Div. B, Title I, § 1103, Dec. 26, 2013, 127 Stat. 1196; Pub.L. 113-93, Title I, § 103, Title II, §§ 216(b)(1), 218(a)(2)(A), (b)(2), Apr. 1, 2014, 128 Stat. 1041, 1059, 1064, 1069; Pub.L. 114-10, Title I, §§ 101(e)(2), (3), Title II, § 202(a), (b)(1), Title V, § 514(a), Apr. 16, 2015, 129 Stat. 117, 122, 143, 171; Pub.L. 114-74, Title VI, § 603, Nov. 2, 2015, 129 Stat. 597; Pub.L. 114-113, Div. O, Title V, § 502(b), 504(b)(1), Dec. 18, 2015, 129 Stat. 3019, 3021; Pub.L. 114-255, Div. A, Title V, § 5012(c)(1), Div. C, Title XVI, §§ 16001(a), 16002(a), (b), Dec. 13, 2016, 130 Stat. 1202, 1324, 1325.)

EFFECTIVE DATE OF AMENDMENT OF SUBSECTION (A)(1)

<Amendment of subsection (a)(1) by Pub.L. 114-255, Div. A, Title V, § 5012, shall apply to items furnished on or after Jan. 1, 2021, under the terms of Pub.L. 114-255, Div. A, Title V, § 5012(d), see Pub.L. 114-255, Div. A, Title V, § 5012(d), set out as a note under this section.>

Notes of Decisions (34)

Footnotes

1 So in original.

2 So in original. The word “and” probably should not appear.

3 So in original. See Pub.L. 111-148, § 4103(c)(3)(B).

4 So in original. “(O)” following “1395m” probably should be lower case.

5 So in original. Probably should be preceded by “a”.

6 So in original. The comma after “subclause (II))” probably should follow “is performed”.

7 So in original. Probably should be “such paragraph applies”.

8 So in original. The word “this” probably should not appear.

9 So in original. Probably should be “are--”.

10 So in original. Probably should be “subparagraph”.

11 So in original. No paragraph “(2)” has been enacted.

12 So in original. Probably should be preceded by “under”.

13 See References in Text note set out under this section.

14 So in original. Probably should be “paragraphs”.

15 So in original. Two subsecs. (z) have been enacted.

16 So in original. Probably should be “exceed”.

17 So in original. Probably should be preceded by “section”.

18 So in original.

42 U.S.C.A. § 1395***l***, 42 USCA § 1395l
Current through P.L. 115-68. Also includes P.L. 115-72. Title 26 current through 115-73.

End of Document

Exhibit C

American Hospital Association

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September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–1678–P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule (Vol. 82, No. 138), July 20, 2017.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) proposed rule for calendar year (CY) 2018. We will submit separate comments on the agency's request for information related to regulatory burden.

The AHA strongly opposes CMS's proposal to reduce Medicare Part B payment for drugs acquired through the 340B Drug Pricing Program and urges the agency to withdraw it from consideration. First, CMS lacks statutory authority to impose such a drastic reduction in the payment rate for 340B drugs, effectively eviscerating the benefits of the program. Medicare payment cuts of this magnitude would greatly undermine 340B hospitals' ability to continue programs designed to improve access to services – which is the very goal of the program. In addition, Medicare beneficiaries, dually eligible Medicare beneficiaries included, would not directly benefit from a lowered drug copayment amount as claimed by the agency. In contrast, the proposal would actually increase their out-of-pocket costs for other Part B benefits. Rather than punitively targeting 340B safety-net hospitals serving vulnerable patients, including those in rural areas, we urge CMS to redirect its efforts to halt the unchecked, unsustainable increases in the price of drugs.

Further, the AHA opposes the removal of total knee replacement from the inpatient-only list. We do not believe it is clinically appropriate and are concerned that it could put the success of the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payments for Care Improvement (BPCI) programs at

risk. **In addition, we oppose the removal of partial hip arthroplasty and total hip arthroplasty procedures from the inpatient-only list and urge CMS to take caution if it contemplates this change in future years.** We do not believe it is clinically appropriate. Additionally, we are similarly concerned that it could put the success of the CJR and BPCI programs at risk.

At the same time, we support a number of the OPPS proposed rule's provisions. For instance, we support CMS's proposal to reinstate the moratorium on enforcement of its burdensome direct supervision requirement for outpatient therapeutic services provided in critical access hospitals and small and rural hospitals. However, we urge the agency to make the enforcement moratorium permanent and continuous (i.e., without a gap in 2017). In addition, the AHA supports CMS's proposal, with certain revisions, to update its laboratory date-of-service (DOS) billing policies for separately payable molecular pathology and Advanced Diagnostic Laboratory Tests (ADLTs) that are performed on specimens collected from hospital outpatients. Updating the current DOS policy will enable performing laboratories to bill Medicare directly for certain laboratory services excluded under the OPPS packaging policy.

A summary of our other key recommendations follows.

- The AHA recommends that CMS not finalize its proposal to conditionally package payment for Level 1 and 2 drug administration services and instead continue to provide separate payment for all drug administration services.
- The AHA opposes the implementation of a proposed code edit for claims with brachytherapy services that will require the brachytherapy application code to be included on the claim with the brachytherapy insertion procedure as it would be burdensome for facilities when the insertion procedure is not performed during the same encounter.
- The AHA believes it would be premature to implement a claims edit conditioning payment on the provision of 20-hours of therapeutic services per week for partial hospitalization program (PHP) services. Instead, CMS should work with hospitals and community mental health centers to evaluate the variety of factors, beyond hours-per-week, that appropriately represent the "intensity" of services for a PHP and further educate providers about the agency's expectations regarding service intensity.
- On CMS's comment request for whether physician-owned hospitals could play a more prominent role in the delivery system, given the current statutory bans and limits, the AHA opposes any changes that would allow additional physician-owned hospitals to participate in Medicare or allow grandfathered hospitals to expand or increase their capacity beyond what is allowed currently.
- The AHA supports the removal of several measures from the Hospital Outpatient Quality Reporting (OQR) program, although we believe these should be removed as soon as possible rather than staggered until CY 2021. AHA also agrees that the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems survey-based measures are not appropriate for inclusion in the OQR and appreciates the delay in their implementation.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, AHA director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

Enclosure

American Hospital Association (AHA)
Detailed Comments on the Outpatient Prospective Payment System (OPPS) Proposed Rule for Calendar Year (CY) 2018

TABLE OF CONTENTS

ALTERNATIVE PAYMENT METHODOLOGY FOR DRUGS PURCHASED UNDER THE 340B DRUG PRICING PROGRAM

The Centers for Medicare & Medicaid Services (CMS) proposes to pay for separately payable, non pass-through drugs acquired through the 340B program at the rate of the average sales price (ASP) minus 22.5 percent. Currently, these drugs are paid at ASP plus 6 percent. CMS estimates this proposal could decrease payments for Part B drugs by $900 million in 2018. The agency proposes to implement the policy in a budget neutral manner within the OPPS through an increase in the conversion factor. However, it also seeks comment on several other options to achieve budget neutrality, including by using all or part of the savings to increase payments for specific services paid under the OPPS or applying the savings to other Part B payment systems, outside of the OPPS. Finally, CMS proposes to effectuate the policy through a modifier that would be applied to separately payable drugs that were not acquired through the 340B program.

CMS states several primary rationales for its proposal:

- First, it asserts that due to the drug price discount available to 340B hospitals, one of its goals 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 while continuing to provide access to care."[1]
- Second, CMS states that another goal is to reduce Medicare beneficiaries' drug copayments when seeking care from 340B hospitals.[2]
- Third, the agency states that this payment reduction is justified and necessary because the drug discounts provided through the 340B program has led to an overutilization of drugs purchased through the program by 340B hospitals.[3]

The AHA strongly opposes CMS's proposal to reduce Medicare Part B payment for drugs acquired through the 340B program. It is based on flawed policy arguments, and we urge the agency to withdraw it from consideration. In short:

- **CMS lacks statutory authority to impose a payment rate for 340B drugs that so dramatically reduces payments and effectively eviscerates the benefits and intent of the 340B program for hospitals.**
- **Medicare payment cuts of this magnitude do not recognize the intent of the 340B program as CMS claims; in contrast, they would greatly undermine 340B hospitals' ability to continue programs designed to improve access to health care services.**
- **The proposal would not directly lower Medicare beneficiaries' drug copayments when seeking care from 340B hospitals, as CMS claims. In fact, it would actually cause increases in their**

[1] CMS OPPS Proposed Rule, Federal Register, Vol. 82, No. 138, July 20, 2017, p 33633
[2] Ibid, p 33633
[3] Ibid. p 33633

out-of-pocket costs for other Part B benefits because of the proposed increase in the conversion factor.

- **Punitively targeting 340B safety-net hospitals serving vulnerable patients, including those in rural areas, does not address the real reason for increased spending on drugs – the skyrocketing cost of pharmaceuticals.**

CMS LACKS STATUTORY AUTHORITY TO IMPOSE A PAYMENT RATE FOR 340B DRUGS THAT SO DRAMATICALLY REDUCES PAYMENTS TO AND EFFECTIVELY EVISCERATES THE BENEFITS OF THE PROGRAM

CMS lacks the statutory authority to impose a payment rate for 340B drugs that so dramatically reduces payments and effectively eviscerates the benefits of the 340B program for hospitals. CMS's statutory authority to establish payment rates for separately payable drugs under the OPPS is limited by the plain and ordinary meaning of the precise terms used in the provision CMS purports to rely on for its 2018 proposal (subclause (II) of section 1395*l*(t)(14)(A)(iii)). Indeed, the overall statutory scheme of section 1395*l*(t)(14) evidences an intent by Congress to tightly constrain the power of CMS in setting payment rates. Moreover, CMS's proposal is inconsistent with the Public Health Service Act, because it effectively would repeal section 340B as it applies to most drugs purchased by 340B program hospitals.

CMS's Authority Limited by Statute's Plain Meaning. **CMS's contention that the agency has specific statutory authority to reset the payment rate to ASP minus 22.5 percent is contradicted by the plain and ordinary meaning of the text of the statute.** CMS argues that subclause (II) of section 1395*l*(t)(14)(A)(iii) gives the agency broad discretion to discard the current rate and set a new rate as the agency deems appropriate because when hospital acquisition cost data are not available, the average price for drugs in the year is to be "calculated and adjusted by the Secretary as necessary."

However, the plain and ordinary meaning of the terms "calculate" and "adjust" express a limited and circumscribed authority to set the payment rate. 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 statutory subclause restricts the agency to determining mathematically an appropriate, slight alteration that should be applied to the statutory default rate in any given year. It does not convey, as CMS asserts, the power to adopt 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[4], according to our estimates. CMS's proposal is not the slight alteration to the payment rate permitted under the statute.

Overall Statutory Scheme Reinforces Limited Authority of Agency. **That this statutory subclause conveys only limited authority to CMS is further reinforced by the overall scheme of section 1395*l*(t)(14), which directs CMS to establish payment rates for separately payable OPPS drugs**

[4] The AHA's own analysis of the CMS methodology discussed later show that the proposal would reduce payments by a greater amount of $1.65 billion.

within significantly prescribed parameters.[5] Specifically, the first two subparagraphs of this section, ((t)(14)(A)(i) and (t)(14)(A)(ii)), provide the agency with no separate authority to adjust the 2004 and 2005 payment rates. Subclause (I) of the next subparagraph ((t)(14)((A)(iii)) ─ establishing 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 requirements spelled out in a subsequent statutory subparagraph ─ also provides no adjustment authority for the agency. Subclause (II) of (t)(14)((A)(iii) directs CMS, where such acquisition cost data are not available, to set payment rates by reference to ASP provisions. Considered in context, the statute reflects an intent by Congress to limit CMS's authority to set payment rates and, consequently, is consistent with reading any adjustment authority under subclause (II) ─ which CMS relies on ─ as conveying only limited authority for the agency to adjust the payment rate.

Current Agency View Contrasts with Long-standing Practice. **CMS's assertion that it has very broad authority to make the substantial adjustment proposed here contrasts sharply with the agency's previous view and long-standing practice applying the statutory scheme of section 1395*l*(t)(14).** Since CMS began relying on subclause (II) in 2012 to set the payment rate, the agency has never invoked the discretionary authority. Instead, CMS stated that the statutory default of ASP plus 6 percent "requires no further adjustment" because it "represents the combined acquisition and pharmacy overhead payment for drugs and biologicals."[6] Moreover, CMS has applied the rate *without further adjustment* in each subsequent year. CMS's proposal for 2018, in contrast, departs dramatically from long-standing prior practice and adopts a substantially reduced payment rate of ASP minus 22.5 percent.

CMS Effectively Repeals 340B Program In Proposal. **Regardless of the actual breadth of adjustment authority conferred upon the agency by the statutory provisions for establishing payments rates for separately payable drugs under OPPS, section 1395*l*(t)(14)(A)(iii)(II) 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**.[7] Specifically, CMS's proposal would eliminate all, or nearly all, of the differential between 340B covered entities acquisition costs and Medicare payment. It would cut off a well-recognized and critical source of revenue for the hospitals and reduce their ability to offer vital health services to vulnerable populations. The proposal effectively would repeal section 340B as it applies to most drugs purchased by these hospitals.

The purpose of the 340B program, as the report of the House Committee on Energy and Commerce states, is to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[8] Since the program's inception, the Health Resources and Services Administration (HRSA) and other agencies have consistently recognized that such purpose means that the 340B program is intended to allow covered entities to leverage their lower

[5] *See 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.").
[6] 77 Fed. Reg. at 68386.
[7] See *Roberts*, 566 U.S. at 132. (In interpreting statutes, the "task is to fit, if possible, all parts into a harmonious whole.").
[8] H.R. REF. No. 102-384(II), at 12 (1992).

acquisition costs to generate "[a]dditional program resources" that will enable them to provide more access to, and more comprehensive, health care services.[9]

The 340B program's history is reflective of that well-recognized purpose. HRSA has consistently implemented the 340B program since its inception in a manner that expressly supports the purpose of providing covered entities with a revenue source to provide additional or more comprehensive services.[10] Moreover, despite such longstanding and consistent program implementation, Congress has never sought to amend the statute in a way that would reduce or eliminate surpluses generated through the 340B program. Rather, recognizing the benefit of the 340B program in providing access to health services to vulnerable populations, Congress has steadily increased the categories of "covered entities" over the years. Continued program expansions, without an accompanying limitation on the program beneficiaries, is consistent with congressional recognition that the 340B program should continue be implemented in a manner that allows covered entities to leverage discounts received under the program to provide more comprehensive services. That CMS's payment rate proposal significantly undercuts, if not altogether eliminates, any ability of covered entities to leverage discounts received under the program to provide more comprehensive services cannot be reconciled with this well-recognized purpose and historically consistent operation of the 340B program.

Proposal is Procedurally Defective. **CMS's proposed new payment rate also is procedurally defective under the OPPS statute.** CMS's justification for the proposed reduced rate rests in part on intertwined issues related to clinical use and hospital cost of drugs. Pointing to a study suggesting that 340B hospitals may be unnecessarily prescribing more drugs and/or more expensive drugs relative to non-340B hospitals, CMS suggests that a payment rate that eliminates the differential between acquisition cost and Medicare OPPS payment may help to reduce the incentive to overprescribe. These are precisely the kind of factors that should have been considered by the expert Advisory Panel with which CMS is obligated by section 1395*l*(t)(9)(A) of the statute to consult, and from which it is obligated to seek advice, 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 statute mandates CMS review and revise the payment groups and the relative payment weights for the groups not less often than annually. As part of the process, CMS must consult with the outside Advisory Panel for advice relative to the clinical integrity of the payment groups and the payment weights, which encompass considerations of data on hospital costs and clinical use.[11] However, CMS did not consult with the Advisory Panel on Hospital Outpatient Payment as the statute mandates before publishing its proposed payment rate of ASP minus 22.5 percent for 340B drugs.[12] This is contrary to the statute. At an Aug. 21, 2017 meeting that occurred after publication of the proposed rule, the Advisory Panel urged that CMS not finalize the proposed payment reduction. Rather, it urged CMS to: (1)

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[9] See, e.g., HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Services Act*, at Part 1.G (July 2005), available at https://www.hrsa.go9v/hemophiliatreat,emnt/340manual.htm#21 (last accessed Aug. 22, 2017). See also U.S. Gov't Accountability Off., GAO-11-836, Manufacturer Discount in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (Sept. 2011), at 17-18 (finding that studied covered entities generated revenue from the 3408 Program and used the revenue in ways consistent with the program's purposes, e.g., by providing additional services at more locations, patient education programs, and translation and transportation services that the entities otherwise could not afford).

[10] See *Hemophilia Treatment Manual*, *supra*.

[11] *See* § 1395*l*(t)(2)(C).

[12] *See* Mar. 14, 2016 and Aug. 22, 2016 Meeting Agenda, found at CMS, Advisory Panel on Hospital Outpatient Payment, https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html (last accessed Aug. 22, 2017).

collect data from public comments and other sources, such as state 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 from changing the payment rate and, (2) assess the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved.

CMS's proposal also violates section 1395*l*(t)(2)(E) because it is not authorized and because the agency had not offered 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. Consistent with the Administrative Procedure Act, the agency itself must offer a reasoned basis for taking the unprecedented action it proposes to take here.[13] The agency, as a matter of longstanding policy and practice, has never applied savings from OPPS outside of OPPS. The agency's announcement in the proposed rule that it might do so is an unprecedented departure from previous policy and practice. It also is not authorized by section 1395*l*(t)(2)(E) and would result from a legally questionable proposal that by CMS's own estimates would reduce direct payments to 340B hospitals by as much as $900 million a year. The significant reduction in direct payments to 340B participating hospitals and redistribution of resulting savings to other Part B programs and services would have a tremendous negative impact on 340B hospitals and unquestionably diminish their ability to offer vital health services to vulnerable populations for which the 340 program is designed. The proposal cannot be maintained as part of any final rulemaking from the agency.

CMS'S PROPOSED CUTS WOULD UNDERMINE THE CONGRESSIONALLY-MANDATED MISSION OF THE 340B PROGRAM

CMS states that one goal of its proposal 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 while continuing to provide access to care." However, in reality, the proposal does not recognize the intent of the program and would, in fact, do great harm to hospitals serving our most vulnerable citizens, undermining the purpose of the 340B program established by Congress. Specifically, it would undercut the 340B program's value as a tool for lowering drug prices and disrupt access to care for those in greatest need, including low-income Medicare beneficiaries.

Intent and Effect of the 340B Program. Congress created the 340B program to permit safety-net hospitals that care for a high number of low-income and uninsured patients "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[14] Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. For 25 years, the 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to build healthy communities. In 2015, the

[13] *Motor Vehicle Assn of US, Inc. v. State Faun Mut. Auto lns. Co.*, 463 U.S. 29, 42 (1983) (an agency proposing to "chang[e] its course" from a longstanding practice "is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.").
[14] https://www.hrsa.gov/opa/index.html

340B program accounted for only 2.8 percent of the $457 billion in annual drug purchases made in the U.S. However, hospitals were able to use those savings to support many programs that are improving and saving lives.[15] In addition, in 2015, 340B hospitals provided $23.8 billion in uncompensated care.[16]

340B hospitals serve vulnerable communities. Specifically, 30 percent are located in rural communities. Nearly 50 percent significantly exceeded the minimum Medicare disproportionate share hospital (DSH) adjustment percentage of 11.75 percent, which serves as the qualifying threshold for the 340B program. One-fifth of these hospitals have a Medicare DSH adjustment percentage of more than 25 percent, which further underscores the services they provide to low-income and vulnerable populations in their communities.

340B hospitals reinvest the savings they receive in programs that help vulnerable communities. Specifically, these programs enhance patient services and access to care, as well as provide free or reduced priced prescription drugs to vulnerable patient populations. For example, hospitals use the savings to:

- provide financial assistance to patients unable to afford their prescriptions;
- provide clinical pharmacy services, such as disease management programs or medication therapy management;
- fund other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- establish additional outpatient clinics to improve access;
- create new community outreach programs; and
- offer free vaccinations for vulnerable populations.

In addition, an examination of key hospital services[17] illustrates that these 340B hospitals provide essential services to their communities and the vulnerable patients they serve:

- Trauma care: Nearly two-thirds of 340B hospitals provide trauma care compared to 56 percent of all hospitals.
- Pediatric Medical Surgical: Three-quarters of all 340B hospitals provide pediatric medical surgical services while about two-thirds of all hospitals provide such services.
- Obstetrics (OB) Units: Nearly all 340B hospitals have OB units while about 85 percent of all hospitals have an OB unit.
- Psychiatric Care: About two-thirds of 340B hospitals provide psychiatric services while about 58 percent of all hospitals provide such services.

[15] ASPE Issue Brief: Observations on Trends in Prescription Drug Spending, March, 2016 https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf and HRSA's FY 2018 Budget Justifications to Congress https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf
[16] AHA 2015 Annual Survey Data
[17] Ibid

- Alcoholism-Drug Abuse or Dependency Outpatient Services: 42 percent of 340B hospitals provide substance abuse or dependency services while just over one-third of all hospitals provide such services.
- Neonatal Intensive Care Units (NICU): 58 percent of 340B hospitals have NICUs while less than half of all hospitals have a NICU.
- Breast Cancer Screening: Nearly all 340B hospitals provide breast cancer screening while 93 of all hospitals provide such services.

Financial Status of 340B Hospitals. As noted, many 340B hospitals are the lifelines of their communities, and the discounts they receive through the 340B program play an important role in allowing them to care for patients. However, these facilities are financially vulnerable. In 2015, one out of every four 340B hospitals had a negative operating margin. In addition, 340B hospitals paid under OPPS had total and outpatient Medicare margins of negative 18.4 percent and negative 15.4 percent, respectively, whereas hospitals overall had total and outpatient Medicare margins of negative 15.5 percent and negative 13.5 percent, respectively. [18]

CMS's proposed cuts would make these hospitals' financial situations even more precarious, thus putting at great risk the programs they have developed to expand access to care for their vulnerable patient populations. CMS estimates that its proposal would reduce OPPS payments for separately payable drugs, including beneficiary copayment, by as much as $900 million. However, based on our analysis, the proposed cut would reduce payments for 340B-acquired drugs by almost double that much – $1.65 billion. Even our lower bound impact estimate of $1.25 billion, which considers only the top 60 drugs that we believe are eligible for 340B program pricing, is significantly higher than CMS's estimate. Further, these estimates are conservative, as our analysis, unlike CMS's, strips out data for those separately payable drugs (i.e. status indicator K drugs) that are packaged into comprehensive ambulatory payment classifications (APC)s, and we have not inflated our numbers to account for claims completeness. Given that CMS provided virtually no information as to how it computed its $900 million estimate, we cannot comment as to why our estimate is so different. However, we have consulted with many stakeholders and experts and have confidence in our analysis.

Moreover, if CMS implements the policy as it proposed, in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, our analysis shows that payments for non-drug APCs would increase across hospitals by about 3.7 percent (in contrast to CMS's estimate of 1.4 percent). This redistribution would result in a net decrease in payments to 340B hospitals of about 2.6 percent, or approximately $800 million. **Plainly stated, even accounting for adjustments to ensure overall budget neutrality, CMS's proposal would remove $800 million intended to support 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. This would not only undermine the purpose of 340B, but also would further erode the financial viability of 340B hospitals.** Other approaches to achieving budget neutrality under consideration by the agency, such as applying off-setting savings to specific services within the OPPS or outside of the OPPS to Part B generally (such as physician services under the Medicare Physician Fee Schedule) would similarly penalize these most vulnerable hospitals and inhibit their efforts to carry out the purpose of the 340B program. Finally,

[18] Ibid

implementing the proposed policy in a non-budget neutral manner would effectively gut the 340B program, devastating the hospitals that rely on it.

MOST MEDICARE BENEFICIARIES WOULD NOT DIRECTLY BENEFIT FROM CMS'S PROPOSAL

Part of CMS's rationale for proposing a reduction in payment for Part B drugs acquired under the 340B program is that the agency believes the proposal would reduce Medicare beneficiaries' drug copayments when seeking care from 340B hospitals. However, this is not accurate. The majority of Medicare beneficiaries coming to 340B hospitals do not pay their own copayments. According to a Medicare Payment Advisory Commission (MedPAC) analysis, 86 percent of all Medicare beneficiaries have supplemental coverage that covers their copayments, of which 30 percent have their copayments paid for by a public program, such as Medicaid, or by their Medigap plan.[19] **Thus, CMS's 340B payment reduction proposal would not directly benefit many Medicare beneficiaries, dually eligible Medicare beneficiaries included.**

Further, Medicare beneficiaries may even see increases in out-of-pocket costs for other non-drug OPPS services. This is because the redistributions that result from budget neutrality would increase reimbursement for other services, thus increasing beneficiaries' copayments in a parallel manner. The AHA modeled the impact of CMS's proposal on payments and copayments in 340B hospitals after applying offsetting increases to non-drug services. When reviewing the impact at the claims level, we found that there was a net payment decrease in only 3 percent of claims under CMS's proposal. In contrast, in 97 percent of claims, there was a net payment increase. We conducted a similar analysis at the beneficiary level and found that 3 percent of beneficiaries being treated at 340B hospitals would see their copayments reduced overall, whereas, 97 percent of beneficiaries would see their copayments increase overall. While we recognize that an analysis of the number of claims and beneficiaries experiencing increases or decreases in copayments does not reflect the absolute change in beneficiary copayment amount, we again reiterate that most beneficiaries do not directly pay their copayments due to supplemental coverage. **Moreover, the drastic cuts in payments to 340B hospitals would certainly reduce their ability to support programs that enhance patient services and access to care programs that currently benefit low-income Medicare beneficiaries, both financially and with regard to their health and wellness.**

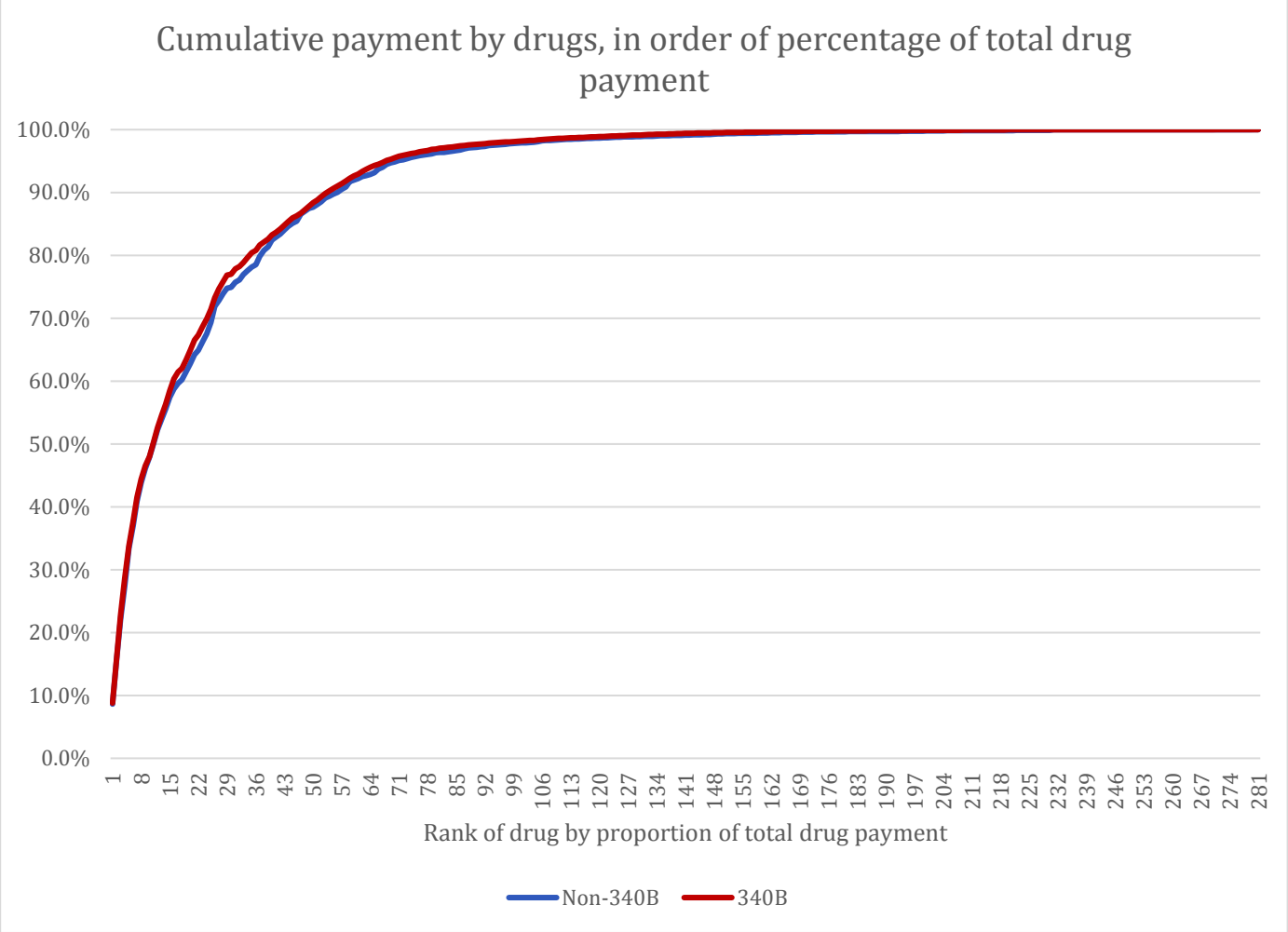
PART B DRUG EXPENDITURES INCREASES ARE LARGELY A RESULT OF OUT OF CONTROL DRUG PRICES

As part of the impetus for its proposal, CMS states a concern that "the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs."[20] However, our data do not support this concern, and, in fact contradict it, showing that 340B hospitals utilize separately payable drugs in the same manner as other hospitals. In addition, our data show that increases in drug prices – not utilization – are largely to blame for increases in Part B drug expenditures. First, our analysis of the cumulative payment by Part B drug in order of the percentage of total drug payment shows that 340B and non-340B hospitals utilize the same drugs at the same rates. See Figure 1 below. That is, the proportion of drugs utilized is very similar between the two types of hospitals, indicating that 340B hospitals use drugs

[19] MedPAC, June 2016 Databook, Section 3, p 27.
[20] CMS OPPS Proposed Rule, Federal Register, Vol. 82, No. 138, July 20, 2017, p 33633.

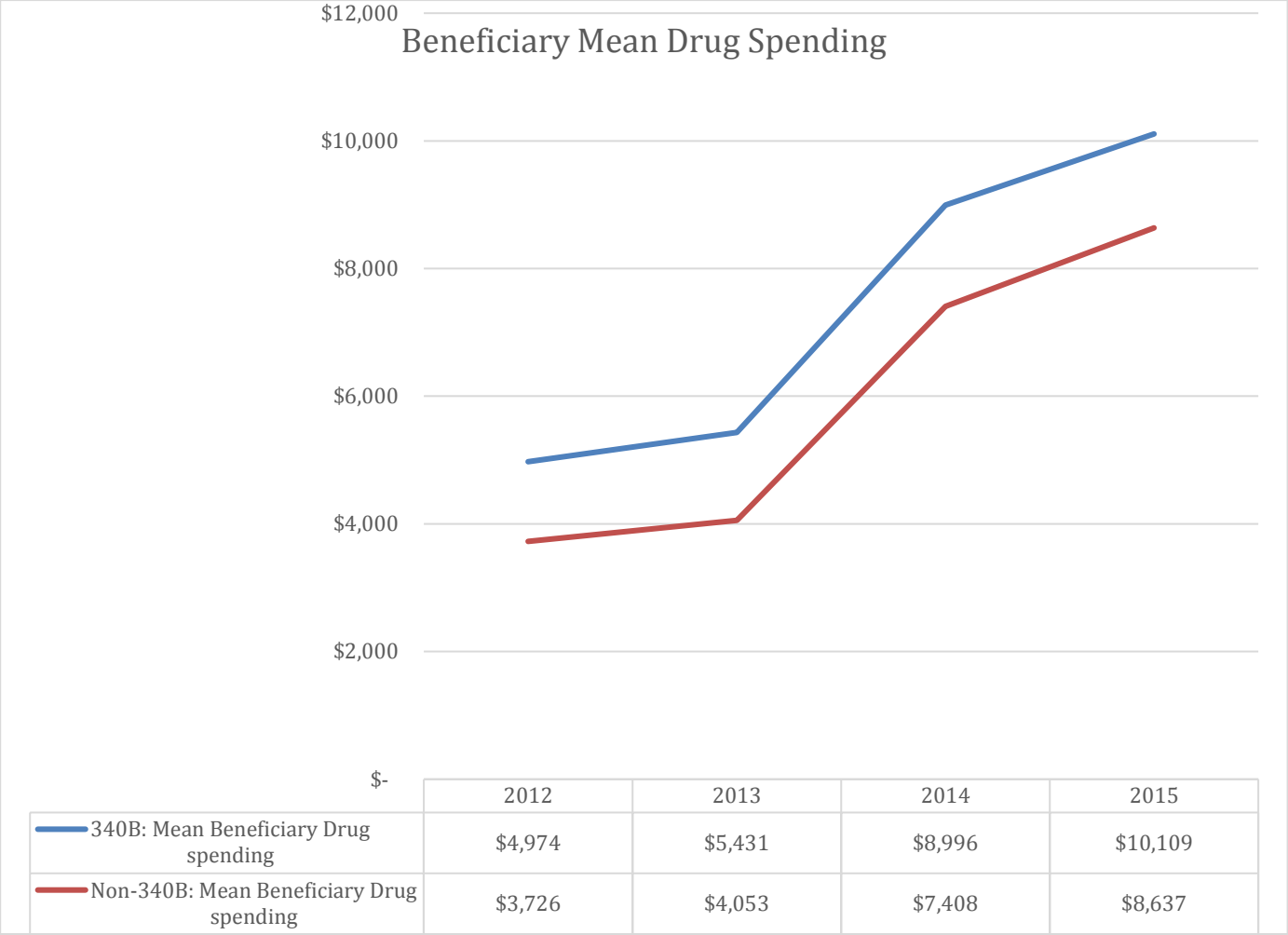
in the same mix as the non-340B. Therefore, using drugs as a proxy, 340B hospitals generally treat the same conditions in the same proportions, as non-340B hospitals and so are not overutilizing these drugs.

Figure 1: Cumulative payment by drugs, in order of percentage of total drug payment



In addition, in our analysis of beneficiary mean drug spending, we found that even without adjusting for difference in case mix between 340B and non-340B hospitals, Part B drug expenditures increase along parallel tracks in these two types of hospitals over time (See Figure 2). We acknowledge that beneficiary mean drug spending is consistently higher in 340B hospitals; however, this is to be expected because, as even the Government Accountability Office (GAO) acknowledged in its 2015 report, beneficiaries at 340B hospitals are in general sicker/have a higher case mix and so have higher expenditures.

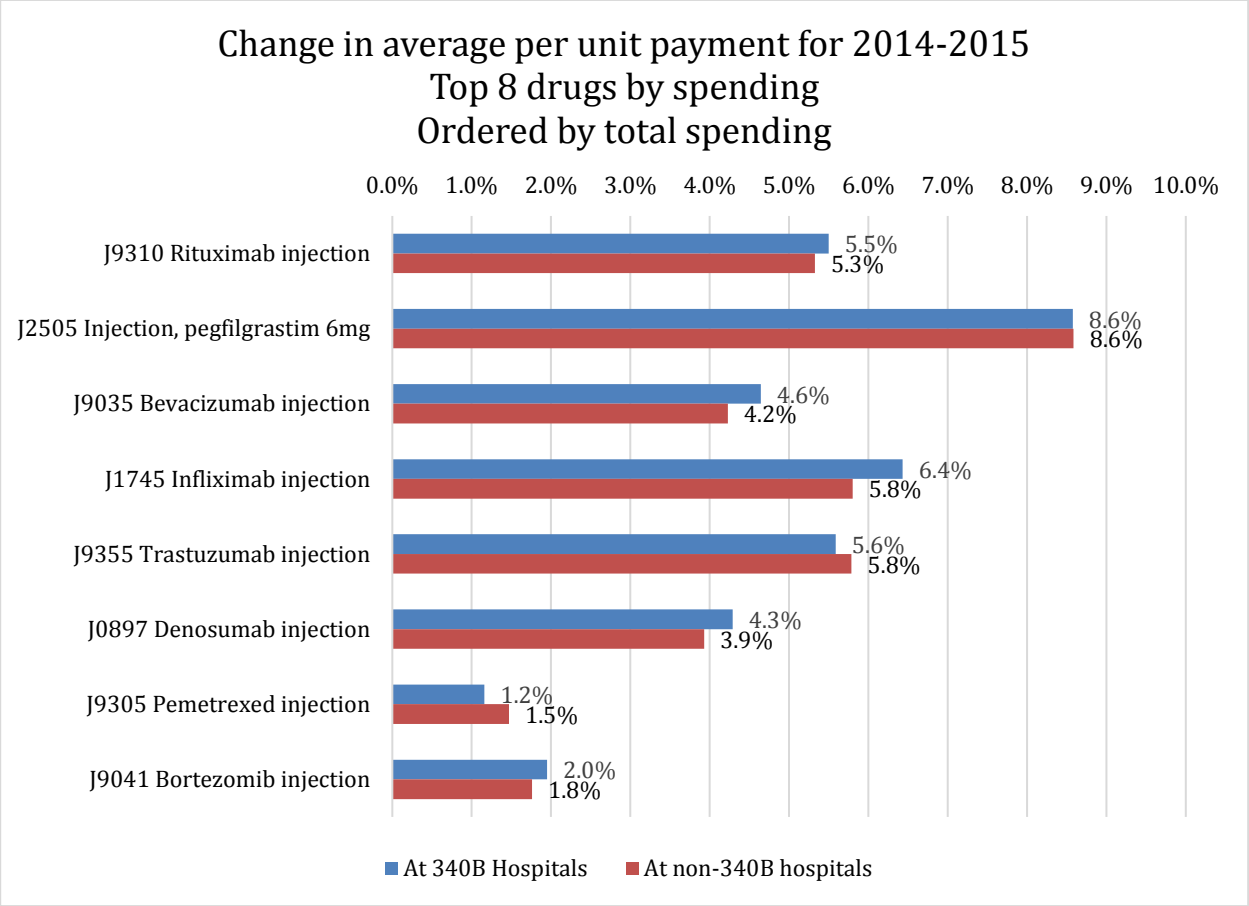
Figure 2: Beneficiary Mean Drug Spending



	2012	2013	2014	2015
340B: Mean Beneficiary Drug spending	$4,974	$5,431	$8,996	$10,109
Non-340B: Mean Beneficiary Drug spending	$3,726	$4,053	$7,408	$8,637

While the data above show that differential utilization is not the cause of increases in Medicare Part B drug expenditures, the data below demonstrate that increasing drug prices are a cause of increases in Part B drug expenditures. Specifically, in our analysis of Medicare data for the top eight Part B drugs that represent nearly half of the spending at 340B hospitals, we found that they increased in price by an average of 4.2 percent from just 2014 to 2015 (See Figure 3). The price of one of these drugs went up by almost 9 percent in this one year and the three others went up by at least 5 percent. See figure 3 below.

Figure 3.



These findings contradict the agency's conclusion that 340B hospitals overutilize drugs, compared to non-340B hospitals. They also demonstrate that the skyrocketing cost of pharmaceuticals is the main driver of Part B drug expenditure increases. As such, rather than punitively targeting 340B safety-net hospitals serving vulnerable patients, including those in rural areas, we strongly urge CMS to redirect its efforts toward direct action to halt the unchecked, unsustainable increases in the cost of drugs. The AHA has prepared a slate of policy options that would more directly address rising drug prices. See http://www.aha.org/content/16/aha-drug-policy-recommendations.pdf. We urge the agency to evaluate these policy options in lieu of its current proposal.

Indeed, the rapidly increasing price of drugs presents hospitals and their patients with remarkable challenges. CMS itself is projecting significant annual increases in drug spending: according to the agency, drug spending grew 12.6 percent in 2014, 9 percent in 2015 and an additional 5 percent in 2016. CMS projects that this trend will continue, particularly as a result of high-cost specialty drugs, with average annual increases of 6.4 percent from 2017-2025.[21] Total drug spending has increased to $475 billion – or

[21] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2015.pdf.

16.7 percent of overall personal health care services, which includes both spending on retail and non-retail drugs, such as those purchased by hospitals and other providers.

OTHER ISSUES REGARDING CMS'S 340B DRUG PAYMENT PROPOSAL

CMS Proposal is Based on Questionable Studies and Assumptions. CMS cites the work of the MedPAC, GAO and the Office of Inspector General (OIG) as the basis of for its recommendation to cut 340B hospitals' Part B payments.[22] The AHA has raised significant concern with the analysis from these studies and reports. **It is inappropriate to finalize a policy that poses a threat to the viability of 340B hospitals on a foundation of questionable assumptions and mere estimations.** Our concerns about these studies are described below.

MedPAC Report and Recommendations. CMS draws heavily from the work of MedPAC as it examined the interaction of 340B and Medicare Part B payments to hospitals. It should be noted that as MedPAC began its 340B work in earnest in 2015, the past chair, Glenn Hackbarth, questioned the path MedPAC was on, stating: "Is it an appropriate thing for MedPAC to do to recommend a Medicare payment policy change that may frustrate the intent of the 340B program?"[23] Despite the chair's concerns, the commission continued its study of the 340B program and Medicare drug payments concluding with a recommendation in its March 2016 *Report to Congress* to reduce Medicare Part B payments for 340B hospitals by ASP minus 10 percent, with the Medicare savings to be directed to fund the Medicare uncompensated care pool for hospitals.

In preparation for its recommendation, MedPAC estimated that the average discount 340B hospitals receive on outpatient drugs was approximately 22.5 percent of ASP – a number and underlying analysis that CMS adopted in its entirety for the basis of its recommendation.[24] MedPAC, however, notes several data limitations with its analysis, such as lack of public access to the 340B drug ceiling prices that suggest its estimates, which are based on proxies for 340B prices, likely undervalue the discount.[25] This leads back to the former Chairman's point that "…the extent that you reduce Medicare prices to match 340B acquisition costs, you're frustrating the intent of 340B."[26] It also is important to note that CMS's proposal goes far beyond MedPAC's 2016 recommendation to Congress on this topic. In its March 2016 report, the Commission stated that, "This reduction would allow 340B hospitals to still make a profit on these drugs..."[27] Thus, even MedPAC recognized that taking away the entire estimated discount that 340B hospitals receive would defeat the purpose of the 340B program. Cutting Medicare Part B payments to 340B hospitals would reduce the financial resources these hospitals have available to put toward improvements in patient care services and access to more affordable pharmaceutical costs.

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[22] CMS-1678-P, Proposed Rule, Medicare Hospital Outpatient Prospective Payment Program, pp 33632-33634

[23] MedPAC Public Meeting Transcript March 5, 2015 p. 175. http://www.medpac.gov/docs/default-source/meeting-materials/march-2015-public-meeting-transcript.pdf?sfvrsn=0

[24] MedPAC Report to Congress, May 2015, p. 7 http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0

[25] MedPAC Report to Congress, May 2015, p. 27. http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0

[26] MedPAC Public Meeting Transcript March 5, 2015, p. 155.

[27] MedPAC Report to Congress, March 2016, p. 26. http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0

CMS also adopted MedPAC's rationale that reducing 340B hospitals' Medicare Part B payment would lead to reductions in Part B drug copayments of Medicare beneficiaries. Yet, as noted previously, according to MedPAC's own analysis, 86 percent of all Medicare beneficiaries have supplemental coverage, of which, 30 percent have their copayments paid for by a public program, such as Medicaid, or by their Medigap plan.[28] It suggests that CMS's recommendation would not directly benefit many Medicare beneficiaries, dually eligible Medicare beneficiaries included.

GAO. CMS also relies on the GAO's 2015 report that claimed financial incentives were driving 340B Medicare DSH hospitals to prescribe more expensive drugs to treat Medicare Part B patients. CMS cites this report as evidence of higher Medicare spending in 340B hospitals. However, the Department of Health and Human Services (HHS) in its comments to GAO, notes that GAO's methodology did not support its conclusion that financial incentives were driving 340B Medicare DSH to prescribe more drugs or more costly drugs to treat Medicare Part B patients.[29] HHS further noted that a high volume of drugs in 340B DSH hospitals could lead to better clinical outcomes.[30]

GAO acknowledged in its report that 340B DSH hospitals treat sicker, more complex patients. However, it did not adequately account for differences in patients' health status or outcomes – a point underscored by HHS in its comments on the report.[31] In addition, GAO stated that 340B DSH hospitals had lower outpatient Medicare margins compared with other hospitals and provided more uncompensated care as a percent of revenue.[32]

OIG. A third report CMS relies on to justify its recommendation was OIG's 2015 report that attempted to quantify what Medicare Part B pays 340B hospitals for 340B discounted drugs. In addition, the OIG report proposed options for ways Medicare could share in 340B savings by reducing Medicare Part B payments to 340B hospitals. In the report, OIG acknowledged limitations in its own analysis by stating that, "We did not review Part B claims, pricing data, or covered entity enrollment data for accuracy. Because there is no identifier on Part B claims indicating that a drug was purchased through the 340B Program, we could not confirm that claims submitted by covered entities were in fact for drugs purchased at or below the 340B discount price.[33] In addition to OIG not verifying the accuracy of the underlying data, it noted that the report did not examine the impact the proposed payment reductions would have on covered entities' ability to provide services to their communities.[34] While OIG proposed ways Medicare could share in 340B savings, it did caution that any change in payment methodology needed to provide enough financial incentives to ensure that covered entities continue to purchase Part B drugs through the 340B program.[35]

Implementing CMS's Proposed Modifier Would be Administratively Burdensome, Costly and Place Hospitals at Risk for Non-compliance. The agency proposes to require hospitals to report a modifier on the Medicare claim that would be reported with separately payable drugs that *were not* acquired under the

[28] MedPAC, June 2016 Databook, Section 3, p. 27.
[29] GAO-15-442, Medicare Part B Drugs Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, June 2015, p 31-32
[30] Ibid.
[31] Ibid.
[32] Ibid. p 12.
[33] Office of Inspector General: Part B Payments for 340B Purchased Drugs (OEI-12-14-00030), Nov. 2015.
[34] Ibid, p. 7.
[35] Ibid, p. 13.

340B program. **The AHA is concerned that this modifier, which CMS proposes to establish in order to effectuate its proposed reduction in payment for 340B-acquired drugs, would be administratively burdensome, costly to operationalize and, for some hospitals, nearly impossible to implement correctly. It also is at odds with the agency's commitment and active efforts to reduce regulatory burden for providers.**

We believe that the proposed modifier would be problematic for several reasons. First, CMS's approach is the exact opposite of how a number of state Medicaid agencies administer their Medicaid rebate programs to prevent duplicate discounts on 340B drugs. The Medicaid Drug Rebate Program requires that pharmaceutical manufacturers pay rebates to states on covered outpatient drugs paid for by Medicaid and dispensed to Medicaid beneficiaries. Duplicate discounts are prohibited by federal law and occur when manufacturers sell drugs at the discounted 340B price and later pay the state Medicaid rebates on the same drugs. To accurately collect rebates, some state Medicaid agencies identify 340B drugs with a modifier or their National Drug Code (NDC) code so that if the modifier or NDC code is not on the claim, the drug is eligible for a Medicaid rebate. CMS's proposal is the exact opposite and will add confusion and complexity to an already complicated system. In fact, CMS commented on an OIG 2016 report that examined state efforts to exclude 340B drugs from Medicaid rebates and opposed OIG's recommendation that CMS should require that states use claims-level methods for identifying 340B drug claims.[36]

In addition, 340B hospitals have concerns about whether they can implement CMS's proposed modifier accurately. That is, 340B hospitals would have to put the modifier onto the claim at the time service is rendered, or go back and retroactively apply it, thus delaying the submission of the claim. In particular, this would be difficult in mixed-use areas, such as emergency departments, catheterization laboratories and pharmacies, where both 340B eligible patients and non-340B patients are served. To keep 340B and non-340B drug transactions separate, many 340B hospitals use an inventory management system that enables the 340B hospital to dispense drugs for both 340B patients and non-340B patients using one physical drug inventory. Software tools, such as split-billing software, help 340B hospitals distinguish whether a patient is 340B-eligible or not. However, this kind of 340B patient determination is not done when the drug is dispensed for administration. 340B hospitals typically do not download such information from the split-billing software on a daily basis and CMS's proposal could result in delays in billing of days to weeks. Further, for some hospitals, the proposal would create a significant increase in workload as the modifier may need to be reported manually. While some hospitals may be able to configure their systems to receive 340B information sooner, it would be very challenging, particularly for smaller hospitals with fewer resources.

Finally, for many 340B DSH hospitals, non-340B drugs may be dispensed in the outpatient setting. It is important to note that 340B DSH hospitals are prohibited by federal law from using Group Purchasing Organizations (GPO) for outpatient drugs. Current HRSA 340B policy requires hospital clinics within the four walls of the hospital to purchase outpatient drugs at the higher Wholesale Acquisition Cost rather than the discounted GPO price if that clinic serves a patient population that may not meet the definition of eligible 340B patient. There are many reasons outside of the 340B hospital's control that it would be administering such drugs in a 340B site; for example, the 340B programmatic patient definition, and

[36] OIG Report, June 2016 https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf p. 28.

Medicaid and state policies. Applying the proposed modifier correctly in these circumstances would be complicated, cumbersome and prone to error.

As previously stated, the AHA strongly opposes CMS's proposed 340B drug payment policy. In addition to our concerns about the impact that the drug payment reduction would have on 340B hospitals financial viability in general, we are concerned that the costs associated with operationalizing CMS's proposed modifier would erode even further the margins for these already-vulnerable 340B facilities.

Hospitals Cannot Report 340B Ceiling Prices to CMS. CMS requests comments on hospital reporting of 340B acquisition costs and ceiling prices. According to current HRSA rules, drug manufacturers submit pricing information to HRSA and HRSA develops the 340B ceiling prices from that data. What CMS fails to understand is that hospitals do not have access to 340B drug ceiling prices. The Affordable Care Act required that HRSA make public its 340B program ceiling price calculation methodology and develop a system that will grant 340B hospitals access to drug ceiling prices. However, to date, HRSA has not completed its work to create a more transparent and publicly accessible system for stakeholders to access 340B ceiling prices. **As such, 340B hospitals would not be able to report 340B ceiling prices to CMS.**

PROPOSED CHANGES TO THE INPATIENT ONLY LIST

PROPOSED REMOVAL OF TOTAL KNEE REPLACEMENT FROM THE INPATIENT ONLY LIST

CMS proposes to remove TKA or total knee replacement, CPT code 27447, from the inpatient-only list. **The AHA opposes the removal of TKA from the inpatient-only list. We do not believe it is clinically appropriate and are concerned that it could put the success of the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payments for Care Improvement (BPCI) programs at risk.** TKAs remain complicated, invasive surgical procedures. While they may be successfully performed on an outpatient basis for non-Medicare individuals, we do not believe it is appropriate for the Medicare population. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which will make even a simple procedure more complicated. In addition, spinal anesthesia often is used for TKAs and waiting for full sensation to return can take hours. Finally, pain management, particularly in the immediate postoperative period, remains a challenge. Management of postoperative pain is controlled best in the inpatient setting.

With regard to CJR and BPCI, hospitals share CMS's goal of achieving success under these programs, not only for themselves, but also for Medicare and its beneficiaries. As such, we are concerned that the agency did not present any proposals to modify the CJR and BPCI initiatives if the TKA procedure were moved off the inpatient-only list, especially since the agency itself has noted in the past the problems that could arise if this were not addressed properly. Specifically, shifting the less medically complex Medicare TKA population to the outpatient setting would increase the risk profile of the inpatient Medicare TKA population. This would, in turn, create an apples-to-oranges comparison within bundling programs when evaluating hospitals' actual expenditures versus their historical target

prices. Performance under the programs would be inappropriately negatively impacted, potentially to a large degree.

In last year's OPPS proposed rule, CMS asked for public comment on how it could modify CJR and BPCI if the TKA procedure were moved off the inpatient-only list. Accordingly, we put forth several suggestions for how the agency could modify the CJR and BPCI programs to attempt to account for this change to the inpatient-only list, and we reiterate them below. These changes would be meaningful and complex and require much more policy development, stakeholder feedback, and implementation time for CMS and program participants. **Notwithstanding our clinical concerns, we strongly urge the agency to modify the CJR and BPCI programs to account for the removal of TKA from the inpatient-only list if it were to finalize such a policy.**

Our first suggestion is that the agency could incorporate a comprehensive risk-adjustment methodology into the CJR and BPCI programs. This would ensure that actual and historical episode spending is adjusted to reflect comparable patient populations. We have previously urged CMS to incorporate risk adjustment into the CJR program; its unwillingness to do so remains perplexing to us. Specifically, the agency stated that it did not incorporate risk adjustment into the program because it does not believe that a sufficiently reliable approach exists, and that there is no current standard on the best approach. However, the agency last year finalized a risk-adjustment methodology as part of its measure of "Hospital-Level, Risk- Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)," which will be included in the inpatient quality reporting program. This measure's risk-adjustment methodology accounts for many factors that are both beyond hospitals' control and also affect their performance on the measure, including type of procedure, age, obesity and the presence or absence of many different chronic conditions, such as chronic heart failure and diabetes. We note that while it has many shortcomings, not the least of which is that it applies to both TKA and THA, this methodology certainly provides a starting point from which CMS could proceed in developing an appropriate adjustment.

CMS also may want to evaluate including *outpatient* TKA in the CJR and BPCI programs. To do so, it could, for example, reimburse for this procedure at the outpatient APC rate, but substitute the relevant inpatient Medicare-Severity Diagnosis-Related Group (MS-DRG) rate when calculating a participant hospital's actual episode spending. To ensure a level playing field, CMS also would need to specify that TKA could be performed in a hospital outpatient department (HOPD) only – not in an ASC. Many additional considerations also would need to be evaluated, such as which quality measures would apply to participant hospitals and whether there would be sufficient information on the outpatient claim to assign the appropriate MS-DRG (i.e., the Major Joint Replacement *with* Major Complications MS-DRG vs. the Major Joint Replacement *without* Major Complications MS-DRG).

SOLICITATION OF PUBLIC COMMENTS ON THE POSSIBLE REMOVAL OF PARTIAL HIP ARTHROPLASTY AND TOTAL HIP ARTHROPLASTY PROCEDURES FROM INPATIENT-ONLY LIST

CMS is soliciting comment on whether partial and total hip arthroplasty also should be removed from the inpatient-only list. It also requests comment on the effect of removing partial hip arthroplasty (PHA) and total hip arthroplasty (THA) procedures from the inpatient-only list on the CJR and BPCI programs. **The AHA opposes the removal of PHA/THA from the inpatient-only list and urges CMS to take caution if**

it contemplates this change in future years. We do not believe it is clinically appropriate and are further concerned that it could put the success of the CJR and BPCI programs at risk.

PHA/THA patients often are medically complex and functionally impaired – they have serious renal, cardiovascular and liver disease, as well as multiple comorbidities. They may require care in an inpatient rehabilitation facility (IRF); in fact, hip fractures are one of the 13 clinical conditions on which Congress and CMS has directed IRFs to concentrate their services. CMS itself has noted that the non-elective PHA/THA patient population have "higher mortality, complication, and readmission rates," and that such procedures "are typically performed on patients who are older, frailer, and who have more comorbid conditions."[37]

For CJR and BPCI, we have the same concerns related to PHA/THA coming off the inpatient-only list as we do related to TKA, as described above. We also have the same suggestions for how the agency could potentially modify the CJR and BPCI programs to attempt to account for this change. However, we continue to note that these modifications would be meaningful and complex and require much more policy development, stakeholder feedback, and implementation time for CMS and program participants.

PROPOSED PACKAGING OF LOW-COST DRUG ADMINISTRATION SERVICES

For CY 2018, CMS proposes to conditionally package payment for low-cost drug administration services when these services are performed with another service. This policy would package the costs of APCs 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration) into a primary service when these APCs are billed on the same claim as another primary services. **However, the AHA recommends that CMS not finalize its proposal to conditionally package payment for Level 1 and 2 drug administration services.** CMS's own Advisory Panel on Hospital Outpatient Payments, at its recent meeting, also recommended that CMS not finalize this proposal until further analysis occurs.

In its justification for this proposal, CMS states that it would establish a more consistent approach to packaging services under its current packaging categories and would "promote equitable payment between the physician office and the hospital outpatient department." The agency also notes that low-cost drug administration services are similar to other low-cost ancillary services, which are already conditionally packaged and are similarly supportive, dependent or adjunctive to a primary procedure. However, for a number of reasons outlined below, the AHA believes that drug administration services are separate and distinct, and deserve to continue to be paid as such.

Contrary to CMS's statements in the proposed rule, its proposed approach would not "promote equitable payment between the physician office and hospital outpatient department." CMS asserts that hospitals currently receive separate payment for clinical visits and a drug administration service, while "physicians are not eligible to receive payment for an office visit when a drug administration service is also provided." However, this statement is incorrect. Medicare does permit physicians to be paid for both a drug administration services and an office visit service code in certain circumstances. Specifically, in Chapter 12

[37] 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) – Version 4.0 and Isolated Coronary Artery Bypass Graft (CABG) Surgery – Version 2.0.

of CMS's Claims Processing Manual, the agency states this may occur "when a medically necessary, significant and separately identifiable E/M service (which meets a higher complexity level than CPT code 99211) is performed, in addition to one of these drug administration services, the appropriate E/M CPT code should be reported with modifier -25."[38] Moreover, as all drugs are separately payable in the physician office setting, unlike the OPPS, the proposed expansion of packaging to include most Level 1 and 2 drug administration services, as well as the increasing packaging of higher cost drugs, exacerbates differences in reimbursement between the physician office and HOPD.

In addition, due to the annual increases in the drug packaging threshold, drugs are increasingly being packaged into other APCs. CMS's proposal to package low-cost drug administration services represents packaging on top of packaging that could have a disproportionate impact on certain types of services that frequently require drug administration to be furnished during treatment. For example, conditionally packaging payment for these drug administration services on top of the proposed increase in the packaging threshold from $110 to $120 would mean that an increasing number of services that are critical to cancer treatment would not be separately reimbursed. We understand that under CMS's methodology, the costs of these packaged items and services would be included in the mean cost data used to establish payment for other services billed with them. As there are many entirely unrelated services that could be billed on the same claim as a drug administration service, we are concerned that this multi-level packaging could distort appropriate payment for cancer care by packaging these costs into unrelated services. Further, in a system based on averages, there is no assurance that the full costs of a packaged drug administration service or drug would be accounted for in the payment for another separately payable procedure.

Finally, CMS's own National Correct Coding Initiative (NCCI) coding policy has more than 700 code pairs that include the same HCPCS drug administration codes that CMS proposes for conditional packaging. This NCCI coding policy identifies certain services that are related in such a way that they should not be billed separately in the same patient encounter; that is, billing certain services together on a claim is prohibited under this policy. Thus, it largely accounts for the packaging of drug administration services that are supportive, dependent or adjunctive to another code. To package these already packaged services into another primary service as CMS proposes is unnecessary. That is, even when these low-cost drug administration services are furnished together with an emergency department visit or another service outside of the NCCI code pairs, the drug administration service represents a separate and distinct service that should not be packaged.

Therefore, the AHA recommends that CMS not finalize this policy and instead continue to provide separate payment for all drug administration services.

POTENTIAL REVISIONS TO THE LABORATORY DATE OF SERVICE POLICY

The AHA supports CMS's proposal to update its laboratory date-of-service (DOS) billing policies for separately payable molecular pathology and Advanced Diagnostic Laboratory Tests (ADLTs) that are performed on specimens collected from hospital outpatients. Many hospitals do not perform these

[38] Modifier -25 identifies a "significant, separately identifiable evaluation and management services by the same physician on the day of the procedure."

types of more technologically advanced laboratory tests in-house, and, upon receipt of a physician's orders, instead send patient specimens to independent laboratories for testing. Specifically, we agree with those stakeholders described in the rule who have expressed concern that the current DOS policy is inconsistent with the agency's OPPS laboratory test packaging policy, is administratively burdensome for hospitals and laboratories and can create delays and other barriers to patient access to critical diagnostic testing. **As such, we urge CMS to finalize its proposed policy change, with certain revisions recommended below, which would allow the laboratory that performs certain tests using a specimen obtained from a hospital outpatient to bill the Medicare program directly in certain specified circumstances.** We recommend that this policy apply to all molecular pathology tests and ADLTs that are paid separately under the OPPS packaging policy.

In the proposed rule, CMS discusses two separate regulatory requirements that together often require hospitals to bill for clinical diagnostic laboratory tests that they do not perform. These are the agency's DOS policy for clinical laboratory tests and the "under arrangements" regulations. The DOS policy, known as the "14-day rule," establishes the date of service for a laboratory test that uses a specimen obtained during a patient's hospital encounter as the date of performance for the test *only* when the test was ordered at least 14 days after the patient has been discharged from the hospital (and when various other conditions are met). The "under arrangements" regulations establish that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement with that entity to furnish the particular service in question. CMS explains that as a result of the DOS rule's interaction with these "under arrangements" provisions, when the specimen used in a laboratory test is collected during an outpatient encounter, the hospital—not the laboratory that performs the test—is often required to bill Medicare, even though the hospital laboratory does not perform the test.

The AHA agrees with CMS's concerns that the current DOS policy is administratively burdensome for hospitals and for the laboratories that furnish these tests. We understand that some hospitals may be reluctant to bill for Medicare laboratory tests that they do not perform, which can result in orders being delayed for 14 days after discharge. This can lead to interference in timely access to care through delays in testing and treatment. Further, we agree that the DOS policy is inconsistent with CMS's OPPS packaging policy, which recognizes the uniqueness of molecular pathology tests and ADLTs by allowing separate payment for them under the Clinical Laboratory Fee Schedule (CLFS). That is, the agency excludes both types of tests from packaging because "these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged." Further, ADLTs, by definition, are proprietary and performed by a single laboratory.

RECOMMENDED CHANGES TO THE PROPOSED DATE OF SERVICE POLICY

As noted, the AHA supports CMS's intent to update the current DOS policy to enable performing laboratories to bill Medicare directly for certain laboratory tests excluded under the OPPS packaging policy. However, we recommend several clarifications and revisions to the agency's proposed policies, as follows.

- **The AHA recommends that in addition to ADLTs, CMS should also include molecular pathology tests in the proposed DOS modification.** Doing so would be consistent with CMS's laboratory packaging policy, which allows separate payment under the CLFS for both types of tests because the agency believes they are generally less tied to a primary service in the hospital outpatient setting than conventional tests. In addition, as with ADLTs, molecular pathology tests are not typically performed by hospital laboratories. Thus a revised DOS policy that allows the performing laboratory to bill for molecular pathology tests, rather than the hospital, would both reduce administrative and billing complexity for hospitals and promote timely access to patient testing. Further, including these tests in the revised DOS policy would not affect those hospitals that perform molecular pathology testing in-house, such as certain academic medical centers, because in those circumstances, the hospital would already be the entity that bills Medicare for these services.

- **The AHA recommends that CMS remove the proposed requirement that the physician must order the test *following the date of a hospital outpatient's discharge*.** While molecular pathology tests and ADLTs performed using tissue-based specimens are often ordered after the patient is discharged from the hospital, for testing using blood-based and urine-based specimens, the test ordering practice is different. That is, for practical and clinical reasons, tests performed on such nontissue-based specimens are usually ordered prior to or upon specimen collection in the hospital, and such specimens are not typically stored but instead sent to the outside laboratory for testing. For example, a Medicare patient is seen in an outpatient department and the physician orders a blood-based molecular pathology test in order to help guide future treatment. The hospital's laboratory performs a venipuncture to obtain the specimen, which is then sent to the performing laboratory. In this instance, the order is made during the outpatient encounter. Another scenario would be a physician ordering a molecular pathology test in a free-standing physician office, and the patient undergoing a venipuncture in a hospital-based laboratory the following week. The hospital laboratory then sends the specimen out to the performing laboratory. In this case, the physician order was placed before the patient's hospital outpatient encounter. In both of these examples, CMS's proposed policy would not allow the laboratory to bill for the test directly even though it performed the test.

  As technology for molecular pathology tests and ADLTs advance, it is expected that more of these tests will be approved for use with these types of nontissue-based specimens. As such, ensuring that the performing laboratory may bill Medicare directly will become more critical over time. However, like tissue-based molecular pathology and ADLTs, these nontissue-based tests have a pattern of clinical use that makes them unconnected to the primary service in the hospital outpatient setting and also, like other molecular pathology tests, most hospital laboratories are not equipped to perform these tests.

- **The AHA recommends that CMS revise its proposed requirement regarding the medical appropriateness of the specimen collection to ensure that tests using nontissue-based specimens are not unintentionally excluded from separate payment.** The current proposed requirement states, "It would be medically inappropriate to have collected the sample other than from the hospital outpatient during the hospital outpatient encounter." We are concerned that a strict interpretation of this language would require the hospital laboratory to bill for testing using nontissue-based specimens collected during an outpatient encounter because the patient could have

had their blood drawn or urine collected at a location outside of the hospital. Such an interpretation would defeat the purpose of the proposed change in the DOS policy. Therefore, we recommend that CMS modify the proposed requirement to state that, "it would be medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter."

POSSIBLE CHANGES TO THE "UNDER ARRANGEMENTS" PROVISIONS

As noted, the agency also is considering an alternative approach to addressing the concerns raised by stakeholders about its laboratory billing policy. Under this alternative, the agency would modify its "under arrangements" policy to add an exception for molecular pathology tests and ADLTS that are excluded from the OPPS packaging policy. Modifying the "under arrangements" provisions would not change the DOS for these laboratory tests, which would remain the date of the specimen's collection, but would instead permit the performing laboratory to directly bill Medicare. This approach has the advantage of maintaining consistency in the DOS for laboratory tests conducted on specimens obtained from inpatients and outpatients. While we would like to review the details of a proposed exception to the "under arrangements" regulation before it is finalized, the AHA generally believes that such an approach could address our concerns, and we encourage the agency to pursue this alternative approach.

CAVEAT ABOUT TESTING CONDUCTED USING SPECIMENS OBTAINED FROM HOSPITAL INPATIENTS

Finally, as CMS described in the proposed rule, its current DOS "14-day rule" policy applies to specimens obtained from both hospital outpatients and inpatients. Updating the DOS policy for testing using outpatient specimens makes sense for all the reasons we describe above. As such, we support CMS limiting its proposal to only outpatient laboratory tests that are separately payable under the CLFS – doing so would merely change which entity bills for the laboratory test. In contrast, since all laboratory testing ordered on specimens obtained from inpatients less than 14 days after discharge is currently bundled into the inpatient PPS rates, a change in the inpatient DOS policy would entail many other policy changes. However, we urge CMS to work with providers to address any confusion or additional administrative burden resulting from this disparate treatment of specimens and to minimize the impact on beneficiary timely access to testing.

ENFORCEMENT INSTRUCTION FOR THE SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS HOSPITALS (CAHS) AND CERTAIN SMALL RURAL HOSPITALS

Hospital outpatient services always have been provided by licensed, skilled professionals under the overall direction of a physician and with the assurance of rapid assistance from a team of caregivers, including a physician, should an unforeseen event occur. However, in the 2009 OPPS final rule, CMS mandated a new policy for "direct supervision" of outpatient therapeutic services that was burdensome, unnecessary and potentially detrimental to access to care in rural and underserved communities. At the time, the policy required that a supervising physician be physically present in the relevant department at all times when Medicare beneficiaries were receiving outpatient therapeutic services. Because CMS characterized the new policy as a "restatement and clarification" of existing policy, instead of the new policy that it was,

hospitals, particularly small and rural hospitals and CAHs, found themselves at increased risk of unwarranted enforcement actions.

In response to hospital concerns, CMS has, since 2009, adopted several helpful regulatory changes to its supervision policy, including: allowing certain non-physician practitioners (NPPs) to provide direct supervision if they meet certain conditions, modifying the definition of direct supervision to replace physical boundaries within which a supervising practitioner must be located with a standard of "immediate availability," and establishing an independent review process through which CMS can reduce the required level of supervision for individual services. In addition, from 2010 through 2013, the agency prohibited its contractors from enforcing the direct supervision policy. Congress has extended this enforcement moratorium every year since 2014, with the most recent enforcement moratorium having expired on Dec. 31, 2016. **While these extensions of the enforcement moratorium have provided some relief, this annual reconsideration of a misguided direct supervision policy places CAHs and small rural hospitals in an uncertain and untenable position.**

In the proposed rule, CMS proposes to reinstate the enforcement moratorium for CAHs and small rural hospitals having 100 or fewer beds for 2018 and 2019, but not for 2017. The agency indicates that this time-limited moratorium is intended to give these hospitals more time to comply with the supervision requirements, as well as time to submit specific services for evaluation for a potential change in supervision level via the independent review process the agency established.

We support CMS's proposal to reinstate a moratorium on enforcement of its burdensome direct supervision requirement for outpatient therapeutic services provided in CAHs and small and rural hospitals. However, we continue to urge the agency to make the enforcement moratorium permanent and continuous (i.e., without a gap in 2017). We have heard that some CAHs and small rural hospitals have already discontinued important services or limited the days/hours services are offered in order to comply. Other such hospitals are sure to follow suit unless they receive assurance that the direct supervision policy will no longer be enforced. That is, reinstating the enforcement moratorium for two years with the expectation of compliance in 2020 will not help these vulnerable hospitals due to ongoing physician shortages. Further, while we appreciate CMS's establishing the independent review process, it simply is not designed to address the larger concerns about personnel shortages and costs. We further believe that CMS's direct supervision policy is unwarranted and unworkable in CAHs and small rural hospitals because:

- CMS has not offered any clinical basis for its supervision requirements. In fact, the agency admitted that it had no evidence that patient safety or quality of care had been compromised in past years due to inadequate or ineffective supervision.
- A physician does not need to be "immediately available" at all times for hospital staff to provide safe and high-quality outpatient care. This is because non-physician hospital staff are professionally competent, licensed health care professionals who provide services that fall within their scope of practice in accordance with state law. In addition, the provision of care, especially in rural areas, is governed by clinical protocols, policies and procedures approved by the hospital's medical staff. Non-physician staff can contact a physician by phone, radio or other means if needed for routine

consultation. Should an unforeseen situation arise, medical staff physicians can be summoned promptly.

- CMS's requirements severely restrict the ability of hospitals and CAHs to use effectively their existing resources to make supervisory assignments and leave them with limited options to comply. Although CMS asserts that its requirements may be met by assigning the responsibility for direct supervision to a physician of a different specialty from the services being supervised or to a NPP, the details of its policy effectively eliminate a hospital's or CAH's ability to do so. This is because CMS also requires that the supervising professional be authorized to provide the service they are supervising, according to their state license and hospital-granted privileges. Thus, for all practical purposes, for many services, the supervisor must in fact be a physician of the same specialty as the service being furnished. This requirement is impractical, if not impossible, for many hospitals and CAHs to meet, due to severe shortages of specialist physicians in the community.
- The requirement that the supervisor must be "immediately available" to intervene means that the supervising professional cannot be engaged in any other activity that cannot be interrupted at a moment's notice. In effect, the supervising physician or NPP must be on-site at all times outpatient services are being furnished by hospital professionals, waiting for the unlikely circumstance in which they will be called upon to assist. Even if there are physicians or NPPs available and working in a community, they are unlikely to abandon their private practices in order to do nothing other than supervise hospital outpatient services.
- In the current economic climate and with competing patient care and other operational priorities for small rural hospitals and CAHs, it would be financially infeasible for many to hire a group of hospital-privileged specialist physicians and NPPs for the sole purpose of being "immediately available" around the clock to supervise various hospital outpatient therapeutic services. In reality, ensuring compliance forces hospitals and CAHs to consider seriously eliminating certain services or reducing their hours of operation.

For all these reasons, the AHA urges CMS to make its enforcement moratorium permanent and continuous for CAHs and small rural hospitals.

BLOOD AND BLOOD PRODUCT CODING

The CY 2018 proposed rule described the revisions made in 2017 to clarify the confusion between the HCPCS codes for Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets. In the CY 2017 OPPS proposed rule, CMS had indicated that a thorough examination of the current set of HCPCS P-codes for blood products was warranted as these HCPCS P-codes were created nearly a decade ago. However, to our knowledge, CMS has not embarked on such an examination.

The AHA recommends that CMS convene a stakeholder group, including hospitals, blood banks, the American Red Cross and others, to discuss a framework to systematically review and revise the HCPCS codes for blood products. In the decade since the codes were created, clinical processes have evolved to ensure the safety of the blood supply. We believe that HCPCS codes should properly reflect current product descriptions while at the same time minimize the reporting burden. In the interim, we

suggest that CMS consider the following general recommendations when exploring how to improve the HCPCS codes for blood products:

- **Hospitals must retain the ability to bill for blood products using unique HCPCS codes that individually identify each product.** We believe that the HCPCS codes for blood products should continue to identify different blood products individually based on processing methods, since these methods result in blood products that are distinguishable and used for distinctive purposes. Similar to the way that hospitals bill for other products covered by Medicare Part B, we urge CMS to retain individual HCPCS codes for unique blood products with significant therapeutic distinctions. We are concerned that providers would be confused and overly burdened if CMS were to establish a different billing protocol for blood products.
- **CMS should consider establishing a "not otherwise classified" code for blood products.** Once clinical differentiation of more specific HCPCS P-codes becomes available, hospitals can then begin billing for new blood products. This would be similar to the existing codes for other substances (e.g., J-codes for drugs and biologicals). We believe that a "not otherwise classified" code is essential for payment policies capable of accommodating important new technologies and products.

BRACHYTHERAPY INSERTION PROCEDURES

CMS proposes to introduce a code edit for claims with brachytherapy services that will require the brachytherapy application HCPCS code 77778 (Interstitial radiation source application; complex) to be included on the claim with the brachytherapy insertion procedure (HCPCS code 55875). **The AHA opposes the implementation of this edit. It would be burdensome for facilities when the insertion procedure is not performed during the same encounter for the following reasons:**

- There are clinical and other reasons when a patient may receive the brachytherapy treatment at a later date than the brachytherapy insertion procedure. Holding claims to combine the codes would introduce new administrative burdens.
- In some instances, the procedures are done at different facilities within the geographic region making it impossible for the codes to be reported on the same claim.
- To ensure accurate coding, some billing systems already have a soft edit to flag these cases. If the edit is overridden, it often is for one of the reasons above.

PARTIAL HOSPITALIZATION PROGRAM MINIMUM SERVICE REQUIREMENT: 20 HOURS PER WEEK

In the proposed rule, CMS continues to express concern that providers may be providing too few services to beneficiaries enrolled in partial hospitalization programs (PHPs). Specifically, in order to be eligible for PHP, a beneficiary must require a minimum of 20 hours-per-week in services per the plan of care and the agency reiterates its view that a typical PHP beneficiary should receive five to six hours of services per day. However, CMS describes an analysis it conducted to assess the intensity of PHP services provided in which

it found that a majority of PHP patients did not receive at least 20 hours of PHP services per week. As such, the agency seeks comments on the advisability of applying a payment requirement conditioned on a beneficiary's receipt of a minimum of 20 hours of therapeutic services per week. It also seeks comments addressing the need for exceptions to such a policy and the types of occurrences or circumstances that would cause a PHP patient not to receive at least 20 hours of PHP services per week, particularly where payment would still be appropriate.

The AHA understands that the PHP benefit is designed as an intensive benefit requiring physician certification that the patient requires a minimum of 20 hours-per-week of therapeutic services. We agree with CMS that it is critical to ensure that patients eligible for PHP services receive the appropriate intensity of services. We also share the agency's concerns about the possibility that its policy decision in 2017 to replace the previous two-tiered PHP APCs with the single-tiered PHP APCs (which pays providers for furnish three or more services per PHP service day) could provide a financial incentive to reduce patient intensity of services. However, the data needed to assess whether and to what extent this is occurring will not be available until the CY 2019 OPPS proposed rule. **Therefore, we believe it would be premature to implement a claims edit conditioning payment on the provision of 20-hours of therapeutic services per week.**

Furthermore, as we have stated in prior comments, we are concerned that a claims edit that is overly strict could result in inappropriate changes and perhaps reduced access to the PHP benefit. While CMS's eligibility criteria state that PHPs "are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care," CMS has previously clarified that there should be reasonable exceptions for this criterion. For instance, in the preamble to the 2009 OPPS/ACS final rule, in which the agency added the 20 hours per week eligibility criterion to its regulations, it states, "[W]e are clarifying that the patient eligibility requirement that patients require 20 hours of therapeutic services *is evidenced in a patient's plan of care rather than in the actual hours of therapeutic services a patient receives*. The intent of this eligibility requirement is that for most weeks we expect attendance conforming to the patient's plan of care. We recognize that there may be times at the beginning (or end) of a patient's transition into (or out of) a PHP where the patient may not receive 20 hours of therapeutic services." (Emphasis added).

In the meantime, the AHA recommends that CMS work with hospital and community mental health center (CMHC) PHP providers to evaluate the variety of factors, beyond hours-per-week, that appropriately represent the "intensity" of services for a PHP. That is, intensity includes other factors, such as the number of units of services provided per day and the types of services provided. The AHA believes that CMS's focus exclusively on hours-per-week is too limiting. We also believe that CMS should look to local coverage determinations (LCDs) for PHP services in evaluating intensity; these LCDs often allow for exceptions to the 20-hour programming week for situations involving patient physical illness, bad weather, holidays, transportation issues or medically necessary absences.

Lastly, we believe that additional education for PHP providers would impact provider behavior. We understand that CMS recently rescinded a Medlearn Matters letter and its associated Change Request[39] that would have initiated such informational messaging, effective Oct. 1, 2017. **The AHA recommends that CMS revise and re-issue an educational Change Request that incorporates a message about both the expected minimum hours-per-week as well as other appropriate indicators of service intensity.**

REQUEST FOR COMMENTS ON PAYMENT DIFFERENTIALS FOR SIMILAR SERVICES PROVIDED IN INPATIENT AND OUTPATIENT SETTINGS

CMS previously requested public comment on potential payment policy options to address the issue of payment differentials between services provided in the inpatient and outpatient settings. It now seeks additional public comment on transparent ways to identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings. The AHA has provided the agency with comments in this area, most recently in response to the same request in the inpatient PPS proposed rule for FY 2018. We reiterate these comments below.

The AHA previously conducted an analysis of potential short-stay models that could supplement the agency's original two-midnight policy. However, while our models reduced payment differentials between inpatient stays and similar outpatient stays, we found that new payment differentials between short-stay and non-short stay inpatient cares were created. We also provided comments to MedPAC as it considered similar outpatient stays in the context of the two-midnight policy. In addition, in the OPPS proposed rule for CY 2016, CMS made significant modifications to the two-midnight policy, and the AHA provided comments in support of those changes.

Hospitals around the country are currently implementing this revised two-midnight policy and it appears to be working smoothly. We believe more time must pass before the full effect of those modifications is reflected in the publicly available data. **In the meantime, however, the AHA continues to believe that hospitals must be reimbursed appropriately and adequately for the care they provide to beneficiaries, and we support efforts to align payment rates to the resources used to furnish services. We encourage CMS to consider maintaining an ongoing dialogue with hospitals, physicians, beneficiaries, skilled nursing facilities and other stakeholders on this issue.**

REQUEST FOR INFORMATION ON PHYSICIAN-OWNED HOSPITALS

CMS requested feedback from stakeholders on "whether physician-owned hospitals could play a more prominent role in the delivery system." The AHA would like to reiterate our comments in response to a request for comment on the same topic in the FY 2018 inpatient PPS proposed rule. **Specifically, we emphasize that the statute bans new physician-owned hospitals from participation in Medicare and**

[39] According to CMS Change Request (CR) 9880, when the minimum 20 hours per week care is not provided, Medicare contractors will include a statement on the Remittance Advice: "Alert: An eligible PHP beneficiary requires a minimum of 20 hours of PHP services per week, as evidenced in the plan of care. PHP services must be furnished in accordance with the plan of care."

sets very clear limits on expansion of grandfathered physician-owned hospitals. CMS has little-to-no discretion to increase the role of these providers in the delivery system.

Accordingly, the AHA opposes any changes that would allow additional physician-owned hospitals to participate in Medicare or allow grandfathered hospitals to expand or increase their capacity beyond what is allowed currently. Congress enacted strict restrictions on physician-owned hospitals to address physicians' clear incentive to steer the most profitable patients to facilities in which they have an ownership interest, potentially devastating the health care safety net in vulnerable communities and jeopardizing communities' access to full-service care.

Further, it has been well demonstrated, by entities including the Congressional Budget Office (CBO) and MedPAC, that physician self-referral leads to greater utilization of services and higher costs for the Medicare program. Specifically, GAO, CMS and MedPAC all have found that physician-owned hospitals' patients tend to be healthier than patients with the same diagnoses at general hospitals. Further, MedPAC and GAO found that physician-owned hospitals treat fewer Medicaid patients. This trend creates a destabilizing environment that leaves sicker and less-affluent patients to community hospitals. It places full-service hospitals at a disadvantage because they depend on a balance of services and patients to support the broader needs of the community. For example, the current payment system does not explicitly fund standby capacity for emergency, trauma and burn services, nor does it fully reimburse hospitals for care provided to Medicaid and uninsured patients. Community hospitals rely on cross-subsidies from the well-reimbursed services targeted by physician-owned hospitals to support these and other essential but under-reimbursed health services. Revenue lost to specialty hospitals can lead to staff cuts and reductions in subsidized services such as inpatient psychiatric care, as well as lower operating room utilization, which decreases efficiency, strains resources and increases costs. Siphoning off the most financially rewarding services and patients threaten the ability of community hospitals to offer comprehensive care – and serve as the health care safety net for all patients.

Finally, we note that the statute does provide grandfathered physician-owned hospitals the opportunity to expand if they meet certain qualifications. Specifically, a physician-owned hospital can expand to up to double its capacity if it can demonstrate that it has a higher percentage of Medicaid inpatient admissions than other hospitals in its county, or that it is located in an area with significant population growth and high bed occupancy rates (i.e., that it would be creating needed beds). To date, five hospitals have applied for an expansion, and CMS has not denied expansion to any hospital that has applied. This indicates that the exceptions process is working as Congress intended, and, therefore, needs no changes.

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

CMS proposes to remove a total of six measures from the OQR program—two removed starting with the CY 2020 payment year (which is based on 2018 provider performance) and four more removed starting with the CY 2021 payment year (based on 2019 performance). CMS also would delay the implementation of the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey-based measures proposed for adoption in the CY 2017 OPPS final rule.

Measures for Removal. **The AHA supports CMS's proposals to remove six measures. We appreciate CMS's efforts to remove measures that provide little meaningful information on quality of care and do not support ongoing hospital quality improvement efforts**. We agree that the criteria used to identify measures for removal—i.e. a lack of scientific link between the measure and improved patient outcomes or "topped out" national provider performance—are appropriate. In particular, we applaud CMS for recognizing the potential unintended consequences that the Median Time to Pain Management for Long Bone Fracture (OP-21) measure might have on opioid prescribing practices, and we appreciate CMS's strategy of using regulatory relief to address the opioid crisis.

However, CMS could do even more to remove measures that do not encourage improvements in hospital quality. **First, CMS should remove all six of the measures for the CY 2020 OQR program.** While two of the measures proposed for removal would be removed from the Hospital OQR in CY 2020, the removal of the four other measures is delayed until CY 2021. If performance on a measure like Aspirin at Arrival (OP-4) is already topped out, for instance, we do not see a reason to continue collecting data on performance for another year.

In addition, there are several other measures that meet the same criteria as those addressed here, and thus should be considered for removal. For example, the measure Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival, OP-2, was finalized for removal from the FY 2019 Inpatient Quality Reporting Program because it focuses on a relatively narrow aspect of care and improvement in the measure does not result in better patient outcomes; if this measure was deemed appropriate for removal in the inpatient setting, it should likely be considered for removal in the outpatient setting.

Delay of OAS CAHPS Survey-based Measures. **The AHA has long supported the use of rigorously designed surveys of patient experience of care. However, we agree with CMS that the implementation of the OAS CAHPS is premature and appreciate CMS's proposal to delay the survey-based measures pending further analysis and modification.** In the CY 2017 OPPS final rule, CMS finalized the adoption of five measures (OP-37a-e) that would be derived from the OAS CAHPS survey. On Jan.1, 2016, CMS initiated a voluntary national reporting program for OAS CAHPS, and the CY 2017 final rule finalized requirements for providers to collect and submit data on a quarterly basis starting with visits on Jan. 1, 2018 and using CMS-approved survey vendors to collect and submit the data.

However, since publishing the CY 2017 final rule, CMS determined that they "lack important operational and implementation data" regarding the survey. While CMS continues to believe that these survey-based measures "address an area of care that is not adequately addressed in our current measure set" and "will enable objective and meaningful comparisons between hospital outpatient departments," the agency proposes to delay implementation of measures OP-37a-e until further action in future rulemaking.

If CMS is intent on implementing the OAS CAHPS in the future, we urge the agency to use the delay to address several critical implementation issues. CMS acknowledges in the proposed rule that it is currently unsure whether these survey-based measures appropriately account for patient response rates, as these may vary depending on how the survey is administered. In addition, the agency states that it needs to perform additional analysis to account appropriately for the burden associated with administering the survey in the outpatient setting of care. The AHA raised these same concerns in our September 2016 comment letter regarding that rule, and would like to take this opportunity to reiterate our recommendation

that **CMS explore the development of more economical survey administration approaches for this (and all other) CAHPS surveys in the future, such as emailed or web-based surveys.** Not only do mailed and telephonic surveys have widely differing response rates, but they also are more expensive and burdensome to administer.

Another area that CMS plans to analyze is the reliability of national OAS CAHPS survey data. The AHA echoes this concern, as the CAHPS program already includes multiple, and potentially overlapping, survey tools. Correct attribution of performance results could be especially problematic if a new survey for ASCs and HOPDs is implemented because two existing CAHPS surveys—the Clinician/Group CAHPS (CG-CAHPS) and the Surgical CAHPS—capture closely related information. These surveys evaluate providers on several issues, including access to appointments, physician communication with patients, courtesy of office staff and follow up on testing results. Another survey relevant to outpatient surgical patients may result in patients receiving three separate but similar surveys for exactly the same care episode. **Thus, we urge CMS to ensure survey administration protocols clearly identify which particular institution is being surveyed to help guarantee correct attribution of experiences as the agency conducts analyses of the national survey data and plans necessary modifications.**

Finally, the OAS CAHPS survey measures are not endorsed by the National Quality Forum (NQF). Through the process of seeking endorsement, all stakeholders are given insight into whether the measures portray hospital performance in a fair and accurate manner. Given the significant resources needed to collect survey data, **we encourage CMS to pursue NQF endorsement of these measures before the OAS CAHPS is required of hospitals.**

Future Measure Topics. CMS requests public comment on future measure topics. We provide the following suggestions for the agency as it continues to develop the quality reporting programs for the hospital outpatient and other settings.

General Considerations. CMS notes that the agency is "moving towards the use of outcome measures and away from the use of clinical process measures" across its various quality and value-based purchasing programs. In this vein, CMS invites public comment on possible measure topics for future consideration in the hospital OQR program, specifically around outcomes measures that should be added and process measures that should be eliminated.

The AHA appreciates CMS's explicit acknowledgment of the need to shift toward more meaningful quality measures. We stand ready to work with CMS to focus the OQR program (as well as other quality programs) on measure sets that align with concrete national priority areas. To provide a starting point for this vital effort, the AHA has engaged hospital leaders in efforts to identify high priority hospital measure topics. In 2014, the AHA Board of Trustees approved a list of 11 hospital measurement priority areas. That list was updated in July 2016 and is provided below.

AHA Identified Priority Measurement Areas

1. Patient Safety Outcomes
   - Harm Rates

- Infection Rates
- Medication Errors

2. Readmission Rates
3. Risk-adjusted Mortality
4. Effective Patient Transitions
5. Diabetes Control
6. Obesity
7. Adherence to Guidelines for Commonly Overused Procedures
8. End of Life Care According to Preferences
9. Cost per Case or Episode of Care
10. Behavioral Health
11. Patient Experience of Care/Patient-reported Outcomes of Care

Hospital leaders believe using well-designed measures in these 11 areas in national measure programs would promote most effectively better outcomes and better health for the patients they serve. However, having measures addressing the right topics is only part of the solution – the particular measures also must be methodologically sound, reliable, accurate and actionable. Moreover, hospital leaders also understand the list of priority areas will evolve over time, and thus recommend "retiring" areas where sufficient progress has been achieved, and replacing them with new core areas that address emerging issues. To provide a strategic grounding for ongoing discussions about measurement priorities and specific measures, the AHA Board of Trustees also approved a list of seven strategic principles for selecting measures that was developed with extensive input of hospital leaders.

AHA Principles for Measure to be Included in Hospital Payment and Performance Systems

1. Provider behavior must influence the outcome(s) being measured;
2. Measures must have strong evidence that their use will lead to better care and outcomes;
3. Measures should be used in programs only if they reveal meaningful differences in performance across providers, although some may be retained or re-introduced to reaffirm their importance and verify continued high levels of importance;
4. The measures should be administratively simple to collect and report, and to the greatest extent possible, be derived from electronic health records data;
5. Measures should seek to align the efforts of hospitals, physicians and others along the care continuum, and align with the data collection efforts of the other providers;
6. Measures should align across public and private payers to reduce unnecessary data collection and reporting efforts; and
7. Risk adjustment must be rigorous, and account for all factors beyond the control of providers, including socioeconomic factors where appropriate. In addition, adjustment methodologies should be published and fully transparent.

To provide a "proof of concept" of how the 11 priorities and the principles for selection might be applied, AHA reviewed all of the approximately 90 measures in CMS's inpatient quality reporting and OQR

programs. While some of the existing measures are in line with these principles and the priority areas that were identified, most were not. Appendix A provides more detail on the measures the AHA recommends for retention, and how they map to our 11 measurement priority areas. With respect to the OQR, the AHA believes that only eight OQR measures should be retained, and all but one of those eight likely would require significant modifications to improve their reliability and accuracy.

eCQM Retooling. In addition to requesting general public comment on possible measure topics for future consideration, CMS also noted that the agency is considering transforming the current measure OP-2, Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival, into an electronic clinical quality measure, or eCQM. CMS believes that eCQMs, which are informed by electronic extraction and reporting of clinical quality data, will reduce administrative burden for providers. CMS has chosen OP-2 for transformation into an eCQM because the agency believes this measure is the "most feasible" out of all the existing Hospital OQR measures.

The AHA continues to believe eCQMs have the potential to provide timelier data and reduce data collection burden in the future. However, we disagree that eCQMs are inherently less burdensome than chart-abstracted measures at this time. In a 2016 survey led by The Joint Commission, many hospitals noted that they struggled with complying with eCQM reporting requirements, as their electronic medical record (EMR) systems were either not ready or recent changes in EMR systems made it difficult to collect the required amount of data. The same survey showed that many hospitals would not implement eCQMs if CMS did not require them, and many were not confident that eCQMs accurately reflect quality of care. Because of these ongoing concerns and challenges, **The AHA does not support the transformation of OP-2 into an eCQM solely because it was deemed "feasible" by CMS. Unless and until the feasibility and accuracy of eCQMs improves, eCQMs do not necessarily decrease reporting burden for providers.**

APPENDIX A: CURRENT CMS QUALITY MEASURES FOR RETENTION ALIGNED BY AHA QUALITY MEASUREMENT PRIORITY AREA

AHA Measurement Priority Areas	Measures Kept (possible minor modifications)	Measures Kept If Major Modifications Made
Patient Safety Outcomes • **Harm Rates** • **Infection Rates** • **Medication Errors**	Central-line associated bloodstream infection (CLABSI) Surgical site infection (colon and hysterectomy procedures only) Catheter-associated urinary tract infection (CAUTI) *Clostridium Difficile* (C Difficile) Methicillin Resistant Staphylococcus Aureus (MRSA) Global influenza vaccination Influenza vaccination coverage among health care personnel (inpatient) OP-27: Influenza vaccination coverage among health care personnel (outpatient)	Risk-standardized complication rate following elective primary total hip and/or total knee arthroplasty Severe sepsis and septic shock management bundle
Readmission Rates **Effective Patient Transitions**		AMI 30-day risk standardized readmission HF 30-day risk standardized readmission PN 30-day risk standardized readmission Total Hip / Total Knee Arthroplasty (THA/TKA) 30-day risk standardized readmission COPD 30-day risk standardized readmission CABG 30-day risk standardized readmission Acute ischemic stroke (STK) 30-day risk standardized readmission Hospital-wide all cause unplanned readmission OP-32: Facility 7-day risk-standardized hospital visit rate after outpatient colonoscopy
Risk Adjusted Mortality		Acute myocardial infarction (AMI) 30-day mortality rate Heart failure (HF) 30-day mortality rate Pneumonia (PN) 30-day mortality rate COPD 30-day risk standardized mortality Coronary artery bypass graft (CABG) 30-day mortality AMI 30-day risk standardized readmission

AHA Measurement Priority Areas	Measures Kept (possible minor modifications)	Measures Kept If Major Modifications Made
Diabetes Control	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
Obesity	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
Adherence to Guidelines for Commonly Overused Procedures		OP-33: External beam radiotherapy (EBRT) for bone metastases OP-29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients OP-30: Endoscopy/Poly Surveillance: Colonoscopy interval for patients with a history of adenomatous polyps—Avoidance of inappropriate use OP-8: MRI lumbar spine for low back pain OP-11: Thorax CT – Use of contrast material OP-13: Cardiac imaging for preoperative risk assessment for non-cardiac low risk surgery
End-of-Life Preferences	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
Cost Per Case or Episode		Medicare spending per beneficiary (MSPB)
Behavioral Health	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
Patient Experience of Care / Patient Reported Outcomes of Care		HCAHPS survey

Exhibit D

AAMC

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Submitted electronically via www.regulations.gov

September 11, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
7500 Security Boulevard
Baltimore MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program for CY 2018 (CMS-1678-P)

Dear Ms. Verma:

The Association of American Medical College (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS's) proposed rule entitled *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program for Calendar Year (CY) 2018*, 82 *Fed. Reg.* 33558 (July 20, 2017).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 147 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their nearly 167,000 full-time faculty members, 88,000 medical students, and 124,000 resident physicians.

Summary of Major Issues on Which AAMC Provides Comments

CMS should rescind the proposal to cut the reimbursement for non-pass-through drugs for 340B hospitals. The AAMC strongly opposes CMS's proposal to cut Medicare Part B drug payments to hospitals that participate in the 340B Drug Pricing Program (340B Program) and recommends that CMS rescind this proposal. The 340B Program was designed to allow safety-net hospitals, many of which are teaching hospitals, to support programs to help low-income, vulnerable patients at no cost to taxpayers. The proposal represents a significant payment reduction that will undermine the purpose and benefits of the 340B Program, while crippling the ability of 340B hospitals to provide support and programs to serve vulnerable and low-income patients.

Among the other issues on which AAMC comments are the following:

- CMS should not finalize the proposal to remove Total Knee Arthroplasty from the Inpatient Only List until it makes revisions to bundled payment programs to avoid a significant negative impact on hospitals participating in those programs
- CMS should not package low-cost drug administration services of unrelated lab tests until further analysis occurs; and,
- CMS should account for sociodemographic factors in hospital quality provisions.

CMS Must Rescind the Proposed Cuts to Reimbursement for Part B Drugs Purchased Under the 340B Drug Pricing Program

In the calendar year (CY) 2018 Outpatient Prospective Payment System (OPPS) proposed rule, CMS has targeted safety net hospitals for Medicare reductions by proposing to dramatically cut the reimbursement rate for Medicare Part B drugs purchased under the 340B Drug Pricing Program. Currently, Medicare pays for separately payable, non pass-through drugs for all hospitals at the average sales price (ASP) **plus 6 percent** (ASP +6%). CMS proposes to pay ASP **minus 22.5 percent** (ASP -22.5%) for these drugs for only 340B hospitals beginning January 2018. **In actuality, the devastating cut to 340B hospital drug payments is 28.5%.**

At the August 21, 2017 meeting, the CMS Advisory Panel on Hospital Outpatient Payment, voted overwhelmingly that CMS not finalize the proposed cut to drugs furnished by 340B hospitals for CY 2018. The panel also recommended that CMS collect data to understand the impact of the proposal and assess the regulatory burden associated with the proposed modifier to identify drugs not purchased under the 340B program.

The AAMC strongly opposes the CMS proposal, which is a cut squarely aimed at hospitals that treat the most vulnerable and underserved patients and communities, and urges CMS to rescind the proposal. Those teaching hospitals that participate in the 340B Program do so to expand services and provide medications and treatments to patients who may not otherwise have access. Cutting Medicare payments for 340B drugs undermines the laudable purpose of the 340B Program and reduces critical drug reimbursements needed by teaching hospitals and other safety net providers to furnish services to uninsured and indigent patients. Such dramatic cuts to drug reimbursements will require hospitals to reduce or eliminate services elsewhere, including the programs to assist low-income patients that 340B was designed to support.

Proposed cuts undermine the intent of the 340B Program

Congress created the 340B Program in 1992 to allow certain safety net hospitals and other covered entities to purchase outpatient drugs at a discount from drug manufacturers in order to expand services that benefit vulnerable populations. Savings are generated from the 340B Program because pharmaceutical companies are required to sell the drugs to hospitals at a reduced price. At no cost to taxpayers, the 340B Program has been a success, allowing hospitals that treat large numbers of uninsured and underinsured patients to generate savings from the

discounts that are then used to expand health care services and provide access to needed drugs for these vulnerable populations.

Other than modest appropriations to administer the program, the 340B Program is self-sustaining; the financial support hospitals receive is derived from drug manufacturer discounts, rather than federal investments. Under the Program, drug manufacturers offer lower prices on covered outpatient drugs to eligible hospitals and other settings, enabling these eligible entities to reinvest the difference in health care services for underserved and uninsured patients.

The expansion of the 340B Program to include critical access hospitals and rural hospitals is an acknowledgement of its success and the desire to expand program eligibility to reach more patients.

Major teaching hospitals operate a variety of programs and provide services that otherwise may not be financially viable without support from the 340B Program, including:

- Free or substantially discounted prescriptions to uninsured or low-income patients,
- Mobile units to bring care to communities that have no local primary care or pharmacy,
- Multidisciplinary clinics offering substance abuse and mental health needs, and,
- Transportation support to patients who frequent the emergency room.

In the preamble to the proposed rule, CMS states that its 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 while continuing to provide access to care." Unfortunately, the proposal does the opposite—undercutting the ability of 340B hospitals to provide access to care by reducing critical Medicare payments. These cuts will likely result in Medicare and other patients losing access to important services that preserve the health of their communities and could result in higher hospital use of emergency rooms and increased hospital admissions, with resultant higher costs and poorer health outcomes for vulnerable populations.

The CMS proposal uses faulty assumptions and is unsupported by a CMS data analysis

In the preamble to the proposed rule, CMS discusses several reports, including a Medicare Payment Advisory Commission (MedPAC) examination of Part B spending for 340B and non-340B hospitals from 2008-2012[1], noting that the spending increase has been greater in 340B hospitals, and suggests that such increase is inappropriate. However, the MedPAC report fails to account for the fact that 340B hospitals are significantly different from non-340B hospitals, and many compounding factors may contribute to differences in Part B spending. Over the period of time studied, many new types of hospitals joined the 340B Program and 340B hospitals serve a very different patient population and offer a wider range of services than those hospitals that are outside the program. Also, CMS did not provide its own independent analysis to reach the conclusion that 340B hospitals should receive a 22.5% payment cut for Part B drugs.

[1] MedPAC Report to Congress: Medicare and the Health Care Delivery System, June 2017; accessed at http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0

- ***340B hospitals are significantly larger, serve a different patient population, and are financially more fragile than non-340B hospitals***

In the proposed rule, CMS highlights findings from a Government Accountability Office (GAO) report[2] that compared financial and other characteristics between hospitals that participate in the 340B program and hospitals that do not. GAO found that "on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at other non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or by patients' health status." (82 *Fed Reg* 33633) Prior to the publication of the report, the U.S. Department of Health and Human Services (HHS) was given an opportunity to respond to GAO's findings. HHS's response stated that "we are concerned that the report characterizing spending on Part B in 340B DSH hospitals as 'excess,' 'potentially inappropriate,' and 'more than necessary to treat Medicare Part B beneficiaries' is not supported by the study methodology. GAO's study, which only examined average differences in per-beneficiary spending by hospital type, did not examine any patient differences in terms of quality or outcome."[3]

- ***CMS did no independent data analysis to support the cut***

CMS did no independent data analysis to justify its payment cut of 28.5% (ASP-22.5%). Rather, the Agency relied on a MedPAC analysis to support this proposal. The 22.5% is derived from a May 2015 MedPAC estimate of the "lower bound of the average discount received by 340B hospitals for drugs paid under" OPPS. (Appendix A, page 25). MedPAC estimated the difference between drug ceiling prices and average sales prices based on 2013 data. CMS has provided no justification for the use of this data.

Part of the reason why CMS did not do its own analysis may be because the Agency did not know which data to rely upon. CMS acknowledges this fact by writing in the proposed rule preamble that "current data limitations inhibit identification of which drugs were acquired under the 340B program in the Medicare OPPS claims data." (82 *Fed Reg.* 33633). To remedy this lack of data, CMS will establish a modifier, to be effective as of January 1, 2018. (The AAMC discusses the difficulty of adding this modifier later in our comments.)

CMS cannot implement a payment cut of the magnitude proposed without providing a sufficient and replicable methodology that supports the proposal for payment rate of ASP minus 22.5 percent. Relying on a MedPAC analysis does not suffice for this important fiduciary, and legal, requirement.

The 340B Drug Pricing Program is NOT causing unnecessary utilization or overutilization of separately payable drugs

The 340B Program is being unjustly targeted as "unnecessary utilization and potential overutilization of separately payable drugs." According to the Health Resources and Services

[2] Action Needed to Reduce Financial Incentives to prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015; accessed at https://www.gao.gov/products/GAO-15-442

[3] GAO Study, 340B Drug Pricing Program, page 38

Administration (HRSA), which administers the 340B Program, 340B sales are less than three percent of the total U.S. drug market.[4] Reducing how Medicare reimburses hospitals that participate in the 340B Program for these drugs will not address drug use; rather, it will have the detrimental effect of impeding hospitals' ability to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries.

Outpatient drug spending growth is the result of volume, type of service, and price. Outpatient volume can increase for multiple reasons, but two predominant factors are the shift of providing services from the inpatient to outpatient setting. In recent years, hospital outpatient departments have seen dramatic increases in volume as more services are moving from the inpatient to the outpatient setting. MedPAC's analysis[5] shows that outpatient visits per beneficiary have increased by 44.2% between 2006 and 2014, while inpatient discharges per beneficiary decreased by nearly 20% during the same time period. This shift reflects efforts to increase the value of many services and overall represents a savings for the Medicare program. As part of this shift, more complex treatments are able to be performed safely in the outpatient setting. For example, more advanced medication regimens for cancer and immunologic disorders are now often treated in outpatient infusion centers, with a concomitant growth in the volume and related overall costs for the drug regimen.

In 2016, almost 1.7 million new cases of cancer were diagnosed.[6] The median age at cancer diagnosis is 65 years – the age most Americans are eligible for Medicare implying that half of these new cases occur in the Medicare population. Much of this care occurs in the outpatient setting. As a result, more patients with cancer will logically mean more outpatient cancer drug costs.

In addition to volume, drug pricing (as reflected by the average sales price, or ASP) affects overall drug costs. While medications allow patients to live healthier lives, some medications often come with a hefty price tag. There are more expensive drugs on the market than ever before. As MedPAC reports, 8 of the top 10 drugs paid under the ASP system in Medicare are biologics, many of which have limited to no competition. For some chronic conditions, a year of treatment with a specialty drug can easily exceed $100,000. The price of a drug upon entry into the market continues to rise. It is estimated that prices for new drugs entering the market have doubled since 2012. AAMC-member teaching hospitals report dramatic price increases for oncology medications, particularly new medications. There is no question that drugs have become unaffordable for millions of Americans and impose uncompensated care costs on the providers that care for them.

An analysis by Watson Policy Analysis (WPA) showed a similar growth in the unit payment for the top eight outpatient drugs, which account for almost 50% of drugs used in the outpatient setting, for both 340B and non-340B hospitals.

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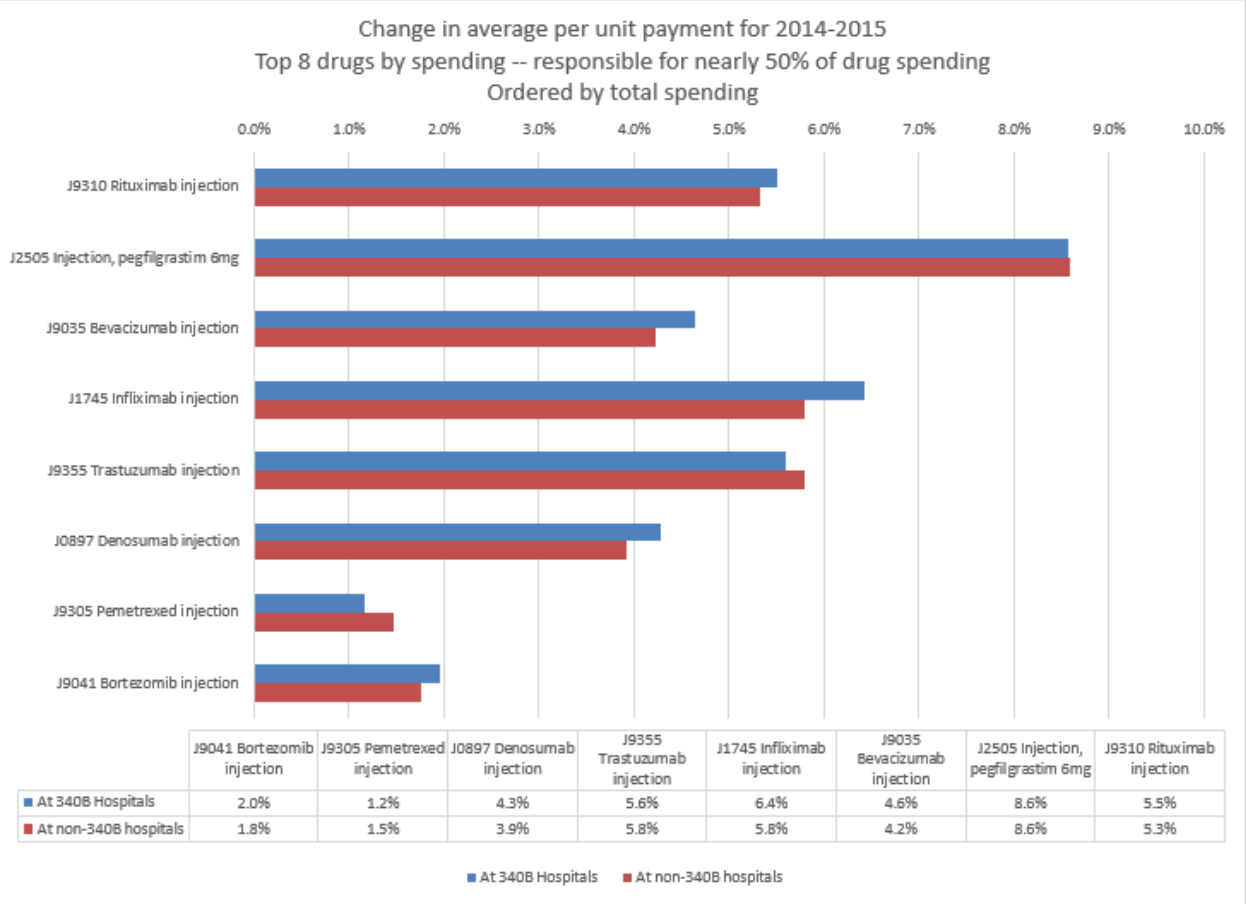
[5] MedPAC June 2016 Report to the Congress.
[6] https://www.cancer.gov/about-cancer/understanding/statistics



	J9041 Bortezomib injection	J9305 Pemetrexed injection	J0897 Denosumab injection	J9355 Trastuzumab injection	J1745 Infliximab injection	J9035 Bevacizumab injection	J2505 Injection, pegfilgrastim 6mg	J9310 Rituximab injection
At 340B Hospitals	2.0%	1.2%	4.3%	5.6%	6.4%	4.6%	8.6%	5.5%
At non-340B hospitals	1.8%	1.5%	3.9%	5.8%	5.8%	4.2%	8.6%	5.3%

It is illogical to suggest that the solution to rising drug costs is to gut a program that represents less than 3% of the total U.S. drug market[7]. Moreover, it is equally illogical to believe that reducing Medicare payments to 340B hospitals will in any way address the fundamental drivers of the increase in Part B drug expenditures: volume and price. If CMS wants to address rising drug costs, the Agency should do so directly, not by cutting critical Medicare payments to safety net hospitals or undermining the 340B Program.

- ***The 340B Program does not incentivize overutilization of drugs***

The AAMC disagrees with the statement in the proposed rule that practitioners in 340B hospitals are prescribing more drugs and more expensive drugs. Relying on findings from MedPAC, GAO, and the HHS Office of Inspector General (OIG), CMS asserts that the current reimbursement structure (ASP + 6%) incentivizes 340B participating hospitals to over-utilize medications and to prescribe more expensive medications. This makes no clinical sense. Clinicians provide the care that patients need. This is particularly true with cancer patients. As a result of new and emerging drug therapies, clinicians often prescribe drug treatments that are more expensive because of the prices set by pharmaceutical companies. Moreover, for these

[7] Department of Health and Human Services Fiscal Year 2018 Health Resources and Services Administration, *Justification of Estimates for Appropriations Committees*, page 244

patients, often the first regimen doesn't work and multiple drug regimens are needed to find the one that will be successful, which can also drive up total costs.

As major referral centers with highly specialized expertise, academic medical centers serve a sicker, more complex, and more vulnerable patient population – patients who often are unable to seek the necessary care elsewhere. These hospitals, many of which participate in the 340B Program, provide a wide variety of services to a diverse patient population. More complex patients often require more medications. Commenters to the GAO report noted that GAO did not adequately take into account case complexity when looking at drug utilization at 340B hospitals. So-called "overutilization" could actually be due to treating a more complex patient population. GAO did note that the average risk scores were higher at 340B DSH hospitals but stated that "the differences we found were likely not explained by the health status of the outpatients served." HHS took exception to this conclusion, stating that "this claim is not supported by the analysis."

CMS Does Not Have the Statutory Authority to Implement the Proposed Cut to 340B DSH Hospitals

As the attached memorandum from Mark D. Polston and Justin A Torres, King & Spalding, LLP clearly demonstrates, the Secretary's attempt to cut payments to 340B DSH hospitals is contrary to law and in excess of his statutory authority. The proposal runs counter to Congress's intent when it designed the 340B Program which was to stretch federal resources and allow covered entities to retain the difference between their drug acquisition costs and payment rates to provide services for vulnerable populations. The proposal also is in excess of the Secretary's authority under §1833(t)(14) of the Social Security Act which requires that any survey data used to set payment rates must be derived from statistically rigorous surveys; impermissibly employs aggregate rather than drug-specific data, contrary to the plain text of the statute; and impermissibly uses 340B status as a "relevant characteristic," to vary payment rates, although doing so fails to take into account Congress's separate treatment of 340B covered entities in the Public Health Service Act.

The CMS estimate of the financial impact of the payment decrease is unsupported by data

In the proposed rule, CMS estimates Medicare payments for the affected Part B drugs would decrease by at least $900 million. An analysis by WPA estimated that the savings are more likely to be in the range of $1.2 to $1.6 billion. In other words, the real financial impact on 340B hospitals will be far greater than CMS projected in the proposed rule, lending support to the notion that the proposal is unsupported by adequate analysis. Should this proposal be finalized, it will have very real and harmful consequences on vulnerable populations. Therefore, it is imperative that CMS be precise in the impact methodology it uses and that the Agency share that methodology with stakeholders to allow them to engage in their own modelling.

The best way to achieve "Budget Neutrality" is to maintain the current system

CMS proposes to implement the cut to 340B hospitals in a "budget neutral" manner by increasing non-drug OPPS payment rates for all hospitals by approximately 1.4 percent in CY 2018. Among other issues, CMS asks for comment on "whether and how the offsetting increase

should be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured."

We appreciate that CMS recognizes the role of safety net hospitals and the need for these hospitals to receive these payments. We believe the best way to achieve this goal is by rescinding the proposal and maintaining the current payment rates for 340B hospitals. Not only will this ensure that all hospitals receive the same Medicare payment for outpatient drugs, but it will eliminate the need to impose an unfair two-tiered payment system, add bureaucracy to an already overly-complex payment system, and place vulnerable populations at risk.

The proposed 340B claims modifier for non-340B drugs is administratively burdensome, may unfairly penalize hospitals, and cannot be implemented by January 1, 2018

CMS acknowledges current data limitations that prevent the Agency from identifying which drugs were acquired under the 340B Program in the Medicare OPPS claims data, but nonetheless uses the assumption that all drugs used in hospitals outpatient departments are purchased under the 340B Program. To remedy this lack of data, CMS states that it will "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."

CMS is proposing to include a claims modifier to identify drugs not purchased under the 340B Program to allow analysis of acquisition costs. The Agency further proposes unless a modifier is appended to the OPPS claim, the payment will be made as though the drug had been purchased under the 340B program. This is not currently possible, however, as many hospitals report that they are not able to determine whether a patient meets HRSA's 340B eligibility requirement at the time of billing, but do so retrospectively.

It also will be impossible for hospitals to comply with the proposed implementation date of January 1, 2018. All hospitals, both 340B hospitals and non-340B hospitals, need additional time to adapt billing systems to accommodate the claims modifier, allow for testing to ensure the modifier is working correctly before using, and educate staff who must append the modifier. This process could take up to 12 months to test and implement. If the modifier does not appear on the claim automatically, it would have to be added manually by hospitals' billing staff, a time and labor intensive task. This proposed requirement is administratively burdensome and will unfairly penalize any hospital that fails to append the modifier. **CMS should not finalize this proposal because it does not have a reasonable methodology for obtaining this information.**

Based on the aforementioned reasons, the AAMC strongly urges CMS to rescind the proposed Medicare cut to hospitals that participate in the 340B Drug Pricing Program. This unconscionable cut to major safety net providers would undermine the intent of the 340B Program, which is to provide life-saving services to underserved patients. Under this proposal, participating hospitals would be forced to reduce or eliminate critical programs that support low-income communities. The AAMC looks forward to working with CMS and the Administration to address rising drug costs, but reducing Medicare payments to 340B hospitals is not a solution to this problem.

CHANGES TO THE INPATIENT ONLY LIST

CMS Cannot Remove Total Knee Arthroplasty from the Inpatient Only List until Significant Revisions to Bundled Payment Program Target Price Methodologies are Made in order to avoid a Significant Negative Impact on Participant Hospitals

In the CY 2017 proposed OPPS rule, CMS requested comments on the removal of total knee arthroplasty (TKA) (CPT code 27447) from the Inpatient Only (IPO) list. Among the criteria for removal from the list are: most outpatient departments are equipped to provide the services to the Medicare population; the simplest procedure described by the code may be performed in most outpatient departments; the procedure is related to codes that have already been removed from the IPO list; a determination is made that the procedure is being performed in numerous hospitals on an outpatient basis; and, a determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by CMS for addition to the ASC list. After consideration of the comments, CMS has proposed in the CY 2018 proposed rule that TKA be removed from the IPO list. In making this proposal, CMS has not addressed the ways in which it will adversely impact hospitals participating in Medicare bundled payment models including TKA patients. **Prior to finalizing the proposal, CMS must establish a methodology to adequately risk-adjust target prices for the shift in patient populations between surgery settings through notice and comment rule-making.**

The AAMC agrees that there may be instances in which physicians deem that a TKA can be safely performed as an outpatient procedure on certain Medicare patients, particularly those who are younger and healthier, just as that procedure commonly is performed in that setting for many non-Medicare patients. However, outpatient TKA may not be reasonable for many Medicare patients who would be older and more complex. The decision as to whether to perform TKA on an inpatient or outpatient basis should rest complete with the physician in consultation with their patient soley based on the patient's clinical circumstances. In addition, the AAMC is concerned that removing TKA from the IPO list will create undue significant negative financial implications for hospitals participating in the Bundled Payments for Care Improvement (BPCI), Comprehensive Care for Joint Replacement (CJR), and future major joint replacement of the lower extremity (MJRLE) bundled payment programs. To avoid unfairly penalizing participants in BPCI Model 2 and CJR, CMS should not finalize its proposal until it makes timely changes to both of these programs through notice and comment rulemaking.

The AAMC supports CMS's proposal to prohibit Recovery Audit Contractors (RACs) from denying inpatient TKA claims for patient status for two years, since this will discourage hospitals from inappropriately shifting TKA procedures to outpatient settings to ensure payment. **CMS should also clarify that its current two-midnight rule policy will apply to the TKA if it were to be removed from the IPO as it does for other inpatient admissions.** That is, if a patient is expected to need two midnights of hospital care, the patient is correctly admitted to the hospital as an inpatient. If the patient is expected to need fewer than two midnights of hospital care, the patient may still be admitted and the hospital paid under the IPPS if the physician's judgement with supporting documentation justifies the need for an inpatient stay. Under CMS'

policy, Quality Improvement Organizations (QIOs) rather than RACs are the first line of review for patient status. Patient status cases are only referred to a RAC if the hospital has repeated problems with two-midnight rule compliance after working with the QIO. **AAMC would not expect TKA to be an area of concern for medical review as we would expect most Medicare patients would be reasonable and necessary for an inpatient admission and we would strongly urge medical reviewers to defer to the judgment of the physician on where to perform TKA.**

Current BPCI Model 2 and CJR Payment Methodology

Both the BPCI and CJR models include 90-day episodes triggered by an inpatient hospitalization for MS-DRGs 469 and 470, and include all related services covered under Medicare Parts A and B during the 90 days following discharge. Aggregate Medicare payments for care provided during episodes are retrospectively compared to a target price to determine the participant's financial results. The target price is based on average episode payments during a baseline period. Under BPCI, this average is based entirely on a hospital's own historical performance. Under CJR, this historical average is a blend of hospital-specific and regional data. This historical average is trended to the performance period and discounted by a certain percentage. If actual payments fall below the target, the hospital is eligible to receive payments from the Medicare program. Conversely, if actual payments exceed the target, the hospital is required to reimburse Medicare for the difference (up to a limit).

Impact of Proposal to Remove TKA from IP List on BPCI and CJR Target Prices

The BPCI and CJR baseline periods include a subset of Medicare FFS TKA cases that could have been performed as outpatient procedures, if outpatient procedures were allowed during that period. CMS' proposal to permit TKA procedures to be reimbursed under OPPS as well as IPPS may significantly alter the composition of BPCI and CJR participant hospitals' patient populations, and thus unfairly hinder hospitals' ability to generate savings under the models. Specifically, younger and healthier patients are more likely to receive outpatient TKAs, meaning a higher proportion of patients receiving inpatient TKAs will be high-risk and/or more likely to require additional post-acute care support. As a result, this change in patient mix could increase the average episode payment of the remaining inpatient TKA BPCI and CJR cases when compared to current payment levels. Because the episode payments for the remaining inpatient TKA episodes are reconciled against the baseline target price calculated using both inpatient and outpatient eligible procedures, the remaining inpatient cases will appear artificially high relative to the target price. Consequently, hospitals will be more likely to sustain losses in the BPCI and CJR models. In the absence of sufficient risk adjustment to modify target prices to reflect CMS' proposed change, some BPCI hospitals may voluntarily leave the program prior to its conclusion in September 2018 in order to mitigate financial losses.

Possible refinements to the BPCI and CJR Models

Without sufficient risk adjustment to account for changes in BPCI and CJR patient populations as a result of CMS's proposal, hospitals will be more likely to sustain financial losses in the

programs that are not due to their own performance. Two primary approaches exist to mitigate financial risk resulting from the removal of TKA from the IPO list:

1) Attempt to stratify the baseline to exclude procedures that could have been performed in outpatient departments and recalculate inpatient targets; or,
2) Allow BPCI Model 2 and CJR episodes to be triggered by TKA performed in the hospital outpatient department, and calculate target prices stratified by inpatient/outpatient setting.

As is discussed in detail in the attachment, the AAMC recommends that CMS adopt the second approach. These options are further explained in the appendix to this comment letter.

CHANGES TO HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

AAMC Encourages CMS to Account for Socio-Demographic Risk Factors in the Hospital OQR Program

In the proposed rule, CMS states that it understands that social risk factors play a major role in health and that one of the Agency's main objectives is to ensure all beneficiaries, including those with social risk factors, receive high quality care. The Agency also seeks to ensure that the quality of care furnished by providers is assessed fairly under their programs.

Specifically, CMS seeks public comment on whether OPPS should account for social risk factors, and if so, what method or combination of methods would be most appropriate for accounting for those factors. In addition, CMS requests comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure.

The AAMC is pleased that CMS understands the impact of social risk factors on health and is encouraged that the Agency is requesting comment on how to best incorporate these factors. The Association has long advocated for the inclusion of social risk factors, when appropriate, as that is the only way to level the playing field among providers and to make accurate and useful information about provider quality available to patients and their families. Most outcome measures in the quality performance category and cost measures are affected by sociodemographic status (SDS) factors, which are beyond the control of the provider. Academic medical centers tend to disproportionately treat disadvantaged and vulnerable patient populations and therefore are more likely to be unfairly penalized by performance programs that do not have adequate SDS adjustment.

Over the past several years, a substantial amount of literature has recognized the impact of SDS factors on patient outcomes.[8,9] Recent reports released by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine (NAM) on accounting for social risk factors in the Medicare performance

[8] Michael Barnett, MD, et al. Patient Characteristics and Differences in Hospital Readmission Rates. JAMA, 2015. Retrieved from: http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2434813

[9] Jianhui Hu, et al. Socioeconomic status and readmissions: evidence from an urban teaching hospital. Health Affairs, 2014. Retrieved from: http://content.healthaffairs.org/content/33/5/778.full

programs have provided evidence-based confirmation that accounting for patients' sociodemographic and other social risk factors is critical in validly assessing the quality of providers. The reports demonstrate that providers caring for large numbers of disadvantaged patients are more likely to receive penalties in the performance programs. Lack of SDS adjustment can worsen health care disparities because the penalties divert resources away from providers treating large proportions of vulnerable patients. The failure to account for SDS variables also is misleading and confusing to patients, payers, and policymakers because it fails to provide them with information about important community factors that contribute to poor health outcomes. Finally, as noted by ASPE, the cumulative effect of the penalties across the Medicare performance and penalty programs could significantly hinder the work of those institutions that disproportionately serve beneficiaries with social risk factors.[10]

Both reports clearly show that there are implementable mechanisms by which SDS data elements can be incorporated into quality measurement today. The AAMC urges CMS to incorporate the recommendations below to begin accounting for SDS factors as the first step toward ensuring that all providers are assessed on an even playing field:

- Require measure developers to test a range of national-level sociodemographic data elements, identified in the ASPE4 and NAM5 reports, into the risk adjustment methodology of accountability metrics. Both reports discuss in detail data elements that are publicly available and could be immediately tested to determine whether an empirical relationship exists between SDS and the measure's outcomes. Such elements could include income, education, neighborhood deprivation, and marital status.
- As a first step, consider stratifying certain measures by dual eligible status or other nationally available data elements.
- Implement demonstration projects to encourage eligible clinicians to collect SDS data through their electronic health records (EHR). These elements could be used to supplement the claims data already captured by CMS to greatly improve the measure's risk adjustment methodology. It is essential that CMS include vendors in these discussions.
- Where meaningful and comprehensive neighborhood level SDS-data currently exist, CMS should encourage empirical tests of quality metrics adjusted for those factors to assess the impact of the adjustments on local provider performance metrics. Based on the results of these tests CMS and other agencies will be able to prioritize the national collection of data that are most essential for valid risk adjustment methodologies.

AAMC Supports the Removal of the Six Quality Measures from the Hospital OQR Program quality measures

In the proposed rule, CMS is proposing to remove six measures from the Hospital OQR Program beginning in CY 2020:

[10] "Office of the Assistant Secretary for Planning and Evaluation." Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program. December, 2016. Pg, 92 Retrieved from https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf

- OP-1: Median Time to Fibrinolysis
- OP-4: Aspirin at Arrival
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
- OP-21: Median Time to Pain Management for Long Bone Fracture
- OP-25: Safe Surgical Checklist
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures

The AAMC recognizes the importance of quality measurement to ensure that hospitals and physicians are providing high quality care. However, reporting and transmitting quality measures requires intensive staff training, labor, and resources – and ultimately limits the time clinicians spend with their patients. **AAMC supports removing these measures from reporting.** However, CMS proposes that two of the measures, Median Time to Pain Management for Long Bone Fracture and Hospital Outpatient Volume Data on Selected Outpatient Surgical procedures be removed beginning in CY 2020. The Agency proposes that the other four measures should be removed in 2021. The reason for removing the measures is to alleviate the maintenance costs and administrative burden to hospitals associated with retaining them. **To provide hospitals with more immediate relief related to the costs and burden associated with the measures, the AAMC asks that CMS remove the measures to avoid required reporting after publication of the final CY 2018 rule.**

AAMC supports the delay of inclusion of Outpatient CAHPS Survey Questions

CMS is proposing to delay indefinitely the implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) measures, currently scheduled for inclusion in the OAR Program measure set beginning with CY 2020 payment. AAMC supports CMS's decision to delay inclusion of the question as it lacks important operation and implementation data and review survey data from 2016 and 2017 to reaffirm the reliability of national OAS CAHPS survey data.

In the past, AAMC has stated its concerns that CMS did not discuss how the questions would be displayed on the Hospital Compare website and noted that this would be discussed in future rulemaking if the measure is finalized. The AAMC is also concerned that the OAS CAHPS survey measures are not NQF-endorsed.

The AAMC supports the use of feedback surveys to assess the overall quality of patient care. However, the Association has serious concerns with the proliferation of these surveys across settings and the potential unintended consequences that may result from an over-surveyed patient population. Currently, there are patient-experience of care surveys for physicians, hospitals, nursing homes, and home health agencies. In addition to the OAS CAHPS, CMS has implemented the Hospital CAHPS for inpatients and is testing an Emergency Department (ED) survey. Patients who receive overlapping care in these settings could receive multiple surveys, leading to confusion for the patient as to which clinicians or facilities are being assessed. The receipt of multiple surveys also may makes it less likely that the patient will choose to respond to

any of them. Compounding this problem is the fact that surveys are distributed long after patients have received care such that the responses may not be accurate due to the time lapse.

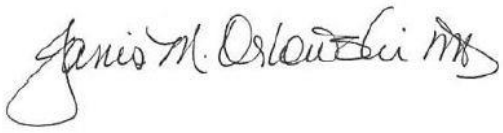
In addition, the AAMC is concerned that mail and telephone surveys, the method by which the CAHPS surveys are currently distributed, are both expensive to administer and are no longer the methodology of choice for certain patient populations. The cost associated with a mailed survey prevents hospitals from sampling a larger population of recent patients, thereby having a negative impact on their ability to respond to concerns at the provider and unit level. CMS should consider allowing patients to opt to receive these surveys electronically, which would allow hospitals to collect feedback from a larger sample and would give patients the flexibility to respond to the survey format that works best for them.

The AAMC does not support the inclusion of another patient experience survey until these issues are resolved. The Association strongly recommends that CMS convene a stakeholder group of providers, patients, venders, and other relevant parties to discuss the CAHPS survey questions holistically to address how these surveys should be distributed in the future, prioritize the development of these survey tools to a limited subset of provider settings, and determine how to manage the issue of overlapping care. Finally, these survey measures should be NQF-endorsed and approved by the MAP before they are proposed for inclusion in the OQR program.

CONCLUSION

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Ivy Baer at 202.828.0499 or ibaer@aamc.org or Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,



Janis M. Orlowski, M.D, MACP
Chief, Health Care Affairs, AAMC

Attachments (2):
Memorandum from Mark D. Polston and Justin A. Torres, King & Spalding, LLP
Proposed Transitional Methodology for Bundling Programs

cc: Ivy Baer, J.D., MPH, AAMC
Mary Mullaney, AAMC

Exhibit E

AMERICA'S ESSENTIAL HOSPITALS

September 11, 2017

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave. SW
Washington, DC 20201

Ref: CMS-1678-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Ms. Verma:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates and supports the Centers for Medicare & Medicaid Services' (CMS') work to improve the delivery of high-quality, integrated health care across the continuum. We are concerned about several provisions of the proposed rule that would have a disproportionately negative financial impact on essential hospitals—those that provide stability and choice for people who face financial barriers to care.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to providing high-quality care to all people. Filling a vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care and devote nearly three quarters of their inpatient and outpatient care to Medicare, Medicaid, and uninsured patients. Our members provide state-of-the-art, patient-centered care while operating on margins less than half that of other hospitals: 3.2 percent in aggregate compared with 7.4 percent for all hospitals nationwide.[1] Individual essential hospitals often operate on negative margins and key sources of savings, such as the 340B Drug Pricing Program, are critical to their viability. Essential hospitals treat more patients who are dually eligible for Medicare and Medicaid than the average hospital. Through their integrated health systems, members of America's Essential Hospitals offer a full range of primary through quaternary care, including organ transplant services, trauma care, outpatient care in

[1]Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2015 Annual Member Characteristics Survey. America's Essential Hospitals. June 2017. www.essentialdata.info/. Accessed August 12, 2017.

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their ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services critical to disadvantaged patients.

Essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring services to where patients live and work. The average member operates a network of more than 30 ambulatory care sites and saw nearly three times more non-emergency outpatient visits in 2015 than other acute-care hospitals nationwide. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—that freestanding physician offices typically do not offer. Our members' ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

The high cost of providing complex care to low-income and uninsured patients leaves essential hospitals with limited resources, driving them to find increasingly efficient strategies for providing high-quality care to their patients. But improving care coordination and quality while maintaining a mission to serve the vulnerable is a delicate balance. This balance is threatened by aspects of the proposed rule.

We are particularly concerned that CMS' proposed payment reduction for separately payable drugs provided by hospitals participating in the 340B program would drastically limit the ability of essential hospitals to provide coordinated care to disadvantaged populations. The proposal also would inhibit our members' ability to provide heavily discounted drugs to patients in the face of rapidly increasing drug prices. In our detailed comments below, we urge CMS to withdraw this proposal. We also provide recommendations on:

- CMS' implementation of Section 603 of the Bipartisan Budget Act of 2015 (BBA);
- the Outpatient Quality Reporting (OQR) Program;
- the proposed removal of the total knee arthroplasty (TKA) procedure from the inpatient only (IPO) list;
- refining CMS' comprehensive ambulatory payment classification (C-APC) policy; and
- differential payment for services performed in the inpatient and outpatient settings.

To ensure essential hospitals have sufficient resources to provide access and are not unfairly disadvantaged for serving vulnerable populations, CMS should adopt the following recommendations when finalizing the above-mentioned proposed rule.

1. **CMS should withdraw its proposal to reduce Part B drug payment for hospitals participating in the 340B program. This proposal exceeds the agency's legislative authority, undermines the Public Health Service Act (PHSA), and would devastate low-income patients and the hospitals committed to treating them.**

For hospitals purchasing certain separately payable drugs through the 340B program, CMS proposes to cut Part B reimbursement to 77.5 percent of average sales price (ASP), compared with current payment at 106 percent of ASP, the statutory default payment methodology for these drugs. This represents a 27 percent reduction in Medicare reimbursement targeted at hospitals participating in the 340B program, while those not participating in the program would continue to receive payment at 106 percent of ASP. **America's Essential Hospitals strongly urges CMS to withdraw the proposal to reduce payments for 340B drugs and to instead continue to pay all hospitals at the statutory default of 106 percent of ASP.**

The 340B program, codified in section 340B of the PHSA, was created by Congress to allow covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] Under the 340B program, covered entities can purchase certain outpatient drugs at discounted prices, enabling savings that are critical to the operations of these hospitals that fill a safety-net role. The 340B program is structured by statute to provide hospitals discounts for covered outpatient drugs provided to patients of the entity, regardless of the patient's insurance status. Congress expected that various public and private payers would reimburse hospitals at higher rates than the discounts they received from drug manufacturers, which is how hospitals were expected to stretch resources to expand access to medications and other vital services.

Essential hospitals reinvest 340B savings into programs to coordinate care and improve outcomes for vulnerable populations, including initiatives aimed at reducing readmissions, ensuring medication compliance, and identifying high-risk patients in need of ancillary services. CMS' ill-advised proposal to enact a targeted cut is essentially a redistribution of Medicare funds from those hospitals Congress intended to benefit from the 340B program to non-340B hospitals. The policy would take money from the safety net and redirect it to hospitals that do not fill a safety-net role, including for-profit hospitals that are excluded by law from participating in the 340B program.

We urge the agency to withdraw its proposal; in doing so, CMS would act on the recommendations of its own Advisory Panel on Hospital Outpatient Payment. CMS' proposal is inconsistent with Medicare statute—a conclusion supported by reports from Government Accountability Office (GAO) and the Office of Inspector General (OIG)—and conflicts with section 340B of the PHSA, which governs the program.[3,4] CMS has

[2]H.R. Rep. No. 102-384, pt. 2 (1992).
[3]Government Accountability Office. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. June 2015. https://www.gao.gov/assets/680/670676.pdf. Accessed August 29, 2017.
[4]Office of Inspector General. Part B Payments for 340B-Purchased Drugs. November 2015. https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf. Accessed August 29, 2017.

not demonstrated that its proposal would lower drug prices, help beneficiaries financially, or improve access to or quality of care provided to Medicare beneficiaries. On the contrary, as we establish in more detail in the following sections, CMS' proposal would undermine a key policy lever that already has proved effective in combating high drug prices and improving medication adherence.

a. CMS' proposal is inconsistent with the plain language of the Social Security Act (SSA) and is impermissible under the Administrative Procedure Act.

CMS should withdraw its proposal to reduce payment for separately-payable drugs purchased through the 340B program, because it is inconsistent with the agency's statutory authority under the SSA. In the proposed rule, CMS cites reports from advisory and oversight agencies as justification for its policy to reduce Part B payment for 340B drugs. But in discussing Part B drug payment, these same reports specifically note that any changes to Medicare reimbursement for 340B drugs can only be made through legislation and are outside of the authority of CMS. For example, GAO noted that CMS is unable to change Part B reimbursement for 340B discounted drugs "because they do not have the statutory authority to do so."[5] The Medicare Payment Advisory Commission (MedPAC) specifically directed to Congress its recommendations on Medicare payment for Part B drugs purchased through the 340B program.[6] OIG echoed these concerns about CMS' statutory authority, noting that sharing 340B discounts "is not possible under the current design of the 340B Program and Part B payment rules."[7] We agree with these experts that CMS does not have legal authority to implement its proposal.

First, the proposal significantly diverts from the statutory default payment of 106 percent of ASP. CMS pays hospitals for separately payable Part B drugs under section 1833(t)(14)(A)(iii)(II) of the SSA. Under this section, referred to as the statutory default methodology, if CMS cannot implement a payment methodology based on acquisition cost under section (iii)(I), then Congress directs CMS to pay for Part B drugs based on average price. This paragraph specifically references sections 1842(o), 1847A, and 1847B of the SSA as the source of definitions for average price. Under section 1847A, which governs most of the drugs at issue, CMS is to pay at "106 percent of ASP." The level of 106 percent of ASP is not a regulatory choice; it is specified in statute. By reducing the payment for these drugs by 27 percent—from 106 percent to 77.5 percent of ASP—CMS is exceeding the discretion Congress granted it in section 1833(t)(14)(A)(iii)(II), which specifically references payment at 106 percent of ASP.

Nor can CMS rely on the authority provided in section 1833(t)(14)(A)(iii)(II) to calculate and adjust the average price, to make such a significant cut. The adjustments

[5]Government Accountability Office. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. June 2015. https://www.gao.gov/assets/680/670676.pdf. Accessed August 29, 2017.
[6]Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. March 2016. http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf. Accessed August 29, 2017.
[7]Office of Inspector General. Part B Payments for 340B-Purchased Drugs. November 2015. https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf. Accessed August 29, 2017.

allowed by the statute under subparagraph (II) are meant to allow the agency to adjust for overhead costs in the form of an add-on percentage, as CMS itself noted in the calendar year (CY) 2013 Outpatient Prospective Payment System (OPPS) final rule.[8] Absent a specific directive from Congress allowing these types of adjustments, CMS' proposed reduction of Part B payments to 77.5 percent of ASP is inconsistent with its statutory authority.

Second, CMS inappropriately proposes to adjust rates by incorporating considerations of acquisition cost into a statutory methodology based on average price. In the preamble to the proposed rule, CMS offers the justification that the proposed payment change would more appropriately reflect the resources and acquisition costs of 340B hospitals. However, section 1833(t)(14)(A)(iii)(II) does not provide CMS the authority to base payments on cost considerations; CMS would have to use the average acquisition cost methodology under section 1833(t)(14)(A)(iii)(I) to do so. Congress provided explicit discretion for CMS to adjust rates based on acquisition costs under subparagraph (I). The notable absence of the same explicit discretion in subparagraph (II) means Congress did not intend to provide this authority when CMS relies upon the average price methodology.

CMS previously determined that it cannot appropriately make payments under subparagraph (I), because the agency does not have acquisition cost data on which to base payment to hospitals. After attempting to pay hospitals at acquisition cost and realizing the operational difficulties of doing so, CMS in CY 2013 instead began paying hospitals under the separate authority that bases payment on ASP (i.e., section 1833(t)(14)(A)(iii)(II)). Cost considerations no longer are a factor under this section. The agency determined that this statutory default methodology was the preferred approach that "requires no further adjustment" and "yields increased predictability in payment for separately payable drugs and biologicals under the OPPS."[9] Since CY 2013, CMS has determined that this is the most appropriate methodology for paying for separately payable drugs and has continued paying at this statutory default.

CMS incorrectly conflates the two sections of the statute by trying to account for acquisition cost when using a section that mandates payment based on average price. GAO in its June 2015 report also weighed in on this issue, emphasizing 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… ."[10]

Third, Congress already has determined that ASP as defined in statute (specifically under section 1847A of the SSA) should not reflect that certain drugs are purchased at 340B discounts. ASP, as defined under section 1847A, excludes prices paid for 340B

[8]77 Fed. Reg. 68210, 68386 (November 15, 2012).
[9]77 Fed. Reg. 68210, 68386 (November 15, 2012).
[10]Government Accountability Office. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. June 2015. https://www.gao.gov/assets/680/670676.pdf. Accessed August 29, 2017.

discounted drugs.[11] Because CMS does not have the authority to consider 340B drugs in calculating ASP plus 6 percent, it is unreasonable to conclude that CMS would have the authority to make an adjustment to the statutory default based on 340B discounts.

Even if CMS were permitted to adjust the ASP-based payment for acquisition cost under its statutory authority, its reliance on 340B pricing as the sole factor affecting acquisition cost is arbitrary and capricious. CMS notes in the proposed rule that drug acquisition costs "may vary among hospitals depending on a number of factors such as size, patient volume, labor market and case-mix."[12] Yet, CMS does not consider any of these factors in determining acquisition cost. Instead, CMS focuses solely on one factor—participation in the 340B program, which affects only a subset of hospitals—while not attempting to adjust for acquisition costs for other factors or non-340B hospitals. Moreover, CMS' proposed estimate for acquisition cost (77.5 percent of ASP) at 340B hospital relies on scant data and faulty analyses and fails to account for the complexities of drug purchases by 340B hospitals. For example, CMS failed to consider that not all separately-payable drugs purchased at 340B hospitals are purchased at the 340B discounted rate. Indeed, due to complexities of inventory management and 340B program rules, a substantial portion of hospitals' affected drugs are purchased at wholesale acquisition cost. It is arbitrary and capricious for CMS to propose an across-the-board payment reduction for one subset of hospitals based on such incomplete and factually inaccurate analyses.

b. CMS' proposal conflicts with another statute, the PHSA, and undermines Congress' intent in enacting the 340B program.

By substantially altering Medicare reimbursement for 340B hospitals, CMS is undermining the intent of section 340B of the PHSA. While the 340B program is not under CMS' purview, the Health and Human Services secretary has an obligation under principles of statutory interpretation to implement the Medicare statute in a way that does not conflict with or undermine another program and its statutory intent, to the extent possible.[13] CMS' existing OPPS policy aligns with this premise, demonstrating that it is possible to implement a reasonable interpretation of Medicare rate-setting authority that also is consistent with 340B program intent. Despite CMS' assertions, the proposed policy is inconsistent with and undermines the purposes of 340B.

In enacting the 340B program, Congress stated that it is "the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care."[14] Congress specifically designated the entities that should benefit from the program, defining eligible DSH hospitals as those serving a disproportionately greater percentage of low-income (Medicaid and Medicare Supplemental Security Income) patients. These hospitals are intended to be the recipients of discounted drugs and are expected to stretch the resources they receive,

[11]Specifically, the ASP definition excludes sales that are exempt from calculation of best price at Section 1927(c)(1)(C)(i)(I), an exemption that explicitly includes 340B discounted drugs.
[12]82 Fed. Reg. 33558, 33635 (July 20, 2017).
[13]See, e.g., Statutory Interpretation: General Principles and Recent Trends (December 19, 2011) at page 29.
[14] H.R. Rep. No. 102-384, pt. 2 (1992).

including Medicare reimbursement, to continue caring for low-income patients—among them, vulnerable Medicare patients.

By redirecting funds intended for 340B hospitals to other hospitals in the Medicare program, CMS' proposed policy violates the intent of the 340B program. Not only would CMS' proposal cut into the scarce resources of hospitals specified in statute, but CMS' budget neutrality adjustment would redistribute these funds to hospitals not participating in the 340B program. As CMS notes in the proposed rule, the $900 million in cuts to 340B hospitals would be reflected in increased payment to all OPPS hospitals for ambulatory payment classifications (APCs) not related to drugs. In essence, CMS is redirecting savings for 340B drugs to hospitals that do not participate in the program, for other OPPS services. Hospitals treating fewer low-income patients would benefit at the expense of essential hospitals. This is clearly not what Congress had intended when it envisioned the 340B program as allowing providers that fill a safety-net role to stretch scarce federal resources as far as possible to reach more eligible patients.

c. CMS has failed to analyze the impact of the proposal on hospitals and is not transparent in its methodology for calculating the aggregate Part B payment reduction.

Before proposing a policy of such magnitude, CMS should ensure that it has calculated the proposal's impact on hospitals and provided the necessary information to stakeholders to verify the accuracy of the agency's analysis. In the proposed rule, CMS includes very limited discussion of the impact of the 340B proposal on hospitals. CMS provides hospital-specific estimates of the impact of its proposed OPPS policies, as well as estimates of impact by hospital groups. Notably absent from these estimates is any consideration of the Part B payment reduction for 340B hospitals.[15] J**ust as CMS does for other policies in the OPPS, CMS should include an analysis of the effect its Part B drug payment reduction would have on hospitals, as well as specific groups of hospitals, such as DSH hospitals and 340B hospitals.**

CMS estimates the total payment Part B drug payment cut across all 340B hospitals to be $900 million, and says that it will re-distribute the $900 million payment cut to 340B hospitals in the form of a 1.4 percent conversion factor increase applied to non-drug APC payments. In its discussion, CMS repeatedly points to the lack of appropriate data to make an accurate estimate of the payment cut or the conversion factor increase. The agency stresses that "it is not possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting" budget neutrality adjustment, and that it will need to re-assess the conversion factor using newly available data in the future.[16] In our attempt to replicate CMS' estimate of the payment cut, we arrived at a significantly larger payment decrease for Part B drugs of $1.52 billion—over $600

[15]See 82 Fed. Reg. 33558, 33712 (July 20, 2017) ("We note that the proposed payment rates and estimated impacts included in this proposed rule do not reflect the effects of this proposal.").
[16]Ibid.

million larger than CMS' estimate of the payment decrease in the rule.[17] Given the lack of transparency in CMS' methodology, it is impossible to determine whether this substantial discrepancy is due to an error on the agency's part or the inclusion of assumptions in its analysis that are not discussed in the preamble to the rule. **It would be ill-advised for CMS to proceed with a proposal that would cut payments to 340B hospitals by up to $1.5 billion without the requisite understanding of how the proposal would affect individual hospitals' Medicare payments and their ability to operate.**

d. If finalized, CMS' proposal would be detrimental to essential hospitals and their patients, while providing minimal benefit to the Medicare program and its beneficiaries.

The 340B program has been critical to ensuring that low-income and other disadvantaged people have access to the types of services best provided by essential hospitals. Hospitals participating in the 340B program operate on margins significantly narrower than margins of other hospitals, with many operating at a loss. Looking specifically at Medicare outpatient margins, 340B hospitals operate on an aggregate negative 15 percent margin, compared to negative 10 percent at non-340B hospitals. Accounting for the reduced OPPS reimbursement resulting from the proposal, 340B hospitals' Medicare outpatient margins would drop even further, to negative 20 percent.[18] At the same time, as a result of the re-distributive nature of the policy, non-340B hospitals would likely see their Medicare outpatient margins increase. Given the fragile financial position of essential hospitals, policy changes that jeopardize any piece of the patchwork support on which they rely, including the 340B program, can threaten a hospital's ability to maintain critical services. CMS' proposal to cut payments on Medicare Part B drugs only for 340B hospitals, which already operate on substantially negative Medicare outpatient margins, would severely restrict essential hospitals' ability to serve their communities.

Essential hospitals provide lifesaving drugs and services through programs made possible by their 340B savings. To cite a few specific examples, essential hospitals have used 340B savings to:

- continue to provide care and medications to all patients, regardless of their insurance status or financial ability;
- provide lifesaving cancer and transplant drugs at no cost or with steep discounts to homeless patients and patients without insurance to ensure they are protected from drug price increases;
- establish clinical pharmacy programs, in which pharmacists interact with patients at bedside and in the emergency department, ensuring patients

[17]Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. August 2017. (see appendix for a more detailed discussion of the methodology used to replicate CMS' proposal).

[18]Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. August 2017. (See appendix for a more detailed discussion of the methodology used to calculate Medicare outpatient margins).

understand and adhere to their medication regimen. Through these programs, essential hospitals have reduced excess readmissions;
- provide meaningful access to patients, including low-income Medicare beneficiaries, through clinic location, hours of operation, transportation availability, interpretation services, and patient education that is not otherwise available in many places;
- support free clinics in their communities;
- reduce ED use through a medical home program providing primary care to uninsured, low-income patients; and
- provide mental health and substance abuse treatment.

The proposed Part B drug payment reduction would jeopardize these critical programs and undermine the financial stability of essential hospitals. Not only does the proposed rule threaten these innovative developments, but it also would raise overall health care costs by increasing avoidable admissions. As CMS endeavors to improve care, this is not the time to weaken core Medicare providers.

A reduction in Medicare payment rates to 340B hospitals would significantly erode the value of the 340B program. These proposals would be most damaging to essential hospitals, given their high levels of uncompensated care, narrow margins, and large proportion of patients with Medicare and Medicaid coverage. Some hospitals would be forced to reconsider programs made possible by 340B savings, and others might consider leaving the 340B program entirely. For essential hospitals in particular, there are significant administrative costs and compliance-related resources involved with 340B program participation, including the cost of hiring the appropriate staff, such as pharmacists and pharmacy technicians, to ensure compliance with the program's very technical and evolving requirements. In addition, 340B hospitals must invest in appropriate billing software and allocate resources to comply with the program and respond to audits. If CMS implements proposals that significantly gut the program's benefit on top of these added expenses, some hospitals might not be able to afford to participate moving forward. By leaving the program, they could purchase outpatient covered drugs through group purchasing organizations (something they are prohibited from doing as 340B participants)—much less of a benefit than 340B discounts, but also much less of a burden. The decision to drop out of the program would be a loss for patients and would undermine efforts to decrease Medicare costs.

If finalized, the proposed rule would have many negative consequences for patients, the Medicare program, and providers, while not saving the Medicare program any money. CMS would implement the proposal in a budget-neutral manner, cutting reimbursement to 340B hospitals by an estimated $900 million. The cut funding would not go back to the Medicare program or directly to beneficiaries; instead, CMS intends to update the OPPS conversion factor, resulting in an estimated 1.4 percent increase in OPPS payment rates for APCs unrelated to drugs. Therefore, in the aggregate, Medicare would not save any money through this proposed policy.

CMS also justifies its proposal by claiming that patients would benefit from reduced costs. America's Essential Hospitals recognizes and is concerned with the burden of even limited cost-sharing on low-income patients, but we question whether this

proposal would benefit individual patients. CMS proposes to implement this policy in a budget-neutral manner that would raise OPPS rates for other APCs, meaning that all beneficiaries would pay higher co-pays for other services. Moreover, most patients would not directly receive the benefit of this copayment reduction even if reduced payments for 340B drugs lower coinsurance amounts for these drugs.

Our analysis shows that nearly 30 percent of the approximately 11.5 million fee-for-service beneficiaries at 340B hospitals are dually eligible for Medicare and Medicaid.[19] This means Medicaid would cover copayments for more than 3 million beneficiaries who would not directly see the financial impact of this proposal. Further, an estimated 25 percent of beneficiaries at 340B hospitals have Medigap coverage for copayments, and thus would similarly not receive much direct benefit from the proposal.[20] In total, MedPAC has noted that 86 percent of Medicare beneficiaries are covered by some source of supplemental coverage, whether Medigap, Medicaid, or employer-sponsored supplemental coverage.[21,22] These supplemental coverage sources are likely to pay for at least part of beneficiaries' copayments, meaning most beneficiaries would hardly benefit from this proposal.

CMS estimates the proposed rule would save approximately $900 million savings, of which 20 percent, or $180 million, would be from reduced patient copays. But, as noted above, 86 percent of Medicare beneficiaries are estimated to have another source of coverage for copays. Therefore, only about 14 percent, or $25 million, of the total $180 million of the savings from lower copays would accrue to beneficiaries with no supplemental insurance coverage. In reality, roughly 1.6 million of the total estimated 57 million Medicare beneficiaries would realize annual savings of $15.56 each, with the remainder accruing to insurance companies and other payers that cover copayments. It is difficult to justify proposing changes to the 340B program to realize minimal savings for individual Medicare beneficiaries, while threatening the ability of 340B hospitals to provide care to the most vulnerable Medicare beneficiaries and other patients.

e. CMS' proposal would do little to alleviate the root causes of astronomically rising drug prices.

CMS cites rising drug costs as a reason for its proposal. Like CMS, America's Essential Hospitals is concerned about rising drug prices; essential hospitals, which are on the front lines of treating low-income patients, have firsthand experience with annual drug price increases. The rising cost of prescription drugs can have serious consequences for patient access and for the health care system at large, especially if patients are unable to afford the very drugs that are meant to keep them out of the hospital. To cite one recent

[19]Data from internal analysis conducted for America's Essential Hospitals by The Moran Company. January 2016.
[20]Ibid.
[21]Medicare Payment Advisory Commission. A Data Book: Health Care Spending and the Medicare Program. June 2017. http://medpac.gov/docs/default-source/data-book/jun17_databookentirereport_sec.pdf. Accessed August 16, 2017.
[22]Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care Delivery System. June 2015. http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf. Accessed August 16, 2017.

example, the price of two lifesaving heart drugs increased exponentially over a matter of just a few years. One of these drugs, which is used to treat high blood pressure, increased in price by 3,000 percent from 2012 to 2015.[23] Essential hospitals directly bear the consequences of such price increases, which put increasing strain on hospital budgets and operating margins.

When the federal government is the primary payer for these drugs through Medicare or Medicaid, these price increases result in increased federal spending. In 2016, the Medicaid program had to pay $3.2 billion more for brand-name drugs because of price increases on common drugs, such as Aleve.[24] The Medicare program continues to experience increased expenditures due to uncontrolled price increases by drug manufacturers, as detailed in an OIG report on Part D spending. The report found that Medicare paid $33 billion in catastrophic coverage payments under Part D in 2015, a threefold increase since 2010. This spending increase was driven by high-price drugs, with 10 drugs accounting for more than a third of Part D catastrophic coverage spending.[25]

While the evidence is clear that drug prices have risen from year to year, the agency has provided no evidence of how lowering reimbursement to 340B hospitals for separately-payable drugs under the OPPS would counter this trend. The 340B program actually saves money for providers, patients, and the federal government. It is a critical tool that insulates patients from rising drug prices and ensures their continued access to needed therapeutics.

A recent study showed that 340B discounts provided by manufacturers only make up 1.3 percent of net drug spending, a percentage so negligible that it is implausible to argue that the program is responsible for rising drug prices. Further, drug manufacturers provide other rebates and discounts, which are much larger in the aggregate than 340B discounts. Discounts through the 340B program represent only 3.6 percent of total drug rebates and discounts. In contrast, rebates manufacturers negotiate with health plan and pharmacy benefit managers accounted for 34 percent of all rebates and discounts.[26]

The sources CMS uses to link 340B and drug spending have serious methodological flaws. In fact, the Department of Health and Human Services (HHS) previously argued against some of these very conclusions. The GAO report on Part B spending at 340B

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[23]Tribble S J. 47 Hospitals Slashed Their Use Of 2 Key Heart Drugs After Huge Price Hikes. NPR "Shots." August 9, 2017. http://www.npr.org/sections/health-shots/2017/08/09/542485307/47-hospitals-slashed-their-use-of-two-key-heart-drugs-after-huge-price-hikes. Accessed August 29, 2017.

[24]Lupkin S. Climbing Cost Of Decades-Old Drugs Threatens To Break Medicaid Bank. *Kaiser Health News*. August 14, 2017. http://khn.org/news/climbing-cost-of-decades-old-drugs-threatens-to-break-medicaid-bank/. Accessed August 29, 2017.

[25]Office of Inspector General. High-Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage. January 2017. https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf. Accessed August 29, 2017.

[26]Dobson DaVanzo & Associates LLC. Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers. July 2017. http://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf. Accessed August 29, 2017.

hospitals fails to appropriately examine the connection between patient health status and spending at 340B hospitals. The report notes that average risk scores of beneficiaries at 340B hospitals were higher than risk scores at non-340B hospitals, but it failed to consider this distinction further, instead concluding that these differences "were likely not explained by the health status of the patients served."[27] In its response to the report, HHS stated that patient status could be causing differences in spending and concluded that further examination of differences in patient risk scores was required. GAO's analysis of patient status also excluded certain characteristics that influence the cost of care and patient outcomes, including sociodemographic factors, such as race and homelessness. Most important, HHS took issue with GAO's conclusions that Part B spending at 340B hospitals was "excess" and "potentially inappropriate," and said these claims are "not supported by the study methodology."[28] Given the lack of analysis proving CMS' proposal would lower drug prices, a proposal to slash payments to 340B hospitals is unsubstantiated and ill-advised.

f. CMS has not considered the practical difficulties and excess administrative burden associated with implementing the proposed 340B policy.

CMS fails to account for many of the complexities of the 340B program and the obstacles the agency and hospitals inevitably would face in implementing this proposal. CMS proposes to reduce OPPS payment to 77.5 percent of ASP for all nonvaccine drugs without pass-through status. However, hospitals do not purchase all Part B drugs in this category at 340B prices. Hospitals participating in the 340B program purchase a considerable percentage of their Part B drugs at list price, or wholesale acquisition cost. CMS' proposal could reduce reimbursement for these drugs as well, even though they were not purchased at the 340B price.

To identify 340B drugs, CMS proposes using a modifier that would be required beginning January 1, 2018. CMS provides no additional related details, so it is not possible for stakeholders to provide comprehensive comments on the feasibility of implementing such a modifier in their billing systems. One significant complexity of CMS' proposal is that it would require the modifier to indicate that drugs were *not* purchased at a 340B discount. Such a process would be the opposite of how Medicaid identifies 340B discounted drugs to avoid claiming a rebate and subjecting a drug to a duplicate discount. Medicaid currently identifies drugs that *were* purchased at a 340B discounts by either appending a modifier to 340B drug claims or using an exclusion file to identify and remove 340B pharmacy claims associated with entities providing 340B drugs to Medicaid patients, depending on the state. This difference between these processes likely would cause confusion for hospital billing staff. Furthermore, CMS' and states' experience with implementation in Medicaid should indicate the potentially immense complexity of the proposal. Given the lack of any details on the modifier, it is unrealistic for hospitals to be expected to update their billing systems and comply with the modifier in a matter of months.

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[27]Government Accountability Office. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. June 2015. https://www.gao.gov/assets/680/670676.pdf. Accessed August 29, 2017.
[28]Ibid.

CMS lacks legislative authority to implement such a substantial reduction in Part B drug payments, and the agency has failed to produce research connecting its proposal to lower drug prices. The proposed rule would have negative consequences for essential hospitals and their patients; therefore, **we strongly urge the agency to withdraw its proposal to reduce Part B drug payments to 340B hospitals.** We believe that preserving the intent of the 340B program would better serve low-income Medicare beneficiaries and the Medicare program at large.

2. CMS should implement Section 603 of the BBA consistent with the legislative text to minimize the adverse effect its policies would have on patient access.

As mandated by Section 603 of the BBA, CMS discontinued paying certain off-campus, provider-based departments (PBDs) under OPPS on January 1, 2017. The BBA instructs CMS to pay these PBDs under another Part B "applicable payment system" instead of the OPPS. In last year's OPPS rulemaking, CMS decided that non-excepted PBDs would be paid under the Medicare Physician Fee Schedule (PFS). The BBA defines which PBDs would be affected by the law and specifically exempts other types of PBDs from changes in reimbursement. Thus far, CMS has adopted an overly restrictive interpretation of Section 603 that goes beyond what Congress has intended in passing the BBA. **CMS should use its statutory authority to offer flexibility and reduce burden on providers, particularly regarding relocation, change of ownership, and expansion of services.**

The BBA's drastic cuts to Medicare payments for new, off-campus PBDs have begun to impede the ability of essential hospitals to provide outpatient services and expand access into underserved communities. CMS' interpretation of the BBA in the CY 2017 OPPS final rule unnecessarily restricted the law's scope. In the CY 2018 PFS proposed rule, CMS would reduce payment rates to non-excepted PBDs by an additional 50 percent. For hospitals operating on narrow (often negative) margins, these cuts are unsustainable. Paying hospital PBDs at 25 percent of what is normally paid under the OPPS inevitably would affect patient access in areas where there is most need for these services. **We strongly oppose this arbitrary payment reduction and provide further comment in our separate letter on the CY 2018 PFS proposed rule.**

Given essential hospitals' expansive networks of ambulatory care in otherwise underserved communities, the BBA will continue to have a pronounced negative effect on patients of essential hospitals. Essential hospitals are the only providers willing to take on the financial risk of providing comprehensive care to low-income patients, including the uninsured and dually eligible beneficiaries. Such clinics enable hospitals to expand access for disadvantaged patients in communities with no other options for both basic and complex health care needs. Essential hospital PBDs often are the only clinics in low-income communities that provide the full range of primary and specialty services. The patients seeking care at off-campus PBDs of essential hospitals tend to be lower income and racial and ethnic minorities, and they are more likely to be uninsured. Excessively burdensome and restrictive policies on PBDs of essential hospitals undoubtedly will have downstream effects, including on patient access.

In drafting the BBA, Congress left many specifics of Section 603 implementation for CMS to clarify through the rulemaking process. But in its interpretation in previous rulemaking, the agency unnecessarily expanded the law's scope, compounding the harm to essential hospitals and the disadvantaged patients they serve. **We urge CMS to exercise its statutory authority to implement the BBA in way that mitigates negative consequences to patient access by adopting the following recommendations.**

a. CMS should continue to allow excepted off-campus PBDs to retain their excepted status, even if they expand services.

In the proposed rule, CMS states that it will not cap service-line expansion in excepted PBDs based on volume or types of services provided. We are pleased that CMS will continue this policy, which will allow essential hospitals to adapt and respond to the changing needs of their communities by adding or changing the types of services they provide.

CMS notes that it will continue to monitor service-line expansion using the claims-based modifiers for services provided in off-campus PBDs to determine if it should address the issue of expansion in future rulemaking. While the need to monitor service line growth is understandable, CMS should apply policies that are consistent with the statutory text of Section 603. Section 603, titled "Treatment of Off-Campus Outpatient Departments of a Provider," clearly states that "the term 'off-campus outpatient department of a provider' shall not include a department of a provider (as so defined) that was billing" for outpatient department services furnished pre-enactment.[29] In other words, a PBD that was billing for services before the date of enactment is completely carved out of the definition of "off-campus outpatient department of a provider." Section 603 only reduces reimbursement to applicable items and services provided at "off-campus outpatient departments of a provider," and by carving out existing PBDs from the definition, the BBA is clear that these PBDs and the services they provide are unaffected by its provisions. Additionally, there is no language in the BBA that suggests these PBDs are excepted for only those services provided before enactment. Even the provider-based rules do not limit the scope of services that can be provided by a PBD. In fact, in rulemaking on the provider-based requirements, CMS previously noted that "the provider-based rules do not apply to specific services; rather, these rules apply to facilities as a whole."[30] **Therefore, we urge CMS to act consistently with the statutory text by continuing to allow excepted PBDs to expand services to meet the changing needs of their communities.**

b. CMS should allow PBDs to retain their excepted status notwithstanding relocation.

CMS should allow PBDs to retain their excepted status, even if they relocate, if they continue to meet the provider-based requirements. In the CY 2017 OPPS final rule, CMS creates a limited extraordinary circumstances exception that allows a PBD to

[29]Section 603 of Bipartisan Budget Act of 2015. Pub. L. 114-74, codified as Social Security Act §1833(t)(21)(B)(ii).
[30]67 Fed. Reg. 49982, 50088 (August 1, 2002).

temporarily or permanently relocate without forfeiting excepted status. However, the exceptions process only covers a few scenarios and does not envision the many reasons for which a PBD might need to relocate. The BBA neither contemplated nor required that PBDs would lose their excepted status if they relocated.

There are many external forces that could compel a hospital to relocate a clinic. For instance, when a provider's lease for a PBD expires, it might find the renewal terms unsustainable. As landlords realize that CMS policy effectively makes a PBD a captive audience, they are likely to raise the rent. While any reasonable business facing such unfavorable economic conditions would consider relocation as a response, a PBD might simply close, given the lack of a financially viable alternative under the proposed relocation policy. Other reasons for relocation beyond a provider's control could include a building being closed for reconstruction or demolition, local zoning changes or ordinances, or other state and local laws. CMS' limitation on relocation is guided by the agency's belief that hospitals are motivated only by financial considerations. As these examples show, there are many reasons a provider might have to relocate that fall outside the agency's narrow exception.

There is precedent for allowing the relocation of provider-based facilities, such as in the context of critical access hospitals (CAHs) and their associated off-campus PBDs that were grandfathered as "necessary providers," a designation that allows a CAH to circumvent certain geographical requirements. While the Medicare Modernization Act of 2003 eliminated this designation, CAHs with necessary provider designation were grandfathered if they existed before January 1, 2006. CMS indicated in rulemaking that grandfathered CAHs and their PBDs with necessary provider designation may relocate without losing their status. As noted in the preamble to the CY 2008 OPPS final rule, in response to a question on relocation of PBDs of grandfathered CAHs, CMS "believe[s] it would be reasonable for a CAH to be able to move its facility." Thus, CMS would be consistent in also allowing PBDs of acute-care hospitals to relocate and maintain their excepted status under Section 603. **For these reasons, CMS should lift the burdensome limitation on relocation and clarify that a hospital can relocate a PBD that is excepted if it continues to meet the provider-based requirements.**

c. <u>CMS should permit non-excepted PBDs to retain their excepted status if they change ownership.</u>

In the CY 2017 OPPS final rule, CMS finalized a policy that allows a PBD to maintain excepted status only if the main provider that owns the PBD changes ownership and the new main provider accepts the existing Medicare provider agreement. In scenarios in which the main provider does not change ownership but an individual PBD does, CMS states that the PBD would lose its excepted status. **We recommend that CMS extend the policy on changes of ownership to circumstances in which an individual PBD changes ownership.** It is not uncommon for provider-based facilities to change hands over time for various reasons. For example, a hospital that finds it unsustainable to continue operating an off-campus PBD for financial or other reasons might decide to sell that particular PBD. But if the loss of excepted status makes the PBD unattractive to potential buyers, the hospital might close it. In such a case, patients in the community would lose access to essential outpatient services. Because these excepted PBDs that

change ownership already operated before the date of enactment and would not be newly created, they should remain excepted.

3. CMS should continue to refine the OQR Program measure set so it contains only reliable and valid measures that accurately represent care quality in the outpatient setting, account for social risk factors, and do not add administrative burden.

CMS should continue to tailor the OQR Program measure set to include measures that are useful to hospitals as they work to improve the quality of their care and beneficial to the public as an accurate reflection of the care hospitals provide. America's Essential Hospitals supports the creation and use of measures that lead to quality improvement. We encourage CMS to verify the measures would not lead to unintended consequences before including them in the OQR Program.

CMS is not proposing any additions to the CYs 2018 and 2019 OQR Program measure sets. For CYs 2020 and 2021, CMS proposes to remove a total of six measures and delay the five survey-based measures derived from the Outpatient Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey. We ask CMS to consider the following comments as it continues to refine the OQR Program to ensure measures are reliable, valid, and useful in improving the quality of hospital care and the transparency of public reporting.

a. CMS should account for sociodemographic factors, including socioeconomic status, by risk adjusting the measures used in the OQR Program.

America's Essential Hospitals supports the creation and implementation of measures that lead to quality improvement. We are pleased CMS is seeking comment on how to account for social risk factors—such as socioeconomic status, employment, community resources, and social support—in quality reporting in the outpatient setting. Before including measures in the OQR Program, CMS must verify they are properly constructed and would not lead to unintended consequences. As quality reporting programs move toward outcome-based measures and away from process measures, CMS must ensure measures chosen for these programs accurately reflect quality of care and account for factors beyond the control of a hospital. The agency should ensure the measure set includes metrics that are valid and reliable, aligned with other existing measures, and risk adjusted for sociodemographic factors. CMS should not include measures in outpatient quality performance standards until those measures have been appropriately risk adjusted for sociodemographic factors, including socioeconomic status.

In previous comments on hospital inpatient quality reporting programs, we urged CMS to consider the sociodemographic factors—language and existing level of post-discharge support, for example—that might affect patients' outcomes and include such factors in the risk-adjustment methodology. We made these comments out of a preponderance of

evidence that patients' sociodemographic status affects outcomes of care.[31] Outcome measures, especially those focused on readmissions, do not accurately reflect quality of care if they do not account for sociodemographic factors that can complicate outcomes. For example, patients who do not have a reliable support structure are more likely to be readmitted to a hospital or other institutional setting. Reducing preventable readmissions is of paramount concern to America's Essential Hospitals and its members. We believe that any program directed at reducing readmissions and improving beneficiaries' health through an episode of care must target readmissions that are preventable and include appropriate risk-adjustment methodology.

Essential hospitals support quality and accountability. What they want, and what their patients and communities deserve, is an equal footing with other hospitals for quality evaluation. When calculating quality measures, Medicare programs should account for the socioeconomic and sociodemographic complexities of disadvantaged populations to ensure hospitals are assessed on the care they provide, rather than on the patients they serve. Differences in patients' backgrounds might affect complication rates and other outcome measures; ignoring these differences would skew quality scores against hospitals that provide essential care to the most complex patients, including those with sociodemographic challenges and the uninsured.

As required by the Improving Medicare Post-Acute Care Transformation Act, HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) in December 2016 released a report in which the connection between social risk factors and health care outcomes was clearly shown.[32] The report provides evidence-based confirmation of what essential hospitals and other providers have long known: Patients' sociodemographic and other social risk factors matter greatly when assessing the quality of health care providers. We urge CMS to further examine the recommendations found in the ASPE report for future incorporation in the OQR Program.

As noted by the National Academies of Sciences, Engineering, and Medicine (the Academies), in its series of reports on accounting for social risk factors in Medicare programs, "achieving good outcomes (or improving outcomes over time) may be more difficult for providers caring for patients with social risk factors precisely because the influence of some social risk factors on health care outcomes is beyond provider control."[33] We urge CMS to closely examine the considerations provided by the Academies for risk adjustment in federal programs.

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[31]See, e.g., America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. October 21, 2015. http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/. Accessed August 2017.

[32]Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Washington, D.C.; December 2016. https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf. Accessed April 7, 2017.

[33]National Academies of Sciences, Engineering, and Medicine. *Accounting for Social Risk Factors in Medicare Payment*. Washington, DC: The National Academies Press; January 2017. http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx. Accessed April 7, 2017.

Like the growing body of research on socioeconomic risk adjustment, the Academies found that community-level elements that providers are unable to change can indicate risk unrelated to quality of care.[34] We urge CMS to examine these criteria, as identified by the Academies, for choosing the risk factors for an adjustment methodology:

- conceptual relationship with the outcome of interest;
- empirical association with the outcome of interest;
- risk factor presence at the start of care;
- risk factor modifiability through the provider's actions; and
- risk factor resistance to manipulation or gaming.

We urge CMS to examine the Academies' report for examples of currently available data to include in measure risk adjustment in the OQR Program. The agency also should develop analytic methods for integrating patient data with information about contextual factors that influence health outcomes at the community or population level. Identifying which social risk factors might drive outcomes and determining how to best measure and incorporate those factors into payment systems is a complex task, but doing so is necessary to ensure better outcomes, healthier populations, lower costs, and transparency. We look forward to working with CMS to account for social risk factors and reducing health disparities across Medicare programs, including the OQR Program.

b. CMS should delay implementation of the OP-37-a-e: OAS CAHPS survey measures for the OQR Program.

In previous rulemaking, CMS finalized the adoption of five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination to assist in collection of information about patients' experiences of care in hospital outpatient departments and ambulatory surgery centers. The survey initially was implemented as a voluntary national reporting program in January 2016; it will conclude in December 2017. The survey covers access to care, communications, experience at a facility, and other topics. As set forth in the CY 2017 OPPS final rule, hospitals would be required to begin collecting data for these measures on January 1, 2018. **We support CMS' proposal to delay implementation the OAS CAHPS survey measures beginning with the CY 2020 payment determination—i.e., CY 2018 reporting.**

In prior comments to CMS, we voiced concerns about factors that influence survey administration and that might create undue hardships for essential hospitals, including additional resources needed to effectively communicate with people who have limited English proficiency. A growing body of evidence demonstrates that language concordance between patients and caregivers increases patient satisfaction, patient-reported health status, and adherence with medication and follow-up visits.[35] Vulnerable patients treated by essential hospitals might have difficulty completing

[34]America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. April 18, 2016. http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/. Accessed May 2017.
[35]Manson A. Language Concordance as a Determinant of Patient Compliance and Emergency Room Use in Patients with Asthma. *Med Care.* 1988;26(12):1119–28.

surveys due to language barriers and low health literacy, and they will require additional support and outreach from facilities administering the survey. **We urge CMS to closely examine the necessity and utility of the proposed OAS CAHPS measures and adjust for all factors that could influence how patients respond to the survey, but that are beyond the control of the hospital and not directly related to hospital performance.**

America's Essential Hospitals supports efforts to better understand patients' experiences in the outpatient setting. However, we continue to believe further development of the OAS CAHPS survey is necessary. We encourage CMS to continue refining the OAS CAHPS survey, with input from stakeholders, to ensure the information collected accurately reflects patient experience in a meaningful way. For these reasons, **we urge CMS to finalize its proposed delay of the OAS CAHPS survey measures implementation date to allow further measure development.**

c. CMS should promptly remove topped-out measures from the OQR Program to ensure quality of care and patient safety, and to reduce administrative burden.

CMS proposes to remove certain measures for the CYs 2020 and 2021 payment determination for the OQR Program. Measures are considered topped out when measure data show: statistically indistinguishable performance levels at the 75th and 90th percentiles; and a truncated coefficient of variation less than 0.10. We urge CMS to remove measures promptly, when topped out, to avoid further reporting and its associated burden by essential hospitals.

CMS proposes to remove these measures from the CY 2020 OQR Program:

- OP-21: Median Time to Pain Management for Long Bone Fracture; and
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures.

For CY 2021, CMS proposes removal of these measures:

- OP-1: Median Time to Fibrinolysis;
- OP-4: Aspirin at Arrival;
- OP-20: Door to Diagnostic CMS-1678-P 45 Evaluation by a Qualified Medical Professional; and
- OP-25: Safe Surgery Checklist Use.

CMS proposes to remove these measures from the OQR Program for various reasons, including: potential misinterpretation of the intent of the measure, performance or improvement on the measure does not result in better patient outcomes, a measure exists that is more strongly associated with a desired patient outcome, or the measure is considered topped out.

CMS considers two measures to be topped out and proposes their removal in CY 2021: OP-4 Aspirin at Arrival and OP-25 Safe Surgery Checklist Use. America's Essential Hospitals appreciates any efforts by CMS to reduce the reporting burden on hospitals. By removing measures that no longer show improvements in quality, CMS will enable hospitals to use their limited resources for quality improvement as opposed to administrative reporting activities. CMS notes that removing such measures would

"alleviate the maintenance costs and administrative burden to hospitals associated with retaining them." That being the case, we seek clarification regarding the agency's delay in removal of these two topped-out measures until CY 2021. **We urge CMS to finalize its proposed removal of measures, and to immediately remove topped-out measures.**

4. **CMS should mitigate concerns about the effect of removing TKA procedures from the IPO list on Medicare payment models.**

Procedures found on the IPO list usually are performed only in the inpatient setting and are reimbursed at inpatient rates, not under the OPPS. Each year, CMS reviews this IPO list for procedures that should be removed because they can be provided in the outpatient setting. Based on developments and innovations in TKA technique and patient care, which allow the procedure to be performed on an outpatient basis, CMS proposes to remove TKA from the IPO list for CY 2018.

We have concerns about the effect the proposed removal of TKA would have on Medicare payment models. The TKA procedure is included in two episode-based payment models—Comprehensive Care for Joint Replacement (CJR) and Bundled Payment for Care Initiative (BPCI). In these models, services are paid on a fee-for-service basis with retrospective reconciliation against target prices based on historical costs associated with the procedure, for a defined period. Being that the TKA procedure has been on the IPO list, CMS does not have claims history for beneficiaries receiving TKA on an outpatient basis. If CMS were to remove TKA from the IPO list, some patients who previously would have received a TKA procedure in an inpatient setting could receive the procedure on an outpatient basis. Therefore, establishing an accurate target price based on historical data becomes more complicated within the CJR and BPCI models. Further, the historical episode spending data might no longer be an accurate predictor of episode spending for beneficiaries receiving inpatient TKA procedures.

Modifications to current Medicare payment models would be required if the TKA procedure is removed from the IPO list. This would lead to confusion among hospitals and CMS, as well as issues of accuracy and fairness in setting target prices.

Additionally, there are differences in patient population for which the TKA procedure is performed on an outpatient basis—i.e., they are younger, more active, have fewer complications, and have more support at home than most Medicare beneficiaries. Further, many Medicare patients have comorbidities and would require intensive rehabilitation after a TKA procedure, making it best performed in an inpatient setting. As such, TKA procedures performed on an outpatient basis might only be appropriate for a small number of Medicare beneficiaries. CMS would need to identify a methodology for payment model participants that appropriately adjusts target prices for inpatient procedures to reflect the shift of less complex procedures to the outpatient setting. Before removing this procedure from the IPO list, **we urge CMS to further study the differences in performing it in both settings to ensure patient safety for all Medicare beneficiaries, as well as fairness among participants in episode-based payment models.**

5. CMS should ensure its C-APC policy does not disproportionately impact hospitals treating more diverse and clinically complex patients.

For the first time since instituting its policy of packaging payment for services into C-APCs, CMS is not proposing to add any new C-APCs for CY 2018. Under the C-APC payment policy, CMS packages payment for the primary procedure with other services that appear on the claim and were provided in association with the primary procedure. CMS pays for these adjunctive services and the primary procedure using a single C-APC payment, instead of paying hospitals separately for the primary procedure and related services and supplies. Adjunctive services include diagnostic procedures, laboratory tests, imaging services, and visits and evaluations provided in conjunction with the primary service. Payments that typically are not made under the OPPS but under a separate fee schedule, including payment for durable medical equipment, also are paid under the OPPS as part of C-APC payment.

We appreciate CMS' decision to not add new C-APCs, but we continue to urge the agency to revise its complexity adjustment methodology to account for the higher costs essential hospitals incur when performing complex procedures and treating sicker patients. To calculate the relative payment weight for the C-APC, CMS uses the geometric mean of the estimated costs on all claims for the primary procedures and all adjunctive services. Thus, a hospital receives a single global payment based on average costs across all hospitals, regardless of the cost of the primary procedure at the particular hospital, the intensity of the services provided, how sick and medically complicated the patient receiving treatment is, or the number and cost of adjunctive services actually provided in conjunction with the primary procedure.

Such a policy adversely affects essential hospitals. Certain types of tests or diagnostic procedures might be performed more often at essential hospitals, most of which are academic medical centers providing high-acuity care and treating sicker patients. The C-APC policy puts essential hospitals at a disadvantage due to the greater resources needed to provide high-acuity care to clinically complex patients.

CMS uses a complexity adjustment under the C-APC policy that only accounts for identified instances of high-cost combinations of primary procedures. It does not account for patient characteristics. For example, to account for complex cases in which more than one primary procedure with a J1 status indicator appears on a claim, CMS applies a complexity adjustment and pays the hospital the next-highest C-APC amount in the clinical family. [36] While this type of complexity adjustment would account for certain higher-cost cases, it does not consider patient characteristics, such as comorbidities and sociodemographic factors, that require more resources for treatment.

Given essential hospitals' low margins, they must find innovative and efficient ways to provide high-quality care. But essential hospitals' diverse mix of patients, in terms of clinical complexity and sociodemographic factors, complicates care and requires intense

[36]The J1 status indicator identifies a primary service that triggers a C-APC payment and results in other services on the claim being packaged into the C-APC payment.

resources. **Therefore, CMS should account for these factors by adjusting for patient complexity in the C-APC methodology.**

In addition to adjusting for patient complexity, CMS should revise its complexity adjustment methodology that more accurately reimburse hospitals for performing certain costly procedures. **First, CMS should identify additional procedure combinations that could qualify for a complexity adjustment, including procedures with status indicators S or T that are performed in conjunction with a primary procedure.** Procedures with S or T status indicators are major procedures, such as costly surgical procedures, that normally are paid for separately. However, under the C-APC methodology, payment for these services is packaged into the C-APC when they appear on a claim with a J1 primary procedure. CMS evaluates claims with combinations of J1 or J2 procedures or add-on codes with status indicator N to determine if the combination of procedures is substantially costlier than the other services in the C-APC. [37] **We urge the agency to evaluate other types of procedures for complexity adjustments—a practice it does not currently do—to avoid potentially underpaying hospitals for the cost of performing resource-intensive procedures in conjunction with the primary procedure on the claim.**

CMS should also move a C-APC to the next-highest C-APC in the clinical family when there is a violation of the two-times rule in the receiving C-APC. Under current policy, when a combination of services on a claim meets the criteria for a complexity adjustment, it is paid at the rate for the next-highest C-APC (the "receiving C-APC") in the clinical family. A procedure violates the two-times rule when its cost is more than twice that of the lowest-cost procedure in the C-APC. **We urge CMS to move the C-APC to the next-highest level—that is, two levels higher than the originating C-APC—when there is a violation of the two-times rule in the receiving C-APC.** Because the costs of the procedure combination are significantly higher than other procedures in the C-APC, CMS should move the C-APC one level higher to ensure adequate reimbursement for the cost of furnishing all the services in question. By adopting these recommendations, CMS would ensure that hospitals have sufficient resources to continue providing cutting-edge services to complex conditions.

6. Before considering any payment changes, CMS should work with providers to better understand the difference between services performed in the inpatient and outpatient settings.

In the proposed rule, CMS refers to differing payment rates across the inpatient and outpatient settings and seeks comment on ways to "identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings."[38] **America's Essential Hospitals urges CMS to work with providers to understand the reasons for performing a service in an inpatient setting, rather than outpatient.** Implementing policies that seek to minimize the payment differential

[37]Status indicator N denotes services that are packaged and therefore do not have a separate APC payment amount.
[38]82 Fed. Reg. 33558, 33704 (July 20, 2017).

or equalize the payment rate would fail to account for the many case-specific reasons a hospital might need to admit a patient.

CMS attempted to resolve the issue of short inpatient stays and excessively long outpatient stays through its two-midnight policy, but ultimately provided additional flexibility and exceptions that would defer to the clinician's judgment on the most appropriate care setting. In deciding whether to treat a patient in the inpatient or outpatient setting, a provider accounts for the patient's specific needs and comorbidities. Any policies that undermine clinician judgment run counter to CMS' stated goals of moving toward patient-centered care and "ensur[ing] that patients and their providers and physicians are making the best health care choices possible."[39] **Therefore, we recommend that CMS defer to clinicians' judgment and the individual needs of the patient in making any future policy recommendations on inpatient and outpatient payment policy.**

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO

[39]Ibid.

APPENDIX: Dobson DaVanzo & Associates, LLC - OPPS Analysis Methodology

Dobson | DaVanzo

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This document summarizes the methodology used in analyzing the proposed reduction in payment for 340B drugs that Dobson | DaVanzo completed for America's Essential Hospitals (AEH) for the 2018 Hospital Outpatient Prospective Payment System (OPPS) Notice of Proposed Rulemaking (NPRM).

Methodology for the 340B Drug Analysis

The 340B Drug Pricing Program, administered by the Health Resources and Services Administration (HRSA), requires drug manufacturers to provide outpatient drugs to eligible health care organizations or covered entities at reduced prices. To participate in the 340B Program, eligible organizations or covered entities must register and be enrolled with the 340B program and must comply with all 340B program requirements.

When Congress first enacted the 340B program in 1992, it targeted disproportionate share (DSH) hospitals that provide high levels of care to Medicaid and low-income Medicare beneficiaries. Hospitals that treat high levels of low-income beneficiaries have often been referred to as "safety net" hospitals. The 340B program was established to provide "safety net" hospitals an avenue for purchasing outpatient drugs at a lower cost. Congress intended for the savings from these discounted prices to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services." This suggests that congressional intent was for resources to be targeted toward specific hospitals and toward low-income patient populations.

Drugs included in the 340B program generally comprise prescription drugs administered by physicians in an outpatient setting, excluding vaccines. Specific 340B prices are determined by statutory formulas based on manufacturers' rates. Because Medicare reimbursement rates are similar across all providers, the dollar difference between discounted drug costs to the provider and Medicare payment to 340B covered entities allows for hospitals to provide services not otherwise paid for by their low-income patients using this source of income.

The purpose of this 340B analysis for America's Essential Hospitals was to model the cash flow impact of the proposal made by CMS to reduce Medicare payment to 340B hospitals for Part B drugs purchased under the 340B Drug Discount Program. This analysis required modeling the reduction in payment for Part B drugs to 340B hospitals by 22.5 percent of ASP, and comparing this to current Medicare payment for outpatient drugs for each hospital and in aggregate. Furthermore, CMS projected that reducing the payment for Part B drugs to 340B hospitals would increase non-drug OPPS payment rates by 1.4 percent, but it did

not include impacts of these increases into the NPRM. This analysis also considered how the increase in the conversion factor will affect payment for other OPPS services.

Step 1: Identify 340B Hospitals

To model this reduction in payment for Part B drugs purchased under the 340B Drug Discount Program, we first identified 340B hospitals. Two criteria were applied to identify 340B hospitals: (1) active participation in the 340B program, based on a current (August 2017) update of the HRSA Office of Pharmacy Affairs (OPA) Drug Pricing Program Database; and (2) inclusion in the OPPS NPRM Impact File for CY 2018. We note that this methodology for identifying 340B hospitals is different than that used by CMS in the NPRM; however, this is a method that we have used successfully in the past, and we feel is appropriate here. CMS has assumed that every governmental-owned, cancer, and children's hospital, as well as those hospitals with a DSH percentage greater than 11.75 percent, sole community hospitals with a DSH percentage greater than 8 percent, and rural referral centers with a DSH percentage greater than 8 percent, all participated in the 340B program. However, we note that participation is voluntary and therefore included just those hospitals that are currently participating in the 340B program.

Step 2: Create Working Dataset

Once the 340B DSH hospitals were identified, a beneficiary-level working claims database was developed using the CY 2018 OPPS NPRM data file, which contains line-level claims for CY 2016. This is the dataset that CMS used in its analysis for the NPRM. Using this beneficiary-level database, we extracted all beneficiary claims for care paid under OPPS. Table 1 provides a list of the status indicators that were present in the 2018 NPRM data and identifies which were eligible to be paid under OPPS. Status indicators were determined by crossing the HCPCS on the line-level claim with the Hospital Outpatient Prospective Payment System Proposed Rule Addendum D1. All claims with these status indicators indicating that the service was eligible for payment under OPPS were retained. The subset of claims for separately billable Part B drugs from 340B hospitals was identified from here.

Table 1. Status Indicators Present in 2016 OPPS NPRM Data

Not Paid Under OPPS	Paid Under OPPS
A	G
B	J1
C	J2
E	K
E1	N
E2	P
F	R
L	S
M	T
Y	U
	V

Separately billable Part B drugs were defined as Part B drugs with a status indicator of "G" (pass-through drugs and biologicals) and "K" (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals, brachytherapy, and blood and blood products). We assumed that all drugs with these status indicators were purchased through the 340B Program at the identified 340B hospitals. (We recognize that some hospitals may elect to carve-out drugs for their Medicaid patients, in which case drugs for dual-eligible beneficiaries may not be purchased under the 340B program. Given the limitations of our data, however, it was not possible to model this scenario.)

We only considered those drugs paid using the ASP methodology and with status indicator "K" to be affected by the proposed reduced payments under the NPRM. Drugs paid under the ASP methodology were identified using the April 2017 ASP Drug Pricing List from CMS. Additional adjustments were made to further exclude any vaccine or immunization from the universe of drugs affected by the proposal, as these products cannot be purchased at a discounted rate by 340B hospitals.

For each of the separately billable Part B drugs included in this analysis, total payments (including Medicare reimbursement and beneficiary responsibility) were obtained using the payment amount located in the NPRM data file. Using the patient-level linked claims database, the payments were summed across patients within each 340B hospital to obtain the total payment amount to that hospital for 2016. The aggregate amount these payments by hospital represents the total amount of money that a hospital received for separately billable Part B drugs in 2016.

Step 3: Calculate hospital-specific financial impact

To model the financial impact of the proposal made by CMS, it was necessary to model a reduction in payment by 22.5 percent of ASP for affected drugs. We made the following assumptions to calculate this payment reduction:

(1) Total payment consists of 80 percent Medicare reimbursement and 20 percent beneficiary responsibility

(2) Reimbursement rates were ASP plus six percent in 2016

(3) The Medicare reimbursement subjected to a 2 percent reduction due to sequestration.

Following these assumptions, reimbursement rates were reduced to ASP and further reduced by 22.5 percent for these drugs. Thus, used the following formula to model the reduction, which includes the additional 2 percent reduction from the Medicare reimbursement:

$$Reduced\ payment = 0.775 * \frac{Current\ Payment}{(0.8 * 0.98 * 1.06) + (0.2 * 1.06)}$$

The difference in total payment and proposed payment methodologies for affected drugs represents the loss in revenue that the hospital will face under the proposed payment reduction.

CMS notes in the NPRM that reducing payment for 340B drugs to ASP minus 22.5 percent would increase non-drug OPPS payment rates by approximately 1.4 percent in CY 2018. We attempted to replicate this number by calculating the total dollar amount of the reduction in reimbursement for eligible separately payable Part B drugs, divided by the total Medicare Part B non-drug OPPS revenue. That is:

$$Payment\ Rate\ Percent\ Change = \frac{340B\ Payment\ Cut}{Medicare\ Part\ B\ Non\ Drug\ OPPS\ Revenue} \times 100$$

In addition, we looked at the results of this analysis in various contexts for each hospital, including:

1. The total dollar amount of the reduction in reimbursement for separately payable Part B drugs, for each 340B hospital individually and in aggregate for all 340B hospitals, and all AEH member hospitals. We also modeled the difference in OPPS payments for non-drug services as currently paid and after accounting for increased payments due to the budget neutrality requirement.

2. The total hospital separately payable Part B drug payment as a percent of current total hospital Medicare Part B OPPS revenue. This was done using the current (2016) drug payment, as well as the modeled (reduced) drug payment under the NPRM methodology. Total hospital Medicare Part B OPPS revenue was obtained by summing the payments for all eligible claims from the 2016 NPRM data.

3. The total dollar amount of the reduction in reimbursement as a percentage of total hospital Medicare Part B OPPS revenue.

4. The total payment for affected separately payable Part B drugs (i.e., excluding vaccines and pass-through drugs) as a percentage of the total payment for all separately payable Part B drugs (including vaccines and pass-through drugs).

5. The total dollar amount of the reduction in reimbursement as a percentage of the current (2016) separately payable Medicare Part B outpatient drug payment (including vaccines and pass-through drugs).

In addition to examining the proposal on a hospital level, we aggregated the results by hospital type to determine the differential effects of CMS' proposal on different types of hospitals.

Step 4. Compare Medicare Outpatient Margins Before and After 340B Cut for Hospitals

After calculating the magnitude of the proposed 340B drug payment reduction on 340B and AEH member hospitals, we used this information to calculate Medicare Part B OPPS margins. Margins were calculated two ways: (1) without adjusting for the proposed reduction in 340B drug payments; and (2) adjusting for the proposed reduction in 340B drug payments and corresponding increase in non-drug payments.

We calculated the unadjusted Medicare Part B OPPS margin using data from the FY 2015 MCR, as follows:

$$Medicare\ Part\ B\ OPPS\ Margin = \frac{Medicare\ Part\ B\ OPPS\ Revenue - Medicare\ Part\ B\ OPPS Costs}{Medicare\ Part\ B\ OPPS Revenue}$$

Medicare Part B revenue and costs were obtained from the FY 2015 Medicare cost reports (July 2017 HCRIS update) using Worksheet E, Part B. Revenue was calculated using Lines 24, 34, 35 and 40.01 for the hospital and all subproviders (Revenue = Line 24 + Line 35 – Line 34 – Line 40.01), while costs were obtained from Line 2 for the hospital and all subproviders.

To calculate the adjusted Medicare outpatient margin, i.e., to account for the proposed reduction in 340B drug payments, we subtracted the amount of the revenue loss, resulting from the Part B drug payment reduction for each hospital as calculated in Task 7, from the hospital's Medicare Part B outpatient revenue. We then added in the net increase resulting from higher non-drug reimbursement rates. This was done separately for two non-drug increase percentages: 1.4 percent, as estimated by CMS in the NPRM, and 3.6 percent, as estimated by Dobson | DaVanzo as part of this analysis. The margin was then recalculated as described above.

In addition to calculating margins at the hospital level, we produced aggregate margins for each different types of hospitals. Margins for hospital groups were case-weighted; that is, an overall group margin will be calculated by summing the revenues and costs over the entire group of hospitals and using these group sums in the overall margin calculation.

Step 6. Create Summary Tables

A set of summary tables was created in Excel for AEH, providing the results of our analysis. Estimates of the impact of the reduction in payment and associated statistics provided by CMS, both in the NPRM and the associated 2018 OPPS NPRM impact file, are presented in Table 1 below.

Table 1. CMS Estimates

Line	CMS Estimates	
1	2018 340B Drug Payment Decrease (NPRM)	$900,000,000
2	2018 Non-Drug Payment Increase (NPRM)	1.40%
3	2018 Non-Drug Payment Total for OPPS Hospitals (Extrapolation)	$64,285,714,286
4	2018 Estimated OPPS Payments (NPRM)	$70,000,000,000
5	2018 Estimated OPPS Payments (Impact File)	$55,003,489,015

We note that the estimates of total 2018 OPPS payments provided by CMS in the NPRM and associated impact file are not internally consistent. We also note that our estimates, a summary of which is in Table 2 below, are not consistent with those provided by CMS (i.e., $70 billion versus $55 billion for 2018 estimated OPPS payments). We note that our estimates are provided in 2016 dollars and have not been inflated to 2018 rates.

Table 2. Dobson | DaVanzo Estimates

Line	Dobson | DaVanzo Estimates	
1	2016 340B Drug Payment	$5,934,930,516
2	Proposed 340B Drug Payment (2016 dollars)	$4,409,774,457
3	**340B Drug Payment Decrease (2016 dollars)**	**$1,525,156,059**
4	2016 Non-340B Drug Payment for OPPS Hospitals[a]	$2,605,404,260
5	2016 Non-Drug Payment Total for OPPS Hospitals	$42,153,352,762
6	2016 OPPS Payments for OPPS Hospitals in 2016 OPPS NPRM Data (Line 1 + Line 4 Line 5)	$50,693,687,537

[a] Includes drugs from non-340B hospitals and non-340B drugs from 340B hospitals
[b] Includes payments for all claims, including those with status indicators not paid under OPPS
[c] There were 106 hospitals with claims in the OPPS NPRM data file that were not included in the OPPS Impact file. These hospitals were included in the total here.
Note: All estimates from Dobson | Davanzo are in 2016 dollars. Individual lines may not sum to total due to rounding.

Detailed results of our analysis are found in the accompanying Excel workbook. The spreadsheets contained within can be divided into two separate models. The first, identified with blue tabs, uses the Dobson | DaVanzo estimate of reduction in 340B drug payments at $1.525 billion, as seen in Table 2. It then utilizes a 1.4 percent increase to non-drug OPPS payments, as estimated by CMS and documented in the NPRM. The first spreadsheet provides hospital-specific data, and the second aggregates this data by hospital type. We note that, despite using the estimate from CMS of 1.4 percent for the increase in non-drug OPPS payments, we have not scaled the 340B drug payment reduction down to $900 million to match that estimate from CMS, nor have we scaled the non-drug payments up to match the $64 billion CMS is anticipating (see Line 3, Table 1). That is, all modeled policy payments reflect the findings of our analyses, aside from the use of the 1.4 percent from CMS.

The second model, identified with green tabs, again uses the Dobson | DaVanzo estimate of reduction in 340B drug payments at $1.525 billion, as seen in Table 2. However, this model utilizes a 3.6 percent increase to non-drug OPPS payments, as estimated by our analysis. Again, the first spreadsheet provides hospital-specific data, and the second aggregates this data by hospital type.

Exhibit F

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September 11, 2017

Seema Verma
Administrator Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1678-P CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. July 20, 2017

Dear Ms. Verma,

On behalf of EMHS member organizations including four general inpatient hospitals, a regional trauma hospital, three critical access hospitals, a psychiatric hospital, nursing facilities, homecare and hospice providers and air/ground ambulance services, we thank you for the opportunity to provide feedback to CMS regarding the proposed rule for 2018 hospital outpatient policy changes and payment rates. The Centers for Medicare and Medicaid Services has a national responsibility to promulgate rules that are critically important for our member organizations. Our comments focus on proposed changes impacting payment for medications purchased through the 340B pharmaceutical discount program and proposed payment changes for services provided by employed providers in hospital outpatient departments.

To understand our concerns it is important to understand our challenges. Maine is a state with a large geography, generally rural in nature. For EMHS member organizations, our comprehensive healthcare system serves as a statewide provider of care serving urban populations in southern and central Maine and rural populations residing in Maine's economically challenged northern and eastern Maine regions. Overall to ensure access to primary care and specialty services in Maine, nearly every physician in our state is employed by a hospital, healthcare system or federally qualified health care center. For primary care providers, employment approaches 100% statewide. EMHS member organizations employ over 700 physicians providing access to care for the 93% of Maine's population living in the EMHS service area. Eastern Maine Medical Center (trauma hospital) and Acadia hospital (psychiatric) serve as an example of the critical role that hospitals have in providing access to physician care in Maine. Access to specialist care for two thirds of Maine's rural geography is provided by physicians employed by EMMC and Acadia Hospital.

Maine citizens are among the oldest in the country with a high incidence of chronic disease, many of which are dually eligible for Medicare and Medicaid. EMHS is honored to have its population health management member organization, Beacon Health, LLC as one of the original Pioneer Accountable Care Organizations, and now in the Next Generation ACO Model, working with the Center for Medicare and Medicaid Innovation to transform payment for care from volume to value based outcomes. The success of our ACO is based upon a primary care model with care coordination and community care teams that specialize in supporting the most challenging patient populations. Accountable care succeeds when a sufficient volume of primary care providers are available to care for Maine citizens. With Maine's heavy reliance on government payment (Medicare and Medicaid) for health care services, employment of providers to provide care through hospital outpatient departments is an economic reality. Additionally, the State of Maine is one of a handful of states in the country that has chosen not to expand Medicaid coverage thus making Maine a state with the highest percentage of adults without health benefits in New England. Providers are unable to sustain independent practice business models with governmental payments below the cost of providing care, charity care burdens and commercial insurance payments unable to offset the financial losses of independent practice. Hospital outpatient department payments are critical to support our ability to recruit and retain providers statewide.

Maine is particularly vulnerable and access to care is at risk when hospital outpatient department and provider based payment policies are changed. The 2018 proposed rule includes changes that negatively impact payment for employed provider outpatient services and payment for medications purchased through the 340B pharmaceutical discount program.

Section 603 of the Bipartisan Budget Act of 2015 mandated site-neutral payment for non-emergency department services in certain "new" off campus provider based departments. The final rule issue by CMS established a payment policy that "non-excepted" services would be paid under the physician fee schedule at 50% of the OPPS rate. The proposed rule for 2018 reduces payment to 25% of the OPPS rate. As outlined in our introductory comments Maine citizens rely upon hospitals for access to primary care and specialty services and we are distinctly disappointed with the additional payment reduction that is proposed in this rule concluding that CMS fails to understand the provider and access challenges that have successfully been addressed by EMHS member hospitals. Reducing payment to 25% of the OPPS rate exposes EMHS member organizations to a payment reduction totaling $1.86 million dollars as we work to ensure access to care in locations on and in regional proximity to hospital campus locations. ***We strongly urge CMS to retain the current payment rate (50% OPPS) for 2018.***

We also express disappointment and concern with the proposal to reduce payment for nonpass-through medications purchased through the 340B pharmaceutical discount program. To qualify for the 340B program hospitals must annually document status as a safety net provider caring for vulnerable citizens. The proposed rule refers to the growth in hospital participation with the 340B program as one rationale for the payment reduction. This comment fails to recognize that the Affordable Care Act extended 340B eligibility to critical access hospitals, our county's most rural and often fragile providers. Increased participation in 340B savings by critical access hospitals has supported financial sustainability across the country and here in Maine.

The rule proposes to reduce payment for nonpass-through medications from the current ASP plus 6% down to a rate of ASP minus 22.5%. The payment reduction proposal comes at a time of escalating costs of medications with no proposals directed toward pharmaceutical company unrelenting increases in charges to purchase medications. Furthermore the proposed payment reduction impacts HCPCS codes with status indicator "K" thus targeting a high volume of cancer treatment drugs. Eastern Maine Medical Center's Cancer Care of Maine is the only oncology program serving northern and eastern Maine, the

proposed payment policy specifically targets an essential regional service and the Medicare beneficiaries who rely on CCOM for life saving treatment. The payment proposal results in a $5.3 million dollar annual reduction in Medicare B payment for EMHS member organizations. EMHS member organizations already receive Medicare payments below the cost of care totaling $101 million dollars annually. ***We strongly urge CMS to retain the current payment rate of ASP plus 6% for medications paid for by the Medicare Part B benefit.***

Thank you for the opportunity to provide comment.

Sincerely,

Lisa Harvey-McPherson RN, MBA, MPPM
EMHS Vice President Government Relations

Exhibit G

HENRY FORD HOSPITAL & HEALTH NETWORK

September 11, 2017

John Popovich, Jr., M.D.
President & Chief Executive Officer

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Seema Varma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-1678-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs: Proposed Rule

Dear Ms. Varma

On behalf of Henry Ford Hospital (HFH), I am pleased to offer comments on the proposed Hospital Outpatient Prospective Payment System (OPPS) proposed rule for CY2018 (CMS-1678P). HFH is part of Henry Ford Health System (HFHS), which is a non-profit integrated health system that offers health care services across the care continuum through a diverse network of facilities in South Central (Jackson) and South East Michigan (Detroit).

HFH is the HFHS flagship hospital, located in Detroit's Midtown. HFH has served the Detroit community for over 100 years. HFH is an 877- bed tertiary hospital, education and research center, which provides comprehensive, advanced inpatient and outpatient care, and is a Level 1 trauma center. The Henry Ford Medical Group (HFMG), a group practice with more than 1,200 physicians, helps staff HFH and the other HFHS hospitals. HFH is a "covered entity" under the 340B Discount Drug Program (340B).

<u>Cuts to Part B Drugs Purchased Under the 340B Discount Drug Program</u>

HFH strongly opposes the proposal to reimburse hospitals for Part B drugs, purchased through the 340B Discount Drug Program, at a rate of average sales price minus 22.5 percent. This amounts to, essentially, a cut of 28.5 percent of current reimbursement, which could amount to as much as 25-40 percent of the 340B discounts on covered drugs that hospitals throughout the country receive. The fundamental effect of this proposed change would be to shift millions and millions of dollars from 340B to non-340B hospitals, which clearly thwarts the intent of Congress in establishing the 340B program, and then extending it in the context of the Affordable Care Act (ACA).

Without the 340B discounts, HFH would not be able to provide the breadth of uncompensated care that we currently provide. While the 340B discounts offset only about half of our uncompensated care costs, the discounts do give us the flexibility to provide charity care and other forms of uncompensated care for the most vulnerable patients we serve including:

- providing charity care to cover patient co-payments, coinsurance, deductibles, and, in some cases, to fully cover patient healthcare costs;
- providing free and reduced-cost medications to the underserved across the system;
- providing reduced cost medical and behavioral health care to the uninsured and underinsured across the system;
- embedding pharmacists in primary care and specialty clinics in Detroit to optimize treatment of chronic diseases and expand patient access through face-to-face appointments;
- providing expanded internal Medication Therapy Management (MTM) program for patient adherence and compliance;
- providing expanded Specialty Pharmacy to include HUBS for most disease states to ensure patient compliance and monitoring;
- providing additional services for all patients including the meds to beds program, home delivery and courier services;
- helping to cover bad debt (uncollected patient payments) from patients who cannot afford to pay for the full cost of care;
- helping to fund the Community Health and Social Services (CHASS) Clinic, which provides free primary care services to about 1.300 uninsured and underinsured Detroit residents every month in Southwest Detroit; Henry Ford physicians staff the clinic;
- operating school-based and community health programs in 11 child and adolescent health centers and two mobile medical units, which provide primary care services in Detroit, Warren and Mount Clemens; and
- providing services to Medicaid and Medicare beneficiaries at less than cost across the system (government health plan provider reimbursement does not cover the full cost of care).

Under one of the budget-neutrality options being considered – restoring some of the funds through an uncompensated care formula of some kind – one very likely effect will be the shifting of millions of Medicare dollars from Medicaid expansion states to non-expansion states. The reason for this shift is that Medicaid underpayments would not be counted under the proposed new uncompensated care formula. Shifting millions of Medicare dollars from states like California and Michigan to states like Texas would seem to need some additional policy justification.

At least two of the claims made for benefits of the proposed change seem to be either greatly exaggerated or non-existent. The estimate of $900 million in savings to the Medicare program would be non-existent if the proposal was indeed implemented in a budget-neutral manner within the OPPS program (page 33711 of proposed rule). An estimate of $180 million to beneficiaries was apparently made in a press briefing before release of the proposed rule. This estimate is presumably simply 20% of $900 million. If the proposal is implemented in a budget-neutral manner, there will be no savings to beneficiaries, for the same reason that there will be no net savings to the Medicare program. Even if the program is not implemented in a budget-neutral manner, though, data from the Kaiser Family Foundation suggests that only 14% of Medicare beneficiaries do not have some form of supplemental coverage that includes copays, or are not dual-eligible (Medicaid pays the co-pays) or are not in Medicare Advantage. Only 14% of beneficiaries then, would actually experience any reduction in co-pays. Any benefits would accrue to private insurance companies or to state Medicaid programs. Again, this seems to be questionable public policy and not at all consistent with the intent of Congress in establishing the 340B program.

The 340B program is under the jurisdiction of the Health Resources and Services Administration (HRSA). Given the absence of any net financial benefit to CMS, and the likelihood of no net benefit to beneficiaries, this proposal is outside the jurisdiction of CMS in that all of the effects would be outside the scope of the Medicare program and would clearly violate the intent of Congress in establishing the program. We strongly believe that if further authority were given to the Administration to promulgate regulations that it should only be done by HRSA. Moreover, the law governing the 340B program is limited as to what constraints may be placed on the program by the Executive Branch. Congress is the only authority to make changes to the current program and recent actions by Congressional Committees show that they intend to do so. Recently, the Energy and Commerce Committee sent a letter to HRSA stating its concerns about the rapid growth

and lack of oversight in the 340B drug discount program and requested that HRSA to do an audit of the program. Following the letter, the Committee's Subcommittee on Oversight and Investigations held a hearing to examine the program with testimony from HRSA, the Governmental Accountability Office, and the Department of Health and Human Services, Office of Inspector General. The letter and hearing are only the beginning of the work that the Congress has indicated that it intends to perform on this vital program, with possible legislation in the near future. We believe it is the intention of Congress to gradually reform the program and this proposed rule would severely hamper its ability to investigate and develop legislation to improve the program.

Moreover, section 1833(t)(2)(C) of the Social Security Act ("the Act") does not allow CMS to create different payment levels based on distinct costs of any particular hospital. According to the statute, CMS is generally required to pay hospitals for their median or mean costs for a particular type of service, and not their hospital-specific costs. Furthermore, under section 1833(t)(14(A)(iii) of the Act, CMS is required to pay the "average" acquisition cost, or in the absence of cost data, the ASP rate for covered outpatient drugs, and under section 1847A(c)(2)(A) of the Act, the ASP calculation specifically excludes 340B pricing. The Act is very clear as to the requirements under the payment system. As the regulation is drafted, CMS does not have the authority to pay hospitals that are under the 340B Discount Program differently than all other hospitals for covered outpatient drugs.

Hospital Outpatient Quality Report (OQR) Program: Quality Metrics

HFH appreciates and supports CMS' willingness to consider adjustment of quality metrics used in the OQR program on the basis of social risk factors (page 33672 in the proposed rule). We understand CMS' caution in moving forward, given the long history at CMS of not adjusting for social risk factors. It is clear, though, that careful consideration of the issue by three groups of experts (the NQF Expert Panel in 2014, the ASPE work group in 2016 and the NAM Committee in 2017) has resulted in a clear, straightforward recommendation in favor of adjustment by all three groups. The NQF Board voted to change its policy to encourage and allow social risk factor adjustment in 2014, and recently voted unanimously to continue a policy of allowing and encouraging such adjustment for an additional three years while formal evaluations are conducted. In addition, the NQF Disparities Standing Committee in its June 2017 meeting encouraged the NQF Board to continue the policy favoring risk adjustment based on social risk factors.

There is a clear consensus, then, from four groups of experts and the NQF Board in favor of adjustment on the basis of social risk factors. The reports clearly show how adjustment can be done without masking disparities or excusing poor quality. It is time now for CMS to move beyond "reviewing" these reports and decision and start acting on their recommendations. Those recommendations are unambiguous. The reports are also very detailed in terms of what variables to consider, potential data sources for those variables, and ways to work through current limitations of data availability at CMS.

HFH supports the CMS proposals to remove six measures from the OQR program. We believe that the rationale for removal of the measures is strong and well-described, and we encourage CMS to continue to remove or change measures that are not of net benefit to the program, to providers, and to beneficiaries. We specifically note, in terms of the rationale presented on pages 33673-33674 for removal of the surgical volume measure, that if a process or structural measure is not associated with patient outcomes, the issue of burden to providers is essentially moot. The measure should not be in the program regardless of burden on providers. The issue of burden on providers should come into play when the benefit of a measure is small or uncertain. If the value is zero, then the measure should be out of the program regardless of any other considerations.

We support and encourage CMS' intent to move in the direction of more outcome measures in the OQR program. We note, though, that a movement to outcomes requires a much more careful approach to risk adjustment than is typically the case for structure or process measures. Many of the measures that seem to have face validity as "outcome" measures are affected by much more than the actual medical care received. If a measure of "outcome" is to be used as a measure of health care quality, then all of the other extraneous influences that work through causal pathways other than quality of care have to be controlled for (including social risk factors). Measure developers and NQF should be pressed to

demonstrate that the measures offered to CMS for use have a good ratio of quality of care "signal" to extraneous "noise", so that variation in the measure can be legitimately interpreted as variation in quality of care.

The proposal to focus audits on poor-performing outliers (page 33682) of proposed rule) seems to require some additional justification. If the audits are triggered by a rate more than five standard deviations from the mean, it would seem that outlier rates both above and below the mean would be equally in need of audit. In fact, if anything, remarkably high or good rates would seem to be more suspicious and in need of audit than remarkably poor rates. In fact, the rationale for an audit of any kind could be made stronger, if the odds of a rate outside of five standard deviations is indeed nearly one in two million (page 33682). A rate that far out of range is almost certainly an error, and it would seem reasonable and prudent to simply ask such hospitals to correct their reports than to incur the expense of an audit.

Telemedicine

As per the CMS telehealth fact, sheet speech therapy services are not listed as an approved telehealth service. Follow through on speech therapy services and care plan can be vital to patient progress, and geographic distance can often be a barrier. Our proposal is for audiologists and speech-language pathologists to be approved distant providers and the following speech therapy services (all charges are currently on the facilities/HB Claim, Not professional PB claim) to be provided through telemedicine:

- Evaluation (non-timed codes): 92521-92524, 92610
- Treatment (non-timed codes): 92506, 92526
- Timed codes: 96105, 96125

All telemedicine privacy and billing/claim guidelines (i.e. Real time secure audio/video, GT modifier, place of service (POS) 02, etc.) should be maintained in these services.

In addition, we would like to propose the addition of pharmacists and Pharm-D as approved distant providers, as they are often engaged in telemedicine encounters when a medication requires a pharmacist consult or the patient has questions about their medications at discharge (i.e. Telehealth Pharmacologic Management, HCPCS code G0459). An additional service would be to facilitate Medication Therapy Management (MTM) within the patient's homes.

We also propose the expansion of originating sites or the location of an eligible beneficiary/patient at the time the service furnished via a telecommunications system occurs, to include schools and the beneficiary/patient's home. These expanded locations would facilitate better access and breakdown care delivery barriers such as distance and resource availability. Integration of healthcare into the school setting can facilitate better wellness and medical care for patients/students, ensuring that there is timely and convenient options to support the wellbeing of our children in an organized and managed environment. Offering telehealth services within a beneficiary/patient's home will foster convenience and access for patients that have a multitude of barriers from seeking healthcare; time, transportation, childcare, work schedule/restrictions, mobility, comorbidity, access to specialty services in area, etc. Telehealth in the home can help alleviate these pain points and open the door to healthcare where, when, and how the patient can access it. This expansion of originating site criteria would also include the elimination of geographic restrictions.

HFH appreciates the opportunity to comment on the Outpatient Prospective Payment System (OPPS) and Quality proposed rule for CY2018.

Sincerely,

John Popovich, Jr., M.D.
President & Chief Executive Officer, Henry Ford Hospital
Executive Vice President & Chief Medical Officer, Henry Ford Health System

HENRY FORD ALLEGIANCE HEALTH

205 N. East Avenue
Jackson, MI 49201
(517) 205-4800
HenryFordAllegiance.com

Via Electronic Submission (www.regulations.gov)

September 11, 2017

Seema Varma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-1678-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs: Proposed Rule

Dear Ms. Varma

On behalf of the Henry Ford Allegiance Health (HFAH), I am pleased to offer comments on the proposed Hospital Outpatient Prospective Payment System (OPPS) proposed rule for CY2018 (CMS-1678P). HFAH is one of six hospitals in the Henry Ford Health System, which is a non-profit, integrated health system headquartered in Detroit that offers health care services across the care continuum through a diverse network of facilities in South Central (Jackson) and South East Michigan (Detroit).

Serving as its community's sole health system since 1918, Henry Ford Allegiance Health (HFAH) in Jackson, Michigan has 475 beds across its acute care hospital, long-term acute care hospital and residential hospice home. With its more than 400 physicians, HFAH's network of 40 facilities complements traditional acute care with mission-based services to address the health needs of its economically-challenged, underserved community. Jackson has a median income of $28K, a 5.7% unemployment rate (compared to 4.3% nationally) and a 36% poverty rate. HFAH is a national leader in forming community partnerships to innovatively leverage wellness and prevention opportunities across the region. HFAH is also a covered entity under the Discount Drug Program (340B).

Cuts to Part B Drugs Purchased Under the 340B Discount Drug Program

HFAH strongly opposes the proposal to reimburse hospitals for Part B drugs, purchased through the 340B Discount Drug Program, at a rate of average sales price minus 22.5 percent. This amounts to, essentially, a cut of 28.5 percent of current reimbursement, which could amount to as much as 25-40 percent of the 340B discounts on covered drugs that hospitals throughout the country receive. The fundamental effect of this

proposed change would be to shift millions and millions of dollars from 340B to non-340B hospitals, which clearly thwarts the intent of Congress in establishing the 340B program, and then extending it in the context of the Affordable Care Act (ACA).

Without the 340B discounts, HFAH would not be able to provide the breadth of uncompensated care that we currently provide. While the 340B discounts offset only about half of our uncompensated care costs, the discounts do give us the flexibility to provide millions of dollars in charity care and other forms of uncompensated care for the most vulnerable patients we serve including:

- providing charity care to cover patient co-payments, coinsurance, deductibles, and, in some cases, to fully cover patient healthcare costs;
- providing free and reduced-cost medications to the underserved across the system;
- providing reduced cost medical and behavioral health care to the uninsured and underinsured across the system;
- providing expanded internal Medication Therapy Management (MTM) program for patient adherence and compliance;
- providing expanded Specialty Pharmacy to oncology patients to ensure patient compliance and monitoring;
- providing additional services for all patients including the meds to beds program, home delivery and courier services;
- helping to cover bad debt (uncollected patient payments) from patients who cannot afford to pay for the full cost of care;
- helping to support our local FQHC with an annual support of $200,000 - $400,000 of cash contributions in addition to recruitment, electronic health record and other support.
- providing services to Medicaid and Medicare beneficiaries at less than cost **across the system** (government health plan provider reimbursement does not cover the full cost of care), including, but not limited to.
    - ✓ Traditional Acute and Outpatient Services
    - ✓ Hospice
    - ✓ LTAC
- Helping lead our community to better health and well-being at every stage of life through regular health fairs, screens and outreach. .

Under one of the budget-neutrality options being considered – restoring some of the funds through an uncompensated care formula of some kind – one very likely effect will be the shifting of millions of Medicare dollars from Medicaid expansion states to non-expansion states. The reason for this shift is that Medicaid underpayments would not be counted under the proposed new uncompensated care formula. Shifting millions of Medicare dollars from states like California and Michigan to states like Texas would seem to need some additional policy justification.

At least two of the claims made for benefits of the proposed change seem to be either greatly exaggerated or non-existent. The estimate of $900 million in savings to the Medicare program would be non-existent if the proposal was indeed implemented in a budget-neutral manner within the OPPS program (page 33711 of proposed rule). An estimate of $180 million to beneficiaries was apparently made in a press briefing before release of the proposed rule. This estimate is presumably simply 20% of $900 million. If the proposal is implemented in a budget-neutral manner, there will be no savings to beneficiaries, for the same reason that there will be no net savings to the Medicare program. Even if the program is not implemented in a budget-neutral manner, though, data from the Kaiser Family Foundation suggests that only 14% of Medicare beneficiaries do not have some form of supplemental coverage that includes copays, or are not dual-eligible (Medicaid pays the co-pays) or are not in Medicare Advantage. Only 14% of beneficiaries then, would actually experience any reduction in co-pays. Any benefits would accrue to private insurance companies or to state Medicaid programs. Again, this seems to be questionable public policy and not at all consistent with the intent of Congress in establishing the 340B program.

The 340B program is under the jurisdiction of the Health Resources and Services Administration (HRSA). Given the absence of any net financial benefit to CMS, and the likelihood of no net benefit to beneficiaries, this proposal is outside the jurisdiction of CMS in that all of the effects would be outside the scope of the Medicare program and would clearly violate the intent of Congress in establishing the program. We strongly believe that if further authority were given to the Administration to promulgate regulations that it should only be done by HRSA. Moreover, the law governing the 340B program is limited as to what constraints may be placed on the program by the Executive Branch. Congress is the only authority to make changes to the current program and recent actions by Congressional Committees show that they intend to do so. Recently, the Energy and Commerce Committee sent a letter to HRSA stating its concerns about the rapid growth and lack of oversight in the 340B drug discount program and requested that HRSA to do an audit of the program. Following the letter, the Committee's Subcommittee on Oversight and Investigations held a hearing to examine the program with testimony from HRSA, the Governmental Accountability Office, and the Department of Health and Human Services, Office of Inspector General. The letter and hearing are only the beginning of the work that the Congress has indicated that it intends to perform on this vital program, with possible legislation in the near future. We believe it is the intention of Congress to gradually reform the program and this proposed rule would severely hamper its ability to investigate and develop legislation to improve the program.

Moreover, section 1833(t)(2)(C) of the Social Security Act ("the Act") does not allow CMS to create different payment levels based on distinct costs of any particular hospital. According to the statute, CMS is generally required to pay hospitals for their median or mean costs for a particular type of service, and not their hospital-specific costs. Furthermore, under section 1833(t)(14(A)(iii) of the Act, CMS is required to pay the "average" acquisition cost, or in the absence of cost data, the ASP rate for covered outpatient drugs, and under section 1847A(c)(2)(A) of the Act, the ASP calculation specifically excludes 340B pricing. The Act is very clear as to the requirements under the payment system. As the regulation is drafted, CMS does not have the authority to pay hospitals that are under the 340B Discount Program differently than all other hospitals for covered outpatient drugs.

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There is a clear consensus, then, from four groups of experts and the NQF Board in favor of adjustment on the basis of social risk factors. The reports clearly show how adjustment can be done without masking disparities or excusing poor quality. It is time now for CMS to move beyond "reviewing" these reports and decision and start acting on their recommendations. Those recommendations are unambiguous. The reports are also very detailed in terms of what variables to consider, potential data sources for those variables, and ways to work through current limitations of data availability at CMS.

We support the CMS proposals to remove six measures from the OQR program. We believe that the rationale for removal of the measures is strong and well-described, and we encourage CMS to continue to remove or change measures that are not of net benefit to the program, to providers, and to beneficiaries. We specifically note, in terms of the rationale presented on pages 33673-33674 for removal of the surgical volume measure, that if a process or structural measure is not associated with patient outcomes, the issue of burden to providers is essentially moot. The measure should not be in the program regardless of burden on providers. The issue of burden on providers should come into play when the benefit of a measure is small or uncertain. If the value is zero, then the measure should be out of the program regardless of any other considerations.

We support and encourage CMS' intent to move in the direction of more outcome measures in the OQR program. We note, though, that a movement to outcomes requires a much more careful approach to risk adjustment than is typically the case for structure or process measures. Many of the measures that seem to have face validity as "outcome" measures are affected by much more than the actual medical care received. If a measure of "outcome" is to be used as a measure of health care quality, then all of the other extraneous influences that work through causal pathways other than quality of care have to be controlled for (including social risk factors). Measure developers and NQF should be pressed to demonstrate that the measures offered to CMS for use have a good ratio of quality of care "signal" to extraneous "noise", so that variation in the measure can be legitimately interpreted as variation in quality of care.

The proposal to focus audits on poor-performing outliers (page 33682) of proposed rule seems to require some additional justification. If the audits are triggered by a rate more than five standard deviations from the mean, it would seem that outlier rates both above and below the mean would be equally in need of audit. In fact, if anything, remarkably high or good rates would seem to be more suspicious and in need of audit than remarkably poor rates. In fact, the rationale for an audit of any kind could be made stronger, if the odds of a rate outside of five standard deviations is indeed nearly one in two million (page 33682). A rate that far out of range is almost certainly an error, and it would seem reasonable and prudent to simply ask such hospitals to correct their reports than to incur the expense of an audit.

HFHS appreciates the opportunity to comment on the Outpatient Prospective Payment System (OPPS) and Quality proposed rule for CY2018.

Sincerely,

Georgia Fojtasek, R.N., Ed.D
President and CEO

Exhibit H

AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

September 11, 2017

VIA ELECTRONIC MAIL
www.regulations.gov

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Re: CMS-1678-P, FY 2018 Hospital Outpatient Prospective Payment System (OPPS) Notice of Proposed Rulemaking

Dear Ms. Verma:

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Calendar Year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. Our organization is the policy voice for five Seventh-day Adventist health systems that include 82 hospitals and more than 300 other health facilities in 17 states and the District of Columbia.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to California. Therefore, we believe that we can provide an objective and sound policy voice in response to CMS' OPPS proposed rule. Below please find AHPA's comments and recommendations to CMS' proposed policies. Specifically, we comment on the following five issue areas:

- 340B Drug Program Payments
- Changes to the Inpatient Only (IPO) List
- Proposed Removal of Outpatient Quality Reporting Program Measures
- Public Reporting of OP–18c
- Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) Measures

340B Drug Program Payments

Beginning in FY 2018, CMS proposes to reduce Part B drug payments to 340B hospitals for all separately payable drugs by nearly 30 percent, from Average Sales Price (ASP) plus six percent to ASP minus 22.5 percent. In the rule, CMS expressed concern that the current payment methodology for Part B drugs may lead to unnecessary utilization and potential overutilization of separately payable drugs at 340B hospitals. The rule cites a Government Accountability Office (GAO) 2015 report, which found that the per beneficiary Part B drug spending, including oncology drug spending, was more than twice as high at 340B disproportionate share hospitals than at non-340B DSH hospitals.

AHPA recommends that the Agency *not* reduce Medicare payments to 340B hospitals. This proposal would hinder the ability of 340B hospitals to serve low-income and rural patients, which would undermine the goals of the 340B program. Per the statute, the 340B program was created to, "allow certain providers to stretch scarce federal resources." Therefore, a payment reduction as significant as the one proposed by CMS would undermine the effectiveness of the 340B program and would diminish federal resources further. A survey conducted by 340B Health revealed that nearly 60 percent of their member hospitals are likely to withdraw from the 340B program if the proposed reduction to the Part B drugs were finalized.

We are concerned that CMS' proposal does not adequately account for the costs incurred by 340B hospitals to comply with the 340B program. This includes complying with the statute's Group Purchasing Organization (GPO) prohibition, which prevents Disproportionate Share Hospital (DSH) qualified 340B hospitals from using a GPO for purchasing covered outpatient drugs at any point in time. To maintain compliance with the 340B program, many hospitals must also maintain software, hire staff, and conduct paid audits. In addition to these costs, CMS' proposal fails to incorporate the costs of purchasing drugs through a Wholesale Acquisition Cost (WAC) account for 340B hospitals. It presumes that all drugs are purchased at the 340B discount. By not accounting for these costs, the proposed payment reduction would make it very difficult for hospitals to continue participating in the 340B program. The inability of hospitals to continue providing these drugs would have an adverse effect on low-income patients who may find it difficult to access the drugs, as physician offices are not as willing to accept the financial risks of treating under or noninsured patients. **Therefore, we recommend that CMS adopt a different payment rate to account for the costs incurred by 340B hospitals.**

According to CMS, the reduced reimbursement is appropriate due to the growth in the 340B program and high drug costs. However, addressing high drug costs by lowering reimbursement to those dispensing the drugs will do nothing to lower the inflated prices charged by pharmaceutical companies. The proposed payment reduction will only make it more difficult for hospitals to purchase these drugs and provide them to patients in need. **In addition to threatening patient access to these drugs, the proposal will not result in any savings to Medicare beneficiaries**. While the copayments for Medicare Part B drugs would decrease under the proposal, the copayment for other outpatient services would increase. This is due to CMS' plan to implement the proposal in a budget neutral manner. According to the proposal, CMS would use the 340B savings to increase payments for other Medicare services paid under OPPS. The Agency estimates that OPPS payment rates would increase by about 1.4 percent in CY 2018 due to the redistribution of savings. Thus, the proposed payment reduction would undermine the 340B program and produce no savings for Medicare beneficiaries.

AHPA is also concerned that the methodology in the GAO study that CMS referenced in support of its proposal to reduce 340B payments is not accurate. The study concluded that 340B hospitals are providing more drugs or more expensive drugs to Part B beneficiaries in potentially inappropriate ways, which we disagree with. The study assumed that 340B hospitals prescribe more drugs than other hospitals

because of the 340B program drug discount. However, the GAO did not fully account for differences in the patient populations between 340B and non-340B hospitals that could explain the spending differences. As noted in the same report, outpatient Medicare margins are lower in 340B hospitals than non-340B hospitals. This could be attributed to 340B hospitals treating more expensive patients compared to other hospitals, which would increase their costs and lower their margins. In commenting on this study, the Department of Health and Human Services (HHS) agreed with these observations. HHS raised concerns with the GAO's conclusions and suggested that further analysis may be needed to examine patient outcomes and differences in health status.[1] The Agency further noted that higher volume of physician-administered drugs can lead to better clinical outcomes. Therefore, we are surprised that CMS has referenced a study previously opposed by HHS to justify the proposed payment reduction.

Furthermore, it is unclear whether CMS has the statutory authority to reduce payments to 340B hospitals. In the same report referenced above, the GAO stated the following:

> "While limiting hospitals' Medicare Part B reimbursement for 340B discounted drugs or eliminating the 340B discount for drugs provided by hospitals to Medicare Part B beneficiaries could diminish the incentive to prescribe more drugs or more expensive drugs than necessary at 340B hospitals, CMS and HRSA are unable to take such actions because they do not have the statutory authority to do so."[2]

Based on the GAO's conclusion, we believe that a legal analysis should be performed to verify whether the Agency has the statutory authority to implement the proposed payment reduction.

Redistribution of 340B Savings

As mentioned earlier, CMS proposes to redistribute all or some of the savings resulting from the 340B payment reduction to increase payments for certain services paid under the OPPS. CMS seeks comments on how to redistribute these savings and whether the proposal would result in unnecessary increases in the volume of covered services paid under the OPPS.

AHPA is significantly concerned about this proposal because the redistribution of 340B funds across other OPPS services could mean that non-340B hospitals would receive increased payments. This could also result in savings from the 340B discount being passed on to others reimbursed under the OPPS, such as Durable Medical Equipment suppliers, Ambulatory Surgery Centers (ASCs) and independent labs. We believe that this would be a violation of the 340B program statute, which requires hospitals to treat a disproportionate share of Medicaid patients to participate in the program and qualify for the savings.

[1] GAO-15-442. (June 2015). Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, p.38. Retrieved at: https://www.gao.gov/assets/680/670676.pdf

[2] GAO-15-442. (June 2015). Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, p.35. Retrieved at: https://www.gao.gov/assets/680/670676.pdf

Modifier for Non-340B Drugs and Potential Reporting of 340B Acquisition Cost

CMS proposes to require hospitals to use a new modifier to identify non-340B separately payable drugs reimbursed by Medicare Part B under the OPPS. CMS will presume that drugs without the modifier were purchased under the 340B program. Therefore, failure to include a modifier would result in a claim being paid at ASP minus 22.5 percent. Although non-340B hospitals will not be subject to reduced reimbursement under this proposal, they will still be required to use the modifier to indicate that drugs were not purchased under the program. CMS suggests that the modifier's purpose is to allow CMS to identify the acquisition cost of 340B drugs.

AHPA opposes the adoption of this new modifier. We believe that its adoption would add significant administrative burden to non-340b facilities. Implementing it would require hospitals to maintain two separate bill code schedules within their Electronic Health Record (EHR) domains, one for 340B sites and another for non-340 sites. The current single modifier schedule for Medicare contains any modifiers that CMS specifically requires, such as the GP, GO or GN modifiers. Therefore, this policy would necessitate an additional schedule in the EHR that would have to be maintained and updated. In addition to this being administratively burdensome, it would also be costly for health care providers to implement. Hospitals would need to upgrade their EHRs and potentially hire additional staff to ensure compliance. Additionally, due to limitations with the Electronic Medication Administration Record (eMAR) system and billing, most hospitals would not be able to indicate when a drug was purchased at WAC and add CMS' proposed modifier to indicate a non-340B drug. Therefore, WAC purchases would likely be reimbursed at the proposed ASP minus 22.5 percent as well. Based on these issues, we strongly advise against the adoption of this modifier.

Impact on AHPA

AHPA covered entities and the communities they serve would be negatively impacted if CMS finalizes the proposal to reduce Part B drug payments for all separately payable drugs by nearly 30 percent. The financial impact of the proposed cuts would be significant. For example, at Florida Hospital's Central Florida Division, which is composed of eight hospitals including a Children's Hospital, the annual payment impact to the infusion business would be approximately $1.9 million. In one of our rural facilities, such as Park Ridge Hospital in North Carolina, the impact of the proposed cuts would be $670,698. This would severely limit the ability of these hospitals to provide needed drugs to patients. The cuts could drive facilities to reduce the number of discounted and free drugs given to patients who are discharged from the hospital, but are unable to afford their medications.

Currently, the 340B program savings are reinvested in several programs designed to increase access to prescription medicines and other health services for low-income patients. Losing those savings may affect the long-term viability of those programs. For example, Adventist GlenOaks Hospital is a rural hospital within the AHPA system located in Glendale, Illinois. This 340B covered entity uses the savings from the program to provide a medication reconciliation and bedside medication delivery. The hospital devotes one full time pharmacist to managing both admission and discharge medication reconciliation, with much of the cost being recouped by 340B savings. Because of this program, GlenOaks can deliver medications to the bedside of approximately 50 percent of their patients and have a pharmacist provide medication and disease state counseling. Their pharmacists also utilize 340B pricing on critical medications like insulin to provide affordable or free medication to uninsured or underinsured patients at the time of discharge.

Due to the reasons outlined above, an advisory committee to HHS, the Hospital Outpatient Panel (HOP), also expressed opposition to CMS' proposed cuts to the 340B program on a meeting that took place on August 21st. At that meeting, the American Hospital Association indicated that its contractor, Watson

Policy Analysis, estimated the savings associated with CMS' 340B proposal at $1.65 billion or $750 million more than CMS' $900 million savings estimate.

In conclusion, the 340B prescription drug program is a vital lifeline for safety-net providers and supports critical health services in our communities. The program is narrowly tailored to reach only hospitals that provide a high level of services to low-income individuals or that serve isolated rural communities. Savings from the 340B program help hospitals meet the health care needs of underserved patients across the country. Congress should preserve and protect the 340B program as an essential part of the safety-net that does not rely on taxpayer dollars.

Changes to the Inpatient Only (IPO) List

CMS seeks comments on its proposal to remove the procedures below from the Inpatient Only (IPO) list for CY 2018.

- **Total Knee Arthroplasty** (TKA)- CPT Code 27447
- **Total Hip Arthroplasty** (THA)- CPT Code 27130
- **Partial Hip Arthroplasty** (PHA)- CPT Code 27125

According to CMS, these procedures meet several of the criteria used by the Agency to determine whether a procedure can be removed from the IPO list and assigned to an Ambulatory Payment Classifications (APC) group for payment. The five criteria are as follows:

1. Whether most outpatient departments are equipped to provide services to the Medicare population or whether the procedures are related to codes that CMS has already removed from the IPO list.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC.

In the rule, CMS states that that the TKA procedure meets a number of criteria for removal from the IPO list, including criteria 1, 2 and 4. From this statement, **we infer that because the TKA procedure does not meet criteria 5, if it were removed from the IPO list, the procedure would not be allowed to be performed in the ASC setting. However, we ask that CMS clarify whether this is true.** We believe it would be unsafe for providers to perform such procedures in ASCs due to the age and medical complexity of the Medicare population. Patients should be treated in the most appropriate setting depending on their age and clinical characteristics. For example, while age alone does not disqualify a patient's ability to have a successful outpatient surgery, age can affect the reaction a patient has to certain anesthetic drugs.[3]

Moreover, AHPA does not agree that CMS should remove the proposed procedures from the IPO list. Due to the clinical characteristics of TKA, THA and PHA, we believe these procedures should not be performed in the outpatient setting and should therefore be retained in the IPO list. For example, TKA procedures involve hospitalizations of 72 hours or more in which the patient can experience significant

[3] http://www.hopkinsmedicine.org/healthlibrary/conditions/surgical_care/outpatient_surgery_85,P01404/. Retrieved on August 25, 2017.

blood loss. Patients undergoing TKA are at a higher risk of postoperative anemia and may also require allogeneic blood transfusions.

While a younger and healthier non-Medicare population may be able to safely undergo these procedures in the outpatient setting, Medicare patients are far more likely to suffer from conditions that would be contraindicative for an outpatient surgery. According to a report by CMS, two-thirds of Medicare beneficiaries have multiple chronic conditions.[4] Conditions such as high blood pressure, high cholesterol, heart disease and diabetes are highly prevalent among the elderly population. Both the age and existing comorbidities of Medicare patients, particularly heart failure, increase the risks associated with an outpatient THA, TKA or PHA.

Evidence also suggests that patient outcomes are worse when a TKA is performed in the outpatient setting. A study released in May 2016 demonstrates that outpatients undergoing TKA continue to experience higher rates of post-discharge complications than inpatients, which may countermand cost-savings. The study found that most TKA complications involved bleeding requiring transfusion, which occurred at similar rates after surgery but at higher rates post discharge in outpatients. In the outpatient setting, 7.5 percent of patients had complications after TKA surgery, compared to 5.6 percent in the inpatient setting. After discharge, 4.1 percent of outpatients had complications, compared to only 0.1 percent for inpatients.[5] The data came from an analysis of patients undergoing TKA between 2011 and 2013. Another study released in 2012 found that patients having TKA as outpatients were significantly more likely to die or need readmission within 90 days compared with inpatients remaining in the hospital for three to four days.[6]

While total knee replacements may be performed safely in the outpatient setting for young and generally healthy patients, we do not believe the same holds true for Medicare patients. Patients undergoing a TKA procedure often experience significant post-operative pain. Inadequate pain relief can cause delayed mobilization, greater risk of developing venous thrombosis, coronary ischemia and poor wound healing.[7] Discharging patients home a few hours after a TKA shifts the responsibility of adequate pain management to the patient, much earlier than if that patient stays in a hospital setting or any other adequate setting. This may significantly increase the risks associated with performing a TKA on a Medicare patient. Particularly in the elderly population, our goal is to optimize the post-operative care in the hospital setting to allow the patient to return home safely. This promotes healthier recovery for the patient and allows them to participate more actively in outpatient therapy services. **Based on these patient safety issues, we ask that CMS reconsider its proposal to remove TKA from the IPO list. We believe that CMS should consider the quality of outcomes to beneficiaries before considering cost savings.**

AHPA is also concerned that removing the proposed procedures from the IPO list will lead to Medicare Recovery Audit Contractors (RACs) pressuring health care providers to perform these services in the hospital outpatient setting. This pressure may lead to the treatment of patients in a setting inappropriate to their health care needs. To address this issue, CMS proposes to prohibit RAC patient status reviews for TKA procedures performed in the inpatient setting for a period of two years. According to the Agency, this will give providers time and experience performing TKA under the outpatient setting.

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[4] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf. Retrieved on August 28, 2017.
[5] "Is Outpatient Arthroplasty as Safe as Fast-Track Inpatient Arthroplasty? A Propensity Score Matched Analysis." Retrieved at: http://www.ncbi.nlm.nih.gov/pubmed/27378634
[6] "Outpatient Total Knee Arthroplasty: A Cost and Outcomes Analysis" Retrieved at: http://bit.ly/2bLhCuZ
[7] "Acute Postoperative Pain Following Hospital Discharge After Total Knee Arthroplasty" Retrieved at: http://www.oarsijournal.com/article/S1063-4584(13)00847-9/fulltext

While we appreciate CMS' effort to address these concerns, we believe that adopting a transition period of two years will not address the underlying issue of Medicare contractors questioning physician decision-making. **To avoid this issue, we recommend that CMS work with specialized organizations to establish specific criteria for when a TKA can be performed in the outpatient setting.** For example, CMS could work alongside the American Academy of Orthopaedic Surgeons (AAOS) to create evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient surgery. CMS could also work with the Hip/Knee Society to establish the criteria for same-day joint replacements. **Moreover, we recommend that CMS postpone the removal of TKA from the IPO list until such nationwide standards are developed.** Having set standards will help ensure patient safety, avoid potential claim denials, and increase uniformity among provider services.

Impact of Proposal on Medicare Payment Models

As noted by CMS, removing TKA from the IPO list would affect the implementation of Medicare payment models such as the Comprehensive Joint Replacement (CJR) model and the Bundled Payments for Care Improvement (BPCI) initiative. Under both models, a hospital's actual expenditures are reconciled against a target price for an episode of care. If a hospital's cost of care is less than the target price, the hospital receives a reconciliation payment from CMS. If the actual cost of care is more than the target price, the hospital is required to pay the difference to CMS. The episode target prices are currently based on a blend of hospital-specific data and regional historical data. Because TKA has always been under the IPO list, there is no claims history for beneficiaries receiving these services on the outpatient setting.

If CMS were to remove TKA from the IPO list, causing many patients to shift to the outpatient setting, the current target prices would no longer be an accurate predictor of episode spending. These target prices would need to be modified to ensure that they accurately reflect the costs associated with treating patients in both the inpatient and outpatient settings. Moreover, they would need to be adjusted to account for those more medically complex patients that continue to receive TKA procedures as inpatients. The failure to accomplish this may impact a hospital's ability to maintain costs within the target rate. Based on these issues, we believe that removing TKA from the IPO list would compromise the validity of both the CJR and BPCI models.

Further, the proposal to remove TKA and THA from the IPO list would also have significant implications on the Hospital Readmission Reduction Program (HRRP) and the Value-Based Purchasing Program (VBP). Because TKA/THA are included in both programs, their removal from the IPO list would require CMS to make changes to those programs' baseline and performance periods. For example, for FY 2019, the baseline period for TKA/THA in the VBP program is July 1, 2010 to June 30, 2013. The performance period is January 1, 2015 to June 30, 2017. Because the data captured during these periods does not account for procedures performed in the outpatient setting, CMS would need to either change these periods or postpone the proposal's implementation date.

Impact to Medicare Beneficiaries

We seek clarification on whether CMS has conducted an analysis on the financial impact of the proposed changes to Medicare beneficiaries, specifically as it relates to their cost-sharing responsibilities. Performing these procedures in the outpatient setting would increase the cost-sharing liability for Medicare beneficiaries and make them ineligible for Medicare coverage of Skilled Nursing Facility (SNF) services. Patients would be required to pay for the cost of their SNF care, which may inhibit their ability to receive those post-discharge needed services. This may consequently result in

hospital admissions and higher health care costs. Therefore, we recommend that CMS conduct further analysis on both the clinical and financial impact of this proposal on Medicare beneficiaries.

If CMS finalizes the removal of these procedures from the IPO list, we also ask the Agency to clarify whether hospitals would have to provide a notice to Medicare beneficiaries informing them of these changes and their financial implications. As the health care industry shifts towards a more consumer-centric model of care, we believe that CMS should take a more active role on educating beneficiaries on Medicare policy. Currently, hospitals have been forced to perform a customer service role for CMS, explaining to beneficiaries what patient status they are in and what implications that had. These issues are being caused by CMS' policies and yet hospitals have to be in the front lines defending said policies to beneficiaries who contest them.

Hospital Outpatient Quality Reporting (OQR) Program

Proposed Removal of OQR Measures

For the Outpatient Quality Reporting Program (OQR), CMS proposes to remove six measures and three ASC QRP measures. For the CY 2020 payment determination, CMS proposes to remove the following:

Proposed measure	Measure ID	Quality reporting program	Payment year of proposed removal	Measure source
Prophylactic Intravenous Antibiotic Timing	ASC-5	ASCQR	CY 2019	Claims-based
Safe Surgery Checklist Use	ASC-6	ASCQR	CY 2019	Web-based
ASC Facility Volume Data on Selected Procedures	ASC-7	ASCQR	CY 2019	Web-based
Median Time to Fibrinolysis	OP-1	OQR	CY 2021	Chart-abstracted
Aspirin at Arrival	OP-4	OQR	CY 2021	Chart-abstracted
Door to Diagnostic Evaluation by Qualified Medical Professional	OP-20	OQR	CY 2021	Chart-abstracted
Median Time to Pain Management for Long Bone Fracture	OP-21	OQR	CY 2020	Chart-abstracted
Safe Surgery Checklist Use	OP-25	OQR	CY 2021	Web-based
Hospital Outpatient Volume Data on Selected OP Surgical Procedures	OP-26	OQR	CY 2020	Web-based

AHPA supports CMS in removing the proposed measures from the OQR program. We agree with CMS' conclusion that the above process measures do not improve the quality of care for Medicare beneficiaries. We recommend that CMS use the same rational to remove other process measures currently adopted in hospital performance programs. We believe that this would support the shift from process measures to outcome-based measures.

Public Reporting of OP–18c

Beginning in July 2018, CMS proposes to require the public reporting of the measure OP-18c: Median Time From Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients—Psychiatric/Mental Health Patients. No new data collection would be required for this measure. Hospitals would be able to preview the data to be reported for OP-18c as part of the regular 30-day data preview process.

We commend CMS' effort to address the mental health gap in the publicly reported hospital OQR measure set. We agree that capturing the quality of mental health services is essential to improving health care outcomes. The OP-18c is a process measure that solely assesses the time taken by hospitals to admit and discharge mental health patients. If CMS decides to report this measure, then it should derive a formula that considers two factors: the number of licensed mental health providers that service Medicare, Medicaid and the uninsured in the community where the hospital is located, and the time it took the hospital to consider the release time of the patient. Both numbers will more accurately reflect the factors that can affect a patient's outcome that are beyond the provider's control (such as an absence of mental health facilities in the provider's area).

Because there is currently a nationwide shortage of mental health resources, the time taken by hospitals to discharge mental health patients will depend significantly on the availability of resources in the community.[8] Therefore, this metric may be interpreted by the public as if hospitals are performing poorly in mental health even though the delays are more likely attributed to a public health issue. **Due to this issue, we recommend that CMS delay the public reporting of OP-18c and instead focus on outcome-based measures for behavioral health.** If CMS were to adopt this measure for public reporting, we recommend that CMS include the qualifier of number of licensed mental health providers serving Medicare, Medicaid, and the uninsured in the community where the hospital is located. We believe this metric should be part of an equation and not a stand-alone number.

Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey

CMS proposes to delay indefinitely the implementation of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) measures, currently scheduled for inclusion in the OQR Program measure set beginning with 2020 payment (2018 data collection).

AHPA believes in the importance of assessing patient experience in the ambulatory surgical setting. However, we think that the timeline for the OAS CAHPS survey tool has moved too quickly, as compared to other CAHPS instruments in the past. **Therefore, we support this delay and ask that CMS**

[8] The American Hospital Association. The State of the Mental healthWorkforce: A Literature Review. Retrieved at: http://www.aha.org/content/16/stateofbehavior.pdf

spend time, with input from the health care industry, evaluating the utility of the specific questions and the length of the survey.

Conclusion

AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact Julie Zaiback, Director of AHPA, at Julie.Zaiback@ahss.org.

Sincerely,

Jeff Bromme
President
Adventist Health Policy Association

Exhibit I

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001, *et al.*,

Plaintiffs,

–v–

ERIC D. HARGAN, in his official capacity as the Acting Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. _____

AFFIDAVIT OF TONY FILER
IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Tony Filer, state as follows under the pains and penalties of perjury.

I am the Senior Vice President & Chief Financial Officer for Eastern Maine Healthcare Systems ("EMHS"), a Plaintiff in this action. I have been employed by EMHS for one year.

The information set forth in this affidavit is based upon my personal knowledge.

EMHS and the Population It Serves

1. EMHS is an integrated health care system that provides services throughout virtually the entire State of Maine – including both the urban populations in south and central Maine and the rural populations residing in Maine's economically challenged northern and eastern regions.

2. Among the health delivery services/programs EMHS offers are: trauma level acute care services, general medical and critical access hospitals, a free-standing acute

psychiatric hospital, primary care and specialty physician practices, long-term care, home health care, hospice, ground and air emergency transport services.

3. EMHS-affiliated entities employ over 700 physicians providing access to care for the 93 percent of Maine's population living in EMHS service areas.

4. Access to specialist care for two-thirds of Maine's rural geography is provided overwhelmingly by physicians on the active medical staff of two Bangor based hospitals (Eastern Maine Medical Center and Acadia Hospital) in the EMHS system.

5. EMHS is a member of the American Hospital Association ("AHA"), another of the Plaintiffs in this case.

6. Maine's population is the oldest per capita in the country, with Medicare beneficiaries forming 23 percent - the largest percentage in America – of the State's population. Maine's citizens suffer a high incidence of chronic disease, and many are dually-eligible for Medicare and Medicaid.

7. During the period FY2013-FY2017, approximately 44-47% of the services provided by EMHS were paid for by Medicare. During this same period, EMHS operations generated average annual operating income of approximately $4 million, or operating margins averaging considerably less than 1% per year.

8. EMHS member organizations include general medical hospitals that qualify as "covered entities," as defined in 42 U.S.C. § 256b(a)(4)(l) for purposes of the 340B drug program created by Congress in 1992 ("the 340B Program"), servicing an aging community with a large proportion of Medicare beneficiaries.

9. EMHS submitted comments to the Center for Medicare and Medicaid Services ("CMS") of the Department of Health and Human Services ("HHS") opposing the regulation at

issue in this case, the 340B Provisions of the OPPS Rule, which CMS issued on November 1, 2017.

The Impact of the 340B Provisions of the OPPS Rule on EMHS PPS Hospitals

10. The 340B Provisions of the OPPS Rule would reduce Medicare outpatient payments to prospective payment hospitals for drugs purchased by those hospitals under the 340B discounted drug program ("340B Program").

11. The current CMS payment rate for these drugs is Average Sales Price ("ASP") plus 6%. The OPPS Rule would reduce this payment rate by almost 30%, to ASP minus 22.5%.

12. EMHS estimates that the payment reduction set forth in the 340B Provisions of the OPPS Rule would result in a reduction in CMS payments associated with this program to EMHS of approximately $5.4 million. Taking into account any redistributions to EMHS under these provisions, EMHS estimates that its net loss under the 340B Provisions of the OPPS Rule would be approximately $2.86 million.

13. Participation in the 340B program and the margin between hospitals' drug acquisition costs and Medicare payment rates that this program creates have helped EMHS provide health care programs to its communities, including underserved and uninsured populations within those communities, that would otherwise be financially unsustainable. For FY 16 EMHS member organizations provided traditional charity care totaling $29,053,327.

14. The 340B Provisions of the OPPS Rule at issue in this case would threaten many EMHS programs by depriving EMHS of the resources that help these programs to exist. Savings achieved through the purchase of eligible 340B discount drugs are foundational in supporting the services provided by EMHS member hospitals. Eroding those savings with a Medicare B payment reduction for certain drugs will erode hospital margins and diminish our capacity to

provide essential services to all patients in need irrespective of their ability to pay for the care delivered.

15. While many factors will have to be considered in determining how to address the greater than $5 million in lost savings annually from the 340B Provisions of the OPPS Rule, the critical EMHS service lines that would likely be impacted by those provisions, to at least some degree, include: oncology services, dialysis services, services for immediate stroke treatment, osteoporosis services, and blood factor services.

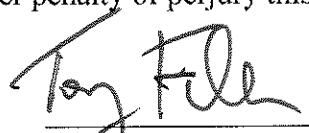
16. As one specific example, the nearly-30% payment reduction set forth in these provisions would threaten the viability of the comprehensive services provided by EMHS's Cancer Care of Maine program, the only oncology program serving the predominantly rural and economically challenged populations of northern and eastern Maine. Any curtailment of this program would have a devastating impact on these populations.

17. As another example, EMHS's The Aroostook Medical Center ("TAMC") is the only provider of kidney dialysis services in Aroostook County, Maine, a predominantly rural county bordering Canada. It is Maine's largest county, and the TAMC dialysis program serves patients residing in a 6000 square mile area. The Medicare payment reduction caused by the 340B Provisions of the OPPS Rule reduces Medicare payment for drugs essential to dialysis treatment. TAMC, along with all of the EMHS PPS hospitals impacted by the proposed rule, would also experience a nearly-30% payment reduction for life-saving drugs administered to patients experiencing a stroke or heart attack.

18. EMHS would be forced to evaluate – and likely curtail, if not cut altogether – some programs as soon as the 340B Provisions of the OPPS Rule and the new payment rate take effect, which is currently scheduled to occur on January 1, 2018.

19. The 340B Provisions of the OPPS Rule, and the short timeframe between issuance of the rule and its effective date, would also have a significant impact more generally on EMHS's overall service capabilities, affecting its budgeted operations, bond covenants, and other systems and arrangements that allow it to offer essential health care to Maine's communities, including the uninsured and underserved in those communities.

Signed under penalty of perjury this 10th day of November, 2017.



Tony Filer
Senior Vice President
& Chief Financial Officer
Eastern Maine Healthcare Systems

Exhibit J

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001, *et al.*,

Plaintiffs,

–v–

ERIC D. HARGAN, in his official capacity as the Acting Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. _____

AFFIDAVIT OF MARY WHITBREAD
IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Mary Whitbread, state as follows under the pains and penalties of perjury.

1. I am Mary Whitbread of Henry Ford Health System ("HFHS"), a Plaintiff in this action.

2. I currently serve as the Vice President of Finance, but have been employed at HFHS for 24 years. I hold a Bachelors degree in Accounting and a Masters in Finance.

3. The information set forth in this affidavit is based upon my personal knowledge.

HFHS and the Population It Serves

4. Founded in 1915 by auto pioneer Henry Ford, HFHS is a non-profit integrated health care delivery system headquartered in Detroit, Michigan. HFHS serves the metropolitan Detroit and Jackson areas of Michigan. The system has 30,000 employees, 26 medical centers, six acute care hospitals with a total of 2,405 inpatient beds, including Henry Ford Hospital ("HFH"), which is our flagship hospital and is a large academic safety net hospital located within the city of Detroit, and Henry Ford Allegiance ("HF Allegiance"), located in the city of Jackson.

5. HFH and HF Allegiance have a long and distinguished history of serving as safety-net hospitals for vulnerable people living in their communities. There are no public hospitals in Detroit or Jackson, so the few private hospitals in these cities share the burden of charity care and other forms of uncompensated care in the city as well as in the surrounding communities.

6. Located in Detroit's Midtown, HFH has served the Detroit community—which has the highest rate of concentrated poverty among the top 25 metro areas in the United States—for over 100 years and serves 22% of the Medicaid population in the region HFH is an 877-bed tertiary care hospital, education and research center, which provides comprehensive and advanced inpatient and outpatient care. HFH is also a Level 1 trauma center and one of the largest U.S. teaching hospitals.

7. Located in Jackson, HF Allegiance is a 475-bed healthcare organization that has served as the sole health system for the south central Michigan community since 1918. With more than 400 physicians, HF Allegiance's network of 40 facilities complements traditional acute care with mission-based services to address the health needs of its economically-challenged, underserved community. Jackson has a median income of $28K and a 36% poverty rate. It serves 19% of the Medicaid population in the region.

8. Both HFH and HF Allegiance are members of the American Hospital Association ("AHA"), another Plaintiff in this case.

9. HFH is also a member of the Association of American Medical Colleges ("AAMC") and American Essential Hospitals ("AEH"), also Plaintiffs in this case.

10. The communities served by HFH and HF Allegiance also include a significant number of Medicare beneficiaries. In fiscal year 2016, Medicare was responsible for approximately 47% of HFH and 48% of HF Allegiance's gross revenues.

11. Both HFH and HF Allegiance are "covered entities," as defined in 42 U.S.C. § 256b(a)(4)(L), for purposes of the 340B drug program created by Congress in 1992 ("the 340B Program"), servicing a large percentage of indigent patients.

The Impact of the 340B Provisions of the OPPS Rule on HFHS, HFH, and HF Allegiance

12. The 340B Provisions of the OPPS Rule, issued by the Centers for Medicare and Medicaid Services ("CMS") of the Department of Health and Human Services ("HHS") on November 1, 2017, would reduce Medicare payments to hospitals for drugs purchased by those hospitals under the 340B discounted drug program ("340B Program").

13. The current CMS payment rate for these drugs is Average Sales Price ("ASP") plus 6%. The OPPS Rule would reduce this payment rate to ASP minus 22.5%.

14. HFHS estimates that the almost 30% payment reduction set forth in the 340B Provisions of the OPPS Rule would result in a total loss of approximately $20 million to HFH and HF Allegiance, approximately $10 million due to reduction in payments from the Medicare program and approximately $10 million due to reduction in payments from Medicare Advantage plans (privately administered plans which tie payments for pharmaceuticals to payments under the OPPS). After accounting for the reduction in payment rates for OPPS covered services that are part of the 340B Provisions of the OPPS Rule, the net reductions would be approximately $6.9 million to HFH and approximately $2.4 million to HF Allegiance.

15. Participation in the 340B program and the margin between hospitals' drug acquisition costs and Medicare payment rates that this program creates have helped HFH and HF Allegiance provide health care programs to its communities, including the underserved and indigent populations within those communities, that would otherwise be financially unsustainable.

16. Because of the 340B program, HFH and HF Allegiance have been able to increase their margin to, among other things, help provide free and reduced cost medications to the underserved in their communities; fund contributions to the Community Health and Social Services ("CHASS") Clinic, which provides free primary care services to about 1,300 uninsured and underinsured Detroit residents every month in Southwest Detroit; operate school-based and community health programs in 11 child and adolescent health centers and two mobile medical units; and embed pharmacists in primary care and specialty clinics in Detroit to optimize treatment of chronic diseases and expand patient access through face-to-face appointments. Collectively, these programs further the goal of preventing the need for "charity care" in the form of expensive treatments for uninsured patients.

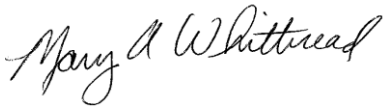
17. In addition, the increased financial resources made available as a result of the 340B program have helped HFHS provide over $391 million in uncompensated care in 2016 across its system. The total uncompensated care includes charity care, bad debt and Medicare and Medicaid underpayments. Only a small fraction of the uncompensated care we provide is counted as charity care, but we need the 340B program savings to help cover all forms of uncompensated care that we provide.

18. In short, without the 340B program, HFHS would not be able to provide the breadth of uncompensated care or other services that it currently provides across its system to vulnerable and low-income individuals.

19. The 340B Provisions of the OPPS Rule at issue in this case may threaten HFHS programs (including the programs described above in paragraph 17) by depriving HFHS of the resources that allow these programs to exist, eroding its margin and diminishing its capacity to provide essential services.

20. HFHS would be forced to evaluate – and likely curtail, if not cut altogether – some or all of its programs as soon as the 340B Provisions of the OPPS Rule and the new payment rate take effect, which is currently scheduled to occur on January 1, 2018.

Signed under penalty of perjury this _10th day of November, 2017.



Mary Whitbread
Vice President of Finance
Henry Ford Health System

Exhibit K

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001, *et al.*,

Plaintiffs,

–v–

ERIC D. HARGAN, in his official capacity as the Acting Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. _____

AFFIDAVIT OF WENDI BARBER
IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Wendi Barber, state as follows under the pains and penalties of perjury.

1. I am the Vice President of Finance and Chief Financial Officer ("CFO") of Fletcher Hospital, Inc. d/b/a Park Ridge Health ("Park Ridge"), a Plaintiff in this action.

2. I have been Vice President of Finance and CFO at Park Ridge for three (3) years. Before joining Park Ridge, I was the CFO at Castle Medical Center on the island of O'ahu in Hawaii for three (3) years – which like Park Ridge participated in the 340B drug program at issue in this case. I hold both a bachelor's degree and master's degree in business administration.

3. The information set forth in this affidavit is based upon my personal knowledge.

Park Ridge and the Population It Serves

4. Park Ridge is a not-for-profit health care system headquartered in Hendersonville, North Carolina, about 15 miles south of Asheville, North Carolina. Park Ridge employs more than 119 providers who practice at 30 locations across Henderson, Buncombe, and Haywood Counties. Our combined network of 250 medical providers serves the

communities of Hendersonville, Mills River, Fletcher, Clyde, Arden, Weaverville and Asheville, North Carolina, and includes more than 35 primary care providers and nearly 75 specialists representing over 20 specialties.

5. Park Ridge has served these communities for over 100 years, including when, in 1916, it employed the very first registered nurses in North Carolina.

6. Park Ridge is part of Adventist Health System ("AHS"), a network of approximately 45 Seventh-day Adventist-affiliated hospitals, as well as skilled nursing facilities, physician offices, home health agencies, hospice providers, urgent care facilities, and other providers in nine states. Park Ridge is the only Adventist-affiliated hospital in North Carolina.

7. Park Ridge is also a member of the American Hospital Association ("AHA"), another of the Plaintiffs in this case.

8. Park Ridge is licensed as a 103-bed hospital, with significant capacity to care for behavioral patients. It also has several outpatient clinics.

9. The communities Park Ridge serves contain a large percentage of elderly and retired persons, including a large number of Medicare beneficiaries. In fiscal year 2016, Medicare was responsible for approximately 52% of Park Ridge's gross revenues.

10. Park Ridge was able to provide over $20 million in uncompensated care in 2016.

11. Park Ridge is a "covered entity," as defined in 42 U.S.C. § 256b(4)(A), for purposes of the 340B drug program created by Congress in 1992 ("the 340B Program"), by virtue of its qualification as a "disproportionate share" hospital that treats a large percentage of indigent patients.

The Impact of the 340B Provisions of the OPPS Rule on Park Ridge

12. The 340B Provisions of the OPPS Rule, issued by the Centers for Medicare and Medicaid Services ("CMS") of the Department of Health and Human Services ("HHS") on November 1, 2017, would reduce Medicare payments to hospitals for drugs purchased by those hospitals under the 340B discounted drug program ("340B Program").

13. The current CMS payment rate for these drugs is Average Sales Price ("ASP") plus 6%. The OPPS Rule would reduce this payment rate by 28.5 percentage points, from ASP plus 6% to ASP minus 22.5%.

14. Park Ridge estimates that this payment reduction set forth in the 340B Provisions of the OPPS Rule would result in a loss to Park Ridge of over $3.7 million. Taking into account any redistributions to Park Ridge under these provisions, Park Estimates that its net loss under the 340B Provisions of the OPPS Rule would be approximately $3.3 million.

15. Participation in the 340B program and the margin between hospitals' drug acquisition costs and Medicare payment rates that this program creates have helped Park Ridge provide, on its own and in partnership with other not-for-profit community-based services, health care programs to its communities, including the underserved populations within those communities, that would otherwise be financially unsustainable.

16. Because of the 340B program, Park Ridge has been able to increase its margin to, among other things, (1) help support increased access to behavioral health and psychiatric services, (2) establish four infusion centers for the comprehensive treatment of cancer and other diseases (centers which provide services to a disproportionately large Medicare population, even as compared to the large Medicare population Park Ridge otherwise serves), (3) expand its obstetrics and gynecology ("OBGYN") capabilities (which service a disproportionate share of

indigent patients in the community), and (4) partner with various community not-for-profits to address other healthcare and social needs within Western North Carolina, such as obesity, prescription drug abuse, affordable housing, community health and wellness, and economic development.

17. In short, the savings from the 340B program allows Park Ridge with increased resources that, in turn, enable it to provide services that it otherwise could not make available, allowing low-income individuals to receive services that they would not otherwise be able to afford.

18. The 340B Provisions of the OPPS Rule at issue in this case would threaten various Park Ridge programs and community-based-partnerships that further serve the indigent as a result of the 340B program savings, by depriving Park Ridge of the resources that allow these programs to exist. For example, the nearly-30% payment reduction set forth in those provisions would threaten the continued health, or even the existence, of Park Ridge's four infusion centers, which as noted above serve a disproportionately large percentage of Medicare beneficiaries. The nearly 30% payment reduction would also threaten Park Ridge's geriatric psychiatric program.

19. Park Ridge would be forced to evaluate – and likely curtail, if not cut altogether – important programs as soon as the 340B provisions of the OPPS Rule and the new payment rate take effect – which is currently scheduled to occur on January 1, 2018.

Signed under penalty of perjury this 10th day of November, 2017.

Wendi Barber

Wendi Barber
Vice President of Finance and
Chief Financial Officer
Park Ridge Health

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001, *et al.*,

Plaintiffs,

–v–

ERIC D. HARGAN, in his official capacity as the Acting Secretary of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. _____

[PROPOSED] PRELIMINARY INJUNCTION ORDER

This matter is before the Court on the motion of Plaintiffs American Hospital Association, Association of American Medical Colleges, America's Essential Hospitals, Eastern Maine Healthcare Systems, Henry Ford Health System, and Fletcher Hospital, Inc. d/b/a Park Ridge Health (collectively, "Plaintiffs") for a preliminary injunction pursuant to Fed. R. Civ. P. 65 and Local Civil Rule 65.1, to enjoin the Defendants the Department of Health and Human Services ("HHS") and Eric D. Hargan, in his capacity as Acting Secretary of HHS, (collectively, "Defendants") from implementing certain provisions of the final rule issued by the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS. 82 Fed. Reg. 52,356 (Nov. 13, 2017). The relevant provisions of the CMS rule are found at 82 Fed. Reg. 52,493-52,511 and 52,622-52,625 and will be referred to as "the 340B Provisions of the OPPS Rule". These provisions would change the payment amount under section 1833(t) of the Social Security Act (42 U.S.C. § 1395l(t)) for certain drugs purchased at a discount under section 340B of the Public Health Services Act.

Upon consideration of the Plaintiffs' motion for a preliminary injunction, the accompanying memorandum of law and exhibits in support thereof, and the Defendants' opposition thereto, the Court finds that Plaintiffs have shown that they are likely to succeed on the merits of this action, that they will be irreparably harmed absent preliminary relief, that absent a preliminary injunction the harm to Plaintiffs would be greater than the harm to Defendants, and that a preliminary injunction is in the public interest. Accordingly, it is hereby

ORDERED that Defendants are enjoined, pending resolution of this lawsuit, including any appeal therein, from implementing the 340B Provisions of the OPPS Rule; it is further

ORDERED that Defendants shall make payments under section 1833(t) of the Social Security Act for drugs as if the 340B Provisions of the OPPS Rule did not apply.

_____ _____

United States District Judge Date

CO-386-online
10/03

United States District Court
For the District of Columbia

The American Hospital Association, et al.,

Plaintiff

vs

Eric D. Hagan, et al.,

Defendant

Civil Action No. 17-cv-2447

CERTIFICATE RULE LCvR 7.1

I, the undersigned, counsel of record for The American Hospital Association certify that to the best of my knowledge and belief, the following are parent companies, subsidiaries or affiliates of The American Hospital Association which have any outstanding securities in the hands of the public:

None.

These representations are made in order that judges of this court may determine the need for recusal.

Attorney of Record

/s/ Carlos T. Angulo
Signature

466257
BAR IDENTIFICATION NO.

Carlos T. Angulo, Zuckerman Spaeder LLP
Print Name

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CO-386-online
10/03

United States District Court
For the District of Columbia

The American Hospital Association, et al.,

Plaintiff

vs

Eric D. Hagan, et al.,

Defendant

Civil Action No. 17-cv-2447

CERTIFICATE RULE LCvR 7.1

I, the undersigned, counsel of record for America's Essential Hospitals certify that to the best of my knowledge and belief, the following are parent companies, subsidiaries or affiliates of America's Essential Hospitals which have any outstanding securities in the hands of the public:

None.

These representations are made in order that judges of this court may determine the need for recusal.

Attorney of Record

/s/ Carlos T. Angulo
Signature

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BAR IDENTIFICATION NO.

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Plaintiff

vs

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Defendant

Civil Action No. 17-cv-2447

CERTIFICATE RULE LCvR 7.1

I, the undersigned, counsel of record for The Association of American Medical Colleges certify that to the best of my knowledge and belief, the following are parent companies, subsidiaries or affiliates of The Association of American Medical Colleges which have any outstanding securities in the hands of the public:

None.

These representations are made in order that judges of this court may determine the need for recusal.

Attorney of Record

/s/ Carlos T. Angulo
Signature

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Defendant

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CERTIFICATE RULE LCvR 7.1

I, the undersigned, counsel of record for Eastern Maine Healthcare Systems certify that to the best of my knowledge and belief, the following are parent companies, subsidiaries or affiliates of Eastern Maine Healthcare Systems which have any outstanding securities in the hands of the public:

None.

These representations are made in order that judges of this court may determine the need for recusal.

Attorney of Record

/s/ Carlos T. Angulo
Signature

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CERTIFICATE RULE LCvR 7.1

I, the undersigned, counsel of record for Henry Ford Health System certify that to the best of my knowledge and belief, the following are parent companies, subsidiaries or affiliates of Henry Ford Health System which have any outstanding securities in the hands of the public:

None.

These representations are made in order that judges of this court may determine the need for recusal.

Attorney of Record

/s/ Carlos T. Angulo
Signature

466257
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United States District Court
For the District of Columbia

The American Hospital Association, et al.,

Plaintiff

vs

Eric D. Hagan, et al.,

Defendant

Civil Action No. 17-cv-2447

CERTIFICATE RULE LCvR 7.1

I, the undersigned, counsel of record for Fletcher Hospital, Inc., d/b/a Park Ridge Health certify that to the best of my knowledge and belief, the following are parent companies, subsidiaries or affiliates of Fletcher Hospital, Inc., d/b/a Park Ridge Health which have any outstanding securities in the hands of the public:

None.

These representations are made in order that judges of this court may determine the need for recusal.

Attorney of Record

/s/ Carlos T. Angulo
Signature

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