NO. 18-5004

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

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

v.

ERIC D. HARGAN, in his official capacity, *et al.*,
Defendants-Appellees.

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

APPELLANTS' EMERGENCY MOTION TO EXPEDITE

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Plaintiffs-Appellants, three hospital associations and three hospital systems, move to expedite this appeal from an order dismissing Appellants' complaint and denying a preliminary injunction that would have suspended implementation on January 1, 2018, of a new Department of Health and Human Services ("HHS") rule drastically reducing payment of Medicare funds to hospitals that provide care to poor and underserved communities. *See* 28 U.S.C. § 1657(a) (appeals from injunction ruling to be expedited; appeals also may be expedited for good cause). The provisions of the Hospital Outpatient Prospect Payment System ("OPPS") rule Appellants challenge (the "340B Provisions of the OPPS Rule") reduce by nearly 30% Medicare payments to certain public and non-profit hospitals for outpatient drugs purchased by those hospitals under section 340B of the Public Health Service Act (the "340B Program").[1] The new rule went into effect January 1, 2018, and the impact of diminished reimbursements will begin to be felt soon, with increasingly severe impacts on 340B hospitals – hospitals that serve communities with a disproportionate share of poor and underserved patients – and to their patients.

Appellants filed this action on November 13, 2017, the day the OPPS Rule was published in the Federal Register, against the Defendants-Appellees HHS and its Acting Secretary, challenging the 340B Provisions of the OPPS Rule as in

[1] 82 Fed. Reg. 52,356, 52,493-52,511, 52,622-52,625 (Nov. 13, 2017).

excess of the Secretary's statutory authority under the Medicare Act. Because the rule jeopardizes essential health programs provided to the communities served by 340B hospitals, Appellants simultaneously sought a preliminary injunction suspending implementation of the 340B Provisions of the OPPS Rule prior to its January 1, 2018 effective date, and an expedited briefing schedule. On December 29, 2017, the District Court issued an order granting Appellees' motion to dismiss for lack of subject matter jurisdiction. The District Court ruled that Appellants had not presented a specific claim to HHS for the payment to which they believed they were entitled, notwithstanding that no such claim could have been presented before January 1, 2018 and that, after January 1, 2018, no HHS decision-maker would have authority to accept reimbursement claims above the drastically reduced rate required by the rule. The District Court also denied Appellants' motion for preliminary injunction as moot.[2]

Appellants are three hospital associations (American Hospital Association ("AHA"), Association of American Medical Colleges ("AAMC"), America's Essential Hospitals ("AEH")), and three of their member hospital systems (Eastern Maine Healthcare Systems ("EMHS"), Henry Ford Health System ("Henry Ford"), and Fletcher Hospital, Inc. d/b/a Park Ridge Health ("Park Ridge")). Appellants

[2] A copy of the District Court's Order and accompanying Memorandum Opinion is attached as Exhibit 1.

request that the Court establish the following expedited schedule, so that briefs would be due by the following dates at the latest:

February 15	Appellants' Brief
March 19	Appellees' Brief
April 2	Appellants' Reply Brief

Appellants also request that oral argument be scheduled as soon as practicable upon completion of briefing.[3]

Appellants' counsel notified counsel for Appellees of Appellants' intent to file this motion and the proposed briefing schedule above. Appellees' counsel has informed Appellants' counsel that Appellees are unable to consent to the motion or to the proposed schedule at this time.

ARGUMENT

I. THIS APPEAL SHOULD BE EXPEDITED BECAUSE IT IS AN APPEAL FROM THE DENIAL OF AN INJUNCTION.

28 U.S.C. § 1657(a) provides for expedited consideration of this appeal: "[E]ach court of the United States shall expedite the consideration of any action . . . for temporary or preliminary injunctive relief." D.C. Circuit Rule 47.2(a)

[3] The Hospital Appellants are currently submitting reimbursement claims to the relevant HHS Medicare Administrative Contractors. Simultaneously, Appellants will also submit a letter to the Secretary requesting expedited review of the claims through the administrative review process and explaining that the rule mandating a nearly 30% reduction in reimbursement is invalid.

implements Section 1657(a) and directs that in such cases, the Clerk shall "prepare an expedited schedule for briefing and argument."

II. THERE IS GOOD CAUSE TO EXPEDITE THIS APPEAL.

Section 1657(a) also mandates expedited review where "good cause therefor is shown." Good cause exists when "delay will cause irreparable injury and . . . the decision under review is subject to substantial challenge" or if "the public generally, or . . . persons not before the Court, have an unusual interest in prompt disposition." D.C. Cir. Handbook, § VIII.B; D.C. Cir. Rule 27(f). Each one of the three good-cause grounds is present here – although, because this is an appeal from the denial of an injunction, the existence of good cause need not be reached.

A. Delay Will Cause Appellants Irreparable Injury.

Appellants will suffer increasing irreparable injury the longer the nearly 30% reduction remains in effect because Medicare reimbursements for 340B drugs, as intended by Congress, support 340B hospitals' ongoing operations and services. These operations and services allow those hospitals to provide critical care to their communities, including underserved populations in those communities, and are increasingly threatened if reimbursements continue to be reduced.

340B drugs are purchased under a statutory program that requires pharmaceutical companies to sell drugs at substantial discounts to certain public

hospitals and certain nonprofit hospitals that disproportionately service the poor. *See* 42 U.S.C. § 256b(a)(1), (a)(4). Congress created the 340B Program to allow covered entities "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). The Program furthers this purpose by lowering the acquisition cost of the 340B drugs while maintaining the reimbursement rates to allow covered entities to generate savings that can be used to serve their communities.

Affidavits submitted below demonstrated that the reimbursement payments for 340B drugs are used by Hospital Appellants (as well as other members of the Association Appellants) to provide essential health services to their communities, including their vulnerable, poor and underserved patients. For example, at Appellant Eastern Maine Healthcare Systems, these services include oncology services, dialysis services, services for immediate stroke treatment, osteoporosis services, and blood factor services. Ex. 2 (EMHS Aff. ¶¶ 15-16). At Appellant Park Ridge, the 340B Provisions of the OPPS Rule would threaten the continued health, or the existence of the hospital's four rural infusion centers and geriatric psychiatric program. Ex. 3 (Park Ridge Aff. ¶ 18).

Thus, the nearly-30% reduction in reimbursements to 340B hospitals will jeopardize essential health programs that are currently funded by the difference

between the amount that the government reimburses for outpatient drugs prescribed to Medicare patients 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 each year, and between $2.86 million and $9.3 million for the Hospital Appellants. *See* Ex. 2 (EMHS Aff. ¶ 12); Ex. 3 (Park Ridge Aff. ¶ 14); Ex. 4 (Henry Ford Aff. ¶ 14). The longer the reduction remains in effect, the more it will impact 340B hospitals' budgeted operations, bond covenants, and other systems and arrangements that allow those hospitals to offer essential care to their communities, as those agreements and arrangements are reviewed for renewal during the course of the year. For 340B hospitals, the ability to provide care to their communities is tied to receipt of third-party reimbursements; constriction in the flow of Medicare revenues to 340B hospitals will increasingly constrict funds for medical care for all their patients, most particularly those who are poor and underserved and most reliant on these services. *See* Ex. 2 (EMHS Aff. ¶ 19).

This restriction on Appellants' ability to provide health care constitutes irreparable harm that cannot be eliminated by a retrospective award of Medicare reimbursements, after sick patients have lost access to care, such as dialysis or a course of infusion services to treat cancer. *See, e.g., Texas Children's Hospital v. Burwell*, 76 F. Supp. 3d 224, 244 & n.7 (D.D.C. 2014) (loss of funds threatening

non-profit healthcare providers' essential services is "different in kind from economic loss suffered by a for-profit entity;" hospitals suffer irreparable harm if *hospital programs* "*may* be" eliminated – even temporarily) (emphasis added); *Arkansas Med. Soc'y v. Reynolds*, 834 F. Supp. 1097, 1101-02 (E.D. Ark. 1992) (irreparable harm found where healthcare providers would not be able to provide services to Medicaid beneficiaries).

B. The District Court's Decision Is Subject to Substantial Challenge.

The District Court's December 29, 2017 dismissal order, ruling that Appellants had not satisfied the presentment requirement under 42 U.S.C. § 405(g), is inconsistent with Circuit precedent. The 340B Provisions of the OPPS Rule are also subject to "substantial challenge."

1. The District Court erred in finding that Appellants had not sufficiently presented their claims under 42 U.S.C. § 405(g).

Section 405(g), as incorporated by 42 U.S.C. § 1395ii through § 405(h), authorizes federal courts to review claims arising under the Medicare Act if the claim has received a "final decision" from the Secretary. *Action Alliance v. Leavitt*, 483 F.3d 852, 856 (D.C. Cir. 2007). This requirement has two components: a "nonwaivable element . . . that a claim for benefits shall have been presented to the Secretary;" and a "waivable element . . . that the administrative remedies prescribed by the Secretary be exhausted." *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976).

The District Court erroneously held that Appellants "have not presented any specific claim for reimbursement to the Secretary upon which the Secretary might make a final decision." Ex. 1 (District Court Opinion at 10). In fact, however, Appellants did present their complaints to the Secretary in the form of extensive comments to the proposed 340B provisions of the OPPS rule, which is the only method by which they could obtain relief.[4] Once the final rule was issued, it required HHS officials to deny any claim for reimbursement of 340B drugs based on a rate that differed from the rate set by the final rule. No HHS official can invalidate or depart from the final rule. *See* 42 C.F.R. § 405.1063(a).

The Secretary considered and specifically responded to the arguments presented, rejecting them in the final rule. 82 Fed. Reg. at 52,499-52,502. Appellants' comments are at least as sufficient for purposes of presentment as the letter submitted outside the formal administrative process that this Court found to be sufficient in *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010), a case which the district court found had "doubtful" precedential value. Ex. 1 (District Court Opinion at 15). In fact, presenting comments objecting to the draft rule was the only meaningful way to present a

[4] *See* Ex. 5 (AHA comments at 6-8); Ex. 6 (AAMC comments at 7 and attached legal memorandum); Ex. 7 (AEH comments at 4-8); Ex. 8 (EMHS comments at 1-2); Ex. 9 (Henry Ford comments at 1-3); Ex. 10 (Park Ridge comments at 2-3, 4-5).

claim under Section 405(g), because the final rule bound all agency decision-makers who could later consider Section 340B reimbursement claims.[5]

2. Appellants Have Raised a Substantial Challenge to the Secretary's Statutory Authority to Promulgate the New 340B Provisions of the OPPS Rule.

The Medicare statute, 42 U.S.C. § 1395*l*(t)(14)(A)(iii), directs the Secretary to reimburse hospitals for separately payable outpatient drugs at average acquisition cost if accurate cost survey data are available, but if such data are not available, to set reimbursement rates at the default rate of average sales price plus 6%, as "adjusted" by the Secretary. The Secretary has never had accurate cost survey data, and acknowledges that no such data currently exist. *See, e.g.*, 77 Fed. Reg. 68,383, 68,383-68,386 (Nov. 15, 2012); 80 Fed. Reg. 70,438, 70,439 (Nov. 13, 2015); 82 Fed. Reg. at 52,501 ("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% . . . ."). Since the current reimbursement system took effect, all Secretaries have used the average sales price formula for reimbursement. *See* 77 Fed. Reg. at 68,383-68,386. From 2006 to 2011, the Secretary adjusted the default rate by no more than one or two percent (s*ee* 77 Fed. Reg. at 68,383-68,386), and

[5] Appellees also argued below that Appellants' claims are subject to statutory preclusion and are not reviewable because they are committed to agency discretion by law. The District Court did not reach these issues.

between 2012 and 2018, the Secretary has applied the default rate without any adjustment (*see* 80 Fed. Reg. at 70,439).

Here, in direct contrast to the ordinary meaning of "adjust," which this Court held in *Amgen Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), is inherently limited to moderate or incremental changes (in this case, from the statutory default rate), the Secretary dramatically reduced reimbursement rates for 340B drugs from the ASP plus 6% statutory default rate to ASP minus 22.5%. Moreover, the Secretary chose the ASP minus 22.5% figure to more closely align the reimbursement rate with some estimates of acquisition costs. Thus, the Secretary's reduction of payments for 340B drugs was inconsistent with the plain meaning of the statute and constituted an improper effort to tie the rate to acquisition costs even though the Secretary lacked the data required to use that measurement.

The Secretary's nearly-30% reduction was not only inconsistent with the term "adjust," but it also was an improper effort to dramatically alter Congress' 340B drug discount program. Indeed, as the Secretary admitted in the OPPS Rule, the very purpose of the reduction was to reduce the savings generated by the 340B program. *See* 82 Fed. Reg. 52,494-52,495. The Secretary's adjustment authority under the Medicare Act cannot be used to fundamentally alter a separate program that Congress has established. *Cf. Howard v. Pritzker*, 775 F.3d 430, 432-33 (D.C. Cir. 2015).

Congress designed the 340B Program to increase resources of hospitals that serve communities with a disproportionate share of low-income patients by lowering the acquisition cost of the 340B drugs, including drugs provided to Medicare patients, to generate funds that can be used to serve their communities, including the vulnerable populations in those communities. The 340B Provisions of the OPPS Rule undermine the 340B statute by reducing a crucial benefit of participation in the 340B program, dramatically cutting resources generated from the difference between the 340B price and Medicare payment for drugs.

C. The Public Interest Favors Expedited Review.

The public—in particular, the poor and underserved communities served by the Hospital Appellants and members of the Association Appellants—also has a strong interest in expedited review. These communities, particularly their vulnerable patients, have a compelling interest in ensuring that the critical services made possible by the 340B program continue with minimal disruption. *E.g.*, Ex. 2 (EMHS Aff. ¶ 13); Ex. 4 (Henry Ford Aff. ¶¶ 15-19); Ex. 3 (Park Ridge Aff. ¶¶ 15-18). This can only be assured through an expedited review by this Court.

CONCLUSION

For the foregoing reasons, Appellants respectfully request that the Court expedite this appeal and set the briefing schedule requested in this motion.

Respectfully Submitted,

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CERTIFICATE AS TO PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

Pursuant to D.C. Circuit Rule 27 (a)(1)(4) and 28(a)(1)(A), Appellants American Hospital Association ("AHA"), Association of American Medical Colleges ("AAMC"), America's Essential Hospitals ("AEH"), Eastern Maine Healthcare Systems ("EMHS"), Henry Ford Health System ("Henry Ford") and Fletcher Hospital, Inc., d/b/a/ Park Ridge Health ("Park Ridge") state as follows:

(1) Parties and Amici.

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

Eric D. Hargan, in his official capacity as the Acting Secretary of Health and Human Services, and the Department of Health and Human Services were Defendants before the District Court and are Appellees in this Court.

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

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

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

(2) Rulings Under Review

Appellants are seeking review of the District Court's order and memorandum opinion issued on December 29, 2017, in *American Hospital Association v. Hargan*, No. 1:17-CV-02447-RC (D.D.C.).

(3) Related Cases

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

CORPORATE DISCLOSURE STATEMENT

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

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

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

3. Appellant AEH is a not-for-profit association headquartered in Washington, D.C. It represents 325 hospital members that are vital to their communities, providing primary care through trauma care, disaster response, health professional training, research, public health programs, and other services.

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

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

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

6. Appellant Park Ridge is a not-for-profit health care system headquartered in Hendersonville, North Carolina. It is a member of the Adventist Health System, a faith-based not-for-profit health care system that provides health care services to communities in 9 states. Park Ridge in particular provides health care and related services at 30 locations across Henderson, Buncombe, and Haywood Counties in North Carolina.

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

CERTIFICATE OF COMPLIANCE

This Emergency Motion to Expedite complies with the type-volume limitation of FRAP 27(d)(2) and 32(c) because, excluding the parts of the document exempted by FRAP 32(f), this document contains 2,347 words. This document also complies with the typeface and type-style requirements of FRAP 32(a)(5) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point font size and Times New Roman type style.

/s/ Michael R. Smith
Michael R. Smith
Attorney for the Plaintiffs-Appellants

CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2018, I electronically filed the foregoing using the court's CM/ECF system which will send notification of such filing to all filers registered in this case. I also hereby certify that I caused four copies to be hand-delivered to the Clerk's Office.

/s/ Michael R. Smith
Michael R. Smith
Attorney for the Plaintiffs-Appellants

EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	:	
Plaintiffs,	:	Civil Action No.: 17-2447 (RC)
v.	:	Re Document Nos.: 2, 17, 19
ERIC D. HARGAN, Acting Secretary, Department of Health and Human Services, *et al.*	:	
Defendants.	:	

ORDER

GRANTING DEFENDANTS' MOTION TO DISMISS; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION; AND DENYING MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

For the reasons stated in the Court's Memorandum Opinion separately and contemporaneously issued, Defendants' Motion to Dismiss (ECF No. 17) is **GRANTED**; Plaintiffs' Motion for a Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**; and the Motion for Leave to File Brief as *Amici Curiae* (ECF No. 19) is **DENIED**. It is hereby:

ORDERED that the case be **DISMISSED**. This is a final, appealable Order.

SO ORDERED.

Dated: December 29, 2017

RUDOLPH CONTRERAS
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	:	
Plaintiffs,	:	Civil Action No.: 17-2447 (RC)
v.	:	Re Document Nos.: 2, 17, 19
ERIC D. HARGAN, Acting Secretary, Department of Health and Human Services, *et al.*	:	
Defendants.	:	

MEMORANDUM OPINION

GRANTING DEFENDANTS' MOTION TO DISMISS; DENYING AS MOOT PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION; AND DENYING MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

I. INTRODUCTION

This case represents a dispute between certain public and not-for-profit hospitals and the Department of Health and Human Services ("HHS") over the rates at which Medicare will begin reimbursing them for pharmaceuticals that they acquire through a federal program known as the 340B Program. Although the 340B Program has enabled eligible hospitals to purchase pharmaceuticals from manufacturers at discounts, Medicare has historically reimbursed those hospitals at rates that were significantly higher than acquisition costs. Healthcare providers, including Plaintiffs, claim that they have used this surplus to provide additional healthcare services to communities with vulnerable populations. But in 2017, the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS, issued a regulation which was designed to begin closing the gap between what hospitals were paying for drugs and the rates at which Medicare reimbursed those hospitals.

Plaintiffs in this action, three hospital associations and three of their member hospitals, contend that the Medicare reimbursement rate for 340B drugs is set by statute and that the Secretary exceeded his authority when he "adjusted" that statutory rate downward by nearly 30%. Compl. ¶¶ 47–49, ECF No. 1. In order to preserve the *status quo*, Plaintiffs now seek a preliminary injunction directing HHS and the Acting Secretary not to implement these provisions pending the resolution of this lawsuit and any appeal. Pls.' Mot. Prelim. Inj., ECF No. 2. In response, Defendants, HHS and the Acting Secretary, have opposed this motion and have themselves moved to dismiss the action pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted. *See* Defs.' Mot. Dismiss, ECF No. 17. For the reasons stated below, the Court concludes that it lacks subject matter jurisdiction because Plaintiffs have failed to present any claim to the Secretary for final decision as required by 42 U.S.C. § 405(g). Accordingly, the Court grants Defendants' motion to dismiss and denies Plaintiffs' motion for preliminary injunction as moot.

II. BACKGROUND

A. The 340B Program

In 1992, Congress established what is now commonly referred to as the "340B Program." Pub. L. 102-585. This program was intended to enable certain hospitals and clinics "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384(II), at 12 (1992). To do this, it allowed participating hospitals and other health care providers to purchase certain "covered outpatient drugs" at discounted prices from manufacturers. *See* 42 U.S.C. § 256b. Under this program, participating drug manufacturers agree to offer certain covered outpatient drugs to "covered

entities" at or below a "maximum" or "ceiling" price, which is calculated pursuant to a statutory formula. *See* 42 U.S.C. § 256b(a)(1)–(2).

B. Setting Medicare Reimbursement Rates for 340B Drugs

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. §§ 1395 *et seq.* Part A of Medicare provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* at § 1395c. Part B, provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* at §§ 1395j, 1395k.

One component of Medicare Part B is the Outpatient Prospective Payment System ("OPPS"), which pays hospitals directly to provide outpatient services to beneficiaries. *See id*. at § 1395*l*(t). Under this system, hospitals are paid prospectively for their services for each upcoming year. As part of the annual determination of OPPS rates, CMS must also determine how much Medicare will pay for "specified covered outpatient drugs" ("SCODs"). *See id*. at § 1395*l*(t)(14). Importantly, some of these SCODs include outpatient drugs that hospitals purchase pursuant to the 340B Program.

Under the statutory scheme applicable here, Congress has authorized two potential methods of setting SCOD rates. First, if available, the payment rates must be set using "the average acquisition cost for the drug for that year." *Id.* at § 1395*l*(t)(14)(iii)(I). If that data is not available, however, then the payment rates must be set equal to "the average price for the drug in the year established under [certain other statutory provisions] . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* at § 1395*l*(t)(14)(iii)(II). For 2018, the applicable provision was 42 U.S.C. § 1395w-3a, which specified that the payment rate should be the "average sales price" for the drug plus six percent ("ASP + 6%"). *See id.* at § 1395w-3a(b).

C. The 2018 OPPS Rule

On July 13, 2017, CMS issued a proposed rule for OPPS rates for the Calendar Year 2018. *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 33,558 (Jul. 20, 2017). In addition to updating the OPPS rates for 2018, CMS also proposed changing the way Medicare would pay hospitals for SCODs acquired through the 340B Program. *See id.* at 33,634. In its proposed rule, CMS noted that several studies in recent years had shown that the difference between the price that hospitals paid to acquire 340B drugs and the amount that Medicare reimbursed hospitals for those drugs was significant. *See id.* at 33,632–33. For example, in 2015, the Medicare Payment Advisory Commission ("MedPAC") estimated that, on average, "hospitals in the 340B program 'receive[d] a minimum discount of 22.5 percent of the [average sales price] for drugs paid under the [OPPS]," yet hospitals were being reimbursed at a rate of ASP + 6%. *Id.* at 33,632 (second alteration in original). The MedPAC report also observed drug spending increases correlated with hospitals' participation in the 340B Program. *Id.* Moreover, the number of hospitals participating in the 340B Program was only going higher. *Id.* at 33,633.

"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, [CMS] believe[d] it [was] timely to reexamine the appropriateness of continuing to pay the current OPPS methodology of ASP + 6 percent to hospitals that have acquired those drugs under the 340B program at significantly discounted rates." *Id.* CMS also expressed concern "about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are responsible for paying 20 percent of

the Medicare payment rate for these drugs." *Id.* Specifically, CMS was "concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs." *Id.*

Accordingly, CMS proposed lowering the Medicare payment rate for 340B Program drugs. CMS's goal was "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." *Id.* CMS, however, did not have the data necessary to "precisely calculate the price paid by 340B hospitals for [any] particular covered outpatient drug[s]." *Id.* at 33,634. For that reason, CMS believed it was appropriate to essentially estimate hospitals' acquisition costs based on hospitals' average discount under 340B. *See id.* Specifically, CMS proposed applying the average discount that MedPAC had estimated—22.5 percent of the average sales price. *See id.* CMS believed that MedPAC's estimate was appropriate and, in fact, conservative because the "actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent." *Id.*

CMS also stated its purported statutory basis for altering payment rates for 340B drugs. Specifically, CMS believed that this proposed change was within its authority "under section 1833(t)(14)(A)(iii)(II) [of] the Act [(codified at 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II))], 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 . . . as calculated and adjusted by the Secretary as necessary. *Id.* CMS conceded that it did not "have hospital acquisition cost data for 340B drugs" and, therefore, it was proposing to continue paying for the drugs under its authority at § 1395*l*(t)(14)(A)(iii)(II). *Id.* CMS proposed "exercise[ing] the Secretary's authority to adjust

applicable payment rate as necessary and, for separately payable drugs and biologicals . . . acquired under the 340B program, . . . adjust[ing] the rate to ASP minus 22.5 percent which [CMS] believe[d] better represents the average acquisition cost for these drugs and biologicals." *Id.*

The proposed rule, of course, solicited comment from the public and Plaintiffs in this case responded. Plaintiffs argued, among other things, that CMS, for various reasons, did not in fact, have the legal authority to change the 340B payment rates in the manner that CMS proposed and that adopting the nearly 30% reduction would severely impact covered entities' ability to provide critical healthcare programs to their communities, including underserved patients. *See* AHA Comments at 1–9, ECF No. 2-6; AAMC Comments at 3–6, ECF No. 2-7; AEH Comments at 3–13, ECF No. 2-8; EHMS Comments at 2–3, ECF No. 2-9; Henry Ford Comments at 1–3, ECF No. 2-10.

Nevertheless, on November 13, 2017, CMS adopted the payment reduction for 340B drugs that it had originally proposed. *See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 52,356, at 52,362 (Nov. 13, 2017). CMS did, however, respond to Plaintiffs' arguments about its authority to change Medicare reimbursement rates for 340B drugs. *See id.* at 52,499. CMS argued that the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" gave the Secretary broad discretion to adjust payments for drugs, which it believed included an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount. *Id.* CMS also disagreed with commenters that the authority to "calculate and adjust" drug rates as necessary is limited to "minor changes" and it saw "no evidence in the statute to

support that position." *Id.* at 52,500. Accordingly, CMS saw fit to use its purported authority "to apply a downward adjustment that is necessary to better reflect acquisition costs of [340B] drugs." *Id.* Under this final rule, the change to 340B reimbursement rates is scheduled to go into effect on January 1, 2018. *Id.* at 52,356.

D. The Present Action

On November 13, 2017, Plaintiffs brought suit in this Court challenging the 340B provisions of the 2018 OPPS Rule under the Administrative Procedure Act ("APA"). *See* Compl., ECF No. 1. Plaintiffs allege, as they did in their comments, that the Secretary's nearly 30% reduction in the Medicare reimbursement rate for 340B drugs was "in excess of [his] authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)" and that it, therefore, violated the APA. Compl. ¶¶ 47–49. That same day, Plaintiffs also moved for a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure. *See* Pls.' Mot. Prelim. Inj. Plaintiffs specifically requested that this Court enjoin Defendants from implementing the new 340B provisions until this case has been fully adjudicated. *See* Pls.' Mot. Prelim. Inj. Defendants opposed Plaintiffs' motion and filed their own motion to dismiss pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.[1] *See* Defs.' Mot. Dismiss. On December 21, 2017, the Court heard oral argument from the parties on both motions.

[1] On December 8, 2017, thirty-two not-for-profit state and regional hospital associations filed a consent motion for leave to submit a brief as *amici curiae* in support of Plaintiffs' motion for preliminary injunction and in opposition to Defendants' motion to dismiss. ECF No. 19. Because the Court does not reach the merits of Plaintiffs' claim, the Court finds it unnecessary to consider the amicus brief. Accordingly, the Court will deny the motion for leave.

III. ANALYSIS

The Court's analysis in this matter necessarily begins and ends with an inquiry into its own subject matter jurisdiction. On a motion to dismiss pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, it is the plaintiff's burden to establish that the court has subject matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). When considering whether it has jurisdiction, a court must accept "the allegations of the complaint as true." *Banneker Ventures, LLC v. Graham*, 798 F.3d 1119, 1129 (D.C. Cir. 2015) (citing *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992)). However, a court may also "consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Id.* (quoting *Herbert*, 974 F.2d at 197).

In this case, there is only one potential source of subject matter jurisdiction—42 U.S.C. § 405(g). "The Medicare Act places strict limits on the jurisdiction of federal courts to decide 'any claims arising under' the Act." *Am. Orthotic & Prosthetic Ass'n, Inc. v. Sebelius*, 62 F. Supp. 3d 114, 122 (D.D.C. 2014) (citing 42 U.S.C. § 405(h)). Indeed, any such claim must be brought pursuant to 42 U.S.C. § 405(g) of the Social Security Act (which is made applicable to the Medicare Act by virtue of 42 U.S.C. § 1395ii) even if the claim has been framed as a challenge under other laws or the Constitution. *See* 42 U.S.C. § 405(h); *Heckler v. Ringer*, 466 U.S. 602, 615–16 (1984) ("§ 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act") (alterations in original); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x 1, 2 (D.C. Cir. 2009) ("Parties challenging Medicare rules must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or

regulatory challenge.") (per curiam). A claim arises under the Medicare Act when its provisions provide "both the standing and the substantive basis" for the complaint. *Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975). Because Plaintiffs' sole claim is substantively based on the Medicare Act, judicial review may occur only if § 405(g)'s jurisdictional requirements are satisfied. *See Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 122 ("As all of [plaintiff]'s claims are substantively based in the Medicare Act, satisfaction of the Act's conditions regarding judicial review is required.")

Section 405(g) permits judicial review only "after [a] final decision of the [Secretary] made after a hearing to which he was a party." 42 U.S.C. § 405(g); *Mathews v. Eldridge*, 424 U.S. 319, 327 (1976). Thus, § 405(g) speaks in terms of both "ripeness" and "exhaustion." And while these are familiar concepts in the administrative law context, the Supreme Court has been clear that the requirements under § 405(g) represent an even more exacting standard. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. at 12 ("the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies'. . . ."). Indeed, while ordinary administrative law doctrines might permit judicial review under various exceptions, the Medicare Act "demands the 'channeling' of virtually all legal attacks through the agency." *Id.*

The Supreme Court has defined two elements that a plaintiff must establish in order to satisfy § 405(g). First, there is a non-waivable, jurisdictional "requirement that a claim for benefits shall have been presented to the Secretary." *Eldridge*, 424 U.S. at 328. "Absent such a claim there can be no 'decision' of any type," which "is clearly required by the statute." *Id.* Thus, the D.C. Circuit has previously described the presentment requirement as an "absolute prerequisite" to review and has found jurisdiction to be lacking where a plaintiff "proceeded

directly to district court, seeking a preliminary injunction barring HHS . . . from implementing [a] new rate reduction." *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1129–30 (D.C. Cir. 1992). The second element is a waivable "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Eldridge*, 424 U.S. at 328. Unlike the first element, however, a plaintiff may be excused from this obligation when, for example, exhaustion would be futile. *See Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992); *Nat'l Ass'n. for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015) ("Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with the other factors . . . ."). Together, § 405(g)'s two elements serve the practical purpose of "preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Salfi*, 422 U.S. at 765; *see also Ill. Council on Long Term Care, Inc.*, 529 U.S. at 13 (§ 405(g)'s requirements "assure[] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts . . . ."). In this case, Plaintiffs argue that they have satisfied the presentment requirement and that they should be excused from the exhaustion requirement. *See* Pls.' Reply at 14–17, ECF No. 20.

The Plaintiffs' problem, however, is that they have not yet presented any specific claim for reimbursement to the Secretary upon which the Secretary might make a final decision. Indeed, the Rule that sets the reimbursement rates at issue and which might form the basis of reimbursement claims that they might submit someday in the future has not yet gone into effect. The Supreme Court addressed similar circumstances in *Heckler v. Ringer*, 466 U.S. 602 (1984).

In *Ringer*, the plaintiff had not presented an actual claim, but was instead "seeking to establish a right to future payments" on a potential future claim. *Id.* at 621. The Court held that allowing an anticipatory challenge to the Secretary's policy choice in the absence of a specific claim "would be inviting [claimants] to bypass the exhaustion requirements of the Medicare Act by simply bringing declaratory judgment actions in federal court." *Id.* Thus, "[b]ecause [the plaintiff] ha[d] not given the Secretary an opportunity to rule on *a concrete claim for reimbursement*, he ha[d] not satisfied the nonwaivable exhaustion requirement of § 405(g)." *Heckler v. Ringer*, 466 U.S. 602, 622 (1984) (emphasis added); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x 1, 2 (D.C. Cir. 2009) ("anticipatory challenges to the lawfulness of a provision that might later bar recovery of benefits must proceed 'through the special review channel that the Medicare statutes create.'" (quoting *Ill. Council*, 529 U.S. at 5)).

Plaintiffs argue, however, that they have met the presentment requirement because they "submitt[ed] detailed comments during the notice-and-comment process for the 340B Provisions of the OPPS Rule." Pls.' Reply at 14. But comments submitted in a rulemaking are not individualized, "concrete claim[s] for reimbursement," as courts routinely require to satisfy presentment. *Ringer*, 466 U.S. at 625 ("Congress . . . has . . . expressly set up a scheme that requires the presentation of a concrete claim to the Secretary."). Not surprisingly then, the few Courts that have specifically considered arguments like those espoused by Plaintiffs have generally found that the submission of letters and comments that are divorced from discrete claims for reimbursement are insufficient for purposes of § 405(g). For example, in *National Association for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103 (D.D.C. 2015), another court in this District held that the presentment requirement was not satisfied when the

plaintiffs "submit[ed] comments to the agency and [] me[t] with agency officials to voice disagreement with [a particular] rule" because "an association may not challenge the constitutionality of Medicare regulations in the abstract on the basis that its members are likely to confront those regulations in the future." *Id.* at 109 n.1 (citing *Ill. Council*, 529 U.S. at 5); *see also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x at 3 (holding that plaintiff's "letter to the PRRB requesting a jurisdictional ruling" did not satisfy the presentment requirement because "[t]he Medicare Act [] requires that parties present all such challenges to the agency in the context of a fiscal year reimbursement claim"); *Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 ("Because [plaintiff's letters] were not tied to any concrete claims, [plaintiffs]'s self-described 'detailed critiques of the [agency action] . . . [were] insufficient to establish presentment.").

Plaintiffs do not cite any authority in this Circuit or elsewhere in which a court has found the submission of comments in response to an agency's request for notice and comment on a proposed regulation satisfies 405(g)'s presentment requirement. *See* Hr'g Tr. at 21:22–22:4 (Dec. 21, 2017) (admitting that Plaintiffs have not seen any "circuit case that specifically finds that commenting in a notice-and-comment period satisfies the presentment requirement"). Nevertheless, Plaintiffs attempt to bolster their argument with two cases that they claim support their position. First, Plaintiffs point to *Mathews v. Eldridge*, 424 U.S. 319 (1976), where the Supreme Court held that the plaintiff's failure to "raise with the Secretary his constitutional claim" was "not controlling." *Id.* at 329. But in that case, even though the plaintiff had not presented his precise constitutional argument to the Secretary, there had been a "'final decision' by the Secretary with respect to the [plaintiff's] claim of entitlement to benefits." *Id.* Indeed, the Court found that the named plaintiff, "[t]hrough his answers to the state agency questionnaire,

and his letter in response to the tentative determination that his disability had ceased, had specifically presented the claim that his benefits should not be terminated because he was still disabled." *Id.* Moreover, "[t]his claim was denied by the state agency and its decision was accepted by the [Social Security Administration]." *Id.* Thus, despite not presenting a particular constitutional argument to the Secretary, the plaintiff in *Eldridge*—unlike the Plaintiffs here—*had* submitted a claim for definite benefits, which the Secretary had denied. Thus, *Eldridge* does not lend support to Plaintiffs' position that comments made during the rulemaking process alone may satisfy § 405(g)'s presentment requirement.

Plaintiffs also place heavy reliance on *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33 (D.D.C. 2009), but it too offers limited support to Plaintiffs' position. In that case, two organizations and one recipient of Medicare benefits sought to challenge the Secretary's decision to recover refunds that HHS had erroneously issued to Medicare beneficiaries. After filing their complaint, plaintiffs sought, and were granted, a preliminary injunction. *See Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852, 854 (D.C. Cir. 2007). The Secretary challenged that injunction in several respects on appeal, but he did not contest subject matter jurisdiction until the D.C. Circuit itself raised the issue *sua sponte* and requested supplemental briefing. *See id.* at 856. Ultimately, the Circuit held that the district court did not have jurisdiction to consider plaintiffs' claims or to issue the preliminary injunction because the plaintiffs had not adequately presented their claims to the Secretary for a final determination. *See id.* It then remanded the case to the district court. *Id.* at 861.

Following the D.C. Circuit's opinion, the plaintiffs sent letters to the agency setting forth their various legal arguments and requesting that it accord the affected Medicare beneficiaries with certain relief. *Action All. of Senior Citizens*, 607 F. Supp. 2d at 37–38; *see also* Joint

Appendix at A-130, *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010) (No. 09-5191). The agency responded by denying the plaintiffs' requests and explaining its rationale. *See Action All. of Senior Citizens*, 607 F. Supp. 2d at 37–40. On remand, the Secretary argued that the two association plaintiffs did not satisfy the presentment requirement because the letters were from the associations rather than their members. *See id.* at 38–39. The Secretary did not argue, however, that presentment must be accomplished, if at all, through a formal submission of a concrete claim. *See* Defs.' Mot. Dismiss at 21–23, *Action All. of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33 (D.D.C. 2009) (No. 06-1607), ECF No. 49. And the district court did not address this issue on its own. Rather, the district court held that associations may present claims on behalf of their members and concluded, without explanation, that the organizations' letters satisfied § 405(g)'s presentment requirement. *See Action All. of Senior Citizens*, 607 F. Supp. 2d at 40. The district court then proceeded to consider the merits of plaintiffs' claims, but ultimately sided with the Secretary and granted his motion to dismiss. *See id.* at 42.

Plaintiffs then appealed the district court's decision. The Secretary did not cross-appeal on the jurisdictional issue and, in fact, conceded that the Circuit "ha[d] jurisdiction to address the issues presented in th[e] appeal." *See* Appellee's Brief at 11 n.2, *Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010) (No. 09-5191). And while the Secretary did present an abbreviated version of the argument made to the trial court, the Secretary still did not argue that the generalized nature of the letters in anyway made them deficient. *See id.* After reviewing the case, the D.C. Circuit affirmed the judgment of the district court and observed in a footnote that, while presentment had at one time precluded judicial review of their claims, "[p]laintiffs ha[d] since cured the jurisdictional defect." *See Action All. of Senior Citizens v. Sebelius*, 607 F.3d

860, 862 n.2 (D.C. Cir. 2010). But like the district court, the Court of Appeals did not offer any explanation as to why generalized letters satisfied the presentment requirement. *See id.* at 862.

Given the lack of any substantive discussion on the issue of whether generalized letters may suffice for purposes of presentment by either the defendant Secretary, the district court, or the Court of Appeals, at least one court has questioned the precedential value of *Action Alliance* in that regard. *See Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 ("The lack of explanation in both cases is likely because the precise question presented here—whether generalized grievance letters rather than discrete claims are sufficient to satisfy presentment—was not raised by the parties in Action Alliance, and the Court therefore questions the precedential value of those opinions."); *see also Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 144 (2011) ("When a potential jurisdictional defect is neither noted nor discussed in a federal decision, the decision does not stand for the proposition that no defect existed."); *Ticor Title Ins. Co. v. FTC*, 814 F.2d 731, 749 (D.C. Cir. 1987) ("[I]t is well settled that cases in which jurisdiction is assumed *sub silentio* are not binding authority for the proposition that jurisdiction exists." (citing *Pennhurst State Sch. & Hospital v. Halderman*, 465 U.S. 89, 119 (1984))). This Court too believes that *Action Alliance*'s value on this underdeveloped issue is doubtful. In any event, there is a meaningful difference between the letters at issue in *Action Alliance* and the comments that Plaintiffs submitted in this case. Indeed, in *Action Alliance,* the associations' letters concerned specific claims that *had already accrued to individuals* and thus "were closer to the 'concrete claim for reimbursement' that the Supreme Court has held is required for proper presentment." *Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d at 123 (quoting *Ringer*, 466 U.S. at 622). By contrast, even though Plaintiffs' comments in this case criticized the proposed 2018 OPPS Rule, they were not advancing any specific, concrete claims for reimbursement.

Thus, they cannot satisfy the presentment requirement of § 405(g). *See id.* ("Because [plaintiff's letters] were not tied to any concrete claims, [plaintiff]'s self-described 'detailed critiques of the [agency action]' . . . [were] insufficient to establish presentment."); *Ringer*, 466 U.S. at 625 ("Congress . . . has . . . expressly set up a scheme that requires the presentation of a concrete claim to the Secretary.").

In conclusion, Plaintiffs' failure to present any concrete claim for reimbursement to the Secretary for a final decision is a fundamental jurisdictional impediment to judicial review under 42 U.S.C. § 405(g). As a result, the Court must necessarily dismiss Plaintiffs' action for want of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss (ECF No. 17) is **GRANTED**; Plaintiffs' Motion for a Preliminary Injunction (ECF No. 2) is **DENIED AS MOOT**; and the Motion for Leave to File Brief as *Amici Curiae* (ECF No. 19) is **DENIED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: December 29, 2017

RUDOLPH CONTRERAS
United States District Judge

EXHIBIT 2

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.

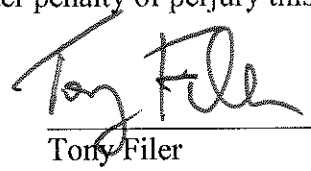
16. As one specific example, the nearly-30% payment reduction set forth in these provisions would threaten the viability of the comprehensive services provided by EMHS's Cancer Care of Maine program, the only oncology program serving the predominantly rural and economically challenged populations of 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 3

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

EXHIBIT 4

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.

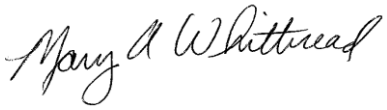
17. In addition, the increased financial resources made available as a result of the 340B program have helped HFHS provide over $391 million in uncompensated care in 2016 across its system. The total uncompensated care includes charity care, bad debt and Medicare and Medicaid underpayments. Only a small 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 5

American Hospital Association

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

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

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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 Ins. 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.**

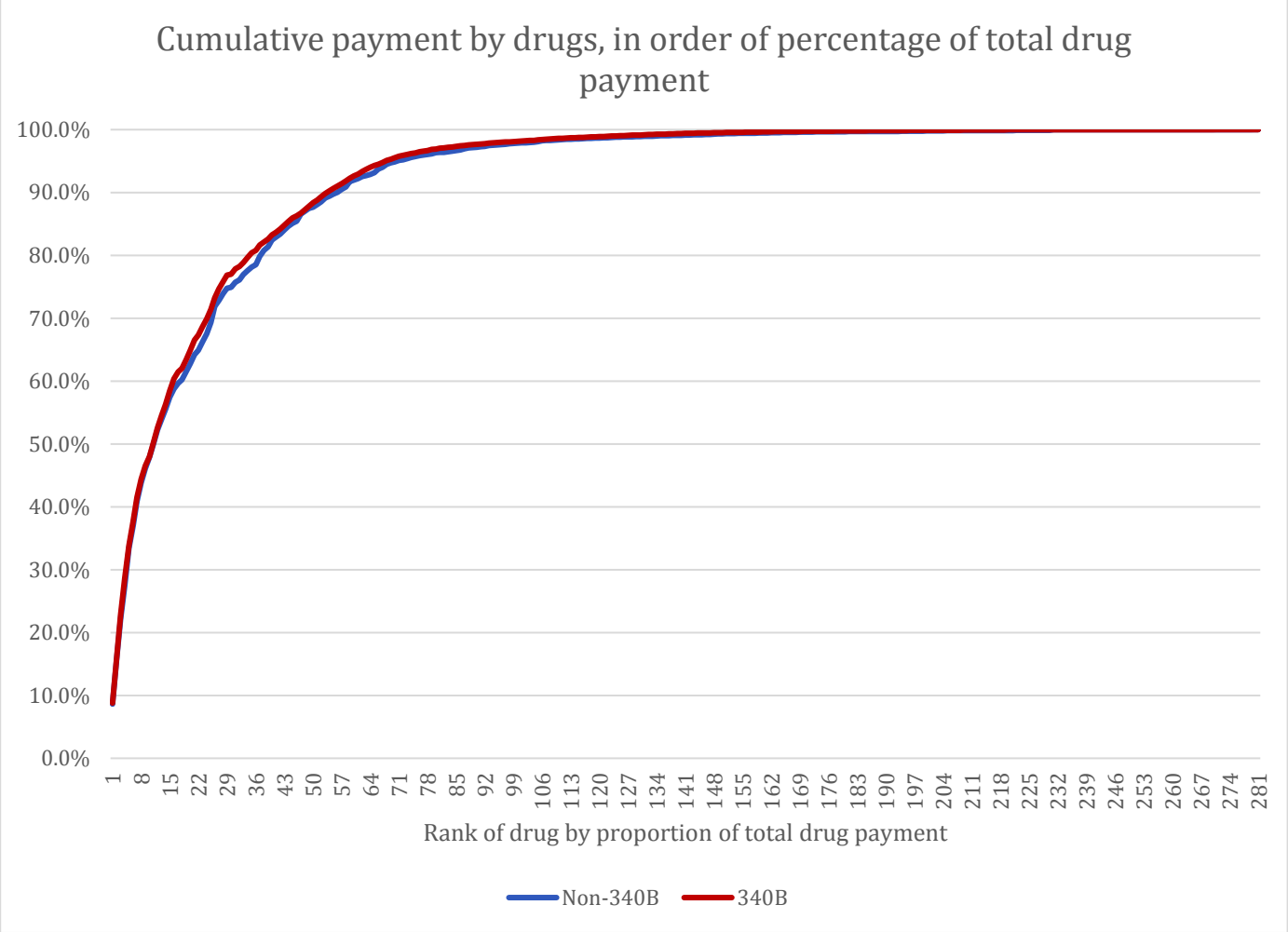
PART B DRUG EXPENDITURES INCREASES ARE LARGELY A RESULT OF OUT OF CONTROL DRUG PRICES

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.

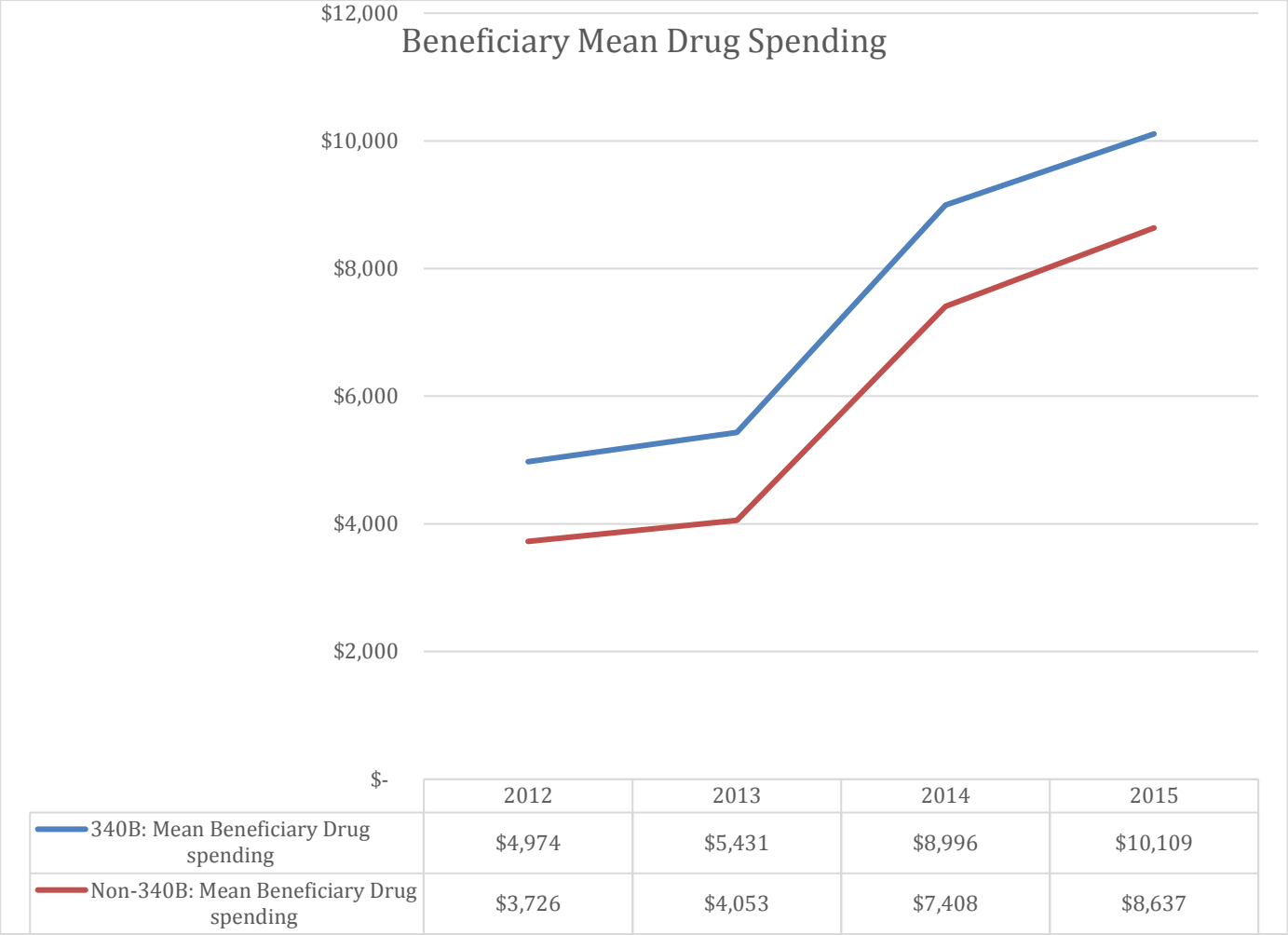
in the same mix as the non-340B. Therefore, using drugs as a proxy, 340B hospitals generally treat the same conditions in the same proportions, as non-340B hospitals and so are not overutilizing these drugs.

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.

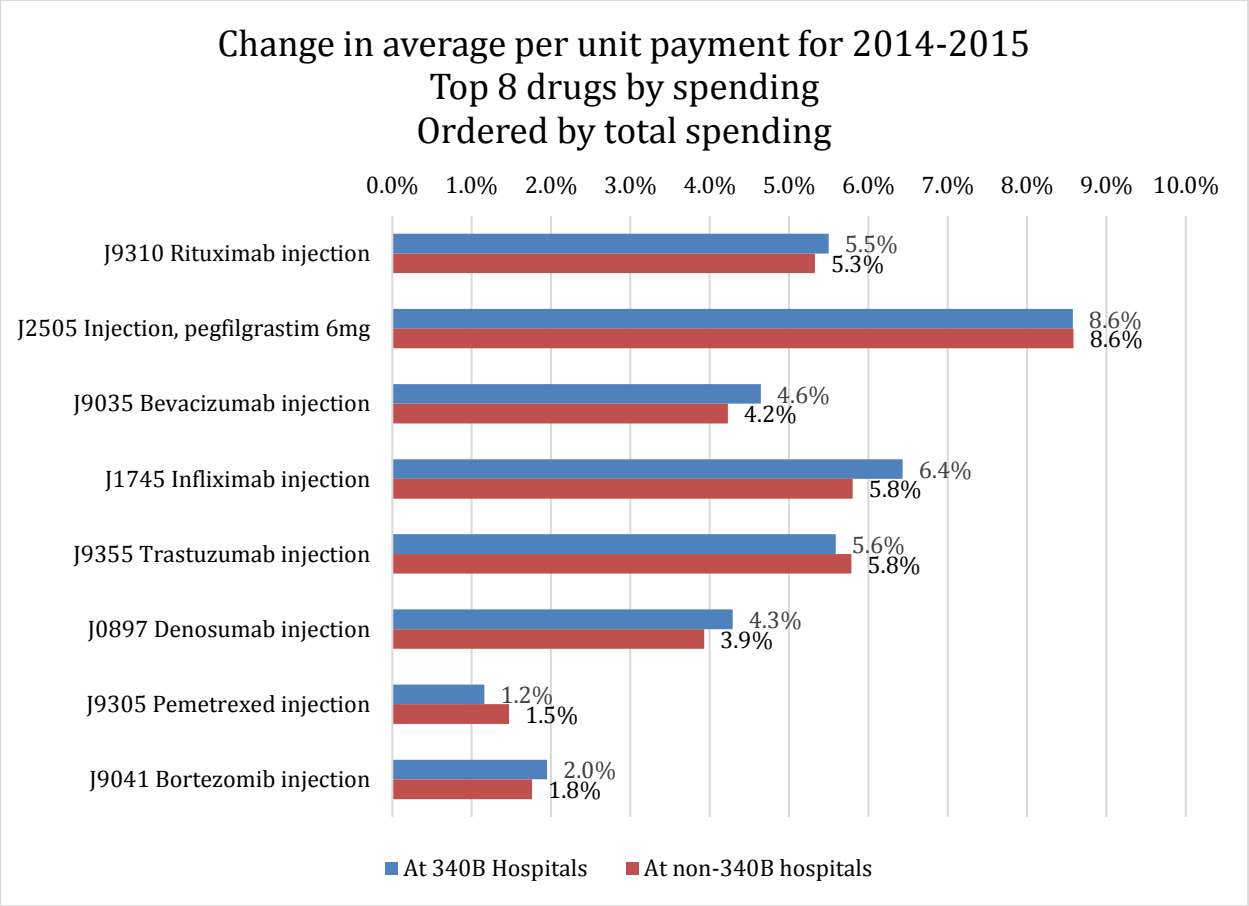
Figure 2: Beneficiary Mean Drug Spending



	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 6

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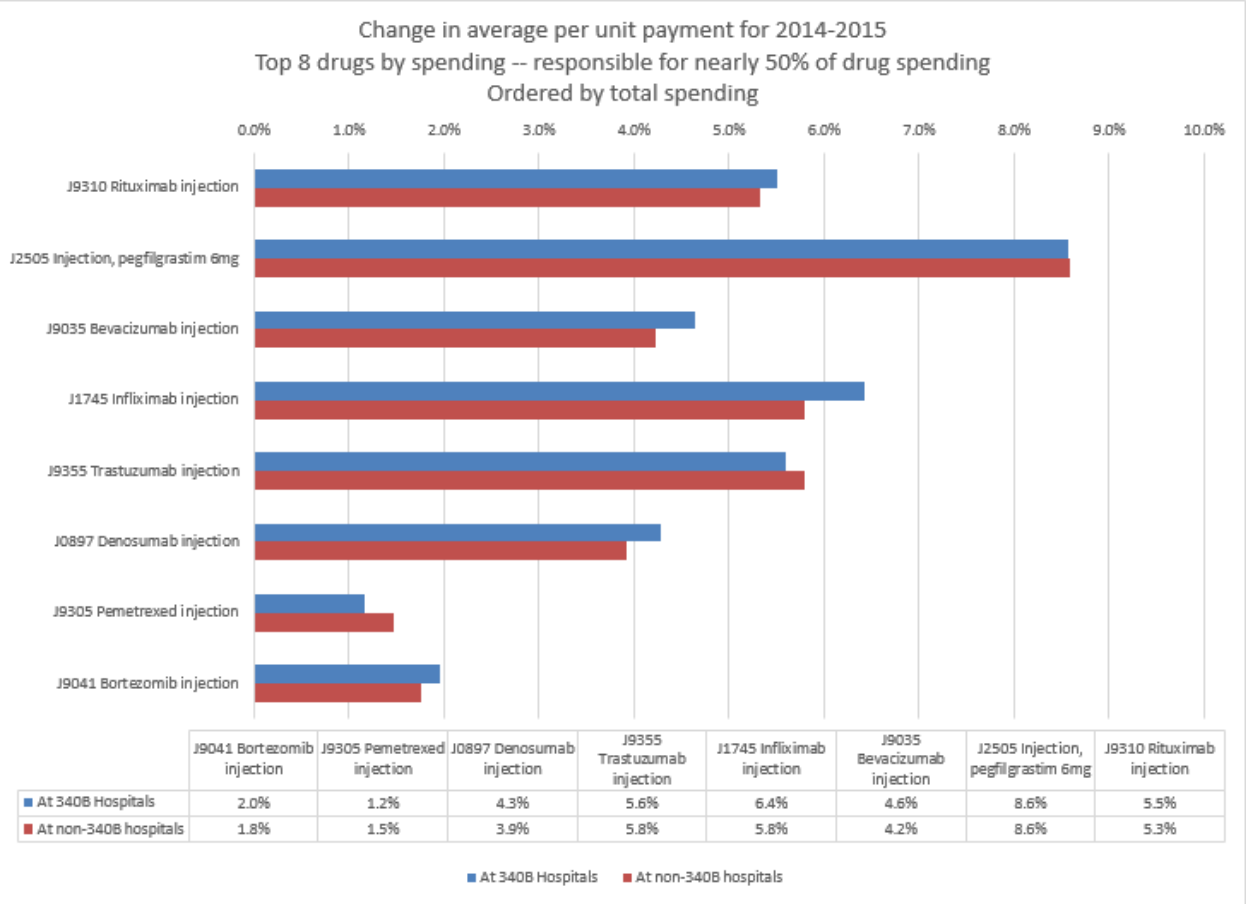
[5] MedPAC June 2016 Report to the Congress.
[6] https://www.cancer.gov/about-cancer/understanding/statistics



	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.

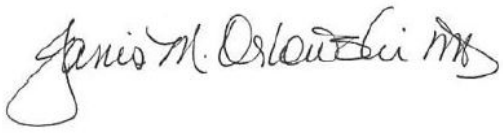
In addition, the AAMC is concerned that mail and telephone surveys, the method by which the CAHPS surveys are currently distributed, are both expensive to administer and are no longer the methodology of choice for certain patient populations. The cost associated with a mailed survey prevents hospitals 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

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Memorandum

TO:	Ivy Baer, J.D., M.P.H. Senior Director & Regulatory Counsel Association of American Medical Colleges	**Privileged and Confidential: Subject To Attorney-Client Privilege and Attorney Work Product Doctrine**
	Mark D. Polston Justin A. Torres	
FROM:	King & Spalding LLP	
DATE:	September 8, 2017	
RE:	Analysis of Statutory Authority for Proposed Changes to 340B Drug Program Payment Rates	

You asked us to analyze those portions of the recently proposed rule on Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payments Systems that relate to payments for separately covered outpatient drugs ("SCODs") under the 340B Drug Pricing Program. *See* 82 Fed. Reg. 33,558, 33,632, *et seq*. (July 20, 2017) ("2018 OPPS proposal"). Specifically, you asked us to determine whether the proposal of the Secretary of Health & Human Services and the Centers for Medicare & Medicaid Services to reduce payment rates to certain 340B "covered entities" for SCODs from average sales price ("ASP") plus 6 percent to ASP minus 22.5 percent was a permissible exercise of the Secretary's authority under the Social Security Act ("SSA") § 1833(t)(14), *codified at* 42 U.S.C. § 1395l(t)(14). In actuality, the proposal is no mere adjustment but is a cut whose purpose is aimed directly at 340B DSH hospitals.

This memo concludes that the Secretary's proposal is contrary to law and in excess of his statutory authority, *see* 5 U.S.C. § 706, for two reasons. First, the Secretary's proposal clearly runs counter to Congress's intent in designing the 340B Drug Pricing Program ("340B Program" or "program") in a way that stretches federal resources by permitting covered entities to retain the difference between their drug acquisition costs and payment rates. Second, the 2018 OPPS proposal is in excess of the Secretary's authority under SSA § 1833(t)(14), because it (a) impermissibly conflates the two alternative methods for setting payment rates, essentially discarding as too onerous Congress's requirement that any survey data used in setting payment

rates must be derived from statistically rigorous surveys; (b) impermissibly employs aggregate and not drug-specific data, contrary to the plain text of the statute; and (c) impermissibly uses 340B status as a "relevant characteristic" in varying payment rates by hospital groups, without taking into account Congress's separate treatment of 340B covered entities in the Public Health Service Act.

I. THE 340B DRUG PROGRAM AND THE 2018 OPPS PROPOSAL

The 340B Program was created to assist hospitals and other institutions that provide services to disproportionately low-income, uninsured, and underinsured populations and allow those entities to purchase drugs at reduced prices. Under the 340B Program, drug manufacturers agree to "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." Public Health Service Act ("PHSA") § 340B(a)(1), *codified at* 42 U.S.C. § 256b(a)(1). Covered entities are statutorily defined at PHSA § 340B(a)(4), and include qualifying hospitals, Ryan White HIV/AIDS program grantees, black lung clinics, rural referral centers, critical access hospitals, Title X family planning clinics, and other institutions that primarily serve the poor, indigent, or the under- or uninsured. The program is designed to enable covered entities to purchase 340B drugs for all eligible patients, including patients with Medicare or private insurance, and retain the difference if the reimbursements for the drugs exceeds their costs.

Every year, the Secretary of Health and Human Services and the Centers for Medicare & Medicaid Services set a payment rate for SCODs. Since 2013, the payment rate to all hospitals paid under OPPS, including 340B DSH hospitals, for all separately payable non pass-through drugs, including SCODs, has been ASP + 6 percent. However, in the 2018 OPPS proposed rule, 82 Fed. Reg. at 33,632, the Secretary has proposed to cut that payment rate to ASP minus 22.5 percent for 340B DSH hospitals only. This figure is based on an estimate of the average 340B discount covered entities receive "for drugs paid under the [OPPS]," which was produced by the Medicare Payment Advisory Commission ("MedPAC") in 2015. *Id*. The Secretary did not perform his own independent analysis of 340B discounts. The Secretary estimates that the proposal will reduce payments for 340B drugs by $900 million annually and will increase non-drug OPPS payment rates by 1.4 percent. 82 Fed. Reg. at 33,712. In offering this proposal, the Secretary's purported "goal is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs." *Id*. at 33,633.

II. THE SECRETARY'S PROPOSAL IS INCONSISTENT WITH CONGRESS'S INTENT IN ENACTING THE 340B PROGRAM

The 340B Program was created to assist entities that provide services to disproportionately low-income, uninsured, and underinsured populations and allow those entities to purchase drugs at reduced prices. Under the 340B Program, drug manufacturers agree to charge at or below statutorily defined prices, known as the "340B ceiling prices," for sales of

certain drugs to "covered entities." The program is designed to enable covered entities to purchase 340B drugs for all eligible patients, including patients with Medicare or private insurance, and retain the difference if the reimbursements for the drugs exceed their costs. Drug manufacturer participation in the 340B Program is essentially mandatory: Manufacturers must participate as a condition of having their drugs covered by Medicaid, *see* H.R. Rep. 102-384, at 12 (1992), and they cannot discriminate against covered entities in the distribution of drugs by, for example, setting minimum purchase amounts or treating covered entities differently from other purchasers during drug shortages, *see* 59 Fed. Reg. 25,110, 25,111 (May 13, 1994) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").

By providing manufacturers a strong incentive to participate in the 340B Program and prohibiting them from treating covered entities differently in drug distribution, Congress acted to create a dedicated, ongoing source of funding for institutions that care for vulnerable patient populations at no cost to taxpayers. The 340B Program thus reflects a Congressional purpose to fund services of covered entities that serve indigent and uninsured populations by allowing them to retain the difference between Medicare payments rates and their acquisition costs. "In giving these 'covered entities' access to price reductions, [Congress] intend[ed] to enable these 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. The fact that CMS pays covered entities more for 340B drugs than it costs covered entities to acquire those drugs—which the Secretary's 2018 OPPS proposal identified as a flaw in the program justifying the move to ASP minus 22.5 percent, *see* 82 Fed. Reg. at 33,632—is no surprise at all. In fact, far from a bug of the 340B Program, this is a *feature*; simply by normal operation of the 340B Program's design, covered entities "*should* have lower acquisition costs for many drugs." Payment for Drugs Under the Hospital Outpatient Prospective Payment System, OEI-03-09-0420, at 4 (Oct. 22, 2010) (emphasis added). *See also id.* at 8 (payment rates that exceed acquisition costs "is an expected result given the purpose of the 340B Program"). The Government Accountability Office has found that access to these reduced price medications enables covered entities "to expand the type and volume of care they provide to the most vulnerable patient populations." U.S. Dep't of Health & Human Servs., *Justification of Estimates for Appropriations Committees* at 325 (2017).

Far from limiting the program's scope to reduce covered entities' access to this funding stream, Congress has in fact acted to expand the definition of covered entity, allowing a wider range of institutions to participate in the program. *See* Pub. L. 111-148, § 7101 (2010) (expanding "covered entity" to include children's hospitals, rural referral clinics, critical access hospitals, and other institutions). HRSA estimated that this expansion enabled up to 1,500 new facilities to become "covered entities." *See* HRSA, 340B Drug Pricing Program Frequently Asked Questions: Affordable Care Act, *available at* http://www.hrsa.gov/opa/faqs/aca.htm. With this expansion, HRSA also increased its audit function to ensure program compliance. The

expansion of the program is strong evidence that the results the Secretary now decries are positive and actually reflect Congress's intent. All available evidence thus confirms that allowing covered entities to retain the difference between statutorily prescribed payment rates and acquisition costs is fundamental to the 340B Program's design and is the intended result of the program's operation.

The Secretary's 2018 OPPS proposal is no more than "a novel attempt to reconfigure Congress's statutory scheme," and is thus contrary to law and in excess of statutory authority under the Administrative Procedure Act. *Howard v. Pritzker*, 775 F.3d 430, 432 (D.C. Cir. 2015). The Secretary relies on his authority to adjust payment rates for SCODs "as necessary for purposes of this paragraph" (*i.e.*, Paragraph 14) under Section 1833(t)(14)(A)(iii)(II) of the Social Security Act. But a statutory provision such as this, which provides the Secretary with general authority to do something, cannot be read in isolation from the rest of Title 42 of the U.S. Code. Rather, this "adjustment" provision of Section 1833(t)(14) must be read in light of the entire statutory scheme. *See United States v. Bass*, 404 U.S. 336, 344 (1971) ("[C]ourts should interpret a statute with an eye to the surrounding statutory landscape and an ear for harmonizing potentially discordant provisions[.]"). Where, as in the case of the 340B Program, "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 exercise of some general authority found elsewhere in the statute. *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012) (quoting *Varity Corp. v. Howe*, 516 U.S. 489, 519 (1996) (Thomas, J., dissenting)). *See also Maracich v. Spears*, 133 S. Ct. 2191, 2204 (2013) (when Congress decides to "target [a] problem" with a specific statutory provision, other provisions "should not be construed to interfere with this statutory mechanism unless the text commands it"). In such a case, the "specific governs the general," *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992), "particularly when the two are interrelated and closely positioned," *HCSC–Laundry v. United States*, 450 U.S. 1, 6 (1981) (per curiam).

These principles govern here. Both the 340B Program and Section 1833(t) of the Social Security Act are codified in Title 42 of the United States Code and are "interrelated," in that they deal generally with the Secretary's authority to regulate outpatient drug payment rates. The Secretary has been given general "adjustment" authority under SSA § 1833(t)(14) relating to SCODs, but that general grant of authority has to be exercised in light of the specific, highly reticulated scheme Congress has enacted under the 340B Program. Congress aimed the 340B Program at a specific problem—increasing resources for care for the indigent and uninsured—and designed the program to generate revenue for covered entities in excess of their acquisition costs, in order to stretch federal resources for these institutions and permit them to expand the scope of their work. It has never acted to limit covered entities' access to funds realized through the normal and expected operation of the 340B Program In fact, Congress has enlarged the definition of "covered entity" to increase the pool of institutions that have access to this funding. Under these circumstances, the Secretary's general adjustment authority must give way to the

specific scheme enacted in PHSA when the 340B Program was created. *See RadLAX Gateway Hotel*, 132 S. Ct. at 2071; *Maracich*, 133 S. Ct. at 2204.

In fact, the import of these cases is even stronger here than in *RadLAX*, *Maracich*, or *Howard*, where the agency applied some general provision to substantially reduce the scope of a specific statutory provision. At least as to the DSH hospitals affected by these cuts, the Secretary's action fundamentally alters the 340B Program by denying DSH hospitals access to the funds that Congress intended to give them access to, which are the result of retaining the difference between acquisition costs and payment rates. *See* 82 Fed. Reg. at 33,632. If an agency is prohibited from using general authority to substantially reduce the scope of a specifically enacted program, it certainly lacks authority to so fundamentally alter a duly enacted Congressional program, even if only to a certain class of intended beneficiaries. Congress does not invest agencies with such authority through obscure statutory provisions in another law; to do so would be to hide an "elephant in a mousehole," which Congress is never presumed to do. *See Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001) ("Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes."); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000) ("Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion."). This presumption is even more warranted in this case where Congress limited the Secretary's authority to adjustments that are "necessary for purposes of" paragraph 1833(t)(14), but the Secretary's true purpose is to rewrite the 340B program.

III. THE SECRETARY'S PROPOSAL IS IN EXCESS OF HIS AUTHORITY UNDER SECTION 1833(T)(14)

Besides being clearly inconsistent with the Congressional purpose in enacting the 340B Program, the 2018 OPPS proposal exceeds the Secretary's authority under Section 1833(t)(14) itself, for three reasons:

- *First*, the Secretary is using a method to determine acquisition costs under subsection (iii)(II) of that paragraph that attempts to approximate the statutorily prescribed method under subsection (iii)(I)—without meeting any of the rigorous requirements imposed by the statute on use of survey data in setting payment rates. This amounts to rewriting the statute to discard onerous provisions.

- *Second*, the Secretary has ignored the statutory directive in Section 1833(t)(14) to set payment rates at the average acquisition cost for specific drugs and not to use averages for all drugs.

- *Third*, the Secretary proposes to use 340B status as a "relevant characteristic" for a hospital group without taking into account Congress's specific separate treatment of these covered entities in the PHSA.

A. The Secretary's Impermissible Conflation of the Two Alternative Methods for Setting Payment Rates

The purpose of Section 1833(t)(14) is to give the Secretary specific directions on how to determine the "amount of payment . . . for a specified covered outpatient drug." SSA § 1833(t)(14)(A). Under the statute, the Secretary was given specific directions on how to set payment rates in 2004 and 2005, but starting in 2006, the Secretary was directed to set payment rates by using one of two alternative processes:

1) Under subsection (iii)(I), the Secretary may set the payment rate to be equal to the average hospital acquisition cost for the drug for that year (to vary, at the discretion of the Secretary, by "hospital group" as defined by "relevant characteristics"), "as determined by the Secretary taking into account … hospital acquisition cost survey data"; or

2) Under subsection (iii)(II), if "hospital acquisition cost data are not available," the Secretary may use the average price for the drug "as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."

The statute also sets certain requirements for the hospital acquisition cost data surveys used to set payment rates for SCODs: Under subsection (iii)(I), such surveys must "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," and the Comptroller General is directed to report to Congress 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)." SSA § 1833(t)(14)(D)(iii)-(iv).

The structure of Paragraph 14 of Section 1833(t) reveals a clear purpose—Congress's preferred method of setting payment rates was to use statistically sound surveys of acquisition costs. The point of using a survey is obvious: to get beyond the data limitations caused by lack of knowledge about average manufacturing prices, the effect of discounts, and other factors that distort sales prices. The survey format also permits the Secretary to rely on recent and reliable data without having to adjust for inflation and increased drug prices. But if those surveys could not be conducted consistent with the statutory focus on statistical rigor, the Secretary was directed to set payment rates based on average price. The choice presented to the Secretary is binary; use statistically rigorous surveys to estimate acquisition costs "for each . . . drug" or use average price. He cannot use some third method of his own design for setting payment rates.

As a historical matter, the Secretary has repeatedly admitted that he has not been able to meet the requirements of subsection (iii)(I) in fashioning a statistically sound survey. *See* 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012); 80 Fed. Reg. 70,298, 70,438 (Nov. 13, 2015).[1] Accordingly, in the past, in order to achieve administrative uniformity and ease of acquisition, the Secretary has settled on an ASP + 6 percent payment rate (in order to account for overhead and administrative costs), which is in effect an exercise of the Secretary's subsection (ii)(II) authority. But here, the Secretary proposes to do something *neither* subsection allows: using a "close-enough" survey of acquisition cost data to "adjust" average sales price in the face of a clear Congressional directive that, if survey data are used to set payment rates, they must be derived from surveys that meet the statutory requirements for statistical rigor.

It cannot be denied that the aggregate estimate of 340B discounts the Secretary has proposed to use to "adjust" average sales price does not meet the requirements of Section 1833(t)(14)(D)(iii). The -22.5 percent adjustment in payment rates in the 2018 OPPS proposal is driven by the May 2015 estimate by MedPAC of "the lower bound of the average discount received by 340B hospitals for drugs paid under the outpatient prospective payment system (OPPS)." MedPAC, Overview of the 340B Drug Pricing Program, at App. A (May 2015) ("MedPAC Report"). MedPAC's method was to estimate the difference between drug ceiling prices and ASPs, based on 2013 data. *See id*. Moreover, it yields an average aggregate discount across all drugs rather than yielding an estimate of acquisition costs for "each . . . drug" as required by Section 1833(t)(14)(D)(iii). But the Secretary has offered no justification for his use of data that is not adjusted for possible changes in ceiling prices and ASPs since 2013. MedPAC was also frank about the numerous data limitations in its estimate, including the lack of information about average manufacturer price, a critical component of the ceiling price.

Here, the Secretary is using MedPAC's estimate of average discounts as a proxy or replacement for the surveys required under subsection (iii)(I). This proposal mimics the process Congress set out in subsection (iii)(I) while being devoid of its substance, *i.e.*, statistical rigor "sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each. . . drug." SSA § 1833(t)(14)(D)(iii). Essentially, the Secretary is rewriting the statute to delete the requirements relating to statistically sound surveys because he has found it impossible to comply with the letter of those requirements. But Congress planned for this possibility and gave the Secretary express direction as to what to do: apply the appropriate statutory formula, which uses the average price for the year established under another provision of the statute. *Id*. at 1833(t)(14)(A)(iii)(II). The Secretary's limited "adjustment" authority under subsection (iii)(II) does not extend so far as to gut this explicit statutory directive. *See, e.g*., *Pettibone Corp.*

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[1] Indeed, in the 2018 OPPS proposal, the Secretary asks for comment about how to undertake subsection (iii)(I) surveys in the future: "Accordingly, in the longer term, we are interested in exploring ways to identify the actual acquisition costs that each hospital incurs rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals." 82 Fed. Reg. at 33,635.

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").

B. The Proposal Impermissibly Uses An Average of the Discount on All 340B Drugs, Instead of Drug-Specific Information

Further, even were it permissible to use an estimate of 340B discounts to adjust payment rates under subsection (iii)(II), the plain text of Paragraph 14 does not permit the Secretary to use—as he proposes here—an average discount for all 340B drugs, as opposed to drug-specific information. *See Public Empls. Retirement Sys. v. Betts*, 492 U.S. 158, 171 (1989) ("[N]o deference is due to agency interpretations at odds with the plain language of the statute itself.")

The whole structure of Section 1833(t)(14) requires the Secretary to rely on an average of drug-specific acquisition cost data and sales prices, not averages for all SCODs. The paragraph is replete with references to "*the* drug" and "*a* drug," an unmistakable directive to the Secretary to use drug-specific average pricing information in fulfilling the purposes of Paragraph 14, *i.e.*, to set payment rates for SCODs. *See, e.g.*, SSA §§ 1833(t)(14)(A)(i)(I) (amount of payment for "*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"); (iii)(i) ("the average acquisition cost for *the* drug for that year"); (ii)(II) ("if hospital acquisition cost data are not available, the average price for *the* drug"); (D)(i)(I) ("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"); (D)(ii) ("The Secretary . . . shall conduct periodic subsequent surveys to determine the hospital acquisition cost for *each* specified covered outpatient drug").

But, the MedPAC discount estimate on which the Secretary proposes to rely to "adjust" payment rates from average sales price is admittedly an "aggregate discount … on OPPS-covered drugs," rather than a drug-specific discount. MedPAC Report at App. A. Indeed, the Secretary frankly admits that because of "the limitations" of the data, he has "not attempted" to calculate a drug-specific discount estimate. 82 Fed. Reg. at 33,634. This use of an aggregate discount is inconsistent with the statutory requirement under both of the methods described in subsection (iii) that payment rates be set on the basis of drug-specific data—and further removed from the clear purpose of Section 1833(t)(14), which is to require rigor in setting payment rates and not permit reliance on gross-level data. *See United States v. O'Hara*, 301 F.3d 563, 568 (7th Cir. 2002) (interpreting a statute in light of the "repeated references" in the statutory text evidencing "Congress's intent" in enacting the statute).

C. The Proposal Impermissibly Uses 340B Status as a "Relevant Characteristic" Without Taking Into Account the Purposes and Structure of the 340B Program

Finally, the 2018 OPPS proposal employs 340B status as a "relevant characteristic" by which the Secretary may vary payment rates, without taking into account the fact that 340B DSH hospitals are governed by a separate and highly reticulated Congressional enactment.

In a parenthetical, Section 1833(t)(14)(A)(iii)(I) permits the Secretary to vary payment rates to hospital groups based "on volume of covered OPD services *or other relevant characteristics*." The 2018 OPPS proposal even describes some potentially relevant characteristics by which the Secretary may, in the future, set payment rates that will vary by hospital group. *See* 82 Fed. Reg. at 33,635 ("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.").

But in the 2018 OPPS proposal, the Secretary has identified only *one* characteristic on which to vary payment—340B status. This is not within the Secretary's authority. Section 1833(t)(14) was enacted long after the Section 340B program was established, and is hardly an obscure Federal program. But Congress did not identify "340B status" as a "relevant characteristic" by which the Secretary could vary payments to hospital groups in Section 1833(t)(14). Congress enacts legislation in light of pre-existing enactments dealing with the same topics, and is not presumed to have given agencies authority to substantially alter long-standing regulatory schemes in fleeting or obscure provisions. *See Am.Trucking*, 531 U.S. at 468; *Brown & Williamson*, 529 U.S. at 160. It seems unlikely that, having created a specific, targeted program to provide drugs to hospitals at reduced cost, Congress would then permit the Secretary to undo the mechanisms of that program based on one fleeting parenthetical in a later enactment, absent any specific statutory directive. To do so would run directly counter to Congress's intent in enacting the 340B program to stretch—not to contract—federal resources directed at the indigent and under- and uninsured.

Accordingly, after reviewing the Secretary's proposal and governing statutes, cases, and regulations, we believe that the 340 Program proposal is vulnerable to challenge on several independent grounds as in excess of the Secretary's statutory authority.

APPENDIX: PROPOSED TRANSITIONAL METHODOLOGY FOR BUNDLING PROGRAMS

CHANGES TO THE INPATIENT ONLY LIST

CMS proposed to remove total knee arthroplasty (TKA) from the inpatient only (IPO) list. Without sufficient risk adjustment to account for changes in the Bundled Payments for Care Improvement Initiative (BPCI) and Comprehensive Joint Replacement (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.

The AAMC recommends that CMS adopt the second approach.

- **Revision of BPCI and CJR Baselines to Exclude Outpatient Eligible Procedures**

In the first approach, CMS would develop criteria to identify historical TKA cases that could have been performed in an outpatient setting, remove the outpatient eligible patients from the baseline episodes, and re-compute the targets without the outpatient eligible episodes. Although this proposal would preserve existing episode definitions (in which an episode may only be triggered by an inpatient admission), it would create significant methodological challenges and negatively affect hospital financial performance in the models.

- **Methodological Challenges**

In order to successfully implement this proposal, CMS must develop criteria to differentiate outpatient eligible cases from cases appropriately performed in an inpatient setting, and validate the outpatient identification methodology. However, this proposal is inherently flawed for the following reasons:

1) Many of the criteria used to determine whether or not a patient can and should receive a TKA in the outpatient setting are based on factors excluded from claims data; and
2) It is not possible to validate selected criteria.

Because CMS only has access to claims data, CMS would only be able to stratify cases by measures found in claims data. This fact poses significant limitations to the efficacy of the methodology, as physicians often consider factors not available in claims data such as body mass index, frailty, socio-economic status and smoking status, when determining the appropriate surgical setting. Consequently, this approach will not fully or accurately capture all of the historical episodes which could have been performed as outpatient procedures. Furthermore, comprehensive clinical criteria would be impossible to validate, since Medicare outpatient TKA procedures were not performed during the baseline.

An additional methodological challenge involves hospital specific variations. Because the determination of surgical setting is sometimes based on nonclinical factors such as physician preference or operating room availability, any adjustments to the targets must incorporate these hospital specific factors, which would be impossible to simulate.

- **Reduced Episode Volume**

Although this proposal would preserve existing episode definitions, it may reduce episode volume, since it would exclude patients who receive outpatient TKA procedures. Because BPCI Model 2 major joint replacement of the lower extremity (MJRLE) and CJR episodes can only be initiated by an inpatient admission, the shift in volume from procedures reimbursed under MS-DRG 469 or 470 to Ambulatory Payment Classification (APC) Code 5115 may reduce the number of episodes eligible for inclusion in BPCI and CJR. Consequently, hospitals' financial performance in the models will be based on fewer episodes compared to baseline and prior performance periods. As the AAMC has learned by aiding hospitals in the implementation of bundled payment models, decreased episode volume negatively impacts financial performance by increasing a hospital's vulnerability to variation in episode cost, as a few expensive cases can turn savings into losses without sufficient volume to compensate for outliers.

AAMC Recommends Refinement to the BPCI and CJR Models

In light of the shortcomings of the first proposal, AAMC recommends that CMS adopt the second proposal under which **BPCI Model 2 and CJR episodes could be triggered by TKA performed in the hospital outpatient department, and target prices would be stratified by inpatient/outpatient setting**.

In this approach, CMS would modify episode definitions to permit episodes to be initiated by TKA procedures performed in hospital outpatient departments. CMS would then assign different targets to outpatient TKA cases, substituting the outpatient prospective payment system (OPPS) payment for the DRG payment, while holding the post discharge portion of the target constant. Assuming that post-acute costs do not change *for the same patient* if the surgery is performed in an outpatient setting, the surplus/deficit per episode will not change and the net financial effect will be zero. That is, this proposal would have no financial impact if the factors that determine surgery setting also impact post-discharge care, but the surgery setting does not directly impact discharge disposition. An example of this calculation is shown below in Tables 1-4.

Under current rules, all patients receive TKAs in an inpatient setting (Table 1). In this example, the target price for all TKA episodes is $22,000, which includes the $11,000 DRG payment and the $11,000 post-acute care component of the target price. The hospital's net loss for all eight TKA patients is $23,000.

Table 1: Net Savings/(Losses) under Current Methodology

All Episodes Receive Inpatient TKA	Target	Index Admission Cost (DRG Payment)	Post-Acute Care Cost	Total Episode Payments	Savings or (Losses) per Episode
Patient 1	$22,000	$11,000	$15,000	$26,000	($4,000)
Patient 2	$22,000	$11,000	$10,000	$21,000	$1,000
Patient 3	$22,000	$11,000	$30,000	$41,000	($19,000)
Patient 4	$22,000	$11,000	$25,000	$36,000	($14,000)
Patient 5	$22,000	$11,000	$15,000	$26,000	($4,000)
Patient 6	$22,000	$11,000	$5,000	$16,000	$6,000
Patient 7	$22,000	$11,000	$3,000	$14,000	$8,000
Patient 8	$22,000	$11,000	$8,000	$19,000	$3,000
Net Payment Reconciliation Amount					**($23,000)**

Tables 2-3 illustrate the net savings or losses (the net payment reconciliation amount) which would result if CMS adopted the AAMC's proposal. In Table 2, the five most expensive patients receive inpatient surgery, resulting in net losses of $40,000 for all inpatient TKA episodes.

Table 2: Proposed Methodology: Impact on Inpatient Episodes

Remaining Inpatient TKA Episodes	Target	Index Admission Cost (DRG Payment)	Post-Acute Care Cost	Total Episode Payments	Savings or (Losses) per Episode
Patient 1	$22,000	$11,000	$15,000	$26,000	($4,000)
Patient 2	$22,000	$11,000	$10,000	$21,000	$1,000
Patient 3	$22,000	$11,000	$30,000	$41,000	($19,000)
Patient 4	$22,000	$11,000	$25,000	$36,000	($14,000)
Patient 5	$22,000	$11,000	$15,000	$26,000	($4,000)
Net Payment Reconciliation Amount					**($40,000)**

However, the three lowest-cost patients receive outpatient surgery (Table 3). Assuming that the OPPS payment for the corresponding CPT code for TKA is $5,000, the outpatient target is $16,000 ($22,000 - $11,000 DRG payment + $5,000 OPPS payment). The net savings for the outpatient TKA episodes are $17,000.

Table 3: Proposed Methodology: Impact on Outpatient Episodes

Outpatient TKA Episodes	Target	Index Admission Cost (DRG Payment)	Post-Acute Care Cost	Total Episode Payments	Savings or (Losses) per Episode

Patient 6	$16,000	$5,000	$5,000	$10,000	$6,000
Patient 7	$16,000	$5,000	$3,000	$8,000	$8,000
Patient 8	$16,000	$5,000	$8,000	$13,000	$3,000
Net Payment Reconciliation Amount					**$17,000**

However, when the losses from the inpatient episodes (-$40,000) are added to the savings generated from the outpatient episodes ($17,000), the overall financial results are identical (-$23,000), as shown in Table 4.

Table 4: Financial Performance Comparison: Current Versus Proposed Methodology

Surgical Setting	Current Methodology	Proposed Methodology
Inpatient	($23,000)	($40,000)
Outpatient	N/A	$17,000
Net Payment Reconciliation Amount	($23,000)	($23,000)

The experience of several AAMC hospitals supports this approach. Because surgery location *itself* does not determine the appropriate post-discharge setting, many AAMC hospitals do not modify post-acute care plans based on surgical setting. If post-discharge costs truly do not change for the same patient regardless of surgical setting, then CMS need only alter the index surgery component of target price while utilizing the same post-discharge payment for both the inpatient and outpatient target prices.

By preserving the current target structure for inpatient episodes, but simply adjusting outpatient targets to reflect surgical setting, this proposal would:

1) Maintain current MJRLE episode volume; and
2) Free CMS from making assumptions about outpatient eligible patients during the baseline period.

Additional Considerations: Short Stays

If CMS includes outpatient TKA procedures in BPCI Model 2 and CJR, CMS should further consider the impact of the substitution of outpatient TKA for short stays and develop an appropriate adjustment. Short stays discharged to post-acute care are defined as inpatient stays: 1) in which the patient is not discharged home or with self-care, and 2) lasting one day less than the geographic mean length of stay.[1] Short stays for MJRLEs, which had a geographic mean length of stay of 2.6 days for MS-DRG 470 in Federal Fiscal Year 2017, last one day/midnight.[2]

[1] *CMS Price (Payment) Standardization-Detailed Methods*. Vol. 5.
[2] FY 2017 IPPS Final Rule, Federal Register, Table 5: List of MS-DRGs, Relative Weighting Factors and Geometric and Arithmetic Mean Length of Stay.

These cases may the ones most likely to move from an inpatient to an outpatient setting. In these cases, an OPPS payment will replace an IPPS payment and the AAMC's recommended target price adjustment would no longer be financial neutral as in the above example. Consequently, CMS needs to develop a methodology to adjust for the difference in payment in this circumstance. AAMC would welcome the opportunity to discuss this further with CMS and suggest potential options.

The AAMC supports CMS' 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. As we note above, TKA, like all other cases where a patient status determination is made, should be subject to the two-midnight rule. 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.

Conclusion

In order to ensure the continued success of the BPCI and CJR models, the AAMC recommends that CMS adopt the following provisions if it finalizes the removal of TKA from the IPO list:

1) Allow BPCI Model 2 and CJR episodes to be triggered by TKA performed in a hospital outpatient department;
2) Calculate target prices stratified by inpatient/outpatient setting; and
3) Explore appropriate adjustments for the shift of some inpatient short stays to the outpatient setting.

EXHIBIT 7

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.

[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. CMS should permit non-excepted PBDs to retain their excepted status if they change ownership.

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.**

****

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 8

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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 9

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).

Cuts to Part B Drugs Purchased Under the 340B Discount Drug Program

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

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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.

Hospital Outpatient Quality Report (OQR) Program: Quality Metrics

HFAH 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.

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 10

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