



**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 OPSS 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 OPSS 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.

Ms. Seema Verma
September 11, 2017
Page 3 of 37

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

Sincerely,

/s/

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

Enclosure

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

TABLE OF CONTENTS

ALTERNATIVE PAYMENT METHODOLOGY FOR DRUGS PURCHASED UNDER THE 340B DRUG PRICING PROGRAM.....	5
CMS’s Proposed Cuts Would Undermine the Congressionally-mandated Mission of the 340B Program.....	9
Most Medicare Beneficiaries Would Not Directly Benefit from CMS’s Proposal	12
Part B Drug Expenditures Increases are Largely a Result of Out of Control Drug Prices.....	12
Other Issues Regarding CMS’s 340B Drug Payment Proposal	16
PROPOSED CHANGES TO THE INPATIENT ONLY LIST	19
Proposed Removal of Total Knee Replacement from the Inpatient Only List.....	19
Solicitation of Public Comments on the Possible Removal of Partial Hip Arthroplasty and Total Hip Arthroplasty Procedures from Inpatient-only List	20
Proposed Packaging of Low-Cost Drug Administration Services	21
POTENTIAL REVISIONS TO THE LABORATORY DATE OF SERVICE POLICY	22
Recommended Changes to the Proposed Date of Service Policy	23
Possible Changes to the “Under Arrangements” Provisions.....	25
Caveat about Testing Conducted using Specimens Obtained from Hospital Inpatients	25
ENFORCEMENT INSTRUCTION FOR THE SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS HOSPITALS (CAHS) AND CERTAIN SMALL RURAL HOSPITALS....	25
BLOOD AND BLOOD PRODUCT CODING.....	27
BRACHYTHERAPY INSERTION PROCEDURES	28
PARTIAL HOSPITALIZATION PROGRAM MINIMUM SERVICE REQUIREMENT: 20 HOURS PER WEEK.....	28
Request for Comments on Payment Differentials for Similar Services Provided in Inpatient and Outpatient Settings	30
Request for Information on Physician-owned Hospitals.....	30
OUTPATIENT QUALITY REPORTING (OQR) PROGRAM	31
Appendix A: Current CMS Quality Measures for Retention Aligned by AHA Quality Measurement Priority Area	36

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 1395l(t)(14)(A)(iii)). Indeed, the overall statutory scheme of section 1395l(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 1395l(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 billion⁴, 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 1395l(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 1395l(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 1395l(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 OPSS 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 OPSS 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 1395I(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)

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.gov/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 340B 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 § 1395I(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 1395I(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 OPSS outside of OPSS. 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 1395I(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 services¹⁷ 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 OPSS 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 OPSS 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 OPSS 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 OPSS or outside of the OPSS 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

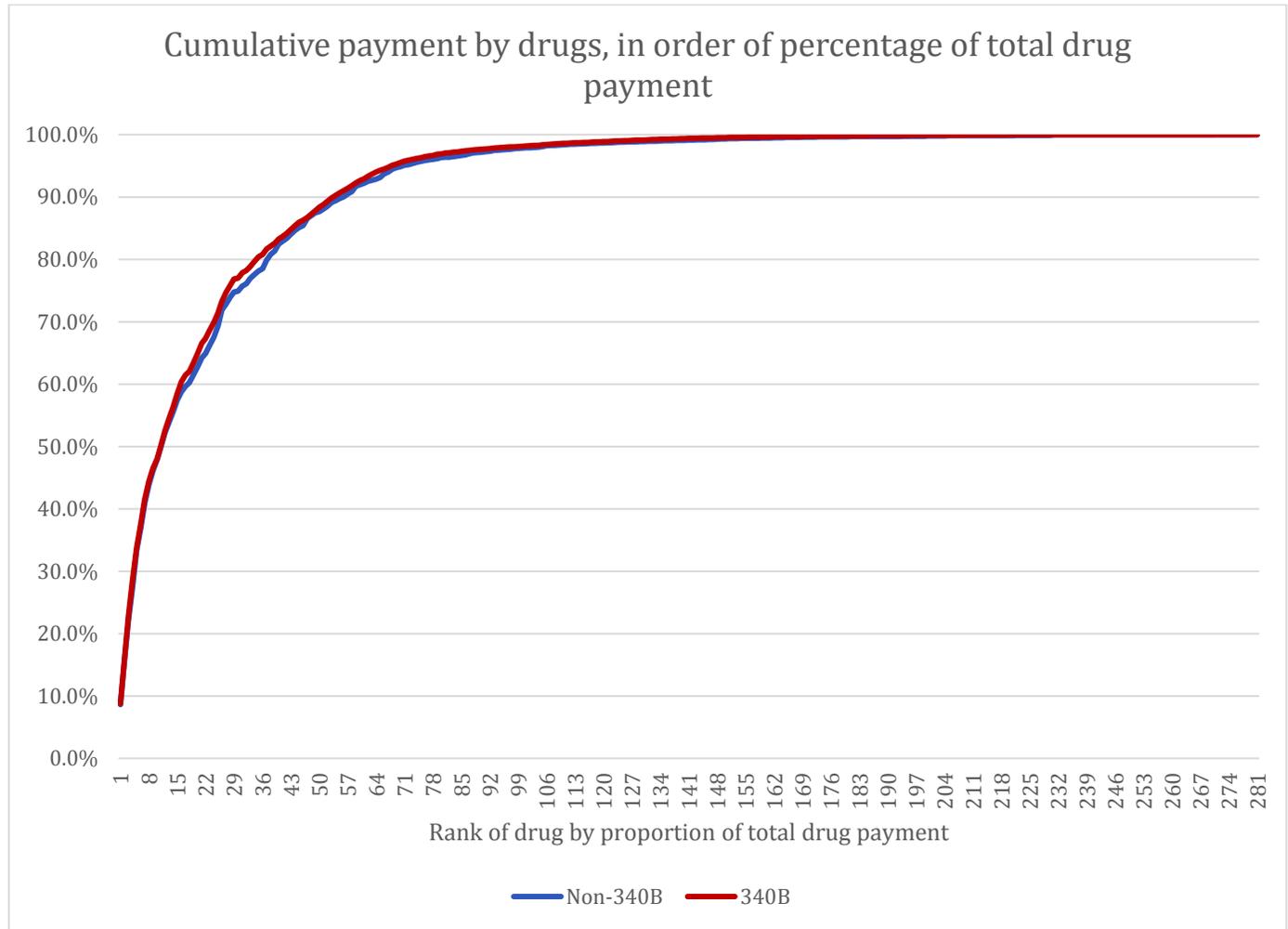
As part of the impetus for its proposal, CMS states a concern that "the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs."²⁰ However, our data do not support this concern, and, in fact contradict it, showing that 340B hospitals 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.

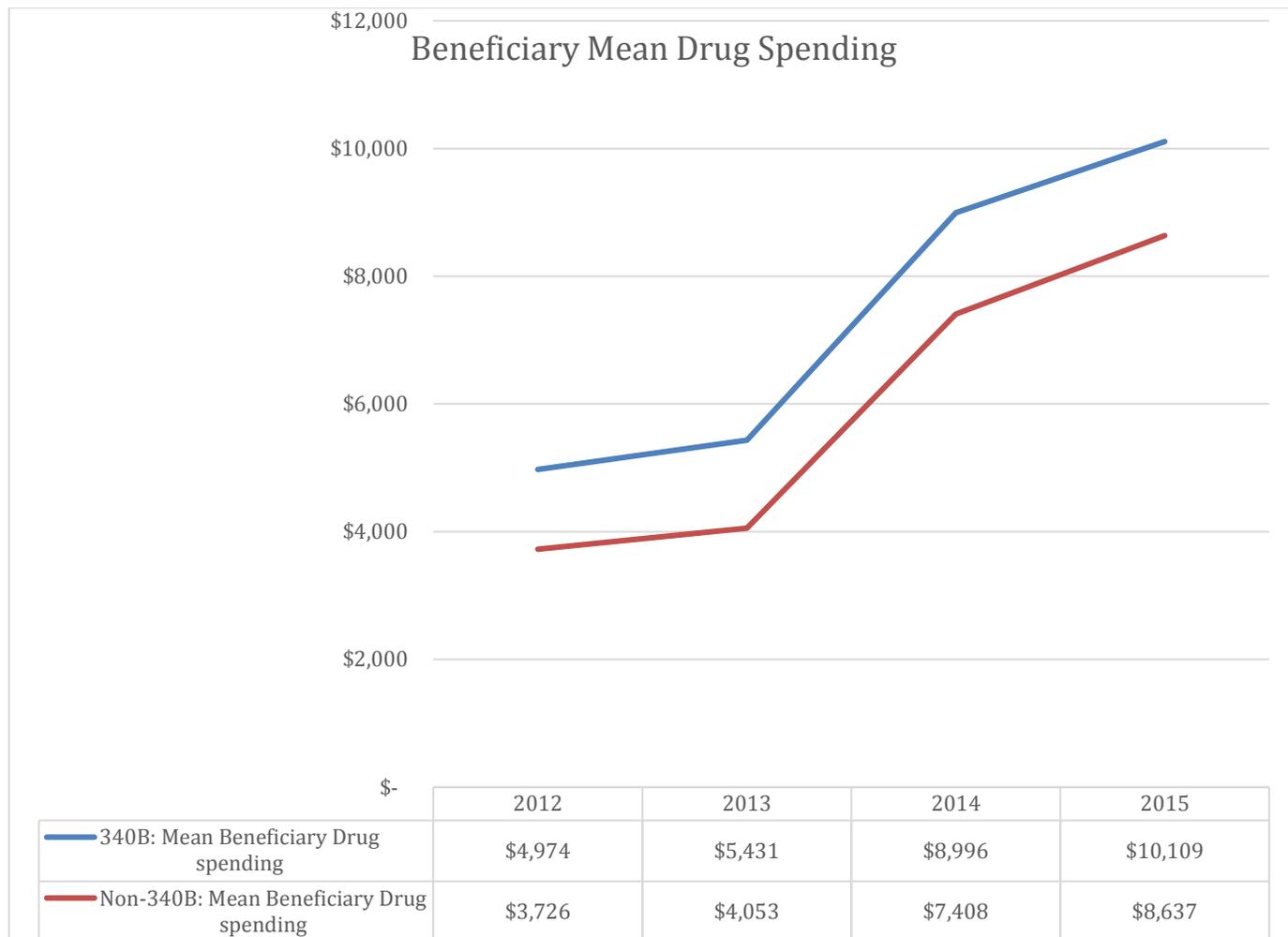
in the same mix as the non-340B. Therefore, using drugs as a proxy, 340B hospitals generally treat the same conditions in the same proportions, as non-340B hospitals and so are not overutilizing these drugs.

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



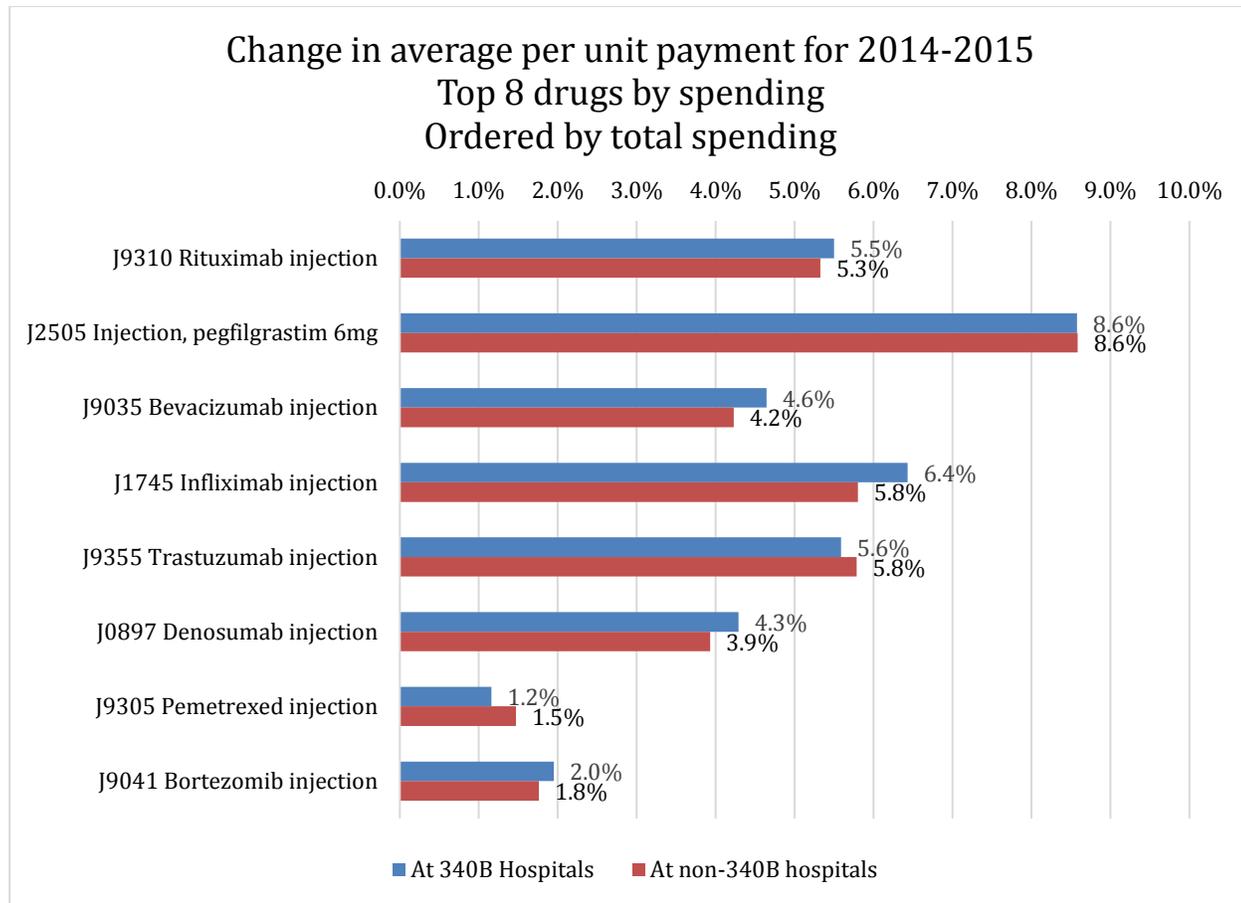
In addition, in our analysis of beneficiary mean drug spending, we found that even without adjusting for difference in case mix between 340B and non-340B hospitals, Part B drug expenditures increase along parallel tracks in these two types of hospitals over time (See Figure 2). We acknowledge that beneficiary 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



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.

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 OPPTS 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 OPDS, 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 OPSS 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 OPSS 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 OPSS 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 OPSS 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 OPSS/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 Request³⁹ 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 OPSS 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 OPSS 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
<p>Patient Safety Outcomes</p> <ul style="list-style-type: none"> • Harm Rates • Infection Rates • Medication Errors 	<p>Central-line associated bloodstream infection (CLABSI)</p> <p>Surgical site infection (colon and hysterectomy procedures only)</p> <p>Catheter-associated urinary tract infection (CAUTI)</p> <p><i>Clostridium Difficile</i> (C Difficile)</p> <p>Methicillin Resistant Staphylococcus Aureus (MRSA)</p> <p>Global influenza vaccination</p> <p>Influenza vaccination coverage among health care personnel (inpatient)</p> <p>OP-27: Influenza vaccination coverage among health care personnel (outpatient)</p>	<p>Risk-standardized complication rate following elective primary total hip and/or total knee arthroplasty</p> <p>Severe sepsis and septic shock management bundle</p>
<p>Readmission Rates Effective Patient Transitions</p>		<p>AMI 30-day risk standardized readmission</p> <p>HF 30-day risk standardized readmission</p> <p>PN 30-day risk standardized readmission</p> <p>Total Hip / Total Knee Arthroplasty (THA/TKA) 30-day risk standardized readmission</p> <p>COPD 30-day risk standardized readmission</p> <p>CABG 30-day risk standardized readmission</p> <p>Acute ischemic stroke (STK) 30-day risk standardized readmission</p> <p>Hospital-wide all cause unplanned readmission</p> <p>OP-32: Facility 7-day risk-standardized hospital visit rate after outpatient colonoscopy</p>
<p>Risk Adjusted Mortality</p>		<p>Acute myocardial infarction (AMI) 30-day mortality rate</p> <p>Heart failure (HF) 30-day mortality rate</p> <p>Pneumonia (PN) 30-day mortality rate</p> <p>COPD 30-day risk standardized mortality</p> <p>Coronary artery bypass graft (CABG) 30-day mortality</p> <p>AMI 30-day risk standardized readmission</p>

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		<p>OP-33: External beam radiotherapy (EBRT) for bone metastases</p> <p>OP-29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients</p> <p>OP-30: Endoscopy/Poly Surveillance: Colonoscopy interval for patients with a history of adenomatous polyps—Avoidance of inappropriate use</p> <p>OP-8: MRI lumbar spine for low back pain</p> <p>OP-11: Thorax CT – Use of contrast material</p> <p>OP-13: Cardiac imaging for preoperative risk assessment for non-cardiac low risk surgery</p>
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