Via Electronic Submission (www.regulations.gov)

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 its 71 acute care hospital members, the New Jersey Hospital Association (NJHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year (CY) 2018 hospital outpatient prospective payment systems (OPPS).

While we support a number of the rule's provisions, we have serious concerns about other proposals. In particular, **NJHA is extremely concerned about the 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. NJHA also opposes the removal of both total knee replacement and PHA/THA from the inpatient-only list.**

NJHA's detailed comments on these proposals follow. In a separate letter for the CY 2018 physician fee schedule proposed rule, we will provide comments on the proposed payment reduction for "nonexcepted" services provided in off-campus provider-based departments.

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

The Centers for Medicare & Medicaid Services 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]

NJHA 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 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 OPPS is limited

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

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

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

However, the plain and ordinary meaning of the terms "calculate" and "adjust" express a limited and circumscribed authority to set the payment rate. The Oxford Dictionaries define "calculate" as "determine (the amount or number of something) mathematically." Likewise, to "adjust" is to "alter or move (something) slightly in order to achieve the desired fit, appearance, or result." Consequently, the statutory subclause restricts the agency to determining mathematically an appropriate, slight alteration that should be applied to the statutory default rate in any given year. It does not convey, as CMS asserts, the power to adopt a novel, sweeping change to the payment rate that is a significant numerical departure from the previous rate and that would result in a reduction in payment to 340B hospitals of at least $900 million, according to the agency's own estimates. CMS's proposal is not the slight alteration to the payment rate permitted under the statute.

Overall Statutory Scheme Reinforces Limited Authority of Agency. **That this statutory subclause conveys only limited authority to CMS is further reinforced by the overall scheme of section 1395*l*(t)(14), which directs CMS to establish payment rates for separately payable OPPS drugs within significantly prescribed parameters.**[4] Specifically, the first two subparagraphs of this section, ((t)(14)(A)(i) and (t)(14)(A)(ii)), provide the agency with no separate authority to adjust the 2004 and 2005 payment rates. Subclause (I) of the next subparagraph ((t)(14)((A)(iii)) ─ establishing that the payment rate for subsequent years be set to the average acquisition cost of the drug taking into account hospital acquisition costs survey data collected through surveys meeting precise requirements spelled out in a subsequent statutory subparagraph ─ also provides no adjustment authority for the agency. Subclause (II) of (t)(14)((A)(iii) directs CMS, where such acquisition cost data are not available, to set payment rates by reference to ASP provisions. Considered in context, the statute reflects an intent by Congress to limit CMS's authority to set payment rates and, consequently, is consistent with reading any adjustment authority under subclause (II) ─ which CMS relies on ─ as conveying only limited authority for the agency to adjust the payment rate.

Current Agency View Contrasts with Long-standing Practice. **CMS's assertion that it has very broad authority to make the substantial adjustment proposed here contrasts sharply with the agency's previous view and long-standing practice applying the statutory scheme of section 1395*l*(t)(14).** Since CMS began relying on subclause (II) in 2012 to set the payment rate, the agency has never

[4] *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.").

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."[5] Moreover, CMS has applied the rate *without further adjustment* in each subsequent year. CMS's proposal for 2018, in contrast, departs dramatically from long-standing prior practice and adopts a substantially reduced payment rate of ASP minus 22.5 percent.

CMS Effectively Repeals 340B Program In Proposal. **Regardless of the actual breadth of adjustment authority conferred upon the agency by the statutory provisions for establishing payments rates for separately payable drugs under OPPS, section 1395*l*(t)(14)(A)(iii)(II) does not authorize CMS to "calculate[] and adjust[]" the payment rate in a manner that would eviscerate the 340B program as it applies to 340B hospitals**.[6] 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."[7] 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 acquisition costs to generate "[a]dditional program resources" that will enable them to provide more access to, and more comprehensive, health care services.[8]

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.[9] 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.

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[5] 77 Fed. Reg. at 68386.
[6] See *Roberts*, 566 U.S. at 132. (In interpreting statutes, the "task is to fit, if possible, all parts into a harmonious whole.").
[7] H.R. REF. No. 102-384(II), at 12 (1992).
[8] See, e.g., HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Services Act*, at Part 1.G (July 2005), available at https://www.hrsa.go9v/hemophiliatreat,emnt/340manual.htm#21 (last accessed Aug. 22, 2017). See also U.S. Gov't Accountability Off., GAO-11-836, Manufacturer Discount in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (Sept. 2011), at 17-18 (finding that studied covered entities generated revenue from the 3408 Program and used the revenue in ways consistent with the program's purposes, e.g., by providing additional services at more locations, patient education programs, and translation and transportation services that the entities otherwise could not afford).
[9] See *Hemophilia Treatment Manual*, *supra*.

Proposal is Procedurally Defective. **CMS's proposed new payment rate also is procedurally defective under the OPPS statute.** CMS's justification for the proposed reduced rate rests in part on intertwined issues related to clinical use and hospital cost of drugs. Pointing to a study suggesting that 340B hospitals may be unnecessarily prescribing more drugs and/or more expensive drugs relative to non-340B hospitals, CMS suggests that a payment rate that eliminates the differential between acquisition cost and Medicare OPPS payment may help to reduce the incentive to overprescribe. These are precisely the kind of factors that should have been considered by the expert Advisory Panel with which CMS is obligated by section 1395*l*(t)(9)(A) of the statute to consult, and from which it is obligated to seek advice, as part of the process of review and revision of the payment groups for covered outpatient department services and the relative payment weights for the groups. The statute mandates CMS review and revise the payment groups and the relative payment weights for the groups not less often than annually. **As part of the process, CMS must consult with the outside Advisory Panel for advice relative to the clinical integrity of the payment groups and the payment weights, which encompass considerations of data on hospital costs and clinical use.[10] 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.[11] 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) collect data from public comments and other sources, such as state Medicaid programs in Texas and New York, on the potential impact of revising the payment rate, implementing a modifier code, and the effects of possible mechanisms for redistributing the savings from changing the payment rate and, (2) assess the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved.

CMS's proposal also violates section 1395*l*(t)(2)(E) because it is not authorized and because the agency had not offered a reasoned basis for applying savings achieved as a result of its proposal to reduce significantly payments to 340B hospitals to Part B services generally. Consistent with the Administrative Procedure Act, the agency itself must offer a reasoned basis for taking the unprecedented action it proposes to take here.[12] The agency, as a matter of longstanding policy and practice, has never applied savings from OPPS outside of OPPS. The agency's announcement in the proposed rule that it might do so is an unprecedented departure from previous policy and practice. It also is not authorized by section 1395*l*(t)(2)(E) and would result from a legally questionable proposal that by CMS's own estimates would reduce direct payments to 340B hospitals by as much as $900 million a year. The significant reduction in direct payments to 340B participating hospitals and redistribution of resulting savings to other Part B programs and services would have a tremendous negative impact on 340B hospitals and unquestionably diminish their ability to offer vital health services to vulnerable populations for which the 340 program is designed. The proposal cannot be maintained as part of any final rulemaking from the agency.

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[10] *See* § 1395*l*(t)(2)(C).
[11] *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).
[12] *Motor Vehicle Assn of US, Inc. v. State Faun Mut. Auto lns. Co.*, 463 U.S. 29, 42 (1983) (an agency proposing to "chang[e] its course" from a longstanding practice "is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.").

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."[13] 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 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.[14] In addition, in 2015, 340B hospitals provided $23.8 billion in uncompensated care.[15]

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;

[13] https://www.hrsa.gov/opa/index.html
[14] 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
[15] American Hospital Association 2015 Annual Survey Data

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

In addition, an examination of key hospital services[16] 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.
- Alcoholism-Drug Abuse or Dependency Outpatient Services: 42 percent of 340B hospitals provide substance abuse or dependency services while just over one-third of all hospitals provide such services.
- Neonatal Intensive Care Units (NICU): 58 percent of 340B hospitals have NICUs while less than half of all hospitals have a NICU.
- Breast Cancer Screening: Nearly all 340B hospitals provide breast cancer screening while 93 of all hospitals provide such services.

Financial Status of 340B Hospitals. As noted, many 340B hospitals are the lifelines of their communities, and the discounts they receive through the 340B program play an important role in allowing them to care for patients. However, these facilities are financially vulnerable. In 2015, one out of every four 340B hospitals had a negative operating margin. In addition, 340B hospitals paid under OPPS had total and outpatient Medicare margins of negative 18.4 percent and negative 15.4 percent, respectively, whereas hospitals overall had total and outpatient Medicare margins of negative 15.5 percent and negative 13.5 percent, respectively. [17]

CMS's proposed cuts would make these hospitals' financial situations even more precarious, thus putting at great risk the programs they have developed to expand access to care for their vulnerable patient populations. CMS estimates that its proposal would reduce OPPS payments for separately payable drugs, including beneficiary copayment, by as much as $900 million. However, based on an analysis conducted by the American Hospital Association (AHA), the proposed cut would reduce payments for 340B-acquired drugs by almost double that much – $1.65 billion. Even AHA's lower bound impact estimate of $1.25 billion, which considers only the top 60 drugs that they believe are eligible for 340B program pricing, is significantly higher than CMS's estimate. Further, these

[16] Ibid
[17] Ibid

estimates are conservative, as AHA's analysis, unlike CMS's, strips out data for those separately payable drugs (i.e. status indicator K drugs) that are packaged into comprehensive APCs, and they 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 AHA's estimate is so different. However, AHA has consulted with many stakeholders and experts and we have confidence in their analysis.

Moreover, if CMS implements the policy as it proposed, in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, AHA's analysis shows that payments for non-drug APCs would increase across hospitals by about 3.7 percent (in contrast to CMS's estimate of 1.4 percent). This redistribution would result in a net decrease in payments to 340B hospitals of about 2.6 percent, or approximately $800 million. **Plainly stated, even accounting for adjustments to ensure overall budget neutrality, CMS's proposal would remove $800 million intended to support the congressionally-mandated mission of 340B hospitals from these already vulnerable facilities and redistribute these dollars to other hospitals that do not participate in the 340B program. This would not only undermine the purpose of 340B, but also would further erode the financial viability of 340B hospitals.** Other approaches to achieving budget neutrality under consideration by the agency, such as applying off-setting savings to specific services within the OPPS or outside of the OPPS to Part B generally (such as physician services under the Medicare Physician Fee Schedule) would similarly penalize these most vulnerable hospitals and inhibit their efforts to carry out the purpose of the 340B program. Finally, 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.[18] **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, AHA 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. AHA 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.

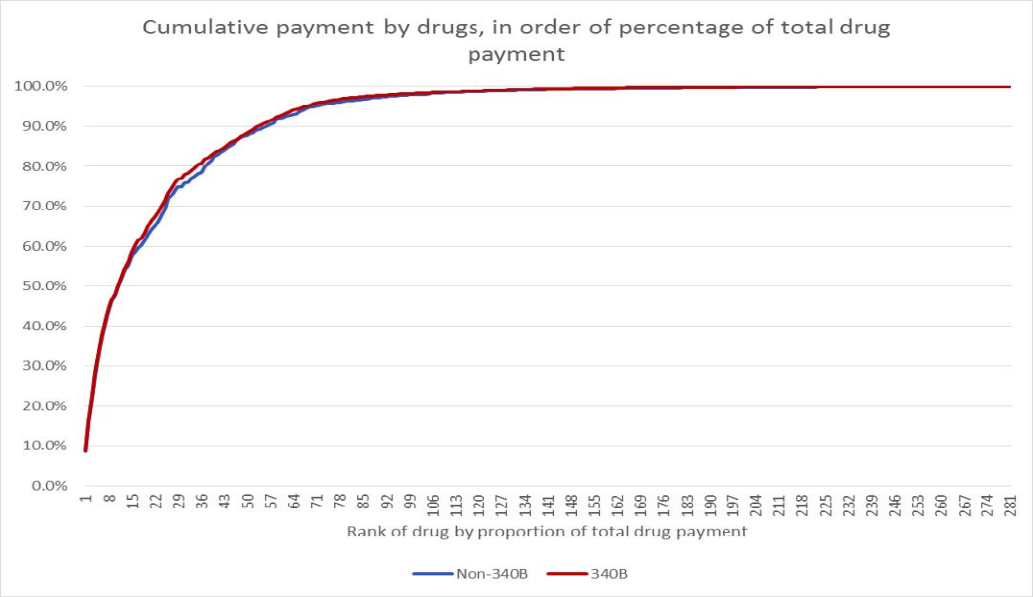
[18] MedPAC, June 2016 Databook, Section 3, p 27.

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."[19] However, AHA's data does not support this concern, and, in fact contradicts it, showing that 340B hospitals utilize separately payable drugs in the same manner as other hospitals. In addition, AHA's data show that increases in drug prices – not utilization – are largely to blame for increases in Part B drug expenditures. First, AHA's 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 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

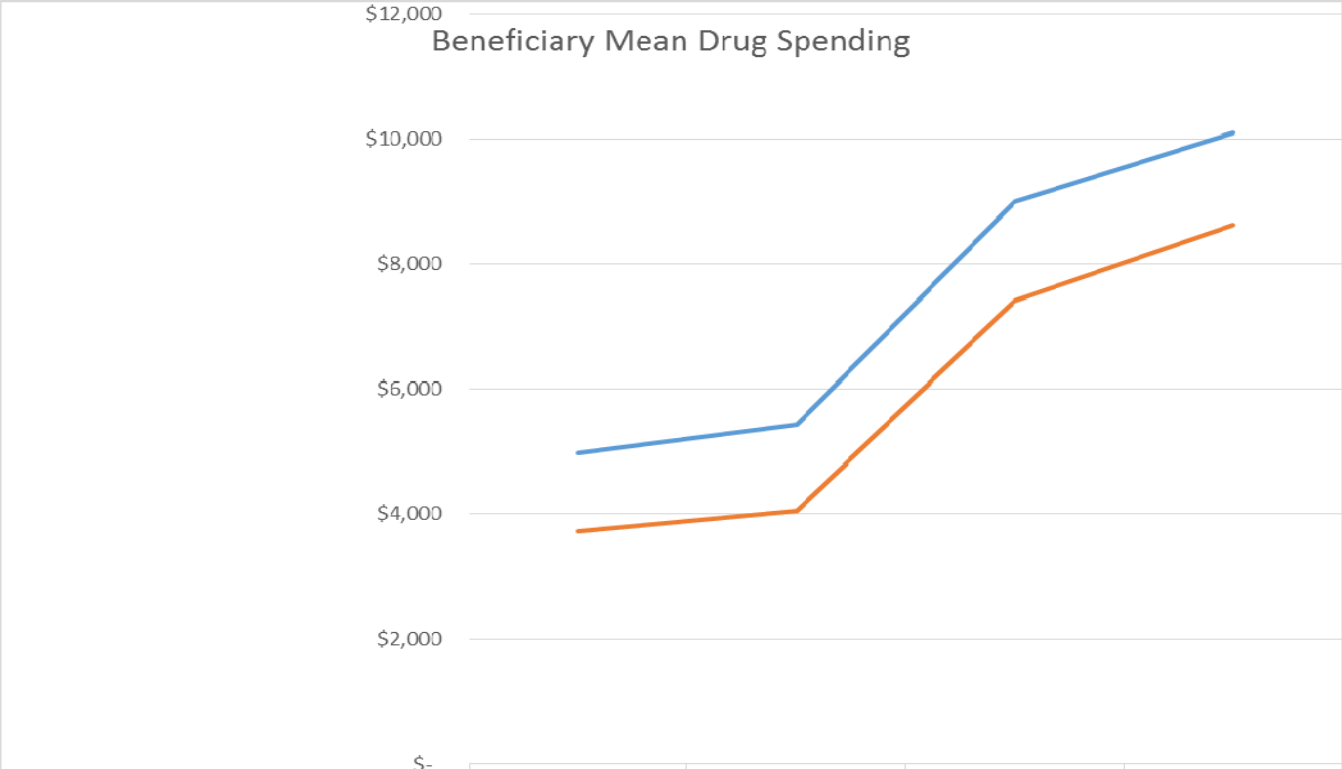


In addition, in AHA's analysis of beneficiary mean drug spending, they found that even without adjusting for difference in case mix between 340B and non-340B hospitals, Part B drug expenditures

[19] CMS OPPS Proposed Rule, Federal Register, Vol. 82, No. 138, July 20, 2017, p 33633.

increase along parallel tracks in these two types of hospitals over time (See Figure 2). We acknowledge that beneficiary mean drug spending is consistently higher in 340B hospitals; however, this is to be expected because, as even the Government Accountability Office (GAO) acknowledged in its 2015 report, beneficiaries at 340B hospitals are in general sicker/have a higher case mix and so have higher expenditures.

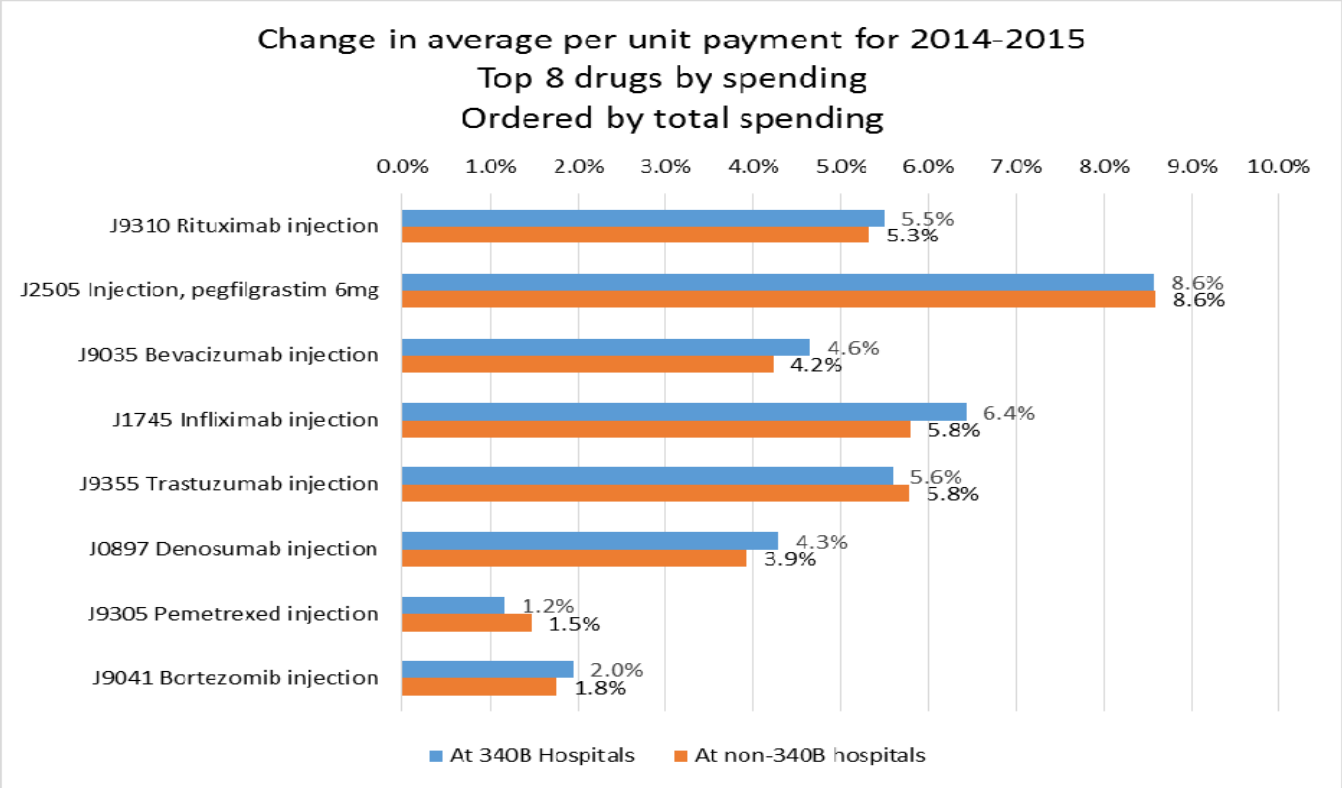
Figure 2: Beneficiary Mean Drug Spending



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

While the data above shows that differential utilization is not the cause of increases in Medicare Part B drug expenditures, the data below demonstrates that increasing drug prices are a cause of increases in Part B drug expenditures. Specifically, in AHA's analysis of Medicare data for the top eight Part B drugs that represent nearly half of the spending at 340B hospitals, they 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.

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.[20] Total drug spending has increased to $475 billion – or 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

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

hospitals' Part B payments.[21] NJHA 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?"[22] 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.[23] 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.[24] 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."[25] 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..."[26] 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. 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.[27] 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

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

[22] 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

[23] 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

[24] 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

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

[26] 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

[27] MedPAC, June 2016 Databook, Section 3, p. 27.

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 costlier drugs to treat Medicare Part B patients.[28] HHS further noted that a high volume of drugs in 340B DSH hospitals could lead to better clinical outcomes.[29]

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.[30] 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.[31]

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.[32] 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.[33] 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.[34]

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 340B program. **NJHA 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

[28] 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
[29] Ibid.
[30] Ibid.
[31] Ibid. p 12.
[32] Office of Inspector General: Part B Payments for 340B Purchased Drugs (OEI-12-14-00030), Nov. 2015.
[33] Ibid, p. 7.
[34] Ibid, p. 13.

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.[35]

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

As previously stated, NJHA 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

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

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

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

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

Our first suggestion is that the agency could incorporate a comprehensive risk-adjustment methodology into the CJR and BPCI programs. This would ensure that actual and historical episode

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

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

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

CMS is soliciting comment on whether partial and total hip arthroplasty also should be removed from the inpatient-only list. It also requests comment on the effect of removing partial hip arthroplasty (PHA) and total hip arthroplasty (THA) procedures from the inpatient-only list on the CJR and BPCI programs. **NJHA 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."[36]

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

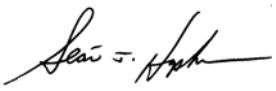
[36] 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) – Version 4.0 and Isolated Coronary Artery Bypass Graft (CABG) Surgery – Version 2.0.

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.

The New Jersey Hospital Association appreciates the opportunity to share our comments with CMS on the hospital outpatient PPS proposed rule for CY 2018.

If you have any questions, please contact me at 609-275-4022 or shopkins@njha.com, or Roger Sarao, vice president, Economic & Financial Information, at 609-275-4026 or rsarao@njha.com.

Sincerely,



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