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September 27, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1717-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

***Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for CY 2020 (CMS-1717-P)***

Dear Administrator Verma:

The Association of American Medical Colleges (the AAMC or Association) welcomes this opportunity to comment on the proposed rule entitled “Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs,” 84 *Fed. Reg.* 39398 (August 9, 2019), issued by the Centers for Medicare and Medicaid Services (CMS or the Agency).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America’s medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The current administration has emphasized two key priorities throughout its tenure: burden reduction for providers and empowering consumers. The Agency also wants to ensure correct payment for items and services. The AAMC strongly supports these goals, but believes that the calendar year (CY) 2020 Outpatient Prospective Payment System (OPPS) proposed rule does not effectively achieve them. The AAMC is disappointed that despite the finding of a Federal Court that the cuts to payments for 340B-acquired drugs to hospitals are beyond CMS’s authority, the Agency has proposed to continue those cuts in CY 2020. The AAMC supports reducing provider burden and providing consumers with accurate information to manage their health care needs, but we believe that several of the proposed policies in the proposed rule do not align with these priorities. Notably, while the AAMC supports providing consumers with the information they need to make informed decisions, the price transparency proposals fail to provide consumers with actionable cost-sharing information, while also creating substantial and unnecessary burden for providers. Similarly, the prior authorization proposal would be burdensome and may result in delays in beneficiary care. The Agency’s price transparency proposal defines the term

“standard charges” to require the posting of information that is beyond what could reasonably be considered a “standard charge” and thereby far exceeds the Agency’s statutory authority. Lastly, the Agency has failed to consider that beneficiary cost sharing may increase as services shift from the inpatient setting and hospital outpatient departments (HOPDs) as CMS allows more procedures to be performed in Ambulatory Surgical Centers (ASCs). The AAMC thanks CMS for this opportunity to comment on these proposals, and has detailed its concerns on these issues in the sections that follow.

### **Summary of Major Policy Issues on Which AAMC Provides Comments**

The following items reflect the AAMC’s recommendations to revise key proposals in the OPPTS proposed rule:

- ***Requirements for Hospitals to Make Public a List of Standard Charges.*** CMS should not finalize the proposed policy requiring hospitals to make public a list of gross and payer-specific negotiated charges for all items and services, as well as the requirement to post at least 300 shoppable services in a consumer-friendly manner. The proposals do not address consumers’ desire for helpful and actionable information related to their out-of-pocket costs, while simultaneously placing significant burden solely on providers. As CMS notes, the amount of data required “may not be immediately or directly useful for many health care consumers” due to the overwhelming amount of information. We stand willing to work with the Agency to develop information that will be actionable and understandable to consumers.
- ***340B Drug Pricing Program Remedies.*** The Agency should not extend the cuts in the 340B Drug Pricing Program (340B Program) to CY 2020 as a Federal Court has found the CY 2018 and CY 2019 cuts to exceed CMS’s authority. As a remedy for the adverse outcome in its 340B Program litigation, CMS should refund payments to each affected 340B hospital calculated using the “JG” modifier, which identifies claims for 340B-acquired drugs that were reduced under the CY 2018 and CY 2019 hospital OPPTS final rules. Providers not adversely impacted by the reductions should be held harmless.
- ***Site-Neutral Payment Policies.*** CMS does not have the authority to make or continue the proposed cuts to provider reimbursement at excepted off-campus provider-based departments (PBDs). Consistent with the federal district court’s decision in the litigation surrounding these cuts, finalizing the continuation of this policy would exceed CMS’s authority. CMS should not finalize the second phase of the cuts, and should restore the higher payment rates for off-campus PBDs and repay hospitals the difference between the amounts received under the unlawful rate and the amount they would have received under the higher payment rates during that period.
- ***Wage Index Policies.*** CMS should explore other ways to ensure that data for the wage index is accurate and that hospitals at the low end of the wage index are paid appropriately. If implemented as proposed, CMS should extend the transitional five-percent cap, limit the policy to four years, and clarify exactly which policies from the fiscal year (FY) 2020 Inpatient Prospective Payment System (IPPS) final rule would apply to the OPPTS wage index.
- ***Prior Authorization Requirements for HOPD Services.*** CMS should not finalize its proposal to create prior authorization requirements for five selected service categories. CMS has not adequately demonstrated that increases in the selected service categories were unnecessary.
- ***Inpatient Only (IPO) List Changes.*** Although there are times when total hip arthroplasty (THAs) can be safely performed in the outpatient setting, the decision on where the surgery is performed should rest with the treating physician in consultation with the beneficiary. CMS should extend the

prohibition on Recovery Audit Contractor (RAC) referrals for inpatient THAs to two years and assess the policy's impact on alternative payment models (APMs) and their target prices.

- ***Ambulatory Surgical Center (ASC) List Changes.*** CMS should consider the impact on beneficiaries' cost-sharing liability as more services are allowed to be performed at ASCs.
- ***Video Electroencephalogram (EEG) Monitoring Services.*** CMS should not finalize its proposal to reassign EEG video monitoring to different Ambulatory Payment Classification (APC) codes. Time should not be the sole distinguishing feature between these codes, as it does not accurately reflect the added costs of complex monitoring associated with these services. CMS should, instead, assign the 2-12 hour monitoring codes to APC 5723, and the 12-26 hour codes to APC 5724 to more accurately reflect the costs that go into complex monitoring at the specialized facilities that most regularly use these codes.
- ***Changes to Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs).*** CMS's efforts to maximize availability of organs to patients who desperately need them is appreciated, but CMS should ensure changes made to the OPO CfCs do not penalize transplant centers that choose not to transplant organs that may be poor quality.
- ***Incorporation of Quality Information with Price Transparency Requirements.*** A thoughtful evaluation of options and additional engagement of patients, providers, insurers, and consumer groups is needed to ensure that any future frameworks for cost and quality transparency prioritize patient-centeredness and aid meaningful conversation between patients and their providers.
- ***Quality Measure Removals.*** Finalize the proposal to remove OP-33 from the Hospital Outpatient Quality Reporting (OQR) Program and consider the removal of additional process measures including OP-18 and OP-8.
- ***Future Potential Quality Measures.*** Measures should be endorsed by the National Quality Forum (NQF), approved by the Measure Applications Partnership (MAP), and demonstrated to provide meaningful information for patients and families before they are proposed in the OQR Program.

## **REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF STANDARD CHARGES**

Price transparency has been one of several key priorities of the current administration. In recent years, CMS has explored numerous ways to provide patients with consumer-friendly information about hospital and physician charges and have engaged in efforts to inform patients about their expected cost-sharing obligations for the items and services they receive. In the FY 2019 IPPS final rule, CMS finalized a policy requiring hospitals to make available via the web their standard charges in a machine-readable format. In that same rule and in other requests for information (RFIs) in 2018, CMS sought stakeholder feedback regarding the lack of adequate price transparency for patients and considered ways to "improve the accessibility and usability of current charge information." (84 *Fed. Reg.* 37212). Despite significant feedback on this issue, CMS has developed a new price transparency proposal in its CY 2020 OPSS proposed rule that seeks to impose significant burden on providers, while ignoring the essential role that insurers and other stakeholders share in the efforts to improve meaningful price transparency for consumers. The proposal would require hospitals to make public in a machine-readable format their standard charges, which CMS is defining as both "gross" and "payer-specific negotiated charges", for all items and services provided by the hospital. In addition, hospitals would be required to post this information for at least 300 "shoppable services" that must be displayed in a "consumer friendly" manner. (p. 39574).

The AAMC supports price transparency but, as we have stated in past comments, we believe that CMS must take a different approach to provide patients and their families with meaningful, actionable information about their potential out-of-pocket costs. Working over many years, and in collaboration with electronic health records (EHR) vendors and insurers, some AAMC members have proactively developed tools to assist patients to better understand their cost-sharing responsibilities. For example, some hospital systems have online tools that enable consumers to find information about their out-of-pocket costs for a variety of procedures. Moreover, large health systems provide consumers with cost-sharing estimates for each facility within the health system to further assist them in deciding where to obtain services. Even if such tools become more widely available in the future, they must be paired with consumer education to make clear that these are estimates based on the best available information prior to treatment. It is not unusual for the actual services provided to the patient to differ from what was anticipated prior to the service. Patients must understand that these medically necessary changes in care may alter their out-of-pocket costs.

Posting hospitals' standard charges would not provide patients with the information that is of most importance or usefulness to them – their financial obligation based on *their* insurance coverage, including *their* plan-specific cost-sharing requirements such as their deductible and applicable co-pay amounts, if any. Additionally, the AAMC has serious questions regarding CMS's authority to require providers to post negotiated charges, and concerns about the proposal itself, as the proposed requirements are outside the scope of CMS's regulatory authority.

It remains imperative that CMS engage insurers, who are better positioned to have accurate information about beneficiaries' out-of-pocket estimates, to move forward with its price transparency efforts.

**Therefore, for the reasons listed below, we urge CMS to not finalize the price transparency proposals in the CY 2020 OPPI proposed rule. Instead, we suggest CMS work with hospitals, insurers, consumers, and other stakeholders to better identify how to make available information that patients need to better understand the costs they will incur for hospital care.**

### ***The Proposed Requirements Would Be Unnecessarily Burdensome***

The proposed rule contains several new requirements relating to price transparency that CMS seeks to place solely on providers. As noted above, the proposal requires hospitals to make public in a machine-readable format their standard charges, which CMS defines as both “gross” and “payer-specific negotiated charges”, for all items and services provided by a hospital. (p. 39574). Hospitals would be tasked with making public both the gross and negotiated charges for every item and service provided in both the inpatient and outpatient settings. (p. 39574). Specific to negotiated charges, hospitals would be required to include not only charges for service packages, but also the individual service items included within them. (p. 39582). Moreover, this means that for any one item or service the provider would be required to post charges for *every* item and service and *each* payer with whom the provider has a negotiated rate. To place these requirements in context, many AAMC member-hospitals have negotiated rates with over 100 plans.<sup>1</sup> Hospitals would be required to gather and publish thousands of negotiated rates, along with other required data elements that can be burdensome to collect and post, such as a list of ancillary items and services for each service provided.

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<sup>1</sup> List of accepted insurance plans for Johns Hopkins Community Physicians and New York-Presbyterian Hospital. Retrieved at: [https://www.hopkinsmedicine.org/community\\_physicians/patient\\_information/insuranceplans.html](https://www.hopkinsmedicine.org/community_physicians/patient_information/insuranceplans.html); <https://www.nyp.org/patients-and-visitors/paying-for-care/hospital-participating-plans>.

During the August 27, 2019 Hospital Open Door Forum to discuss this proposed rule, at least one participant noted that hospitals do not negotiate rates for each item related to a service, but negotiate a rate that encompasses everything related to the service. This means that items and services would be reflected as \$0.00, indicating that no cost can be attached to them. Beneficiaries are likely to find this to be more confusing than elucidating. Additionally, AAMC member hospitals stand to face even greater challenges under the proposal, which imposes these requirements separately for each hospital location. (p. 39585). Academic and teaching institutions have expansive campuses, and requiring each health system to fulfill these requirements separately for each hospital location would increase their burden exponentially.

CMS also notes that the amount of data required “may not be immediately or directly useful for many health care consumers” due to the overwhelming amount of information. (p. 39585). For this reason, CMS believes it is appropriate to require providers to present the required charge data of at least 300 shoppable services in a “consumer-friendly” display, insofar as consumers would have the opportunity to shop for the selected services. (p. 39585). CMS defines a “shoppable service” as a service package that can “be scheduled by a health care consumer in advance” and include those services that are “typically provided in non-urgent situations that do not require immediate action or attention to the patient.” (p. 39585). Hospitals currently do as much as possible to assist patients’ understanding of their cost-sharing liability for all items and services rendered. Posting payer-specific negotiated charges for “shoppable services” in a manner that is considered “user friendly” may still not achieve CMS’s goal of providing actionable information for consumers to understand their cost-sharing liability. Hospitals would have great difficulty in planning and operationalizing a consumer-friendly site with the substantial amount of data CMS is requiring in the proposed rule. Unlike gross charges, information on payer-negotiated charges would have to be collected from countless sources and may need to be manually entered if the charges are not available in a native web format to the hospitals host site the way the chargemaster might be. Moreover, once the data are made public, the hospitals would be tasked with updating the information annually.

### ***Payer-Specific Negotiated Charges are Not Standard Charges***

In several RFIs, issued through five separate proposed rules in 2018, CMS sought public feedback on how “standard charges” should be defined. (p. 39577-39578). In the CY 2020 OPPS proposed rule, the Agency has proposed to define standard charges as both “gross” and “payer-specific negotiated charges”, citing its own research and the feedback it received through these RFIs. (p. 39578). CMS specifies that a “gross charge” would mean a charge “for an individual item or service that is reflected on a hospital’s chargemaster, absent any discounts.” (p. 39578). In contrast, a “payer-specific negotiated charge” would mean a charge “that the hospital has negotiated with a third party payer for an item or service.” (p. 39579). Both types of charges, CMS notes, are considered “standard” because a “standard charge can be identified based on the regular rate established by the hospital for the items and services provided to a specific group of paying patients.” (p. 39579).

**The AAMC believes that CMS does not have the authority to define negotiated charges as “standard charges.”** Section 2718(e) of the Public Health Service Act (PHSA) does not provide CMS with authority to establish these requirements. Under the statute, “each hospital operating within the United States shall for each year establish (and update) and make public...a list of the hospital’s standard charges for items and services provided by the hospital.”<sup>2</sup> CMS’s proposal to define negotiated charges as

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<sup>2</sup> Public Health Service Act § 2718(e). Retrieved at: <https://www.govinfo.gov/content/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>

“standard” charges, is contrary to the plain language of the statute. By definition, a “standard charge” is not privately negotiated and cannot mean different charges for different payers. Both in definition and in the healthcare field, “standard charges” has been understood as a technical term of art that means a hospital’s usual or customary charge listed on the chargemaster. Through this proposed rule, CMS seeks to inappropriately broaden the definition of standard charges. This would likely cause confusion to the consumer and fails to meet the objective of making more useful information available while increasing greatly the burden for providers.

### ***Requiring Providers to Post Negotiated Charges Harms Consumers***

In addition to the questionable foundation of its proposed “standard charges” definition, the proposed requirements to make public negotiated charges also raises serious concerns surrounding competition and the First Amendment, respectively. The Federal Trade Commission (FTC) has issued several warnings against the disclosure of competitively sensitive information, such as payer-negotiated prices. In its comments on a Minnesota transparency law, the FTC stated that too much transparency may “chill competition by facilitating unlawful collusion...undermine the effectiveness of selective contracting by health plans, which serve to reduce health care costs”, which may “harm competition and consumers.”<sup>3</sup> The FTC also urged that transparency should be limited to “predicted out-of-pocket expenses, co-pays, and quality and performance comparisons of plans or providers.”<sup>4</sup> **The AAMC is concerned that the proposal to require hospitals to make public a list of negotiated charges for all provided services could have adverse impacts on competition among insurers and consumers.**

CMS’s proposal to have hospitals make public a list of their negotiated charges may also implicate certain First Amendment issues. In some federal cases, plaintiffs have argued that certain transparency requirements have amounted to “compelled speech”.<sup>5</sup> The proposed rule, as it relates to posting confidential and privately negotiated charges, compels the public disclosure of individual charges between hospitals and health plans. Government regulation of non-misleading commercial speech is unlawful *unless* it “directly advances” a “substantial” governmental interest, and is no “more extensive than is necessary” to serve that interest. **The American Hospital Association (AHA) has provided more detailed comments on these matters with which the AAMC agrees.**

### **340B DRUG PRICING PROGRAM**

In the CY 2020 proposed rule, CMS proposes to continue to pay for separately payable drugs purchased under the 340B Drug Pricing Program (“340B Program”) to nonexcepted off-campus PBDs at a reduced rate. Specifically, CMS finalized policies in CY 2018 and CY 2019 that drugs purchased under the 340B Program and furnished to outpatients and billed by nonexcepted off-campus PBDs would be reimbursed at the average sales price (ASP) minus 22.5 percent. In CY 2020, despite adverse results for CMS in the 340B Program litigation, CMS has proposed to continue paying for 340B-acquired drugs at ASP minus 22.5 percent. (p. 39504).

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<sup>3</sup> FTC, *Letter to Hons. Joe Hoppe and Melissa Hortman* (Jun. 29, 2015). Retrieved at: [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-regarding-amendments-minnesota-government-dat-a-practices-act-regarding-health-care/150702minnhealthcare.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-dat-a-practices-act-regarding-health-care/150702minnhealthcare.pdf).

<sup>4</sup> *Ibid.*

<sup>5</sup> *Merck & Co., Inc. v. HHS* (D.D.C) (1:19-cv-01738) (July 8, 2019). Retrieved at: [https://www.courtlistener.com/recap/gov.uscourts.dcd.208309/gov.uscourts.dcd.208309.32.0\\_1.pdf](https://www.courtlistener.com/recap/gov.uscourts.dcd.208309/gov.uscourts.dcd.208309.32.0_1.pdf).

**The judge concluded in *Am. Hosp. Assoc., et al v. Azar* (D.D.C. 2018)<sup>6</sup> that CMS did not have the authority to reduce the payment rates to for drugs acquired under the 340B Program in CY 2018 and CY 2019. Therefore, CMS also does not have the authority to continue that reduction in CY 2020. In addition to the AAMC’s following comments on potential remedies for the 340B Program litigation, we strongly urge CMS to work to implement drug pricing reforms that address the problem at its source – drug manufacturers set drug prices – rather than reduce the scope of the 340B Program that allows covered entities to provide needed services to underserved communities.**

We continue to believe that the 340B Program has been unfairly targeted as a driver of high drugs prices, and proposals to undermine this important program are counterproductive in addressing access to affordable medication. As we have noted in previous comment letters (CY 2018<sup>7</sup> and CY 2019<sup>8</sup> OPPS proposed rules and HHS Blueprint to Lower Drug Prices<sup>9</sup>), the 340B Program does not drive high drug prices, but rather allows participating hospitals (covered entities) to provide vital support and access to vulnerable patients and communities. Consistent with the intent of the program – to help stretch scarce resources as far as possible, reach more eligible patients, and provide more comprehensive services – safety-net hospitals, many of which are teaching hospitals, invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients. Since the savings come from drug manufacturer discounts, these services are provided at no cost to taxpayers.

In its CY 2020 OPPS proposed rule CMS has solicited comments on potential remedies for the nearly 30 percent reduction in reimbursement for certain 340B hospitals that a district court judge ruled were unlawful. (p. 39504). Specifically, the Agency seeks potential remedies for the CY 2018 and CY 2019 payments and, as noted above, for potential use in CY 2020 payments in the event the Agency receives an adverse ruling by the U.S. Court of Appeals.

**The AAMC believes the remedy for the 340B litigation should be as follows: refund payments should be made to each affected 340B hospital and calculated using the “JG” modifier, which identifies claims for 340B drugs that were reduced under the CY 2018 and CY 2019 hospital OPPS rules. Providers not adversely impacted by the reductions should be held harmless. This remedy would not disrupt the Medicare program and is consistent with those for past violations of law.**

**The AAMC’s specific comments on the remedies related to the 340B litigation are as follows:**

***The Proper Remedy Is Straightforward and Easily Administered***

There is a straightforward remedy that is easy to implement, would not be disruptive, does not require new rulemaking, and is comparable to those the courts and Agency have adopted to correct other unlawful Medicare payment reductions. Specifically, the Agency can recalculate the payments owed to 340B hospitals based on the statutory rate of ASP plus 6 percent provided by the CY 2017 OPPS final rule. Hospitals that have already received partial payment should receive a supplemental payment that

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<sup>6</sup> *Amer. Hosp. Assoc. v. Azar* (D.D.C) (1:18-cv-02084-RC) (Dec. 27, 2018). Retrieved at: <https://www.courtlistener.com/recap/gov.uscourts.dcd.199876/gov.uscourts.dcd.199876.59.0.pdf>.

<sup>7</sup> AAMC CY 2018 OPPS proposed rule comment letter. September 11, 2017. <https://www.aamc.org/download/482774/data/aamccommentlettercv2018opps.pdf>.

<sup>8</sup> AAMC CY 2019 OPPS proposed rule comment letter. September 24, 2018. <https://www.aamc.org/download/492444/data/aamccommentsonthecv2019oppsproposedrule.pdf>.

<sup>9</sup> AAMC comment letter. HHS Blueprint to Lower Drug Prices. July 16, 2018. <https://www.aamc.org/download/490210/data/aamccommentsonthehhsblueprinttolowerdrugpricesrfi.pdf>.

equals the difference between the amount they received and the amount they are entitled to, including ASP plus 6 percent plus interest. Also, Medicare requires that interest must be paid on claims beginning 30 days after the date of receipt.<sup>10</sup> Claims that have not yet been paid should be paid in the full amount, including ASP plus 6 percent.

While the claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case. These calculations should be on a hospital-by-hospital basis. Once the total amount that each hospital was paid is calculated, that amount can be multiplied by a single factor – which will be uniform across hospitals – to determine how much should have been paid and thus how much the reimbursement was reduced. Each hospital can be compensated according to the amount that its reimbursements were reduced plus interest through a single lump sum payment.

### ***There Is Ample Precedent for Full Retroactive Adjustments that Are Not Budget Neutral***

There is ample authority for the Department of Health and Human Services (HHS) to remedy the underpayments caused by its unlawful rule, including: *Cape Cod Hospital v. Sebelius*, (D.C. Cir. 2011) (HHS corrected errors for the future and past claims for which hospitals had been underpaid), *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar*, (D.D.C. 2018), (HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that received a statutorily mandated adjustment a year later than the law required), and *Shands Jacksonville Medical Center v. Burwell*, (D.D.C. 2015), (HHS compensated hospitals for three years of across-the-board cuts with a one-time, prospective increase of 0.6 percent).

The remedy need not be budget neutral. The authority the Agency cites is not applicable because such expenditures would be required by a court decision in service of fixing a prior unlawful underpayment. Moreover, the Agency does not consistently apply budget neutrality to fix its missteps and in other relevant instances. For example, CMS allows for retroactive correction of the wage index without any budget-neutrality adjustment when it made the error and it was not something a hospital could have known or corrected.

### ***There Is No Basis for Paying Hospitals Less than the Statutory ASP Plus 6 Percent***

The OPDS mandates that CMS reimburse hospitals for covered outpatient drugs at ASP plus 6 percent. This was the methodology used from CY 2013 to CY 2017. CMS has now requested comment on adjusting the payment for CY 2018, CY 2019 and CY 2020 from ASP plus 6 percent to ASP plus 3 percent. Although the Agency has some authority to deviate from this law, the Agency is attempting to use a policy rationale that is inconsistent with the law itself and, therefore, would be unlawful to reduce payment to ASP plus 3 percent.

### ***Adjustments to Beneficiary Co-Pays Are Not Required***

Medicare reimburses hospitals 80 percent for covered outpatient services and the remaining 20 percent is collected from the beneficiaries or their supplemental insurance. Because CMS deviated from the lawful payment rate for CY 2018 and CY 2019 with a 30 percent reduction, in theory hospitals could collect

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<sup>10</sup> CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 1 “General Billing Requirements”, section 80.2. Retrieved at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf>



from beneficiaries or their insurance companies the difference between 20 percent of the lawful payment rate and the 20 percent copay that was actually collected. CMS has requested comment on the “most appropriate treatment of Medicare beneficiary cost-sharing responsibilities.”

Although the Agency has raised the specter that a remedy would require beneficiaries’ co-pays to be adjusted retroactively, we do not believe that there is any law that would require hospitals to collect payments altered by the Agency’s illegal act. Neither the False Claims nor anti-kickback statutes would apply since beneficiaries would not have been induced to seek services. Beneficiaries who reasonably believe that they have fully paid for hospital care provided months, or in some cases years, ago should not have to make these payments if hospitals are willing to forego them. **The AAMC urges the Agency to state this clearly in the final rule.**

### **SITE-NEUTRAL PAYMENT POLICIES**

As required by law, CMS introduced the site-neutral payment policy in CY 2017 for nonexcepted off-campus HOPDs, those off-campus PBDs that were not billing under the OPSS prior to November 2, 2015. Payment to those off-campus PBDs that were billing prior to November 2, 2015 were grandfathered into OPSS. Under the policy, CMS pays the nonexcepted off-campus PBDs at 40 percent of the full OPSS rate. In last year’s CY 2019 OPSS final rule, citing its authority under section 1833(t)(2)(F) of the Act, CMS finalized the expansion of that policy to off-campus PBDs specifically excepted from that reduction to address what it deems “an unnecessary shift of services from the physician office to the HOPD,” and implemented the policy in a non-budget neutral manner. CMS claimed that growth in outpatient services is caused by the difference in payment between sites of care.

In the CY 2019 OPSS final rule, CMS finalized its proposal to pay a physician fee schedule-equivalent rate for an outpatient clinic visit, HCPCS code G0463. CMS finalized its change to this code, the most frequently billed service with the “PO” modifier, which is used to identify services in excepted off-campus PBDs, paying for G0463 at 40 percent of the full OPSS rate. In a deviation from the proposed rule, however, the Agency elected to phase in the payment reduction over two years – 50 percent in CY 2019 and the remaining 50 percent in CY 2020. The AAMC strongly opposed the reduction in payments, as the increase in the volume of items and services is caused by many appropriate factors. The AAMC continues to believe that reducing reimbursement for items and services received in excepted off-campus PBDs is detrimental to the important care provided by teaching hospitals to vulnerable Medicare beneficiaries.

### ***CMS Lacks Statutory Authority to Implement Site-Neutral Payment Reductions***

Many commenters on the CY 2019 OPSS proposed rule questioned the assumptions underlying the Agency’s conclusions – especially the conclusion that OPD services had increased unnecessarily. Numerous commenters also questioned CMS’s legal authority to cut payments to excepted off-campus PBDs and to make those payment cuts in a non-budget neutral manner. The AAMC’s comments took issue with a host of CMS’s factual assumptions and legal conclusions. Most significantly, the AAMC submitted several comments in opposition to the policy, which we have highlighted here:

- ***The Shift from Physician Offices to HOPDs Can Be Explained By A Number of Factors Unrelated to Reimbursement Rates.*** There is no evidence that reimbursement rates alone are causing a shift in services to HOPDs and off-campus PBDs; rather, the shift is caused by a confluence of factors. This

includes growth of the Medicare population, improved post-discharge care, increases in prescription drug prices, and the rise of patient referrals to HOPDs.

- ***CMS Lacks the Statutory Authority to Implement the Payment Reduction.*** In the CY 2017 OPSS final rule with comment, CMS finalized that excepted off-campus PBDs were not subject to the site-neutral policies implemented under section 603 of the Bipartisan Budget Act of 2015 (“section 603”). Section 603 merely directed the Secretary not to pay for services provided in a new off-campus outpatient department. CMS has no statutory authority to extend the reduced payment rates to excepted off-campus PBDs. The AAMC commented that section 603 made clear that off-campus PBDs billing OPSS for items and services furnished before November 2, 2015 are exempt from the payment reductions under section 603, and CMS exceeded its authority through the proposed payment reductions.
- ***CMS is Not Required to Implement the Policy in a Budget Neutral Manner.*** CMS noted that under 1833(t)(9)(A) and (B), only adjustments are required to be budget neutral, but claimed that the rate reduction is not an adjustment for the purposes of budget neutrality because it is a method for controlling unnecessary increases in services. Yet, CMS arrived at the payment amount to pay for a clinic visit by multiplying the full OPSS payment by the physician fee schedule relativity adjuster. CMS’s authority rests on the idea that using an adjuster in a methodology does not equate to making an adjustment under 1833(t)(9)(B). The AAMC questioned the Agency’s authority to impose cuts that are not budget neutral on this basis.

The AAMC urged CMS to withdraw its CY 2019 proposal based on these issues. As noted above, despite the many concerns and objections raised by the AAMC and other commenters, CMS finalized the proposal in its CY 2019 OPSS final rule and cut payments to excepted off-campus PBDs in a non-budget neutral manner.

The AAMC, the AHA and three hospitals filed suit in January 2019 to challenge the new clinic visit payment policy. The parties alleged that hospitals with excepted off-campus PBDs faced imminent injury as a result of CMS’s unlawful decision to reduce clinic visit payment rates and to do so in a non-budget neutral manner.

In the CY 2020 OPSS proposed rule, CMS refers readers to the CY 2019 OPSS final rule for “a detailed discussion of the background, legislative provisions, and the changes in payment policies we developed to address increases in the volume of covered OPD services.” (p. 39528). The agency then explains that, through the CY 2020 OPSS rule, it is “completing the phase-in of the reduction in payment for the clinic visit services...furnished in expected [sic] off-campus provider-based departments as a method to control unnecessary [sic] increases in the volume of this service.” (p. 39528).

The AAMC continues to believe that the non-budget neutral payment cut for clinic visits furnished by excepted off-campus PBDs in 2019 is unlawful and is causing undue harm to hospitals for the reasons explained in its lawsuit challenging the CY 2019 OPSS final rule. Among other things, Congress has established a clear structure for CMS to make annual changes to payments for covered hospital outpatient services under Medicare.<sup>11</sup> Changes to payments that target only specific items or services must be budget neutral.<sup>12</sup> In addition, by subjecting excepted and nonexcepted PBDs to the exact same payment system and payment rate, the Agency has inappropriately abolished the statutory distinction between those two entities.

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<sup>11</sup> Social Security Act § 1833(t)(9)(A). Retrieved at: [https://www.ssa.gov/OP\\_Home/ssact/title18/1833.htm](https://www.ssa.gov/OP_Home/ssact/title18/1833.htm).

<sup>12</sup> Social Security Act § 1833(t)(9)(B). Retrieved at: [https://www.ssa.gov/OP\\_Home/ssact/title18/1833.htm](https://www.ssa.gov/OP_Home/ssact/title18/1833.htm).

**The court recently found that the Agency exceeded its statutory authority when it cut the payment rate for clinic services at excepted off-campus provider-based clinics.**

**We therefore urge CMS to:**

- 1. Immediately restore the higher payment rates for clinic visits furnished by excepted off-campus PBDs that existed before CMS adopted the unlawful payment cuts;**
- 2. Promptly repay hospitals the difference between the amounts they would have received under those higher rates and the amounts they were paid under the unlawful payment rates; and**
- 3. Abandon its proposed second phase of the payment cut in 2020. Should the Agency move forward with the second phase of the cut, it will cause additional harm to many AAMC members and the AAMC intends to pursue its legal remedies.**

### **MEDICARE WAGE INDEX POLICIES**

In CY 2000, CMS adopted the IPPS post-reclassified wage index as the wage index for adjusting OPPS standard payment amounts. (p. 39429). The Medicare wage index, now an essential feature for both the OPPS and IPPS, accounts for geographic variation in labor costs and adjusts the labor-related share of standardized payment amounts to account for area differences in hospital wage levels relative to the national average hospital wage level.

Since its inception, the wage index has undergone numerous targeted legislative and regulatory changes resulting in adjustments, special exceptions, and reforms addressing specific issues impacting the system. In its FY 2020 IPPS final rule, CMS finalized several changes to the Medicare wage index to address disparities between high and low wage index hospitals. CMS finalized policies to increase the wage index for low wage index hospitals and maintain budget neutrality through an adjustment to the standardized amount that will be applied to all hospitals. The policy, CMS noted, would provide low wage index hospitals with the opportunity to increase employee compensation over several years. In addition, CMS removed reclassified hospitals from the calculation of the rural floor. Finally, CMS finalized a five-percent cap on reductions to hospitals' final wage indexes between FY 2019 and FY 2020 to limit the impact of these policies.

Now, in its CY 2020 OPSS proposed rule, CMS is proposing to apply these same changes to the OPSS wage index. CMS emphasizes that it continues to believe that "using the IPPS wage index for the OPSS is reasonable and logical...given the inseparable, subordinate status of the HOPD within the hospital overall." (p. 39431). Accordingly, it has proposed to apply "any adjustments for the FY 2020 IPPS post-reclassified wage index, including, but not limited to, any proposed policies finalized under the IPPS to address wage index disparities" to the CY 2020 OPSS wage index (p. 39431).

**Although AAMC supports CMS's goal to address difficulties faced by low wage index hospitals in the OPSS, we again urge CMS to tackle these issues in a more thoughtful and comprehensive manner that addresses the underlying issues with the wage index disparities. Additionally, CMS should limit the length of the policy to raise low wage hospitals wage indexes, consider extending the length of the transitional five-percent cap, and clarify the specific IPPS proposals it seeks to adopt for the OPSS.**

### ***Clarify Which Policies from the IPPS Final Rule Would Be Adopted in the OPSS Wage Index***

At the time the CY 2020 OPSS proposed rule was released, CMS had not yet finalized the wage index policies initially proposed in the FY 2020 IPPS proposed rule. As previously noted, CMS proposed to apply “any adjustments for the FY 2020 IPPS post-reclassified wage index, including, but not limited to, any proposed policies finalized under the IPPS to address wage index disparities” to the CY 2020 OPSS wage index (p. 39431). This broad language suggests that the finalized policies from the IPPS rule are also proposed for the OPSS wage index, but leaves open that the proposals for OPSS would not be limited to the finalized IPPS wage index policies. Given that CMS did not specify exactly which policies are proposed to apply to the OPSS wage index after the FY 2020 IPPS final rule was published, AAMC seeks clarification on the precise proposals CMS is considering for the CY 2020 OPSS proposed rule.

Notably, in the FY 2020 IPPS proposed rule, CMS initially proposed to maintain budget neutrality for the wage index raises to low wage hospitals by reducing the highest quartile hospitals’ wage indexes by 4.3 percent of the difference between each hospital’s wage index and the 75th percentile. CMS agreed with commenters in its final rule that maintaining budget neutrality through this method was not appropriate, and instead elected to maintain budget neutrality through an adjustment to the national standardized amount. **AAMC requests clarification on whether CMS is considering reducing high wage hospitals’ wage indexes to maintain budget neutrality as part of the OPSS proposal. In the event that CMS seeks to apply a reduction to high wage hospitals for the OPSS wage index, AAMC reiterates its stance that raising the wage indexes of certain hospitals by reducing a select quartile of hospitals’ wage indexes is outside the scope of CMS’s authority and runs contrary to the wage index’s underlying purpose.**

### ***Should CMS Finalize the Proposals, Limit the Duration of the Wage Index Policies***

CMS finalized its proposal in IPPS to increase low wage index hospitals’ wage indexes, which it now proposes to apply to the OPSS. As CMS noted in its FY 2020 IPPS final rule, the change is intended to provide low wage hospitals with an opportunity to increase employee compensation, which, if that were to occur, would then be reflected in future wage index data. (84 *Fed. Reg.* 42326). The policy will raise the wage indexes of the lowest quartile wage index hospitals by half the difference between the 25th percentile and the hospital’s individual wage index. At a minimum, CMS noted that the finalized policy would apply each year for the next four years. As applied to the OPSS wage index, the policy would begin in CY 2020.

AAMC is concerned that the proposed policies lack a clear duration. As CMS noted in its IPPS final rule, the policy will be effective for “*at least* 4 years...in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index.” (84 *Fed. Reg.* 42327). CMS acknowledged that after the initial four years of implementation “additional time may be necessary” and they “still intend to revisit the issue of the duration of the policy in future rulemaking.” (84 *Fed. Reg.* 42328). **If CMS finalizes this proposal for OPSS as well, AAMC urges CMS to limit its duration to four years or less.**

While it is possible the policies’ aims may be fully reflected in the wage index by year four, it is also likely that changes to employee compensation may not be reflected due to a variety of reasons (*e.g.* hospitals are not actually raising wages with their additional payments or hospitals choose to gradually raise wages). If, at the end of four years, there is no evidence that wages have been raised sufficiently to make it easier for rural hospitals to recruit employees, then it is incumbent on CMS to determine the reason underlying the problem rather than continuing a flawed policy.

### ***Extend the Length of the Transitional Five-Percent Cap***

In the FY 2020 IPPS final rule, CMS finalized a transitional five-percent cap on any reductions that hospitals may face in FY 2020 as a result of the proposed wage index changes. Specifically, the cap will apply only for FY 2020 and will limit any reductions from a hospital's wage index value to five percent between FY 2019 and FY 2020. The cap will apply to all finalized wage index proposals, including the rural floor wage index policy. CMS now proposes to apply this cap to the OPSS wage index changes as well, limiting changes in a hospital's wage index to five percent between CY 2019 and CY 2020. With some hospitals likely to see significant reductions in their wage indexes in both the IPPS and OPSS, **AAMC requests that CMS extend the cap at least an additional year to reduce the severity of impact on hospitals that may see substantial reductions as a result of these policies.**

### ***Raising Low Wage Index Hospitals Does Not Address the Underlying Issues of Wage Index Disparities***

CMS should work to address concerns of the low wage index market to better align their ability to find and retain skilled employees. The underlying purpose of the wage index is that it reflects area wages. It is troubling that CMS continues to address the superficial consequences of the wage index's flaws without addressing its foundational issues. CMS acknowledges that there are fundamental issues in the wage index but notes that it "does not need to wait for comprehensive wage index reform" to address these disparities. (84 *Fed. Reg.* 42326). However, there have been few indications that comprehensive legislative reform is imminent, and CMS has not addressed any of these issues in the wage index policies finalized in the FY 2020 IPPS final rule, yet seeks to apply these same policies to the OPSS as well. As the AAMC previously commented on the FY 2020 IPPS proposed rule,<sup>13</sup> **we do not believe that CMS's wage index policies finalized in the FY 2020 IPPS final rule and proposed for the CY 2020 OPSS proposed rule would attain the Agency's overarching goal to accurately represent the geographic differences in the cost of labor through the wage index. Therefore, the AAMC encourages CMS to work with stakeholders, including Congress, to identify a way to address the flaws in the current wage index.**

### **PRIOR AUTHORIZATION REQUIREMENTS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES**

In its CY 2020 OPSS proposed rule, CMS has identified five general categories of services that it believes have experienced unexpectedly greater volume increases between CY 2007 and CY 2017. The categories include: blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. The services within the select categories have clinically valid, medically necessary, therapeutic uses for which Medicare and other payers provide reimbursement. In an effort to control what it describes as "unnecessary increases in the volume of OPD services", CMS proposes to introduce stringent prior authorization requirements for these identified service categories. (p. 39604).

Prior authorization is a utilization management tool that payers often use to manage utilization of certain services. However, prior authorization often causes delays in patients' ability to receive timely, medically necessary care and imposes additional administrative burden on providers by requiring providers to manually navigate time-consuming requirements. The clinical and administrative impact resulting from prior authorization requirements prompted the American Medical Association (AMA) to create twelve

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<sup>13</sup> AAMC FY 2020 IPPS proposed rule comment letter. June 24, 2019.  
<https://www.aamc.org/download/498220/data/aamccommentletteronfy2020ippsproposedrule.pdf>

guiding principles related to the appropriateness and execution of any prior authorization process, some of which are noted below as they relate to CMS's proposal.<sup>14</sup>

The AAMC urges CMS to not finalize its proposal to introduce new prior authorization requirements for the five specified service categories. The AAMC requests that, before finalizing this proposal, CMS undertakes a more careful analysis to determine whether the increase in these services are truly "unnecessary." The Agency also should evaluate the process and clinical workflow factors contributing to the burden associated with prior authorization to see how they can be reduced. If CMS finalizes the proposed prior authorization requirements, the AAMC seeks clarification on several issues related to claim denials.







### ***Increased Utilization for Specified Services Does Not Mean Services Were Not Medically Necessary***

CMS claims its authority to institute prior authorization for these services under Section 1833(t)(2)(f) of the Act, which authorizes the Agency to develop methods for controlling unnecessary increases in services. CMS justifies the use of prior authorization as a method to control increased utilization volume for these services, which it claims exceeds what would be expected based on the average rate-of-increase in Medicare beneficiaries. (p. 39604). CMS also specifies that it is "unaware of other factors that might contribute to clinically valid increases in volume." (p. 39604).

### **The AAMC believes that these increases in volume for select services are caused by factors that indicate they are for medically necessary care.**

For example, the increased use of botulinum toxin (BOTOX) injections accounts for the most significant increase in utilization of the service categories. However, the U.S. Food & Drug Administration (FDA) approved BOTOX for new clinical indications between CY 2007 and CY 2017, the period CMS used for its analysis.<sup>15</sup> Notably, in 2010 the FDA approved BOTOX-A (onabotulinumtoxinA) injections for the treatment of chronic migraine.<sup>16</sup> According to the American Migraine Foundation, each Botox-A treatment for migraines involves 31 injections (5 Botox-A units per injection, for a total of 155 units). Areas injected include the bridge of the nose, the forehead, the temples, the back of the head, the neck, and the upper back (just above the shoulder blades).<sup>17</sup> Patients can expect to receive Botox-A injections approximately every 12 weeks to dull symptoms.<sup>18</sup> Providers submit claims for each injection site, which may account for a substantial increase in claims for medically necessary use of BOTOX during the period specified in CMS's analysis.

### **Development History and FDA Approval Process for Botox**

Date	Article
Jun 21, 2019	 FDA Approves Botox (onabotulinumtoxinA) for Pediatric Patients with Upper Limb Spasticity
Jan 22, 2016	 FDA Approves Botox (onabotulinumtoxinA) for the Treatment of Lower Limb Spasticity
Jan 18, 2013	 FDA Approves Botox to Treat Overactive Bladder
Aug 24, 2011	 FDA Approves Botox to Treat Specific Form of Urinary Incontinence
Oct 15, 2010	 FDA Approves Botox to Treat Chronic Migraine
Mar 10, 2010	 Botox (onabotulinumtoxinA) Receives FDA Approval for Treatment of Upper Limb Spasticity in Adults

Source: <https://www.drugs.com/history/botox.html>

<sup>14</sup> AMA, *Prior Authorization and Utilization Management Reform Principles* (2017). Retrieved at: <https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf>

<sup>15</sup> FDA, *BOTOX® Medication Guide* (Jan. 2016). Retrieved at: <https://www.fda.gov/media/77359/download>.

<sup>16</sup> Escher CM, Paracka L, Dressler D, Kollwe K. *Botulinum toxin in the management of chronic migraine: clinical evidence and experience*. Ther Adv Neurol Disord. 2017;10(2):127–135. Retrieved at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5367647/>.

<sup>17</sup> American Migraine Foundation, *Botox-A for Suppression of Chronic Migraine: Commonly Asked Questions* (April 8, 2012). Retrieved at: <https://americanmigrainefoundation.org/resource-library/botox-suppression-chronic-migraine-commonly-asked-questions/>.

<sup>18</sup> Drugs.Com, *FDA Approves Botox to Treat Chronic Migraine* (Oct. 15, 2010). Retrieved at: <https://www.drugs.com/newdrugs/fda-approves-botox-chronic-migraine-2365.html>.

Independent analysis of claims conducted by Watson Policy Analysis revealed that chronic migraine was the most common diagnosis code associated with the use of BOTOX between 2014 and 2017, suggesting that the steep increase was likely a result of increased clinically necessary treatments due to new FDA indications, with the lag reflecting clinical acceptance.<sup>19</sup> **Given that the approved indications for use expanded significantly during the time period in question, the AAMC suggests that CMS reevaluate whether BOTOX truly experienced “unnecessary increases” in volume or whether these increases reflect medically necessary procedures.**

***Prior Authorization May Negatively Impact Beneficiary Well-Being and Would Place Undue Burden on Providers***

In its proposal, CMS would require providers to submit a prior authorization request in order to receive “provisional affirmation” from CMS or the Medicare Administrative Contractor prior to performing a given procedure and submitting the claim for payment. The appropriate reviewer would grant provisional affirmation if the request “includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules.” (p. 39605). CMS specifies that a claim submitted without provisional affirmation would be denied.

CMS notes that requests for provisional affirmation would receive a decision within 10 business days, or, for expedited requests, two business days. (p. 39605). Because a service cannot be provided until the claim receives provisional affirmation, Medicare beneficiaries that suffer from ailments treated by the services offered in these five categories could potentially experience significant delays in care, despite clinician judgement that such care is medically necessary.

**The AAMC urges CMS to not finalize the prior authorization requirements for the specified categories of services. Finalizing the requirements could potentially delay medically necessary care for beneficiaries and would introduce added complexity and administrative burden for providers.** Ultimately, providers strive to deliver quality health care in an efficient manner. However, the operational complexities required of providers in order to obtain prior authorizations hinder efficient care. CMS has not adequately demonstrated that the increase in these services are truly medically unnecessary.

***If the Proposal is Finalized, Claims Should Not Be Denied Once Provisional Affirmation is Granted***

CMS has specified in its proposal that once provisional affirmation is granted to a provider, “a claim for services may be denied based on either technical requirements that can only be evaluated after the claim has been submitted for formal processing or information not available at the time the prior authorization request is received.” (p. 39605).

Under the proposal, providers would be tasked with significant burden to submit a request for prior authorization. However, CMS seeks to retain its ability to deny a claim even after a provider receives provisional affirmation, based on either unspecified technical requirements or information not available when provisional affirmation is granted. This proposed standard is too vague, and offers providers involved in the treatment of the beneficiary insufficient confidence that they would be accurately paid for claims for which they have provided “all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules.” Providers should be afforded confidence that when they provide the necessary documentation and receive provisional affirmation, the claim will be paid. **The AAMC requests that CMS not finalize the proposal to deny claims once a provider is**

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<sup>19</sup> Independent analysis of CMS Standard Analytical Files (SAF) Outpatient Data performed by Watson Policy Analysis (WPA) (Sept. 10, 2019).

**issued provisional affirmation for a medically necessary claim that meets the applicable Medicare coverage, coding and payment rules.**

If a provider receives provisional affirmation and documentation within the medical record – including its presence in the provisional affirmation request – supports the medical necessity of the procedure, then the provider should expect to receive payment for the claim. Affirmation should not be provisional; it should come with the assurance that once the procedure is done payment will follow even though, as is true for any service, there may be post-payment review. If the claim is denied, the provider and beneficiary should have the right to appeal the denial determination.

The AAMC agrees with the AMA’s principles on prior authorization emphasizing the importance of transparency as it relates to adverse determinations – transparency regarding denials creates fairness and sets expectations for providers that regularly provide services that require prior authorization.<sup>20</sup> As currently proposed, the proposals do not provide adequate transparency or reasonable expectations regarding when a claim that has received provisional affirmation would be denied.

Lastly, because the prior authorization requirement is limited to procedures performed in HOPDs, failure to pay medically necessary claims for technical or unknown reasons would have an adverse impact on the provision of future care in HOPDs as it relates to the five service categories proposed in the rule. As a result, this would lead to many of these procedures being performed in other patient care settings that are not subject to the prior authorization requirements.

***Clarification of Responsibility for Requesting Prior Authorization Submission***

The proposal would require the “provider” to submit a prior authorization request to receive the provisional affirmation. The proposed rule does not make clear who is responsible for seeking prior authorization. Is it CMS’s intent that HOPDs *and* physicians seek provisional affirmation from CMS for the identified services? The AAMC requests that CMS clarify who is responsible for submitting the prior authorization request.

***If a Claim is Denied After Provisional Affirmation is Granted, Denial Should Be Narrowly Applied***

CMS has proposed that if a claim is denied *without* receiving provisional affirmation, then the denial would include “any claims associated with the denial of a service listed in proposed § 419.83(a)(1), including services such as anesthesiology services, physician services, and/or facility services.” (p. 39605). **The AAMC requests clarification regarding whether a claim denied with provisional affirmation would also have associated claims denied.** Claims that have received provisional affirmation, but that may be denied for technical issues or other reasons as discussed above, should not have associated claims denied. If the claim is medically necessary but is denied for a technical issue created by the provider who submitted the request for prior authorization and received the provisional affirmation, then only charges associated with that provider should be denied; associated claims for anesthesiology or facility services, for example, should not be denied. In other words, if a claim is denied after provisional affirmation, it should be denied through the narrowest means possible. Specifically, if the treating physician requested prior authorization and received provisional affirmation, entities submitting claims associated with the provisional affirmation claim should be held harmless and not have their claims denied.

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<sup>20</sup> AMA, *Prior Authorization and Utilization Management Reform Principles* (2017). Retrieved at: <https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf>



## **INPATIENT ONLY LIST CHANGES**

CMS is proposing to remove THA from the IPO list beginning in CY 2020. The proposed rule notes that patients suitable to have THA performed in the outpatient setting should be “appropriately selected.” (p. 39524). The AAMC agrees that there may be instances in which physicians deem that a THA can be safely performed as an outpatient procedure on certain Medicare patients – particularly those who are younger, healthier, and have assistance for at-home postoperative care – just as that procedure commonly is performed in that setting for many non-Medicare patients. We agree with CMS that outpatient THA procedures may not be reasonable for many Medicare patients who are older, more medically complex and possibly require post-acute care in a facility. The decision as to whether to perform THA on an inpatient or outpatient basis should rest completely with the physician, in consultation with his/her patient, and solely based on the patient’s clinical circumstances.

### ***Ensure that Alternative Payment Models Are Not Negatively Impacted by Removing THA from the IPO***

In addition to ensuring that patients are appropriately screened to have the procedure performed in the outpatient setting, the AAMC is concerned that removing THA from the IPO list would create undue significant negative financial implications for hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA), Comprehensive Care for Joint Replacement (CJR), and future major joint replacement of the lower extremity (MJRLE) bundled payment programs. CMS should ensure that changes to the IPO list should not unfairly penalize model participants.

### ***Impact of Proposal to Remove THA from IPO List on BPCI Advanced and CJR Target Prices***

The BPCIA and CJR baseline periods include a subset of Medicare fee-for-service (FFS) THA cases that could have been performed as outpatient procedures, if outpatient procedures were allowed during that period. CMS’s proposal to permit THA procedures to be reimbursed under OPSS as well as IPPS may significantly alter the composition of BPCIA and CJR participant hospitals’ patient populations, and thus unfairly hinder hospitals’ ability to generate savings under the models. As the proposed rule discusses, younger, healthier patients and those with at-home assistance, are more likely to receive outpatient THAs, meaning a higher proportion of patients receiving inpatient THAs would be higher-risk and more likely to require additional post-acute care support. As a result, this change in patient mix could increase the average episode payment of the remaining inpatient THA BPCIA and CJR cases when compared to current payment levels. Because the episode payments for the remaining inpatient THA episodes are reconciled against the baseline target price calculated using both inpatient and outpatient eligible procedures, the remaining inpatient cases would appear artificially high relative to the target price. Consequently, hospitals would be more likely to sustain losses in the BPCIA and CJR models. In the absence of sufficient risk adjustment to modify target prices to reflect CMS’s proposed change, some BPCIA hospitals may voluntarily leave the program prior to its conclusion in order to mitigate financial losses. CMS should work to ensure that BPCIA and CJR participants are not negatively impacted with the changes to the IPO list.

### ***Extend the Prohibition on RAC Referrals for Inpatient THAs to Two Years***

CMS also proposes that THA procedures would not be eligible for referral to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule within the first calendar year of their removal from the IPO list. The proposed rule states that a one-year exemption “would be an adequate amount of time to allow providers to gain experience with application of the 2-midnight rule to these procedures and the

documentation for Part A payment. (p. 39527-39528). The AAMC supports CMS's proposal to prohibit referral to the RACs and denials of inpatient THA claims for patient status, since this will discourage providers from inappropriately shifting THA procedures to outpatient settings to ensure payment. However, in prior rulemaking, CMS allowed for a 2-year prohibition on referral to the RACs when total knee replacement was removed from the IPO list in order to allow provides to "gain experience with determining the most appropriate setting to perform these procedures." (82 *Fed. Reg.* 52525). We request that CMS maintain consistency with previous rulemaking and limit referral to the RACs for two years for THA procedures performed in the inpatient setting.

#### **AMBULATORY SURGICAL CENTER (ASC) LIST CHANGES**

##### ***Consider Impact on Beneficiary Coinsurance Liabilities for Procedures Performed in ASCs***

While Medicare's overall costs may be lower in the ASC for some procedures, beneficiaries are not protected from cost-sharing liabilities in the ASC as they are in the HOPD. Currently, a beneficiary's cost-sharing liability is limited to the Part A deductible<sup>21</sup> for a service performed in the HOPD; there is no such protection in the ASC. For beneficiaries who choose to have a total knee arthroplasty (TKA) in an ASC, for example, their cost sharing would be higher than if that same procedure was performed in an HOPD. In HOPDs the OPSS beneficiary coinsurance for the TKA would be capped at \$1,364 for a single procedure in 2019. In contrast, in ASCs, beneficiaries would be subject to 20 percent<sup>22</sup> of the "Addendum AA" amount<sup>23</sup> or \$1,727.99 for that procedure, as well as additional coinsurance for separately paid ancillary services integral to the surgical procedure. In addition, ASCs are often owned by physicians but ASC services are not subject to self-referral prohibitions. As CMS seeks to add more procedures to the ASC list, CMS should carefully consider these issues so beneficiaries are protected from additional liability and the potential to be referred for procedures in an ASC when a hospital outpatient or inpatient stay could be more appropriate for their clinical circumstances.

#### **VIDEO ELECTROENCEPHALOGRAM (EEG) MONITORING SERVICES**

##### ***Assign Video EEG Monitoring Services to APCs That Reflect Time and Resource Intensity to Ensure Adequate Reimbursement***

In both the CY 2020 OPSS proposed rule, as well as the CY 2020 Physician Fee Schedule (PFS) proposed rule, CMS has proposed coding changes that would reduce payment for video EEG monitoring services. These services, which are used for patients with complex medical history of seizures and who experience continued seizures despite use of multiple epilepsy medications, are used to locate areas of the brain causing the seizures to continue.

In this rule, CMS has proposed to include its new, technical component Healthcare Common Procedure Coding System (HCPCS) codes 95X09 (video EEG 2-12 hour intermittent monitoring) and 95X10 (video

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<sup>21</sup> Medicare.Gov, *Outpatient Hospital Services*. Accessed on Sept. 19, 2019. Retrieved at: <https://www.medicare.gov/coverage/outpatient-hospital-services>.

<sup>22</sup> Medicare.Gov, *Ambulatory Surgical Centers*. Accessed on Sept. 19, 2019. Retrieved at: <https://www.medicare.gov/coverage/outpatient-hospital-services>.

<sup>23</sup> CMS, Details for title: CMS-1695-FC (Nov. 21, 2018). Retrieved at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1695-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>.

EEG 2-12 hour continuous monitoring) to APC 5722, and HCPCS codes 95X12 (video EEG 12-26 hour intermittent monitoring) and 95X13 (video EEG 12-26 hour continuous monitoring) to APC 5723. The AAMC is concerned that the proposal would not provide adequate reimbursement for these services, and does not appropriately reflect the time and resources required to monitor complex epilepsy patients.

To put the amount of time and resources in context, the AAMC provides the following explanation of how these services are provided. For example, for a patient that requires live continuous video EEG monitoring, the monitoring physician must be available for 24 hours to read the EEG, and must have a direct live connection with the epilepsy unit staff to read and interpret the EEG changes and initiate immediate medical intervention when warranted. Typically, these patients exhibit many seizures, at times in clusters that become difficult to treat and require high level medical intervention by the treating physician. The interpretation of the study results and the formulation of the plan of care are extremely difficult and require a high clinical expertise and significant physician time commitment.

Using time as the sole differentiator does not fully reflect the costs of active monitoring by a technologist (vs. no monitoring) and the added costs and technologist time for the video recording. In addition, this proposal does not account for the high level of technical expertise and involvement that go into the monitoring of the complex epilepsy cases, such as the most difficult-to-localize epilepsies and those requiring intracranial subdural grids or depth electrodes monitoring (as compared to, for example, the neurophysiological monitoring of non-epilepsy patients). The proposed rule also results in a significant anomaly in payment rates under the Physician Fee Schedule compared to the OPSS. **For these reasons, the AAMC recommends CMS assign codes 95X12 and 95X13 to APC 5724, and assign codes 95X09 and 95X10 to APC 5723. Assigning these codes to APCs with higher reimbursement rates would provide more appropriate payment to the specialized epilepsy centers that would be most greatly impacted by reduced payment for these services. The higher rates provide commensurate payment with the level of time and resources the complex cases that require these services necessitate.**

#### **CHANGES TO ORGAN PROCUREMENT ORGANIZATIONS (OPOs) CONDITIONS FOR COVERAGE (CfCs)**

##### ***Changes to the CfCs for OPOs Should Not Negatively Impact Transplant Centers***

CMS is proposing to change the conditions for coverage for OPOs to incentivize transplantation of viable organs. CMS seeks comments on the validity and reliability of the two following OPO outcome measures. The first potential measure would be the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause the death consistent with organ donation. The second potential measure would be actual organs transplanted as a percentage of inpatient deaths for this same population. (p. 39597).

The AAMC is concerned that a volume-based procurement and placement metric for OPOs would increase transplant centers' organ denial rates because more available organs do not necessarily equate to more organs of transplantable quality. While CMS acknowledges this concern for OPOs, it does not recognize this for transplant centers. Additionally, the patient receiving the organ(s) decides whether or not to accept an organ. The AAMC supports efforts to maximize availability of organs to patients who so desperately need them. However, in doing so, CMS should ensure that changes made to OPOs conditions for coverage do not penalize transplant centers that chose not to transplant organs that may be poor quality.

## REQUEST FOR INFORMATION – QUALITY AND PRICE TRANSPARENCY

### *CMS Should Take Time to Evaluate Options and Engage Stakeholders on How Best to Incorporate Quality Information into Price Transparency Programs and Must Prioritize Patient-Centered Engagement on Cost and Quality of Care*

The AAMC supports efforts to better inform patients of quality outcomes and patient experience as part of broader transparency efforts to assist patients and their families with decision making. CMS's request for information on this topic comes at a time when the President has called on his Administration to align quality measures across programs<sup>24</sup> and policy researchers have initiated efforts to innovate how clinicians talk about cost with their patients.<sup>25</sup> Quality and value-based care leaders are showing that now is an opportune time to establish a path towards patient-centered outcomes measures across all settings of care.<sup>26</sup> Consensus has been building that current quality measures and programs must be revamped to better measure what matters to patients and families and evaluate providers fairly. CMS's Meaningful Measures framework development and a recent report which recommended that CMS commit resources to overhaul the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience survey are examples of the important work that is being done to push our healthcare system to the next generation of measuring the quality and value of care.<sup>27</sup>

This broad area of work towards patient-centeredness will be critical to the development of quality and cost information that is most meaningful for patients. **We urge CMS to take the necessary time to work with stakeholders, including patients, providers, insurers, and consumer groups, to evaluate and integrate these broader patient-centeredness efforts into any future initiatives to build and test a valid and reliable framework for incorporating quality with price transparency.** Providers and clinicians serve a critical role in assisting patients and their families with medical decision-making and have begun important work to incorporate cost and quality of care into these critical discussions. As this work is nascent, the AAMC recommends that CMS prudently develop the frameworks for tools and resources that facilitate these conversations without causing patient confusion or increasing provider burden.

It is not clearly apparent that current quality measures collect and report the information that meets patient and consumer needs. More should be done to evaluate optimal ways of presenting quality information to ensure that patients receive information that enables them to make meaningful distinctions across providers based on provider performance. For example, we lack information about whether patients prefer quality information that is specific to conditions or procedures rather than overall quality information about a hospital. Do they find "traditional" quality information such as mortality or complication rates helpful for assessing a provider? Or might they also want to know a provider's volume of services for such a condition or procedure? Is there a need to revamp quality reporting such that it provides patients with provider performance overall (across all patients) and with patients more similarly situated to themselves (principle diagnosis, co-morbidities, age, sex, etc.)? While policymakers struggle to get consumers information that will allow them to make informed choices, there remains insufficient research

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<sup>24</sup>Executive Order on Improving Price and Quality Transparency in American Health to Put Patients First," specifically Sec. 4 Establishing a Health Quality Roadmap (Jun. 24, 2019). Retrieved at: <https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/>.

<sup>25</sup>Emmy Ganos et al., "Talking About Costs: Innovation in Clinician-Patient Conversations," Health Affairs Blog (Nov. 27, 2018). Retrieved at: <https://www.healthaffairs.org/doi/10.1377/hblog20181126.366161/full/>.

<sup>26</sup>Aparna Higgins et al., "Pathway to Patient-Centered Measurement For Accountability," Health Affairs Blog (Sept. 12, 2019). Retrieved at: <https://www.healthaffairs.org/doi/10.1377/hblog20190910.733376/full/>.

<sup>27</sup>"Modernizing the HCAHPS Survey: Recommendations from Patient Experience Leaders," (Jul. 2019). Retrieved at: [https://www.fah.org/fah-ee2-uploads/website/documents/Modernizing\\_HCAHPS\\_Recommendations\\_from\\_PELs.pdf](https://www.fah.org/fah-ee2-uploads/website/documents/Modernizing_HCAHPS_Recommendations_from_PELs.pdf)

on what information patients find most helpful. This should be studied and validated as a first step in the process. Such an evaluation should cast a wide net to ensure diverse patient perspectives are included (i.e., age, sex, region, insured status, health literacy, etc.), in order to distinguish whether there might be significant differences that suggest a “one-size-fits-all” approach, such as a website with standard cost and quality information, is untenable. **Thoughtful attention to and study of patient and consumer preferences will help to identify precisely what and how quality should be measured and transparently reported.** It would be premature to begin building policies around quality transparency that might not meet the needs of patients.

## **HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM**

### ***AAMC Supports the Removal of OP-33 from the Hospital Outpatient Quality Reporting (OQR) Program***

CMS proposes to remove one measure from the Hospital OQR Program beginning in CY 2022 – OP-33: External Beam Radiotherapy for Bone Metastases. The AAMC recognizes the importance of quality measurement to ensure that hospitals and physicians are providing high quality care. However, reporting and transmitting quality measures requires intensive staff training, labor, and resources – and ultimately limits the time clinicians spend with their patients. **AAMC supports removing this measure from reporting.**

### ***CMS Should Consider the Removal of Additional Measures from the Outpatient Hospital Quality Program as Part of its Meaningful Measures Work***

The AAMC supports the agency’s Meaningful Measures framework and the proposals to remove measures across the hospital quality programs to align programs and better address quality priorities. We urge CMS to continually review measures and consider the removal of additional measures from its programs. **The Association believes that in subsequent rulemaking, at a minimum, CMS should consider removing OP-8: MRI Lumbar Spine for Low Back Pain and OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients based upon feedback from the National Quality Forum (NQF) during recent maintenance review of endorsement for each measure.**

In the case of OP-8, NQF removed endorsement in May 2017 because the measure did not satisfy the validity sub criterion for scientific acceptability.<sup>28</sup> This was primarily due to concerns by the Musculoskeletal Standing Committee with the continued inclusion of “elderly” patients in measurement, even though it is a condition in the Appropriate Use guideline. In addition, the use of administrative claims data to identify use of antecedent conservative therapies (of which, common therapies like NSAIDs, massage therapy, acupuncture, etc.) was deemed inadequate.<sup>29</sup>

The Cost and Efficiency Standing Committee recently did not recommend OP-18 for continued endorsement in its Spring 2018 review cycle, citing a lack of evidence that the measure influences mortality or other patient outcomes.<sup>30</sup> This evaluation of the measure begs the question whether it should

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<sup>28</sup> National Quality Forum Quality Positioning System, “#0514 MRI Lumbar Spine for Low Back Pain,” (May 2017). Retrieved at: <https://www.qualityforum.org/OPS/MeasureDetails.aspx?standardID=670&print=0&entityTypeID=1>.

<sup>29</sup> “Musculoskeletal Off-Cycle Measure Review 2017: Technical Report,” National Quality Forum (Jul. 2017). Retrieved at: [http://www.qualityforum.org/Publications/2017/07/Musculoskeletal\\_Off-Cycle\\_Measure\\_Review\\_2017.aspx](http://www.qualityforum.org/Publications/2017/07/Musculoskeletal_Off-Cycle_Measure_Review_2017.aspx).

<sup>30</sup> “Cost and Efficiency, Spring 2018: CDP Report,” National Quality Forum (Jan. 2019). Retrieved at: [http://www.qualityforum.org/Publications/2019/01/Cost\\_and\\_Efficiency\\_Final\\_Report\\_-\\_Spring\\_2018\\_Cycle.aspx](http://www.qualityforum.org/Publications/2019/01/Cost_and_Efficiency_Final_Report_-_Spring_2018_Cycle.aspx).

be removed from the OQR under removal factor 2, that the performance or improvement on the measure does not result in better patient outcomes. The Consensus Standard Approval Committee (CSAC) reviewed and NQF removed endorsement of the measure in October 2018.<sup>31</sup>

***Request for Feedback: Adoption of Certain Ambulatory Surgical Center Quality Reporting Program Measures in the OQR***

CMS is seeking feedback on the potential to take measures from Ambulatory Surgical Center (ASC) Quality Reporting Program (ASCQR) for future inclusion in the OQR. Specifically, CMS is considering the following measures: ASC-1: Patient Burn, ASC-2: Patient Fall, ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and ASC-4: All-Cause Hospital Transfer/Admissions. **The AAMC agrees that patients should be able to compare the quality of care for the same services between ASCs and hospital outpatient departments (HOPDs).** However, as CMS notes, these measures have been suspended from the ASCQR due to issues with data submission methods and the measures have not been specified for the HOPD setting. The AAMC supports the agency's plan to work with the measure developer to improve the data submission methods and to ensure the measures are appropriately re-specified for the hospital setting.

More generally, the AAMC strongly recommends that all new measures be endorsed by the NQF to ensure that the measure is scientifically valid, reliable, and feasible, and determine whether it is appropriate for review in the NQF Social Risk trial. Any new measure should be approved by the Measure Applications Partnership (MAP) before the measure is proposed, and that the measure be reported on *Hospital Compare* for one year before the measure is included in the agency's overall quality Star Ratings program.

In regard to the specific measures for feedback, the AAMC believes the first three measures (ASC-1, ASC-2, and ASC-3) are appropriate to specify for the HOPD setting. The AAMC asks CMS to clarify how the fourth measure, ASC-4, would provide unique information distinct from current OQR measure OP-36: Hospital Visits after Hospital Outpatient Surgery, which measures inpatient admissions directly after outpatient surgeries in addition to unplanned hospital visits post-discharge and within seven days of surgery. In specifying ASC-4 for the HOPD setting, would CMS be seeking to use the measure to replace OP-36 or for the ASC-based measure to focus specifically on hospital transfers upon discharge, as transfers are not currently included in OP-36?

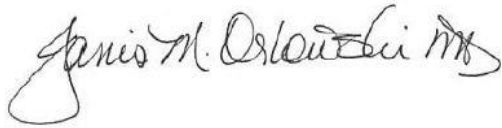
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<sup>31</sup> National Quality Forum Quality Positioning System, "#0496 Median Time from ED Arrival to ED Departure for Discharged ED Patients," (Oct. 2018). Retrieved at: <https://www.qualityforum.org/OPS/MeasureDetails.aspx?standardID=471&print=0&entityTypeID=1>.

## CONCLUSION

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or [mmullaney@aamc.org](mailto:mmullaney@aamc.org) or Andrew Amari at 202.828.0554 or [aamari@aamc.org](mailto:aamari@aamc.org) for questions on the payment policy proposals and Phoebe Ramsey at 202.448.6636 or [pramsey@aamc.org](mailto:pramsey@aamc.org) for questions on the quality proposals.

Sincerely,



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