AMA
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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule for CY 2019 (CMS-1695-P)

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule for calendar year (CY) 2019 for the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System, published in the *Federal Register* on July 31, 2018. A number of the policies in this proposed rule make positive steps to improve current regulations. Specifically, the AMA supports:

- Replacing the Consumer Price Index for Urban Consumers (CPI-U) with the hospital market basket (HMB) as the annual update mechanism for ASC payments;
- Revising the definition of surgery for 2019 to account for "surgery-like" procedures in ASCs; and
- Improving patient access to non-opioid treatments for pain management by separating their payment out from other services in the ASC setting.

There are also policies included in this proposed rule that concern the AMA. These include:

- Site neutrality policies that do not adequately accomplish the goal of encouraging care in the lowest cost setting;
- Insufficient actions to prevent the unnecessary shift of Medicare services from physician offices to hospital outpatient departments (HOPDs);
- Potentially using prior authorization as a method for controlling overutilization of services;
- Rescaling the ASC relative weights to achieve a perceived budget neutrality objective instead of applying the OPPS relative weights; and
- Delaying the immediate removal of the Communication about Pain composite measure from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and from public reporting.

Outpatient Prospective Payment System

While the AMA generally supports site neutral payments, we do not believe that it is possible to sustain a high-quality health care system if site neutrality is defined as shrinking all payments to the lowest amount paid in any setting. In this rule, CMS proposes several policies that would bring payment rates for some services in some hospital outpatient departments closer to the rates paid for the same service when delivered by physicians in independent practices. Distinctions still exist between "off-campus" hospital outpatient clinics formed before or after November 2, 2015, and none of the proposed policies would apply to outpatient departments on the same "campus" as the hospital.

The AMA:

- Supports site neutral payment but believes that the current OPPS payment policies and the proposed policies in this rule are complex, confusing, and are not truly site neutral because the policies do not apply equally to all hospital outpatient clinics.
- Believes that payment differentials between independent physician practices and hospital outpatient departments stem in part from inadequate Medicare physician payment rates—after adjustment for inflation, **Medicare physician pay has declined 19 percent since 2001**—and that any savings from site neutrality proposals derived from OPPS should be reinvested in improvements elsewhere in Part B, including payments to physicians.
- Agrees that CMS should monitor service migration between outpatient settings and prohibit efforts to evade restrictions on expansion of services in off-campus outpatient departments formed after November 2, 2015.
- Endorses the development of a website that allows patients to compare HOPD versus ASC charges for various payment populations. The AMA calls on CMS to expand the website to include a comparison of rates for services performed in an independent physician's office versus a hospital clinic. We note, however, that conveying the differing payment rates for various HOPD categories will be challenging.
- Opposes expanded use of prior authorization and other private payer utilization controls that are inconsistent with Administration's stated goal of reducing administrative burden and putting patients over paperwork.

CMS estimates approximately $760 million in savings would be generated to Medicare and its beneficiaries by lowering facility payments for affected services and sites to CMS' calculation of the equivalent rate in a physician's office. However, none of the savings would be used to improve payments to physicians.

Feedback is also being sought on the potential use of a variety of utilization curbs currently in use by private payers and widely disparaged by physicians. **We are also concerned that the suggested utilization curbs will drive more physicians into hospitals or out of Medicare, creating access problems for patients and potential cost increases for Medicare.**

Encouraging Care in the Lowest Cost Setting

While the AMA fully supports the goal of encouraging care in the lowest cost setting, we doubt that the proposed policies will fully achieve that goal. Because of the Bipartisan Budget Act of 2015 (BBA) and

the subsequent CMS implementation of the BBA,[1] providers are left with a confusing payment patchwork.

- On-campus outpatient departments would receive a $116 facility fee for clinic visits in 2019 while the off-campus departments would be paid a facility fee of $46.
- If office visit rates proposed in the 2019 Physician Fee Schedule (PFS) proposed rule are adopted, the base physician payment for all level 2 to level 5 visits—which the AMA opposes[2]—would be $134 for new patients and $92 for established patients in the physician's office and $103 for new patients and $66 for established patients in the facility. Additional payments of $5 or $14 could be added to certain kinds of care in either setting.
- Total combined facility and physician payments in an off-campus hospital outpatient clinic would be $149 for a new patient and $112 for an established patient. If the clinic is on-campus, however, payments would total $219 for a new patient and $182 for an established patient.
- **With or without the add-ons to some physician visits, on-campus clinics would be paid $70 to $90 more for a patient visit than the off-campus clinics and physician offices. Moreover, even in the off-campus hospital clinic, payments would still be $15 to $20 higher than in a physician's office.**

Table 1: Amount of Payment for a Clinic Visit

	On-Campus	Off-Campus	Physician Office
New Patient	$219	$149	$134
Established Patient	$182	$112	$92

* The calculation is based on the facility fee of $116 for on-campus (e.g., $116+$103=$219) and $46 for off-campus (e.g., $46+$103=$149).

[1] In section 603 of the Bipartisan Budget Act of 2015 (BBA), Congress stipulated that effective January 1, 2017, rather than billing under the OPPS, off-campus hospital outpatient clinics or provider-based departments (PBD) formed after the law's enactment on November 2, 2015 should bill under the "applicable payment system." CMS created an exception for emergency department services, designated the physician fee schedule as the "applicable system" for most other services and then began to make reductions in facility fees at the post-BBA or "nonexcepted" PBDs. Initially, only clinic visits were affected but by 2018, nearly all services in nonexcepted PBDs (other than emergency care) were subject to a 60 percent facility fee reduction. In this rule, CMS is proposing to extend the 60 percent facility fee reduction to clinic visits in the "excepted" PBDs formed before November 2, 2015. Meanwhile, outpatient departments located in a hospital or on its campus will continue to be paid at the prior annually updated facility fee rates for all services.

[2] AMA, Comment Letter in Response to CMS–1693–P; Medicare Program: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019, (Sept. 10, 2018), https://searchlf.ama-assn.org/ undefined/ documentDownload?uri= percent2Funstructured percent2 Fbinary percent2Fletter percent2FLETTERS percent2F2018-9-10-2019-PFS-QPP-Comment-Letter-FINAL-2.pdf.

Table 2: Dollar Difference Between Sites of Service

	Difference between On-Campus and Off-Campus	Difference between On-Campus and Physician Office	Difference between Off-Campus and Physician Office
New Patient	$70	$85	$15
Established Patient	$70	$90	$20

The possible permutations for services other than clinic visits are also very complicated. In the nonexcepted PBDs, where a 60 percent across-the-board facility fee reduction will apply to nearly all services, payments will be substantially lower than in either the older excepted off-campus clinics or the on-campus clinics. However, the difference between physician office payments and hospital outpatient payments is not uniform, so an across-the-board 60 percent facility fee cut could be much more significant for some services than others and in theory might even result in payments that are lower than in a physician's office. **Translating the current payment rates into a coherent and transparent price signal for patients will be difficult if not impossible especially given the Administration's push for greater price transparency. It also seems likely that the remaining payment differences in ambulatory payment sites may drive new migrations of services among hospital outpatient settings rather than to physician offices.** An additional concern is the possibility that the differential impact of an imprecise 60 percent across-the-board reduction on services to the nonexcepted PBDs may lead to concentration of some specialties in on-campus clinics, creating access problems for some patients in remote areas.

Physician Office to HOPD Service Shifts

Stopping the shift of Medicare services from physician offices to hospital clinics will not happen unless Medicare payments are sufficient to ensure physician practices' sustainability and to halt the continued consolidation of hospital purchases of physician practices. A serious disconnect exists between what Medicare pays and what it costs to run a modern physician practice. The disparity between OPPS and PFS payment rates is an indication of inadequate rates paid to physician offices and should not be attributed entirely to OPPS overpayments. **Rather than removing an estimated $760 million a year from Medicare spending for outpatient care, CMS should reinvest these savings in other Part B services, including payments under the PFS. For example, CMS could consider redistributing OPPS savings to the practice expense portion of the physician fee schedule to offset the costs of new administrative burdens such as electronic health records (EHR) and quality reporting.**

Under the OPPS payment system, CMS has the authority to create a method for controlling unnecessary increases in the volume of covered outpatient services. The proposed rule points to various steps CMS has taken to curb increases in the volume of hospital outpatient services. Despite these efforts, the rule notes, total spending under the OPPS has been growing at a rate of roughly 8 percent per year under the OPPS, making the OPPS the fastest growing of any of the Medicare payment systems. Total expenditures are projected to increase from approximately $70 billion in 2018 to nearly $75 billion in 2019.

CMS attributes much of that growth to a shift of visits from independent physician offices to hospital-owned clinics and notes in the rule that from 2012 to 2015 hospital-based visits grew by 22 percent while physician office-based visits declined by one percent. This underlying assumption underpins the use of the long-standing "volume control" directive as authority to extend site neutral payment policies beyond the newly formed off-campus hospital clinics covered under the BBA. An explicitly stated goal is to halt hospital purchases of physician practices and stem the shift of services from physician offices to hospital clinics.

The AMA shares the Administration's concern about potential negative impacts from continued consolidation among health care providers. Reducing the difference in payment rates between the two settings addresses one of the factors that is driving physicians to practice in hospital-owned settings rather than independent physician offices. However, cutting payments to hospitals will not guarantee the continued viability of physician practices that have faced nearly two decades of stagnant Medicare payments accompanied by costly new requirements associated with quality improvement, value-based care, utilization control, and program integrity initiatives imposed by CMS and private payers.

Medicare payments for physician services for many years have failed to keep pace with the actual costs of running a practice and have trailed well behind increases for other providers. From 2001 to 2018, Medicare payments for outpatient hospital care increased 50 percent or an average of 2.4 percent a year while physician pay increases averaged 0.4 percent a year and totaled just 6 percent over 15 years. Over the same period, Medicare's conservative economic index of practice cost inflation rose by 32 percent or 1.7 percent per year on average so that **after adjustment for inflation, Medicare physician pay declined 19 percent from 2001 to 2017 or by 1.3 percent per year on average**.[3]

At the same time, the number and cost of administrative tasks imposed on physicians by CMS and private payers has proliferated. For example, a 2016 study reported in *Health Affairs* found that physician practices across four common specialties spend over $15.4 billion annually to report quality measures.[4] The Office of the National Coordinator for Health Information Technology estimates the cost for implementation and maintenance of an EHR at $70,000 per provider upfront and $8,000 per provider per year in maintenance and upgrade costs.[5] Physician and staff time devoted to these activities has also increased exponentially. The skill level and salary costs of practice employees has also been increasing as administrative tasks and systems have grown more complex. According to the *Health Affairs* article, reporting quality measures requires 16 hours of staff time a week. A time-motion study reported in the 2016 *Annals of Internal Medicine* found that for every hour of clinic time spent with patients, physicians spend two hours per day during office hours and another one to two hours at night on EHRs and desk

[3] Based off of AMA research and analysis of the Medicare payment systems. Available upon request.
[4] L.P. Casalino et al., *US Physician Practices Spend More Than $15.4 Billion Annually To Report Quality Measures*, Health Affairs (Mar. 2016), https://doi.org/10.1377/hlthaff.2015.1258.
[5] Office of the National Coordinator for Health Information Technology, *How Much is This Going to Cost Me?*, (Nov. 2014), https://www.healthit.gov/faq/how-much-going-cost-me.

work.[6] In a 2017 AMA survey, physicians reported that on average they complete 29 prior authorization requests a week and spend 14.6 hours a week in the process.[7]

Accordingly, due to shifting of services into HOPDs, the continued consolidation of the health care system, decline in physician pay, and increase in administrative tasks, **CMS should reinvest the estimated $760 million a year from outpatient care to other Part B services, including payments under the physician fee schedule.**

Proposal and Comment Solicitation on Method to Control Unnecessary Increases in the Volume of Outpatient Services

The AMA is strongly opposed to the increased use of prior authorization as a method for controlling overutilization of services. CMS solicited comments on using the OPPS "volume control" language to impose new utilization management tools to additional items and services paid under OPPS that may represent unnecessary increases in utilization. Specific suggestions include "prior authorization," and an "evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness and efficiency."

Our principal concern with these utilization management tools is the potential effect on Medicare beneficiaries' ability to receive quality, timely care. These tools create significant treatment barriers by delaying the start or continuation of necessary treatment, which may in turn adversely affect patient health outcomes. Care delays associated with prior authorization could negatively impact the quality of care and patient clinical outcomes. To quantify the impact of prior authorization requirements on both patients and physicians, the AMA conducted a survey of 1,000 practicing physicians in December 2017. As detailed in the enclosed survey summary, 64 percent of surveyed physicians reported waiting at least one business day for prior authorization decisions from health plans, while 30 percent reported waiting at least three business days. Not surprisingly, 92 percent of physicians said that prior authorization can delay access to necessary care. These delays may have serious implications for patients and their health, as 78 percent of physicians reported that prior authorization can lead to treatment abandonment, and 92 percent indicated that prior authorization can have a negative impact on patient clinical outcomes.

We also underscore the significant administrative burdens and waste associated with utilization management programs. As mentioned above, the AMA's 2017 survey shows that practices complete an average of 29.1 prior authorization requests per physician per week, and this prior authorization workload consumes **14.6 hours—nearly two business days—per week of physician and staff time**.[8] An overwhelming majority (84 percent) of physicians characterized prior authorization-related burdens as high or extremely high.[9] Moreover, prior authorization hassles have been growing over time, with 86 percent of physicians reporting that prior authorization burdens have increased over the past five years.[10]

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[6] C. Sinsky et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties, Annals of Internal Medicine*, (Sept. 2016), http://annals.org/aim/article-abstract/2546704/allocation-physician-time-ambulatory-practice-time-motion-study-4-specialties

[7] American Medical Association, *2017 AMA Prior Authorization Physician Survey*, (2018), https://www.ama-assn.org/sites/default/files/media-browser/public/arc/prior-auth-2017.pdf.

[8] *Id.*

[9] *Id.*

[10] *Id.*

Furthermore, the utilization management tools are unnecessary because physicians already have ample incentives to reduce unnecessary services under the Quality Payment Program.

Over the last several years, the AMA and other physician organizations have repeatedly been asked by various congressional committees and executive agencies for suggestions on how Medicare's paperwork burden could be reduced. In response, virtually every physician group has identified prior authorization requirements as a serious burden that takes time away from patient care, delay treatment, and—in the most extreme cases—can lead to permanent impairment or even death. It is disheartening that despite these repeated concerns and the oft-stated CMS goal of putting patients before paperwork, the agency is still considering new prior authorization requirements in addition to the current demonstration.

The AMA strongly opposes the addition of prior authorization requirements in fee-for-service Medicare. We further recommend that CMS create and enforce standards for prior authorization in Medicare Advantage (MA) plans. We have attached a prior authorization consensus statement developed by the AMA along with national provider and health plan associations. This document calls for more selective application of prior authorization requirements and more frequent reviews and transparency for prior authorization lists. It could serve as a guide in the development of prior authorization standards in either MA or fee-for-service Medicare.

Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Department of a Hospital

The AMA continues to have ongoing concerns that patients who clinically benefit from receiving treatment in their community practice where care coordination and continuity of care are enhanced increasingly do not have this option. Specifically, community practices that do not have an affiliation with a hospital (such as a hospital outpatient department or an off-campus hospital-owned clinic) are not able to secure Medicare Part B covered drug at the average sale price (ASP) plus 6 percent (which is adjusted downward to account for sequestration). As a result, such community practices must send their patients for treatment to hospital affiliated practices where costs are higher, care fragmentation is an issue, and patients may have increased difficulty navigating. **The AMA strongly supports efforts to afford patients access to medically necessary treatments among their community providers and urges CMS to work with the AMA to advance such solutions.**

The AMA also appreciates efforts to advance site neutrality. However, as the AMA urges caution when extending the ASP-22.5 percent for 340B drugs policy to post-2015 campus clinics. It is very important to ensure that the -22.5 percent adjustment does not reduce payments so much so that these other sites of care, like community physician practices, are not able to offer patients treatment. The goal should not be to reduce payment to the point that offering treatment is not an option at any site of service. **The AMA strongly urges CMS to provide a clear analysis of how the ASP-22.5 percent adjustment for 340B drugs ensures continued access to patients.** Ultimately, an important step to reducing costs and enhancing patient care would be efforts to ensure that community-based physician practices are able to afford Medicare Part B covered drugs.

Outpatient Quality Reporting Program

- **Proposed New Measure Removal Factor 8**

The AMA strongly supports the intent of Factor 8 (The costs associated with a measure outweighs the benefit of its continued use in the program). However, we seek clarification from CMS on the cost/benefit threshold CMS plans to utilize when determining whether the cost outweighs the evidence supporting the benefits to patients in the future. For example, how will CMS balance the costs associated with the data collection and reporting of the measure with an estimated number of lives saved or the prevention of a minimum number of infections?

While we understand that it may be hard to delineate a specific threshold, providing information regarding what cost estimates and evidence providers must present to demonstrate that this new factor should be applied to a measure would be appreciated. Quality measures incorporated into CMS programs should demonstrate that by measuring a certain process or outcome, a facility or physician can improve on performance in a meaningful way.

- **Proposal of an Additional Removal Factor**

The AMA recommends that CMS create an additional removal factor around reliability and validity:

- Factor 9. Availability of a new measure which is more reliable and/or valid than a current measure.

As measure development and implementation become more sophisticated and measures are better able to precisely and accurately represent the quality of care provided to patients, this removal process should recognize and facilitate replacement with these "better" measures. Specifically, when there is a new measure available that provides results which are more reliable and/or valid, its availability should be considered.

- **Addressing Patient Safety and Harm**

We also seek clarification on the level of evidence needed to immediately remove a measure(s) from the program without rulemaking due to a patient harm or safety issue with the measure. Moreover, we seek clarification on the process for facilities and physicians to raise and address patient harm or safety issues with CMS. We are aware of measures in other CMS quality programs causing unintended consequences, but CMS has chosen to maintain the measures in the programs.

It is also unclear whether patient harm is intended to be captured in Factor 4 and if not, we request CMS address this important issue. Currently, Factor 3 (availability of a more broadly applicable measure), Factor 4 (performance or improvement on a measure does not result in better patient outcomes), and Factor 5 (availability of a measure that is more strongly associated with desired patient outcomes for the particular topic) focus on a replacement with a "better" measure based on its association with outcomes.

- **Proposed Removal of Quality Measures from the Hospital OQR Program Measure Set**

The AMA appreciates CMS' efforts to ease administrative and regulatory burden through CMS' Meaningful Measures Initiative. Specifically, we support CMS' proposal to remove the following measures from the OQR program measure set: OP-29, OP-30, OP-31, and OP-9. These measures were developed for physician-level use and not appropriate for a facility-based quality reporting program.

Ambulatory Surgical Center Payment System

The AMA fully supports the ability of physicians to select the most appropriate site of service for their patients, in consultation with patients and families, for surgical procedures as well as other services. To ensure the ability of physicians to select the most appropriate site for their patients, we believe CMS should increase ASC payments to level the playing field between HOPDs and ASCs.

Updating the ASC Conversion Factor

AMA strongly supports the CMS proposal to replace the CPI-U with the hospital market basket HMB as the annual update mechanism for ASC payments. Moreover, CMS should not consider any alternative proposals to maintain CPI-U while collecting evidence to justify a different payment update. The CPI-U is not suitable for updating ASC payments because it measures changes in the prices of consumer goods, only a very small portion of which is related to health care, and is therefore flawed for the purposes of the ASC payment system. The ASC payment system is also among the last to continue to be tied to the CPI-U, along with the fee schedules for ambulances, clinical labs, and durable medical equipment.

The HMB, on the other hand, is an available proxy for ASC costs and is superior to the use of the CPI-U. The HMB includes data reflecting the cost of items and services necessary to furnish outpatient surgical procedures, so it is a more appropriate adjustment factor than the CPI-U. The HMB is also used to update the OPPS payment rates. Because the OPPS cost structure looks much like the cost structure of ASCs, if the HMB is appropriate for updating OPPS payment rates, then it is also appropriate for updating ASC payments. The HMB index is used for updating Medicare payments for hospice and inpatient hospitals, in addition to the hospital OPPS. We therefore urge CMS to finalize its proposal in adopting the HMB instead of the CPI-U to update ASC payment rates for inflation.

Since the OPPS update is based on the HMB, this would reduce some of the widening disparity between HOPD and ASC rates and create a more level playing field. We also urge CMS to use the same wage index values for hospitals and ASCs. This disparity creates a considerable financial incentive to perform these procedures in hospital settings, whereas for many patients, the ASC is the more appropriate setting to receive care. Higher reimbursement for HOPD procedures also increases aggregate costs for the Medicare program.

Updating the ASC Relative Payment Weights for CY 2019 and Future Years

The AMA recommends that CMS stop its practice of rescaling the ASC relative weights to achieve a perceived budget neutrality objective. ASC services should apply the OPPS relative weights. CMS should adopt a consistent payment methodology to level the playing field across all sites-of-service. The weight-scalar site-of-service differential impedes the provision of high-value care because it incentivizes

payment based on the location where a service is provided. No evidence has demonstrated any growing differences in capital and operating costs in HOPDs compared to ASCs to support this growing payment differential: from 2.5 percent in 2009 to a proposed 11.5 percent in 2019. Thus, ASC services should apply the OPPS relative weights to promote outpatient services that are site-neutral without lowering total Medicare payments.

Notably, CMS already has the authority to apply the OPPS relative weights to ASC services. CMS previously implemented the scalar pursuant to its own authority and, importantly, this implementation was not pursuant to any identified statutory requirement. Thus, CMS has the similar, discretionary authority to discontinue the scalar and align payment methodologies across these sites of service.

Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

AMA supports the CMS proposal to revise its definition of surgery for 2019 to account for "surgery-like" procedures that are assigned codes outside the AMA Current Procedural Terminology (CPT) surgical range (10000-69999). As indicated in the proposed rule, AMA's CPT code manual states that listing of a procedure in a specific section of the book should not be interpreted as strictly classifying the procedure as "surgery" or "non-surgery" for insurance purposes.[11] The AMA also believes that CMS should expand its definition of "surgery" to include procedures that fall outside the CPT surgical range but fall within the definition of "surgery" developed by the AMA/Specialty Society Relative Value Scale Update Committee for use in the agency's PFS professional liability insurance relative values and that meet the ASC setting criteria.

AMA agrees with the CMS proposal to add the 12 cardiac catheterization procedures (CPT codes 93451-93462) to the list of covered surgical procedures that could meet the standards to be safely performed in an ASC setting. **AMA also strongly requests that CMS include all the invasive cardiology services (CPT codes 92920-93657) on the list of ASC codes.** CMS already covers these codes in their published list under the Physician Payment Schedule file. Furthermore, by not including all the invasive cardiology services, CMS may not see the desired migration of these services into ASCs.

Proposal to Review Recently Added Procedures to the ASC Covered Procedures List

The AMA supports the efforts of CMS to assess and evaluate the safety of codes being performed regardless of the site of service. AMA is concerned, however, and seeks clarification regarding the structure of the systematic review of recently added procedures in the future.

CMS states that "all available data," "prevailing medical practice," and public comments will be used to determine if CMS will continue to include the procedure. However, CMS is silent as to what findings would prompt CMS to remove a code from the Covered Procedure Lists (CPL). Moreover, CMS should clarify whether reviewing and removal of codes occurs within the same payment rule cycle. Additionally, reviewing recently approved codes (e.g., codes added 2017) is a waste of valuable CMS resources because there will be little data or research after only one year. Instead, CMS should review recently added procedures one year at a time and when sufficient data and research exists to make a reliable and valid evaluation (i.e., five years). The evaluation should also be completed by an advisory panel like the

[11] 83 Fed. Reg. 37046, 37152 (July 31, 2018).

Advisory Panel on Hospital Outpatient Payments. **Therefore, the AMA recommends that CMS provide information as to when CMS would remove a code from the CPL, clarify whether reviewing and removal of codes occurs in the same payment rule cycle, and create a review process that examines procedures one year at a time when sufficient data and research exist.**

Regarding the 38 procedures that CMS is reviewing, **the AMA believes that all 38 should remain on the CPL**. This would ensure patient access to services in the most clinically appropriate setting, depending on their needs, and the severity of their conditions as determined by a physician.

Proposed Device-Intensive Procedures

The AMA recommends that CMS finalize its proposals in designating device-intensive procedures. We agree with CMS that (1) allowing single use devices regardless of whether the device remains in the patient's body and (2) lowering the threshold to 30 percent of the procedure's mean cost will better capture costs for procedures with significant device costs. We also agree with applying a 31-percent default device offset to new codes describing procedures requiring the implantation of a medical device that does not yet have associated claims data. These policy changes will help achieve costs savings and save beneficiaries money.

The AMA also recommends that **CMS should only adjust the non-device portion of the payment by the wage index**. First, this adjustment would align with how separately payable drugs and biologics are treated. Second, devices cost the same to physicians regardless of whether purchased in an urban or rural community. Thus, CMS should maintain parity between urban and rural practices and only adjust the non-device portion of the payment.

ASC Quality Reporting Program

The AMA appreciates CMS' efforts to ease administrative and regulatory burden through CMS' Meaningful Measures Initiative. Specifically, we support the proposal to remove the following measures from the Ambulatory Surgery Center Quality Reporting Program (ASCQR); ASC-8, ASC-9, ASC-10 and ASC-11. We also thank CMS for recognizing that ASC-9, ASC-10 and ASC-11 are measures that were developed for physician-level use and not appropriate for a facility-based quality reporting program, which we have stated in previous comments.

The AMA recommends that CMS should not move forward with its proposal to remove 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/Admission. Although these events are rare, and there is little deviation in reporting amongst ASCs, we continue to believe the areas of measurement are important information to patients, physicians and facilities. We request that CMS reconsider the removal of these measures.

The AMA continues to support the delay in mandatory implementation of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) survey. While AMA recognizes the benefits of having ASC and HOPD patient experience data for the facilities and patients, additional time is needed to allow CMS to evaluate (1) the cost and administrative burden to facilities and patients and (2) the feasibility to implement in the ASC and HOPD setting given the case volumes and heterogeneity among facilities.

Proposed Additional Hospital Inpatient Quality Reporting (IQR) Program Policies—Proposed Updates to the HCAHPS Survey Measures

The AMA believes patient satisfaction surveys have a valuable place in evaluating health care; however, there are significant dangers in tying patient experience surveys to publicly reported ratings and accountability. In the 2018 IPPS final rule, CMS finalized the replacement of the HCAHPS survey measures pain management questions with new questions that address "Communication about Pain during Hospital Stay," beginning with the FY 2020 payment determination year. Starting with the FY 2024 payment determination and subsequent years, CMS proposes to remove the new questions from the HCAHPS survey. **The AMA strongly supports CMS' proposal to remove the new "Communication about Pain" survey measures. We also strongly urge CMS to immediately remove the measures from the program and from public reporting and not wait until the January 2022 patient discharges for the 2024 payment determination.** Measuring pain is subjective and a one-size-fits-all approach related to patient experience is inappropriate. It can also encourage the overprescribing of opioids. In light of the opioid epidemic, CMS should avoid fostering an environment that has the potential, even though unintentionally, to promote the use of opioids.

As CMS noted in the 2018 IPPS proposed rule, the Communication about Pain composite measure was reviewed by the Measures Application Partnership (MAP) in December 2016. The AMA submitted comments both to the MAP and CMS recommending they not adopt the measure, as we believe it may create similar unintended consequences as the original pain measures by creating patient expectations that hospital personnel should "always" discuss pain and its treatment with patients. This is precisely the type of approach to pain management that can encourage inappropriate prescribing and unrealistic expectations. The MAP recommended that this composite measure be refined and resubmitted prior to rulemaking. The MAP also recommended that the measure be sent to the National Quality Forum for review and endorsement. Instead, CMS continued to move ahead by finalizing the new pain measurement questions in the 2018 IPPS rule and now delaying removal until 2022 discharges.

In addition, the wording of the new pain management questions is problematic. Under the new pain management scoring, a patient must report that the hospital staff "always" talked to them about how much pain they had and "always" talked to them about how to treat their pain for the hospital to receive full credit for the measure. In practice, this will encourage hospital staff to "never" stop talking about pain and overemphasize pain when it may not even be an issue for the patient. Accordingly, the **AMA urges CMS to immediately remove the Communication about Pain composite measure from HCAHPS and from public reportin**g.

Furthermore, the concerns AMA has repeatedly expressed regarding the earlier pain management questions were not addressed in the new questions CMS has finalized. While we believe the removal of a reference to medication for pain management is an improvement, the new questions fail to explicitly address variations in pain treatment regimens due to physician preference, patient behavior, or health care facility practices. There are also clinical challenges in applying this approach to patient populations who are particularly vulnerable to inadequate pain assessment or management, including the elderly, pregnant women, individuals with English as a second language, and those with low socioeconomic status. We are still a long way from ending the country's opioid epidemic and implementing the National Pain Strategy. Therefore, resources would be better spent focusing on executing the National Pain Strategy than spending additional taxpayer dollars on revised HCAHPS pain questions.

In addition, the AMA frequently hears from physicians that their compensation is being tied to HCAHPS scores. Often, the only recourse these physicians have to push back is to cite old CMS regulations stating that it is inappropriate to utilize a facility-level survey to measure physician-level performance. **Therefore, we recommend that CMS issue new guidance stating that it is inappropriate to tie physician compensation to HCAHPS, a facility-level survey.**

Improving Access to Non-Opioid Pain Management

The AMA supports the CMS proposal to improve patient access to non-opioid treatments for pain management by separating their payment out from other services in the ASC setting. A recent JAMA paper that examined coverage of non-opioid pharmaceuticals found that insurance plans' coverage and payment policies frequently pose barriers to accessing non-opioid pharmaceuticals for the management of lower-back pain. In addition to problems accessing non-opioid pharmaceuticals, patients often face barriers to accessing other types of non-opioid therapies for pain. As we continue to work to end the epidemic of opioid overdose deaths, increasing access to non-opioid therapies could have a profound impact. The AMA appreciates the in-depth analysis conducted by CMS to inform its new policy, particularly the different approach to payment for post-surgical pain supplies in the ASC as compared to the hospital outpatient department based on an analysis of the claims experience in the different sites of service.

In comments on the 2019 Physician Fee Schedule proposed rule, the AMA also addressed the need to improve patient access to non-opioid therapies for pain. In addition to the ASC policy change proposed in this rule, **we encourage CMS to prohibit any of the prior authorization and similar so-called utilization management strategies that are often employed by Part D prescription drug and Medicare Advantage plans to reduce utilization of non-opioid pharmaceuticals and other pain management modalities.** Interviews conducted as part of the JAMA study referenced above reinforced that insurers have largely focused on efforts to constrain opioids rather than to promote comprehensive strategies to improve pain treatment. The report concluded: "Requiring patients and health care professionals to navigate burdensome and diverse utilization management policies for opioid alternatives likely results in slower adoption and implementation of these treatments."[12]

These findings were underscored by a recent survey by the American Board of Pain Medicine finding that "93 percent of pain medicine specialists report that they have been required to submit a prior authorization for non-opioid pain care," causing nearly 70 percent of those specialists to hire additional staff. Prior authorization was for a wide variety of non-opioid pain care, including:

- Physical therapy limits, psychiatric services, and occupational therapy.
- Pain creams and patches (e.g., lidocaine, Lidoderm, Voltaren, topical NSAIDs).
- Non-opioid prescription medications (e.g., Cymbalta, Lyrica, Celebrex).

[12] D.H. Lin et al., *Prescription Drug Coverage for Treatment of Low Back Pain Among US Medicaid, Medicare Advantage, and Commercial Insurers*, JAMA Network Open, 2018;1(2):e180235, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2685625?resultClick=3.

- Non-opioid pain treatments (e.g., TENS, facet blocks, spinal cord stimulators, epidural injections).[13]

Physical and occupational therapy limits are exacerbated by high co-pays or other challenges patients face in accessing such care, such as transportation to physical therapy appointments, and aggravated by many plans' limited networks of specialists—a problem that could be addressed in part through CMS policy. Regarding pain creams and patches and similar non-opioid treatments, the problems are two-fold. First, in addition to prior authorization, these treatments may not even be available on an insurance products' formulary. And second, if they are on the formulary, they may be placed on a high-cost specialty tier, thereby making the non-opioid option cost-prohibitive for many patients. The AMA seeks CMS support to remove these administrative burdens to non-opioid therapies for pain.

Requests for Information

Request for Information on Promoting Interoperability and Electronic Health Care Information

CMS requests comments on how it could use the CMS health and safety standards required for providers and suppliers participating in Medicare and Medicaid (i.e., Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities) to "further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers."

CMS notes that it might consider revisions to CoPs for hospitals such as: "requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested."

In general, **we do not believe that a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information is necessary in the context of other current and forthcoming policies.** We are concerned that compliance fears and costs associated with new standards could hinder investments and actions to enhance interoperable data exchange. Furthermore, health care stakeholders have not had sufficient time to evaluate the impact of forthcoming regulations and enforcement around information blocking, the impact of the PI program, and the operations of Trusted Exchange Framework and Common Agreement and U.S. Core Data for Interoperability—each of which will affect interoperability going forward.

The AMA strongly suggests CMS examine fundamental issues that continue to hinder interoperability and identify the appropriate methods to address these issues. The AMA urges CMS to further leverage appropriate regulation that advances outcomes and goals including establishing a focused interoperability strategy with the goal of clinical necessity rather than exchanging data simply for reporting requirements. Moreover, the AMA recommends that CMS establish a plan with proper

[13] American Board of Pain Medicine, *Survey of Pain Medicine Specialists Highlights Plight of Patients with Pain, And Barriers To Providing Multidisciplinary, Non-Opioid Care*, (2018), http://abpm.org/uploads/files/abpm percent20survey percent20results.pdf.

stakeholder feedback to focus interoperability efforts on promoting data consistency and access. These concepts are further explored in our response to the 2019 Physician Fee Schedule and Quality Payment Program proposed rule.[14]

Request for Information on Price Transparency

The AMA appreciates the opportunity to provide feedback to CMS in response to its request for information regarding price transparency to empower patients, improve the quality of care and lower health care costs. The lack of complete, accurate, and timely information about the cost of health care services prevents health care markets from operating efficiently. As the health care market evolves, patients are increasingly becoming active consumers of health care services. Achieving meaningful price transparency can help lower health care costs and empower patients to make informed care decisions. Specifically, the AMA believes that patients should be able to compare procedures costs across sites of service including between physician offices, HOPDs, and ASCs. The AMA supports efforts to ensure price transparency, but recognizes that providing meaningful price and cost information to patients in the current environment is challenging.

While the AMA strongly supports physicians playing an active role in assisting patients in acquiring cost information, we are concerned about discussions regarding new requirements for physicians to provide this information. Physicians are currently ill-equipped to readily provide this information to insured patients without a significant added administrative burden on their practice. For physicians to incorporate discussions with patients regarding health care cost information in to treatment planning, patient benefit and formulary information needs to be available at the point-of-care. Ideally, this information would be made available by payors for easy access through a patient's EHR. However, currently, the only way for a practice to assist a patient in finding this information would be for practice staff to contact a patient's health plan directly to inquire about a patient's share of costs for a particular service or procedure. As one can imagine, if physicians were required to do this for every patient for every visit, it would add an overwhelming administrative burden to physician practices. A requirement for physicians to engage in an activity this burdensome would be unreasonable given the current capabilities to access this type of information.

CMS should also note that providing accurate information regarding the costs, out-of-pocket or otherwise, is extremely difficult before patients are furnished the needed services. Anticipating the need for health care services is often difficult. It is not uncommon for a service or procedure to encounter secondary conditions or otherwise unanticipated complications that would be impossible for a physician practice to foresee at the time cost information would be provided. The intensity and scope of service required often leave patients without time or ability to evaluate their options prior to receiving care. For these reasons, providers and suppliers should not be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service. Instead, the cost information provided to patients would be an estimate of charge information to help patients better understand what their potential financial liability might be for services they obtain and to enable patients to compare charges for similar services.

[14] The discussion on promoting interoperability starts on page 104.

Request for Information on Leveraging the Authority for the Competitive Acquisition Program for Part B Drugs

As a tool to give buyers a stronger hand in negotiations with drug manufacturers, President Trump's Drug Blueprint proposed to revive the short-lived Competitive Acquisition Program (CAP) established under the Medicare Modernization Act of 2003 and opened for participation from mid-2006 through 2008. **The AMA believes that a Center for Medicare & Medicaid Innovation (CMMI) demonstration to test different CAP models would be a good first step as long as physician participation in the CAP is entirely voluntary.**

Ideally, a well-designed CAP might offer an attractive alternative for small and mi.d-sized practices that do not have the resources or volume to acquire drugs at prices that are at or below Medicare payment rates. Currently, such practices are being forced to move care from their offices to hospital outpatient departments, where both Medicare and its beneficiaries pay more. Keeping these practices viable could reverse a trend that has contributed to rising Medicare expenditures but significant changes to the original CAP will be needed to avoid a repeat of the earlier failure.

Reportedly, few physician practices participated in the original CAP because it significantly increased inventory costs, made it difficult to provide patients with same day dosage or regimen changes, and added significant burden to the billing and collection process. The Medicare Payment Advisory Commission (MedPAC) proposed to eliminate much of this additional burden by creating a CAP in which the vendor would negotiate prices with drug manufacturers but physicians would order drugs in bulk directly from the manufacturer without the need to provide orders for individual patients. The proposal also would impose a number of burdensome new utilization restraints on physician participants with the goal of extracting large price reductions from manufacturers and then sharing any savings with other parties, including patients and physicians. The plan does not detail how and when savings would be shared with physicians but it appears that the government and the vendor would get a cut off the top with remaining savings distributed either at the will of the vendor or based on some calculation of a physician's contribution to savings.

The AMA believes there is merit in MedPAC's proposal to eliminate the vendor from the ordering and distribution process. However, we question the assumption that physicians will be drawn to participate in a Pharmacy Benefit Manager (PBM) look-alike that imposes a variety of costly and administratively burdensome utilization restraints—including prior authorization and step therapy—that are vigorously opposed in the physician community and would undoubtedly discourage physician participation in the CAP, especially in view of the ephemeral nature of MedPAC's shared savings provisions.

We are pleased that CMMI appears to be considering a variety of options and looking for detailed input from stakeholders. Our comments in this rule will address some of the general issues raised, but **we believe that the best way to answer many of the questions is through a listening session or by meetings** with individual physician specialties or medical groups that have an interest in creating a CAP and could identify specific drugs, geographic locations, and potential vendors.

Voluntary Participation: **CAP participation must be truly voluntary**—aimed at making it possible for physicians to continue providing all or most of the drugs that they normally would have before agreeing to participate in a CAP. There should be an opportunity to opt-out after an initial try-out period or when a vendor's performance is unsatisfactory. As a positive incentive for physician participation, CAP vendors

should be encouraged to include a comprehensive list of drugs, especially those which physicians typically cannot purchase at prices that are lower than Medicare's reimbursement for the drug. As an alternative, however, CMMI could start with smaller specialty-specific CAPs with a more limited drug formulary.

Patient Protections: A major deterrent to CAP participation for many physicians is the fear that timely access to the most appropriate drugs for their patients will suffer. As mentioned above, physicians are likely to avoid CAP models that are accompanied by all the utilization controls employed by the Medicare Advantage plans and PBMs. Step therapy and prior authorization have negative consequences for patients and are not likely to attract physician participants. In selecting vendors, CMS should give priority to those who can deliver a comprehensive list of drugs that will provide physicians with choices among different drugs that can be used to treat a particular condition. **Timely vendor adoption of newly approved drugs should be required or incentivized. Mid-year substitutions and eliminations from the vendor's formulary should be prohibited.**

Regardless of how drug copayments are collected, there also should be specific steps in place to assist Medicare beneficiaries who do not have supplemental insurance or sufficient resources to cover the co-payments. No one should be denied drug treatment because they cannot afford the co-payment. But what happens when the patient cannot afford the co-payment. Today, physicians generally absorb the loss but under the CAP, there will be no ASP add-on to help offset these losses. Will CMMI provide waiver of co-payments for these patients? Will vendors be required to absorb losses on certain co-payments? Or will vendors be expected to immediately stop delivery of this patient's drugs to the physician?

Operational Issues: There are a variety of operational issues which will also have a significant impact on patients, such as maintaining integrity of the medication throughout the chain of custody and ensuring that appropriate drugs are available on a timely basis (including emergencies) for all patients (including those at satellite clinics). Chain of custody issues would be largely avoided in the MedPAC model where the vendor never takes possession of the drugs, but other models would need to include protections to ensure medication integrity. These protections include:

- Vendors not being allowed to hold up shipments of the second or third round of a drug until claims for the initial treatment have been filed and approved.
- Vendors not being allowed to delay delivery of the ordered drug until after a claim has been filed and approved.
- Given the wide range of circumstances in which a physician will have immediate need for a drug that had not been ordered, CMS should work with the medical profession to develop a list of situations in which the physician is automatically entitled to provide a drug in their private stock and then order a replacement from the vendor. The option should not be limited to life-threatening situations but should also take patient circumstances into consideration such as proximity to treatment and needed pain relief.
- All treatment options must be available for patients participating in the program, including drugs that are being used off-label and drugs for which other alternatives exist. Determination of the appropriate treatment must rest with the physician, not the vendor.
- Vendors must be able to provide next day delivery to any location where the patient is being treated and physicians not be prohibited from transporting drugs to a satellite location.
- Policies in place for how vendors are expected to handle drug shortages.

Physicians' Costs: Physicians who administer Part B drugs face significant expenses beyond the purchase price of the drug. Some, but not all, of the costs associated with acquiring, storing, and administering the drug are covered through the practice expense component. But physicians typically rely on the ASP add-on to cover a portion of the additional costs. Under MedPAC's plan, the physician might eventually receive shared savings payments to help compensate for the loss of the ASP but there could be a lengthy wait before the shared savings were available. Under other models, it does not appear that there would be any reimbursement for these expenses. It is unrealistic to expect physicians to sign up for a CAP without opportunities to offset the costs that are now offset by the ASP. Thus, CMMI should consider how to offset these costs.

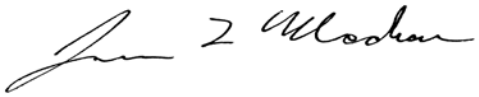
Program Integrity: Any potential model will most likely include a participation agreement. If this potential model resembles other models' participations agreements, CMS will have all the tools and strategies needed to minimize fraud waste and abuse.

The participation agreements already have many program integrity safeguards, including transparency of data and monitoring for indicators of abuse or gaming. For example, Participation Agreements generally require participant screening by CMS for program integrity issues prior to and during program participation; certification of completeness, truthfulness, and accuracy of virtually all data generated and submitted to CMS; patient protections including notice and freedom of choice; a compliance program with reporting of any probable violation of fraud; and enhanced CMS monitoring through identification of all participants, site visits, and multi-year maintenance of record provisions. Thus, internal controls are already layered on top of every model and provide greater assurance of program compliance and monitoring capabilities than providers operating outside of the models.

Conclusion

The AMA appreciates the opportunity to provide our comments and thanks CMS for considering our views. If you should have any questions regarding this letter, please feel free to contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD