

September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the *CY 2020 Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals (CMS-1717-P) (RIN 0938–AT74)*.

The following is a summary of our key comments and our detailed comments follow:

- CMS should re-consider the appropriateness and usefulness of several proposals to update the Hospital Outpatient Quality Reporting Program. CMS should only utilize quality measures that have been validated for use in the outpatient setting and should convene a Technical Expert Panel to identify appropriate measures to publicly report. We also caution CMS with moving forward with expanding the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey as patient experience surveys often depends more on patient perceptions than on evidence-based medicine.
- The AMA generally supports site neutral payments, but it is not possible to sustain a high-quality health care system if site neutrality is implemented by reducing all payments to the lowest amount paid in any setting. CMS should reinvest the estimated \$810 million a year in savings from outpatient care to other Part B services, including payments under the physician fee schedule. Furthermore, the current Outpatient Prospective Payment System (OPPS) payment policies and proposed changes are not site neutral because the policies do not apply equally to all hospital outpatient clinics.
- While the AMA understands there may be a role for prior authorization in health care, including fee-for-service Medicare, we believe it must be right-sized and used judiciously. The AMA appreciates CMS' effort to target the proposal on services that are most often considered cosmetic and to incorporate some of the prior authorization consensus principles developed by national provider associations and insurer trade organizations in 2018 (described further below). We include in our comments suggestions for how CMS can strengthen its proposal to ensure that the

prior authorization requirements do not take time away from patient care, delay treatment, or negatively impact patient health outcomes.

- CMS should not modify the existing clinical laboratory date of service (DOS) policy as the proposed changes will significantly delay and restrict patient access to medically necessary clinical testing and are not consistent with the original DOS policy to ensure accurate reporting and payment and improved patient access.
- CMS has the authority to base reimbursement rates on the hospitals' acquisition costs for certain separately payable drugs and biologicals that are acquired through the 340B Program if CMS considers hospital acquisition cost survey data. We urge CMS to collect such data. We have continued concerns that CMS' proposal to pay and adjust payment for 340B covered products to average sale price (ASP) minus 22.5 percent may curtail patient access. Furthermore, it does not address the fundamental issue of lack of adequate payment to community-based providers for physician administered drugs and biologicals.

Hospital Outpatient Quality Reporting (OQR) Program

CMS seeks comment on the potential future adoption of four patient safety measures that were previously adopted for the Ambulatory Surgery Center Quality Reporting (ASCQR) program: ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/ Admission. Prior to proposing and finalizing the safety measures for use in the Outpatient Quality Reporting (OQR) Program CMS must test the measures and allow comment to determine whether they are valid and reliable to apply in the outpatient setting. Testing must include transparent evaluation of the necessary sample size to achieve high reliability. CMS cannot assume that measures developed for the ASC setting are appropriate to apply to the outpatient setting.

Request for Information (RFI): Quality Measurement Relating to Price Transparency for Improving Beneficiary Access to Provider and Supplier Charge Information

As part of CMS' efforts to enhance future efforts to improve transparency in health care charges, CMS seeks feedback on quality information that should be publicly displayed. The AMA believes that any information related to cost should be displayed in conjunction with quality information to ensure providers continue to provide quality care and it does not lead to stinting on care. In addition, we urge CMS to develop better safeguards against beneficiaries assuming that low cost is poor quality. However, CMS cannot assume the quality information displayed in settings outside of the outpatient facility, such as the quality measures individual physicians and groups report for the Merit-based Incentive Program System (MIPS) is appropriate for a public website related to outpatient services. Most physicians do not practice in the facility setting or report facility related measures so the information that they report to CMS for MIPS is inappropriate to display alongside outpatient facility information. It is more appropriate to direct patients to individual physician information on quality through Physician Compare.

To determine and prioritize the most appropriate measures to publicly report on outpatient care, we recommend CMS convene a Technical Expert Panel (TEP). There is existing precedent to utilize a TEP to shape next steps on public facing websites on quality as CMS regularly convenes TEPs for the Hospital and Physician Compare websites. We also urge CMS to take a methodical and iterative approach to publicly posting any information, including quality measures. At a minimum, we encourage CMS to follow the standards CMS has set for publicly reporting information on Physician Compare. All quality

information publicly posted must meet high reliability standards, be deemed valid and resonate with consumers.

We also caution CMS with moving forward with expanding the Consumer Assessment of Healthcare Providers and Systems (CAHPS) communication questions. CAHPS is a patient experience survey and often depends more on patient perceptions than on evidence-based medicine. Any new questions added to CAHPS must be tested to ensure they do not lead to over emphasizing certain patient experience domains and lead to diverting efforts and resources away from quality improvement. CAHPS is also already a lengthy survey and administered in various provider settings so we are concerned that expansion will lead to further survey fatigue. There is also a need for CMS to begin to look outside of the CAHPS survey to measure patient experience. We believe CAHPS survey administration protocols are outdated and there is a need to allow for measures that use multiple modes of data collection. For instance, allowing facilities to collect the information at the facility through a tablet or smartphone app, and other mechanisms leveraging user-centered design principles.

Furthermore, recognizing the potential burden of collecting the various types of measures (experience, satisfaction, outcomes, etc.) and patient interest in experience, we encourage CMS to conduct user testing to understand whether patients would prioritize experience over satisfaction or over measures that really evaluate outcomes to narrow what we are measuring, better focus quality improvement efforts and reduce burden and cost. Otherwise, CMS is potentially designing an unsustainable transparency program given facilities and physicians will be required to manage various tools and surveys and at the same time be expected to act on all the measures.

Increasing Choices and Encouraging Site Neutrality

Method to Control for Unnecessary Increases in Utilization of Outpatient Services

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. CMS proposes to continue phasing in a proposal that would reduce payment rates for some services in some hospital outpatient departments to bring them 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:

1. Supports increasing payment parity without lowering total Medicare payments but continues to believe that the current OPSS 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.
2. 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 20 percent since 2001—and that any savings from site neutrality proposals derived from OPSS should be reinvested in improvements elsewhere in Part B, including payments to physicians as inflation is not a factor in annual physician payment updates and this contributes to the payment differential.

3. Urges CMS to reinvest the estimated \$810 million a year in savings by lowering facility payments for affected services and sites to other Part B services, including payments under the physician fee schedule.

While we understand this policy may change due to a recent federal court decision vacating initial implementation of this policy in last year's final rule due to lack of adherence to budget neutrality in OPSS, we continue to underscore our position that CMS should not implement site neutrality in a way that reduces payment to the lowest common denominator and should reinvest savings from lowering facility payments to other Part B services, including payments under the physician fee schedule.

CMS estimates approximately \$810 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.

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 OPSS and PFS payment rates is an indication of inadequate rates paid to physician offices as physician payments are not inflation adjusted and should not be attributed entirely to OPSS overpayments. Rather than removing an estimated \$810 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 OPSS savings to the practice expense portion of the PFS to offset the costs of administrative burdens such as electronic health records (EHR) and quality reporting.

Under the OPSS 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 this policy as driving the site-of-service decision and, as a result, unnecessarily increasing the service volume in HOPDs. Another 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. Payment differentials between HOPDs and independent physician practices stem in part from inadequate Medicare physician payment rates. Notably, Medicare physician pay has barely budged over the last decade and a half, increasing just seven percent from 2001 to 2019, or just 0.4 percent per year on average. Adjusted for

inflation, Medicare physician pay has declined 20 percent from 2001 to 2019, or by 1.3 percent per year on average. In comparison, Medicare hospital pay has increased roughly 50 percent between 2001 and 2019, with average annual increases of 2.5 percent per year for inpatient services, and 2.4 percent per year for outpatient services. Notably, the cost of running a medical practice has increased 34 percent between 2001 and 2019, or 1.6 percent per year.

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.¹ 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.² 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 work.³ In a 2018 AMA survey, physicians reported that on average they complete 31 prior authorization requests a week and spend 14.9 hours per week in the process.⁴

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 \$810 million a year from outpatient care to other Part B services, including payments under the physician fee schedule.

Additional Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems

Procedures Proposed for Removal from the Inpatient Only (IPO) List

The AMA supports CMS' proposal to remove total hip arthroplasty (THA) (CPT code 27130) from the IPO list. Given thorough preoperative screening by medical teams with significant experience and expertise involving hip replacement procedures, the THA procedure could be available on an outpatient basis. The AMA believes that the benefits of providing the THA procedure on an outpatient basis would lead to significant enhancements in patient well-being, improved efficiency, and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

¹ 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>

² 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>.

³ 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-timeambulatory-practice-time-motion-study-4-specialties>

⁴ American Medical Association, 2018 AMA Prior Authorization Physician Survey, (2019), <https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf>

Short Inpatient Hospital Stays

The AMA supports CMS' proposal that procedures that have been removed from the IPO list would not be eligible for referral to Recovery Audit Contractors for noncompliance with the two-midnight rule within the first calendar year of their removal from the IPO list. We appreciate CMS' efforts to facilitate compliance with their payment policy for inpatient admissions and to provide an educational period for providers regarding compliance with the two-midnight rule.

Overall, the "two-midnight" rule has had significant unintended negative consequences that burden Medicare beneficiaries. It remains an artificial construct reflecting a flawed approach that gets in the way of the patient-physician relationship and unnecessarily increases the administrative burden of admitting physicians. The Medicare Payment Advisory Commission voted unanimously on a recommendation to withdraw the "two-midnight" rule as it detracts from admission criteria that depend upon clinical judgment. Accordingly, the AMA recommends that CMS should rescind the "two-midnight" rule by terminating observation status in total and instead rely on physicians' clinical judgment to determine a patient's inpatient/outpatient status.

ASC Covered Procedures List

The AMA supports CMS' proposal to add total knee arthroplasty (TKA) procedure, a mosaicplasty procedure, and six coronary intervention procedures to the ASC list of covered surgical procedures. Many ASCs are equipped to perform these procedures and orthopedic surgeons in ASCs are increasingly performing these procedures safely and effectively on non-Medicare patients and appropriate Medicare patients.

CMS also solicits comments on the appropriate approach to provide safeguards for Medicare beneficiaries who should not receive the TKA procedure in an ASC setting. The AMA does not believe CMS should establish a new modifier or require more documentation with a plan of care. Establishing a modifier or requiring other information sets a bad precedent and increases administrative burden. CMS should defer to physicians when exercising their clinical judgment when making site-of-service determinations and already documenting medical necessity.

Device Pass-Through Eligibility and the Substantial Clinical Improvement Criterion

CMS is proposing an alternative approach to qualify for device pass-through status beginning with applications received on or after January 1, 2020, by proposing that *in lieu* of providing evidence of substantial clinical improvement, devices approved under the Food and Drug Administration (FDA) Breakthrough Devices Program would be deemed as having met a comparable standard. This is similar to a proposal made in the Inpatient Prospective Payment System (IPPS) proposed rule, where CMS also solicited comment on how to revise the definition of the "substantial clinical improvement" criterion for the device pass-through payment. The AMA strongly supports CMS policies that establish a clear and predictable pathway to payment for innovative technologies with clinical benefit. Furthermore, CMS should adopt policy changes that advance the quadruple aim. Developers and manufacturers should be incentivized to pursue technological advances that demonstrably improve patient health outcomes, lower costs, result in better population health, and improve the experience of physicians and the extended health care team. The foregoing should underpin the assessments of all new technologies. While the AMA supports increasing flexibility that incentivizes the development of innovative technologies, removing the

clinical improvement criterion would not necessarily advance the quadruple aim. To the extent that CMS does not adopt expanded evidentiary requirements for establishing substantial clinical improvement, it might be appropriate to eliminate the substantial clinical improvement criterion for medical technologies that have received FDA Breakthrough Device Program status. However, in lieu of establishing an alternate pathway, the AMA strongly urges CMS instead to expand the type of evidence the Agency will consider when assessing substantial clinical improvement to include, for instance, real world evidence. Furthermore, the AMA would not support waiving this requirement in the context of a 510(k) clearance, but it could be appropriate for a *de novo* authorization or pre-market approval if CMS has not modified the evidence utilized to establish that the substantial clinical improvement criterion has been met.

Prior Authorization

The AMA understands there may be a role for prior authorization in health care, including fee-for-service Medicare, but we believe it must be right-sized and used judiciously. CMS does provide some rationale for its prior authorization proposal, such as categorical increases in financial expense, utilization volume, and unique patients; however, we note a lack of data corresponding to each CPT code associated with the services CMS proposes to subject to prior authorization beyond an increase in utilization. For example, a 25 percent increase in utilization could be a change from 1,000 services to 1,250 services per year, which is insignificant. CMS also fails to supply information about the actual costs of such services, so stakeholders cannot evaluate whether reimbursement for those services in the outpatient department (OPD) context is greater than the costs of implementing the proposed prior authorization program. Regardless, cost-containment provisions that do not have proper medical justification can put patient outcomes in jeopardy. **Any prior authorization program applied to a service, device, or drug should be based on accurate and up-to-date clinical criteria and never cost alone.**

CMS proposes to initially add prior authorization to five categories of services that it suspects are inappropriately used for cosmetic purposes but provides no support for its suspicion other than the previously-mentioned utilization increase figures. We are concerned that the proposal creates a glidepath to more widespread use of prior authorization in Medicare through the creation of a new subpart I under part 419 that would codify prior authorization policies for OPD services. Accordingly, we urge CMS to provide more detailed justification in any future proposals for additional OPD services requiring prior authorization. Our principal concern 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. Likewise, 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 2018.⁵ As detailed in the survey summary, 65 percent of surveyed physicians reported waiting at least one business day for prior authorization decisions from health plans, while 26 percent reported waiting at least three business days. Unsurprisingly, 91 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 75 percent of physicians reported that prior authorization can lead to treatment abandonment, and 91 percent indicated that prior

⁵ 2018 AMA Prior Authorization Physician Survey, available at <https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf>.

authorization can have a negative impact on patient clinical outcomes. Most alarming, 28 percent of physicians report that prior authorization has led to a serious adverse event (e.g., hospitalization, disability, death) for a patient in their care. The proposed rule did not attempt to quantify the burden of adding prior authorization to OPD services on Medicare beneficiaries. We believe that these statistics capturing the potential patient harms associated with prior authorization suggest a significant patient burden associated with codifying a new Medicare utilization management program. Beyond the obvious negative impact in human terms, beneficiaries who deteriorate clinically due to prior authorization-related care delays would likely incur greater health care costs, meaning that this program could have the unintended consequence of raising overall Medicare expenditures.

The AMA's survey results also detail the existing administrative burdens associated with prior authorization. Practices report completing an average of 31 prior authorizations per physician per week, with this workload consuming 14.9 hours—nearly two business days—of physician and staff time. Moreover, over one-third (36 percent) of physicians employ staff who work exclusively on prior authorization. An overwhelming majority (86 percent) of physicians characterized prior authorization-related burdens as high or extremely high. Moreover, prior authorization hassles have been growing over time, with 88 percent of physicians reporting that prior authorization burdens have increased over the past five years. These data reflect the significant administrative costs associated with practices' current prior authorization workload. We are very concerned that the creation of a new subpart establishing a prior authorization program for OPD services could lead to substantial growth in these burdens that already challenge the limited resources of financially strapped smaller physician groups. Furthermore, the utilization management tools are unnecessary because physicians already have ample incentives to reduce unnecessary services under the Quality Payment Program.

Prior Authorization Principles

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, delays treatment, and—in the most extreme cases—can lead to permanent impairment or even death. The AMA is encouraged by the discussions we are having with senior CMS leadership regarding prior authorization, and we urge it to lead by adopting the following principles, developed in consensus with other national provider associations and insurer trade organizations in 2018 (Consensus Statement Principles), into all of its prior authorization policies:

1. Selective application of prior authorization to only “outliers”;
2. Review/adjustment of prior authorization lists to remove services/drugs that represent low-value prior authorization;
3. Transparency of prior authorization requirements and their clinical basis to patients and physicians;
4. Protections of patient continuity of care; and
5. Automation to improve prior authorization and process efficiency.⁶

⁶ AMA, Consensus Statement on Improving the Prior Authorization Process (2018), available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

We applaud CMS for including some of these principles in its proposal. However, we encourage CMS to go further by adopting the recommendations below, which will help to reduce the harms and burdens of prior authorization and utilization management.

Selective Application of Prior Authorization

CMS proposes to exempt providers who achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. The AMA supports this selective application of prior authorization requirements to outliers and urges it to include it in regulation, not only in the preamble. We further recommend that CMS analyze claims data during the six-month period before the rule becomes effective to identify outlier practitioners from the beginning of the program. For example, claims for the identified surgeries and procedures should have associated diagnosis codes that establish medical necessity (e.g., migraines for botulinum toxin injections, a car accident for rhinoplasty, or circulation problems for vein ablation). CMS should target practitioners filing claims without concurrent diagnoses indicating medical necessity, thereby suggesting cosmetic use of these services.

Suspension of Prior Authorization Processes or Services

CMS proposes in §419.83(d) to permit suspension of prior authorization processes or services. We support this proposal and suggest that CMS suspend the need for affirmations for services (not just providers) exceeding a 90 percent approval rate. This would support the first and second Consensus Statement Principles above. We recommend that CMS not only issue notification about these prior authorization requirement changes but also include updates to practices through MLN Connects, CMS listservs, contractor communications, and other mechanisms.

Withdrawal of Exemption

CMS proposes that if a practitioner's rate of non-payable claims becomes higher than 10 percent during a biannual assessment, it will consider withdrawing the exemption, noting that the withdrawal may take approximately 90 calendar days to effectuate. Any claims submitted by the practitioner whose exemption is being withdrawn should not be subject to the prior authorization requirements until the practitioner has received sufficient notice of the exemption withdrawal. This is critical in light of CMS' proposal to deny any claim lacking affirmation prior to submission—a clinician may not know that his or her exemption has been withdrawn and would therefore not seek affirmation prior to performing the service and submitting a claim for payment. CMS should propose through regulation a process to notify practitioners that their exemption has been withdrawn.

Inappropriate Use of Prior Authorization as Fraud Deterrent

CMS has identified fraud deterrence as the primary reason for expanding prior authorization to OPD services. Specifically, the proposal seeks to identify “cosmetic surgical procedures that are not covered by Medicare but may be combined with or masquerading as therapeutic services.” Health plans traditionally use prior authorization to ensure that services are appropriate and medically necessary for a particular patient, not to identify and address fraudulent billing. CMS already devotes significant resources specifically to eliminating fraud, and it is unclear what additional value prior authorization will bring to CMS' fraud detection program. More importantly, it is unlikely that prior authorization will eliminate criminal activity in the Medicare program, as a fraudster masquerading a service as therapeutically

necessary in claims billing would be equally inclined and capable of doing so through the prior authorization process. Rather than serving as an effective fraud deterrent, it is far more likely that implementing prior authorization for OPD will create a barrier to timely patient care.

Premature Effective Date

CMS proposes to implement prior authorization for OPD services effective July 1, 2020. If CMS proceeds with implementing prior authorization for the services identified in the proposed rule, we urge reconsideration of the timeline for this program change to ensure sufficient time for physician and staff education and preparation on this new policy and its associated administrative processes. We have significant concerns that the proposed timeline does not support an adequate education and training period, which leaves physicians at major financial risk if they unknowingly provide one of the services newly requiring prior authorization without obtaining the needed authorization. Moreover, we note that it is not just the primary surgeon who will be at risk of nonpayment for unmet prior authorization requirements, as the proposed rule clearly indicates that claims for associated services (e.g., anesthesiology) will also be denied. Because this proposal represents a significant shift in Medicare requirements, we request that CMS delay the effective date to allow physicians and staff to become familiar with the new prior authorization requirements.

Understatement of Practice Expenses Associated with Prior Authorization

In its calculation of the average practice labor costs that would be incurred with these new prior authorization requirements, CMS used an average hourly rate of \$16.63 (loaded rate of \$33.26). This rate reflects the compensation for a clerical employee; however, we note that clinical staff, from nurses up to and including physicians, are often involved in completing the documentation required for prior authorizations. As these clinicians would be paid significantly higher hourly wages than the clerical staff rate used in CMS' calculations, we must stress that the actual increased labor costs associated with these additional prior authorization requirements would be much higher and exacerbate the existing problems with administrative waste in our health care system. In addition, we note that CMS only includes the time spent on completing and submitting a prior authorization response in calculating labor costs. One major and time-consuming burden associated with prior authorization is determining which services require authorization and the documentation requirements associated with a particular procedure code. Indeed, nearly seven in 10 physicians (69%) report that it is difficult to determine whether a prescription or medical service requires prior authorization.⁷ The AMA has also conducted physician focus groups where it was reported that physicians increasingly have to engage in peer-to-peer prior authorization communications with plans which also contribute to costs.

Overstatement of Technology's Role in Reducing Prior Authorization Burdens

In the proposed rule, CMS references current advancements in health information technology that can be leveraged to reduce the practice burdens associated with prior authorization. The AMA fully supports automation of the prior authorization process using standard electronic transactions, and we appreciate that CMS has invested heavily in the Da Vinci Project, which leverages technology to facilitate electronic

⁷ Because physicians and staff will be adjusting to these new prior authorization requirements, the time and labor costs associated with identifying these newly restricted services and the correct documentation to support a prior authorization request should not be overlooked.

exchange of clinical data by extracting information from physicians' EHRs. While the AMA believes these efforts hold promise to improve prior authorization transparency and efficiency, we note significant concerns about exclusive reliance on this technology to fully address prior authorization burdens:

- *Data privacy/security and usage:* Da Vinci processes will allow payers unprecedented access to EHRs. Protections are needed so that plans will not inappropriately access information, coerce physicians into using the technology, or interfere with medical decision making.
- *Clinical criteria variation and opacity:* The lack of uniformity and transparency in prior authorization clinical criteria between payers will hinder automation efforts.
- *Technology access and costs:* Da Vinci represents nascent technologies that have yet to be widely implemented. Moreover, the costs and timeframe for availability across EHR vendors are unclear. Certainly, we do not anticipate that Da Vinci prior authorization support tools will be routinely used across practice types by the July 1, 2020, effective date of the OPD service prior authorization requirements. We must also stress that Da Vinci offers no prior authorization relief for small practices in the near future. As acknowledged in the proposed rule, most practices impacted by these new prior authorization requirements are small businesses that will face major challenges in managing this additional workload. Moreover, small practices do not have the resources needed to invest in the newer technologies that could improve process efficiency.
- *Patient care delays:* A fully automated/electronic prior authorization process will not eliminate or prevent dangerous care delays, as manual review of medical documentation will still be required by CMS contractors following the electronic exchange of data.
- *Ease leading to increases:* We are concerned that overreliance on automation will set the stage for increased volume of prior authorization in the Medicare program because it will be "easier."

Review Timelines

We urge CMS to reconsider the processing time requirements outlined in the rule. If implemented as proposed, patients in need of non-urgent care would have to wait up to 10 business days for a prior authorization decision. This lengthy waiting period is unacceptable, especially given the fact that the requirement is defined in business days. Weekends and holidays could therefore extend care delays by more than 15 days, leaving the patient in limbo while waiting for medically necessary care. In addition, many practices may not schedule an OPD service until authorization is received, meaning that patient care will be even further delayed—with the associated increased risk of negative clinical outcomes. We recommend that CMS establish a 48-hour processing time for routine prior authorization requests.

We also disagree with the characterization of and processing time requirements regarding prior authorizations for emergency and urgent care. The proposed rule indicates that physicians can seek expedited prior authorization reviews "when a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function," and that such requests will be considered within two business days. First, we note that cases involving a patient's life being in jeopardy should be characterized as emergency care and therefore never require prior authorization. CMS should clearly state that emergency care is exempted from any prior authorization requirements. In cases in which the need for treatment would be characterized as urgent, we agree that expedited processing should be required. However, the proposed allowance of two business days is unacceptable for patients requiring urgent treatment, especially when the additional time added by weekends and holidays is considered. We urge CMS to set the deadline for responding to urgent authorization requests at 24 hours. Additionally, we object to the requirement that physicians must submit documentation establishing the need for expedited

processing of the request, as this will both further burden the practice and slow the processing time due to CMS or its contractor needing to make determinations related to both treatment urgency and medical necessity. A physician's judgment that a patient needs urgent treatment should be sufficient to trigger an expedited processing timeframe, and CMS should not impose additional burdensome documentation requirements in such cases.

No Appeal Rights

The AMA strongly opposes CMS' proposal that no appeal rights attach to a non-affirmation decision. While we understand that Medicare DMEPOS operates without these rights, the AMA is unaware of any other payer not having some form of appeal available of an adverse decision regarding prior authorization. Instead, CMS would require the physician to either (1) constantly re-submit the same request anew until the contractor accepts the claim, further delaying medically necessary care, or (2) provide the service without receiving affirmation.⁸ If CMS finalizes its proposal to not provide appeal rights to a non-affirmation decision, it must clearly state in the final rule that a lack of prior affirmation is not sufficient to deny an appeal of a negative Medicare coverage determination. In other words, if CMS (or a contracted claims adjudicator) denies payment for a service that the physician believes to have been medically necessary, the physician must be able to appeal the payment denial with assurance that the appeal will not be denied solely because of a non-affirmation decision. Rather, the appeal must consider whether the item or service was indeed medically necessary and reasonable.

Non-binding Affirmations

The proposal defines prior authorization as a process through which providers obtain a provisional affirmation of coverage. Provisional affirmation is described as "a preliminary finding that a future claim for the service would meet Medicare's coverage, coding, and payment rules." The rule goes on to state, "[E]ven when a provisional affirmation has been received, 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." This proposal is extremely troubling, as it explicitly leaves open the ability for Medicare to change its application of rules and reconsider the medical necessity of a service after it has been provided, which clearly creates financial risk for the practice. The "provisional affirmation" should be binding in the absence of fraud, and the physician should be able to rely on the authorization as a guarantee of future payment. If medical necessity determinations are required prior to treatment, CMS must accept those decisions as final and not allow the possibility for reconsideration later during billing. Physicians, and more importantly Medicare beneficiaries, should not be presented with the possibility that CMS will change its affirmation after going through the burdensome PA process. Contrary to CMS' statement in the rule, the addition of prior authorization requirements does nothing to protect a practice's cash flow, as an authorization does not ensure that CMS or its contractor will not later reverse a coverage decision and recoup payment.

⁸ The latter would result in a denial of payment for the service because the claim would not meet a condition of payment due to the lack of prior authorization. CMS proposes that this denial is the initial determination and where appeal rights attach. However, any appeal would ultimately be meaningless because, regardless of whether the service was medically necessary, the physician still would not meet a condition of payment—the lack of prior authorization. Accordingly, the AMA recommends that CMS consider the non-affirmation decision to be an initial determination.

Enforcement of Time Frame

The AMA recommends that CMS include a regulatory provision that allows for prior authorization approval when the contractor or CMS fail to meet regulatory defined time frames. Currently, as proposed, no recourse exists if CMS or a contractor fails to issue an affirmation within the timeframe of receipt of the prior authorization requests. Thus, CMS or a contractor could go beyond the proposed two or 10 business day deadline with no consequences. The pending request could be held indefinitely. Most state laws and regulations involving prior authorization provide for the recourse of payer noncompliance with a deadline to be that the service be deemed authorized. Accordingly, CMS should add a regulatory provision that when a contractor or CMS fails to comply with the deadlines specified in the regulation, it will result in any hospital outpatient department services subject to review to be automatically deemed authorized by the contractor or CMS.

Identification of Applicable Coverage, Coding, and Payment Rules

The AMA is concerned about the lack of clear identification of the applicable coverage, coding, and payment rules for the list of hospital outpatient department services requiring prior authorization. Individuals need to first understand the intricacies of CMS policies to even know where to find this information or to combine statements from multiple CMS manuals to attempt to find a potential answer for questions regarding payment and coverage. Unfortunately, no one set of rules exists that physicians can go to for clarity. Instead, physicians must navigate a patchwork of state and federal regulations and contractor-specific requirements that govern what information is necessary to support a service and who can perform elements of the service. Therefore, the AMA recommends that CMS or its contractors must make any prior authorization requirements and restrictions readily accessible on its website to beneficiaries, health care professionals, and the general public. This includes the written clinical criteria. Requirements must be described in detail but also in easily understandable language. We appreciate CMS' work to date on its documentation requirement look-up service and look forward to when it may be integrated into the provider's EHR so that he or she does not need to exit his or her workflow to use the tool.

Explanation of Denial

In proposed new §419.82(d) and in the preamble, CMS states that if the request does not meet the applicable Medicare coverage, coding, and payment rules, CMS or its contractor would issue a non-affirmation decision to the requesting provider. The AMA believes that this issuance of non-affirmation must include what *specific* coverage, coding, and payment rule were not met. Thus, physicians would know what the applicable additional relevant documentation would be for resubmission. While this requirement may seem intuitive or superfluous, the AMA is concerned that without this regulatory provision requirement, contractors will only provide the minimal amount of information required. We note that this would also support the third Consensus Statement Principle included above.

Physician-Determined Decisions

Health care providers want nothing more than to provide the most clinically appropriate care for each individual patient. Prior authorization programs must therefore have a clinically accurate foundation for provider adherence to be feasible. The referenced clinical information should be readily available to the prescribing/ordering provider and the public. However, the proposed regulations do not set forth any

requirements as to the qualifications of the personnel authorized to make adverse determinations. Thus, the proposal would allow anyone—including those without clinical knowledge or experience—to decide whether a service is medically reasonable and necessary. For example, with the proposed list of hospital outpatient department services, anyone could determine whether a procedure is cosmetic. Accordingly, the AMA recommends that the adverse decisions be made by a physician who: (1) possesses a current and valid non-restricted license to practice medicine; (2) is of the same specialty as the physician who typically manages the medical condition or disease or provides the health care services involved in the request; (3) has experience treating patients with the medical condition or disease for which the health care service is being requested; and (4) makes the adverse decision under the clinical direction of one of CMS' or the contractor's medical directors (who also possesses an active license).

Transparency into the Process

Data are critical to evaluating the effectiveness, potential impact and costs of prior authorization processes on patients, providers, health insurers and the system as a whole; however, limited data are currently made publicly available for research and analysis. CMS should provide the health care community with relevant data, which may be used to improve efficiency and timely access to clinically appropriate care. Therefore, CMS should make statistics regarding prior authorization approval and denial rates, as well as the number of practitioners exempted from prior authorization requirements, available on its website (or another publicly available website) in a readily accessible format. The statistics should include (but not be limited to) the following categories related to prior authorization requests: (1) health care provider type/specialty; (2) medication, diagnostic test or procedure; (3) indication; (4) total annual prior authorization requests, approvals and denials; (5) reasons for denial such as, but not limited to, medical necessity or incomplete prior authorization submission; and (6) denials overturned upon appeal. These data should inform efforts to refine and improve the prior authorization program such as additional provider exemptions or suspension of prior authorization process or services.

Payment Methodology for 340B Purchased Drugs

CMS is proposing to continue to pay an adjusted amount of the average sale price (ASP) minus 22.5 percent for certain separately payable drugs or biologicals that are acquired through the 340B Program. The Agency is also soliciting comments on alternative payment options. Since CMS has the authority to base reimbursement rates on the hospitals' acquisition costs (the 340B price) if the Agency considers hospital acquisition cost survey data, we urge CMS to collect such data. 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 drugs at the 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 which payment of ASP minus 22.5 percent for certain separately payable drugs or biologicals that are acquired through the 340B Program was presumably intended to achieve. However, the AMA urges caution when extending the ASP minus 22.5 percent for 340B drugs policy. It is very important to ensure that the minus 22.5 percent adjustment does

not reduce payments so much so that these 340B eligible providers, 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 minus 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.

Proposed Updates to ASC Payment Rates

Updating the ASC Conversion Factor

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.

The AMA continues to strongly support CMS replacing the CPI-U with the hospital market basket HMB as the annual update mechanism for ASC payments. 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.

Updating the ASC Relative Payment Weights for CY 2020 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. 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.

Potential Revisions to Laboratory Date of Service (DOS) Policy

The AMA opposes changes to the test results requirement and limiting the laboratory DOS exception to Advanced Diagnostic Laboratory Tests (ADLTs) as both would restrict access to precision diagnostic testing and timely treatment.

Changing the Test Results Requirement

The AMA urges CMS to not implement the proposed changes to the test results requirement as these would limit beneficiary access to medically necessary clinical tests and create additional administrative

burden and documentation costs and complexities. Under this proposed change, certain tests would be considered a hospital service and be excluded from the DOS policy. The hospital would then bill for the test through the “under arrangements” if the ordering physician determines that the test results are intended to guide treatment during a hospital outpatient encounter, including a future hospital outpatient encounter. This would change the current policy (under which the DOS is the date of test performance) to the date of specimen collection. This is administratively unworkable because it does not reflect current clinical practice. An ordering physician will often not have sufficient information to predict whether the results of a given test will be used in a subsequent outpatient encounter. An ordering physician typically utilizes a clinical test to determine the next clinical intervention. In addition the ordering physician who diagnoses the patient may not be the same physician who ultimately treats the patient based on the test results. The ability of the ordering physician to make a prediction as to whether the test results will guide treatment management will vary widely based on the type of physician, the type of test, the treatment options available to the patient, and other factors. The “totality of the circumstances” standard and the decisional factors listed in the proposed rule will not assist the physician in making a prediction in many of these circumstances because there will not be sufficient information to make a prediction in the first place. The broad range of clinical scenarios where this policy may have applicability dictates against a uniform or one-size-fits-all standard. CMS should not determine the applicability of the DOS policy exception based on the ordering physician’s determination of whether the results of a test are intended to guide the treatment provided during a hospital outpatient encounter.

Limiting the laboratory DOS exception to ADLTs

The AMA opposes removal of molecular pathology tests from the laboratory DOS exception and limiting it only to ADLTs. CMS justifies rescinding the DOS policy’s inclusion of molecular pathology tests on the grounds they are “not required by statute to be furnished by a single laboratory, so hospital laboratories and independent laboratories are not prevented from performing molecular pathology testing.” CMS asserts that many molecular pathology tests are becoming available by kits and thus can be performed by hospitals. This is not accurate. CMS implemented changes to the DOS policy in 2017 because independent laboratories were unable to bill for tests and hospitals were instead required to bill for them because these tests are not commonly performed by hospitals.

The use of sole source laboratories is not necessarily a leading or even contributing factor to delays in care, nor should only tests provided by these laboratories be afforded an exception. Hospitals do not often use a “single source laboratory” but rather just a few or perhaps a single major reference laboratory to which they are contracted to provide patients access to advanced esoteric testing at the lowest possible cost with fastest available turnaround time. Performing any number of test tests in house in either a hospital or regional lab is not always practical or cost effective due to lower test volumes, hence the referral to commercial reference labs or other regional labs or specialty-focused esoteric testing labs which can run more frequent set ups of tests in larger batches to reduce costs.

The Current Procedural Terminology (CPT) Panel code set includes nearly 800 Category I tests in the molecular pathology sections, and it is estimated by the College of America Pathology (CAP) that there are fewer than 80 FDA approved devices for testing nucleic acid. In CAP’s analysis after excluding platforms, instruments, software, and sole source tests, and redundant tests (i.e., for same analyte) there are no more than 15-20 unique kits available for molecular testing that might be used by a hospital laboratory.

The focus of any policy should be on the timely and accurate provision of results leading to prompt diagnosis and therapeutic intervention. Distinctions based on the existence and use of kits are irrelevant. In addition, even if a hospital has a molecular department and staff, not all molecular testing is performed on site due to cost and expertise limitations. A minority of hospitals have capabilities or expertise to perform certain testing in house. For many hospitals, a large percentage of molecular test orders are sent to other laboratories for interpretation regardless of whether the test is an ADLT, molecular pathology test, or provided by a single laboratory.

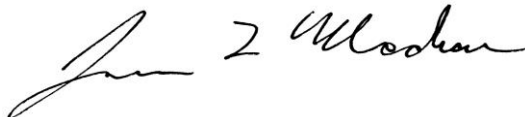
The DOS rule should encompass all molecular pathology testing. Molecular pathology testing is no longer an exception but is widely acknowledged as both medically beneficial and cost-effective for many patients. By their nature, ADLTs and molecular pathology testing are appropriately separable from the hospital stay that preceded the test and should have a DOS that is the date of performance rather than the date of collection. To continue to handle them otherwise could lead to delayed access to medically necessary care, regardless of whether the services are provided “under arrangements” or not. The AMA supports the DOS policy that allows laboratories to bill Medicare directly for certain laboratory tests excluded from the OPSS packaging policy.

Limiting the DOS policy to ADLTs would materially limit access. Many Medicare fee-for-service beneficiaries who need a sole-source molecular pathology test may face access constraints because these tests are not ADLTs. Limiting the DOS exception to ADLTs does not address the issues that potentially delay patients’ receipt of results of testing and create burdens for laboratories and hospitals and would in fact increase operational complexity without benefiting patient care. Molecular pathology testing ensures informed decisions about treatment based on a patient’s unique molecular profile. Molecular pathology testing now generates many actionable results and routinely guides therapy including influencing targeted therapy for some cancer treatments ordered consistent with accepted standards of care. Retaining the exclusion of molecular tests from the current DOS policy, therefore, furthers CMS’ goal of promoting personalized medicine. The AMA the urges CMS to retain the exception to the laboratory DOS policy that covers molecular pathology tests. Additionally, we again urge CMS to establish that the date of performance should be the date of final report.

Conclusion

We greatly appreciate this opportunity to share the views of the AMA regarding the proposals, issues, and questions which CMS has raised in this proposal. If you have any questions please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD