AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT

james.madara@ama-assn.org

September 13, 2022

The Honorable Chiquita Brooks-LaSure
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

Re: File Code CMS–1772–P. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure:

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 calendar year (CY) 2023 Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare Payment Policies under the Hospital Outpatient Prospective Payment System (OPPS), published in the *Federal Register* on July 26, 2022 (87 Fed. Reg. 44502).

The AMA continues to support the stated goals of CMS to reduce regulatory burden and increase flexibility for physicians and patients, especially during the SARS-CoV-2 or COVID-19 public health emergency (COVID-19 PHE). The AMA continues to put the concerns of our physicians, our medical students, and the patients they serve at the forefront of everything we do. We are particularly concerned that the impact of some proposals, combined with COVID-19, will continue to widen the gap for marginalized and minoritized communities. The AMA is committed to not only reducing health disparities, but to increasing health equity in the wake of the pandemic, the public health emergency, and beyond.

The following is a summary of our key comments followed by detailed comments:

- The AMA recommends that CMS stop its practice of rescaling the Medicare ambulatory surgical center (ASC) relative weights to achieve a perceived budget neutrality objective. Removing this secondary scaling adjustment is necessary to truly align the payment systems and enable ASCs to capture the value of the conversion factor.
- CMS should continue use of the hospital market basket as the annual update mechanism for ASC payments.
- The AMA strongly opposes removing the requirement that physicians supervise outpatient diagnostic services and requests CMS not enact this proposed provision. The AMA believes that

diagnostic testing should only be performed by those individuals who possess appropriate clinical education and training, under the supervision of licensed physicians (MD/DO).

- The AMA does not support the CMS proposal to add a category of service to the Hospital Outpatient Department Prior Authorization Program effective for services on or after March 1, 2023. The proposed rule did not attempt to quantify the physician and patient burden that will result from adding prior authorization to Hospital Outpatient Department (OPD) services on Medicare beneficiaries.
- The AMA generally supports the proposed payment for Rural Emergency Hospitals (REH), including the additional five percent payment to REH, and calls on CMS to similarly provide for added reimbursement for physicians who provide services to patients in the REHs. The AMA calls for CMS to closely monitor and to report through existing cost reporting on whether a sufficient share of revenue to the REH, which includes the monthly facility payment, is being directed to outpatient care.
- The AMA does *not* think that Current Procedure Terminology (CPT®) codes 0649T, 0722T, and 0724T should be considered "certain services" that are packaged under the regulation and recommends that CMS allow for separate payment of these important services without creating C-codes.
- The AMA commends CMS for seeking to understand the costs associated with innovative artificial intelligence (AI) technology. Identifying these costs is critically important in ensuring Medicare beneficiaries and clinicians can access these kinds of services. Although resource costs such as practice expense are accounted for differently in the OPPS payment system, it is important that the direct practice expense included in the CPT code is not only considered for payment when a service is provided in physician offices under the Medicare Physician Payment Schedule (MPFS) but is also considered as a resource cost when APC assignments are determined under the OPPS payment system.
- The AMA believes the U.S. Food and Drug Administration (FDA), not CMS, is best positioned to evaluate an AI product's potential for introducing inappropriate bias into clinical decision making, especially bias which could influence outcomes for minoritized groups, and that such evaluation should be incorporated into the requirements to be met by AI developers seeking authorization to market.
- The AMA strongly supports CMS' proposal to include as organ acquisition costs the costs for donor management when death is imminent.
- While the AMA generally supports the concept of allowing ASCs to tailor their quality measurement and improvement efforts to those procedures more frequently treated at the facility, we urge CMS not to consider implementing or adapting the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) for other quality programs since much work is still needed.

A. Proposed Updates Affecting OPPS Payments

Recommendations:

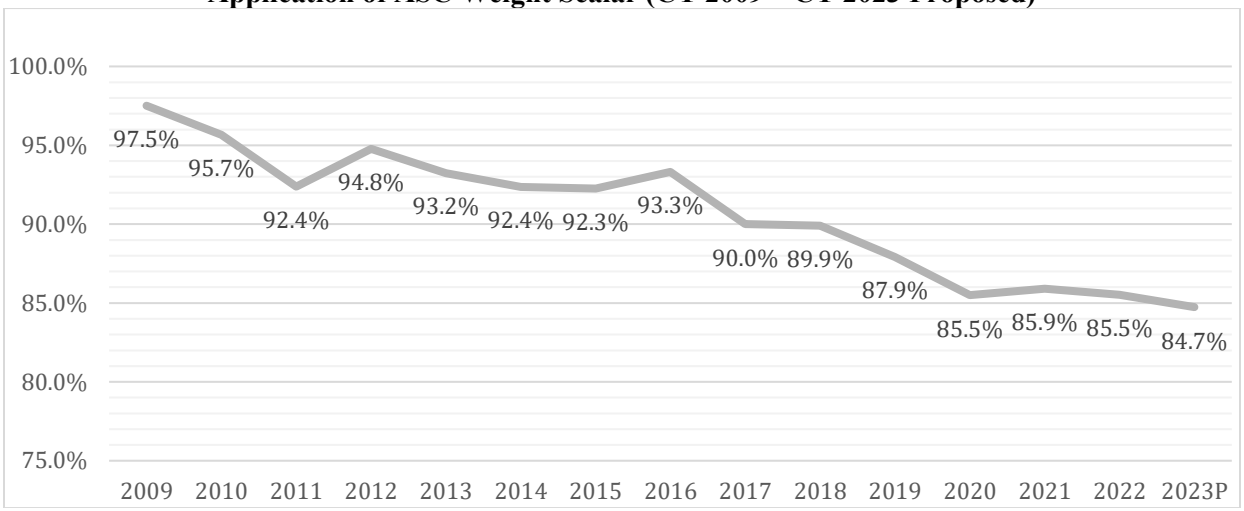
- The AMA recommends that CMS stop its practice of rescaling the ASC relative weights to achieve a perceived budget neutrality objective.
- The AMA continues to strongly support CMS replacing the CPI-U with the hospital market basket (HMB) as the annual update mechanism for ASC payments.
- The AMA generally 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 and looks forwarding to working with the Agency to strengthen the MPFS.

1. *Updating the ASC Relative Payment Weights for CY 2023 and Future Years*

The AMA urges CMS to discontinue its practice of rescaling the ASC relative weights to achieve a perceived budget neutrality objective. Since the payment systems were aligned, CMS has taken the relative weights in the OPPS, which have already been scaled, and then applies a secondary weight scalar, known as the ASC weight scalar, before arriving at the ASC payment weights. ASC services should apply the OPPS relative weights and CMS should adopt a consistent payment methodology to level the playing field between ASCs and hospital outpatient departments. CMS has asserted that the scaling of the relative weights is a design element that will protect ASCs from changes in the OPPS relative weights that could significantly decrease payments for certain procedures. However, as seen below, the trend in the OPPS relative weights suggests that the ASC weight scalar will rarely, if ever, result in an increase in ASC relative weights.

Application of ASC Weight Scalar (CY 2009 – CY 2023 Proposed)



In 2018, the ASC weight scalar fell under 0.9000 to 0.8995, for a 10.1 percent reduction to the ASC weights, and in 2023, CMS is proposing an adjustment of 0.8474 that, if finalized, would result in a devastating 15.26 percent reduction.

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 Hospital OPDs 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.

2. *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 Hospital OPDs and ASCs. **The AMA continues to strongly support CMS replacing the Consumer Price Index for All Urban Consumers (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.

3. *Proposal to Exempt Rural Sole Community Hospitals from Certain Site Neutrality Payment Policies*

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. We are not surprised by CMS' proposal to exempt rural Sole Community Hospitals from the site-specific MPFS-equivalent payment for clinic visits (HCPCS code G0463) when provided at an applicable off-campus provider-based department to ensure access to high quality care for beneficiaries in rural areas. We believe this is indicative of the importance of establishing payments based on the actual costs of providing care, rather than shrinking payments to the lowest common denominator.

CMS continues to believe the difference in payment for these services in the physician practice and hospital outpatient department settings is a significant factor in the shift in services from the physician's office setting to the hospital outpatient department for many hospital types, which unnecessarily increases hospital outpatient department volume and Medicare program and beneficiary expenditures. 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 hospital outpatient departments and independent physician practices stem in part from inadequate MPFS rates.

Adjusted for inflation in medical practice costs, as measured by the Medicare Economic Index (MEI), MPFS rates declined 20 percent from 2001 to 2021. Growth in key contributors to the MEI is much higher now than in previous years, which threatens to significantly widen this gap. Medicare payment rates for all Medicare services except those on the physician payment schedule, such as inpatient and outpatient hospital services and skilled nursing facility services, have updates tied to inflation. Physician payment rates have been further eroded by the manner in which rates are adjusted to meet budget neutrality requirements, as well as Medicare sequestration. The COVID-19 pandemic also has placed enormous stress on medical practices, with an AMA analysis of Medicare claims for physician services identifying a 14 percent reduction in 2020 due to COVID-19.

The AMA has been engaged in a process of working with our partners in the national specialty and state medical associations to determine the best path forward to get the MPFS on a more sustainable track. We have also been working to increase awareness of the problems in the current system among Members of Congress to build interest and support for the needed reforms. In its 2021 annual report, the Medicare Trustees expressed concern that, although the physician payment system put in place in 2015 avoided the significant short-range physician payment issues, it "nevertheless raises important long-range concerns that will almost certainly need to be addressed by future legislation." The Trustees noted, for example, that "the law specifies the physician payment updates for all years in the future, and these updates do not vary based on underlying economic conditions, nor are they expected to keep pace with the average rate of physician cost increases."

The AMA looks forward to working with the Agency to strengthen the MPFS.

B. Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients

Recommendation:

- The AMA strongly opposes removing the requirement that physicians supervise outpatient diagnostic services and requests CMS not enact this proposed provision. The AMA believes that diagnostic testing should only be performed by those individuals who possess appropriate clinical education and training, under the supervision of licensed physicians (MD/DO).

The AMA opposes the proposed changes to the supervision requirements of non-physician practitioners providing outpatient diagnostic services. The proposed rule would revise existing supervision requirements at § 410.28(e) to clarify that nurse practitioners (NPs), clinical nurse specialists, physician assistants (PAs), certified registered nurse anesthetists, and certified nurse midwives may provide general, direct, and personal supervision of outpatient diagnostic services to the extent that they are authorized to do so under their scope of practice and applicable State law. The AMA is adamantly opposed to these proposed changes and believes that diagnostic services should only be performed by those individuals who possess appropriate clinical education and training, under the supervision of licensed physicians (MD/DO). If the proposed changes are enacted, patients will no longer be receiving the best possible care. The execution of diagnostic tests forms the foundation for diagnostic interpretation. As such, properly executing these services is the difference between properly diagnosing a life-threatening disease in time to treat the illness, and the death of a patient.

Presently, CMS acknowledges three levels of supervision: general, direct, and personal. Each level of supervision has a corresponding indicator value assigned for each diagnostic procedure.[1] General supervision requires the procedure to be furnished under the physician's overall direction and control. Direct supervision varies depending on location and the service being provided but, generally requires that a physician is present in the location the service is being performed and is available for immediate assistance and direction. Finally, personal supervision entails the physician being in the room during the procedure. These supervision requirements apply to the technical component of a diagnostic test and coincide with the provision that a physician must provide the professional component of a diagnostic

[1] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11043.pdf.

service.[2] These services must be supervised by a physician due to the need to ensure patient safety and the accuracy of the test results.

If the requirements for general and personal supervision are altered so that it is no longer required that physicians oversee the work of non-physicians, the health outcomes could be devastating. Based on the breadth and depth of this proposed change, it is reasonable to believe that the proposed change will encompass numerous procedures and could potentially even include things like the technical component of ambulatory electroencephalography (EEG), mammograms, monitoring for identification and lateralization of cerebral seizure focus, and electroencephalographic (channel EEG) recording and interpretation, all of which currently require a general level of supervision. It could also span to the technical component of several X-ray studies and could potentially include things like the radiologic examination of the pharynx or larynx, fluoroscopies, and magnification techniques, which currently require personal supervision.[3] These are all highly technical procedures that require extensive schooling to properly perform and oversee. The training one receives could make the difference between identifying a brain tumor in time to operate and missing the warning signs until it is too late.

While all health care professionals play a critical role in providing care to patients, and are important members of the care team, non-physician practitioner (NPP) skill sets are not interchangeable with those of fully educated and trained physicians. This is fundamentally evident based on the difference in education and training between the distinct professions. Physicians complete four years of medical school plus three to seven years of residency, including 10,000-16,000 hours of clinical training.[4] By contrast, NPs, complete only two to three years of education, have no residency requirement, and have only 500-720 hours of clinical training.[5] Moreover, the current PA education model is two years in length with only 2,000 hours of clinical care and no residency requirement.[6] Patients expect the most qualified person—physician experts with unmatched training, education, and experience—to be supervising outpatient diagnostic services. CMS should not be offering a lower standard of care or clinical expertise for outpatient procedures.

It is more than just the vast difference in hours of education and training that matter, but also the difference in rigor and standardization between medical school/residency and NPP programs that matter and must be assessed. During medical school, students receive a comprehensive education in the classroom and in laboratories, where they study the biological, chemical, pharmacological, and behavioral aspects of the human condition. This period of intense study is supplemented by two years of patient care rotations through different specialties, during which medical students assist licensed physicians in the care of patients.[7] During clinical rotations, medical students continue to develop their clinical judgment and medical decision-making skills through direct experience managing patients in all aspects of medicine. Following graduation, students must then pass a series of examinations to assess their readiness for licensure. At this point, medical students "match" into a three-to-seven-year residency program during which they provide care in a select surgical or medical specialty under the supervision of experienced physician faculty. As resident physicians gain experience and demonstrate growth in their ability to care for patients, they are given greater responsibility and independence. NP programs do not have similar time-tested standardizations. For example, between 2010-2017, the number of NP programs grew by more than 30 percent, with well over half of these programs offered mostly or completely online, meaning

[2] https://www.law.cornell.edu/cfr/text/42/410.32.
[3] https://www.aapc.com/blog/26162-understand-medicare-physician-supervision-requirements/.
[4] https://www.ama-assn.org/system/files/scope-of-practice-physician-training.pdf.
[5] *Id*.
[6] https://college.mayo.edu/academics/explore-health-care-careers/careers-a-z/physician-assistant/.
[7] https://medicine.vtc.vt.edu/content/dam/medicine_vtc_vt_edu/about/accreditation/2018-19_Functions-andStructure.pdf.

less in-person instruction and hands-on clinical experience.[8] In addition, many programs require students to find their own preceptor to meet their practice hours requirement, resulting in variation among students' clinical experiences. This variation in preceptorship and lower educational standard creates difference in qualifications among NPs and leaves a large gap in the knowing-doing bridge which leaves NPs unable to handle the complexity of the clinical environment, inexperienced in teamwork, and lacking knowledge about patient care.[9] NPPs are integral members of the care team, but the skills and acumen obtained by physicians throughout their extensive education and training make them uniquely qualified to oversee and supervise patients' care and diagnostic services. Physician-led, team-based care has a proven track record of success in improving the quality of patient care, reducing costs, and allowing all health care professionals to spend more time with their patients.

Without proper supervision, non-physician practitioners' level of training can strain the health care system and endanger patients. Multiple studies have shown that NPs order more diagnostic imaging than physicians, which increases health care costs and threatens patient safety by exposing patients to unnecessary radiation. For example, a study in the *Journal of the American College of Radiology*, which analyzed skeletal x-ray utilization for Medicare beneficiaries from 2003 to 2015, found ordering x-rays increased substantially—more than 400 percent—by non-physicians, primarily NPs and PAs, during this time frame.[10] A separate study published in *JAMA Internal Medicine* found NPs ordered more diagnostic imaging than primary care physicians following an outpatient visit. The study controlled for imaging claims that occurred after a referral to a specialist.[11] The authors opined this increased utilization may have important negative ramifications on costs, safety, and quality of care. They further found greater coordination in health care teams may produce better outcomes than merely expanding NP scope of practice alone. In addition, a recent study from the Hattiesburg Clinic in Mississippi found that allowing NPs and PAs to function with independent patient panels under physician supervision in the primary care setting resulted in higher costs, higher utilization of services, and lower quality of care compared to panels of patients with a primary care physician.[12] Specifically, the study found that non-nursing home Medicare Accountable Care Organization (ACO) patient spending was $43 higher per member, per month for patients on a NP/PA panel compared to those with a primary care physician. Similarly, patients with an NP/PA as their primary care provider were 1.8 percent more likely to visit the ER and had an eight percent higher referral rate to specialists despite being younger and healthier than the cohort of patients in the primary care physician panel. On quality of care, the researchers examined 10 quality measures and found that physicians performed better on nine of the 10 measures compared to the non-physicians.[13]

Moreover, while a common argument to expand the scope of practice of nurse practitioners is to increase access to care, in reviewing the actual practice locations of nurse practitioners and primary care physicians across the country, it is clear they tend to work in the same large urban areas as physicians.[14] This is true even in those states where, for example, NPs can practice without physician involvement. The Graduate Nurse Demonstration Project (the Project), conducted by the Centers for Medicare & Medicaid

---

[8] David I. Auerbach, Peter I. Buerhaus, and Douglas O. Staiger. Implications of the Rapid Growth of the Nurse Practitioner Workforce in the US 10.1377/hlthaff.2019.00686 HEALTH AFFAIRS 39, NO. 2 (2020): 273–279.

[9] https://vdocument.in/closing-the-education-practice-gap-toward-nursing-education-according-to-the-survey.html?page=4.

[10] D.J. Mizrahi, et.al. "National Trends in the Utilization of Skeletal Radiography," Journal of the American College of Radiology 2018; 1408-1414.

[11] D.R. Hughes, et al., A Comparison of Diagnostic Imaging Ordering Patterns Between Advanced Practice Clinicians and Primary Care Physicians Following Office-Based Evaluation and Management Visits. JAMA Internal Med. 2014;175(1):101-07.

[12] https://ejournal.msmaonline.com/publication/?m=63060&i=735364&view=contentsBrowser.

[13] *Id*.

[14] https://www.ama-assn.org/system/files/scope-of-practice-access-to-care-for-patients.pdf.

Services, confirmed this finding.[15] One goal of the Project was to determine whether increased funding for Advanced Practice Registered Nursing (APRN) programs would increase the number of APRNs practicing in rural areas. The results found that this did not happen. In fact, only 9 percent of alumni from the program went on to work in rural areas. In short, the evidence is clear that expanding scope for NPs and PAs will not necessarily lead to better access to care in rural America. Rather than supporting an unproven path forward, the Administration should consider proven solutions to increase access to care, including supporting physician-led team-based care and increasing the cap.

The AMA has long supported physician-led health care teams, with each member drawing on his or her specific strengths, working together, and sharing decisions and information for the benefit of the patient. This includes ensuring that CMS promotes the appropriate standard of care, compensation, and acknowledgment of the valuable service that physicians provide especially in their role as supervisors of diagnostic services. **As such, the AMA strongly opposes removing the requirement that physicians supervise outpatient diagnostic services and requests CMS not enact this proposed provision.**

C. Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

Recommendation:

- The AMA does not support the CMS proposal to add a category of service to the Hospital Outpatient Department Prior Authorization Program effective for services on or after March 1, 2023. The proposed rule did not attempt to quantify the physician and patient burden that will result from adding prior authorization to Hospital OPD services on Medicare beneficiaries.

CMS proposes to add the following category of service to the Hospital OPD Prior Authorization Program beginning for dates of service on or after March 1, 2023: (a) Facet Joint Interventions. The AMA opposes this proposal and urges CMS to withdraw it. Our principal concern with adding prior authorization requirements to these new categories of OPD services is the potential effect on Medicare beneficiaries' ability to receive medically necessary, timely care. Utilization management tools such as prior authorization create significant treatment barriers by delaying the start or continuation of necessary treatment, which may in turn adversely affect patient health outcomes and quality of care. The AMA understands there may be a role for prior authorization in health care, including in Medicare fee-for-service, but we believe it must be right-sized and used judiciously. The proposed rule did not attempt to quantify the physician and patient burden that will result from adding prior authorization to Hospital OPD services on Medicare beneficiaries and, in our view, did not justify the need to add these additional services to the Hospital OPD prior authorization program.

1. Patient and Physician Impact of Prior Authorization

AMA research quantifies the impact of prior authorization requirements on both patients and physicians. In a December 2019 survey of 1,000 practicing physicians, 64 percent of respondents reported waiting at least one business day for prior authorization decisions from health plans, while 29 percent reported waiting at least three business days.[16] Unsurprisingly, but disturbingly, 91 percent of surveyed physicians

[15] The Graduate Nurse Education Demonstration Project: Final Evaluation Report, Centers for Medicare and Medicaid Services. August 2019. https://innovation.cms.gov/files/reports/gne-final-eval-rpt.pdf.
[16] 2019 AMA Prior Authorization Physician Survey, available at https://www.ama-assn.org/system/files/2020- 06/prior-authorization-survey-2019.pdf.

said that prior authorization can delay access to necessary care. These delays have serious implications for patients and their health, as 74 percent of surveyed physicians reported that prior authorization can lead to treatment abandonment, and 90 percent indicated that prior authorization can have a negative impact on patient clinical outcomes. Most alarming, 24 percent of surveyed physicians reported that prior authorization has led to a serious adverse event (e.g., disability, death) for a patient in their care, with 16 percent saying that this process has led to a patient's hospitalization. We believe that these statistics capture the potential patient harms associated with prior authorization and suggest a significant patient burden associated with creating additional requirements to Medicare's 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 33 prior authorizations per physician per week, with this workload consuming 14.4 hours—nearly two business days—of physician and staff time. Moreover, about one-third (30 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 86 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 increasing the number of OPD services subject to prior authorization could lead to substantial growth in these burdens that already challenge the limited resources of financially strapped, smaller physician groups, particularly at a time when practices are reeling from the economic impact of the COVID-19 pandemic. Even though the COVID-19 PHE will likely end before the proposed implementation date for the expanded OPD prior authorization program, physician practices and hospitals will still face a long financial recovery process that will be impeded by these additional administrative burdens.

2. *Prior Authorization Reform Efforts*

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 our ongoing discussions with senior CMS leadership regarding prior authorization. We urge CMS to lead the industry by adopting the following concepts, developed in consensus with other national provider associations and insurer trade organizations in the 2018 Consensus Statement on Improving the Prior Authorization Process, into all of its prior authorization policies:

a. Selective application of prior authorization to only "outliers;"
b. Review/adjustment of prior authorization lists to remove services/drugs that represent low-value prior authorization;
c. Transparency of prior authorization requirements and their clinical basis to patients and physicians;
d. Protections of patient continuity of care; and

e. Automation to improve prior authorization and process efficiency.[17]

Although we applaud CMS for including some of these principles in its OPD prior authorization program, we encourage **CMS to reconsider the proposed additional utilization management requirements for these particular services, as we believe they do not align with the above-referenced industry efforts to reform prior authorization or, more specifically, the goals of the CMS Office of Burden Reduction and Health Informatics.**

3. Transparency into the Process and Program Evaluation

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, only limited data are currently made publicly available for research and analysis. We note that CMS has yet to evaluate the impact of the prior authorization requirements finalized in the CY 2020 OPPS final rule. Without a thorough study of how the existing OPD prior authorization requirements have affected care access, clinical outcomes, utilization, overall Medicare costs, and administrative burdens, it is premature to expand this program. As the AMA research detailed above clearly illustrates, concerns about the negative effect of prior authorization on patients and physicians are not speculative. **We therefore urge CMS to undertake this necessary and important impact analysis before requiring prior authorization for any additional categories of OPD services.**

Specifically, CMS should provide the health care community with relevant data about the impact of the OPD prior authorization program to date, which may be used to improve efficiency and timely access to clinically appropriate care. 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; (6) denials overturned upon appeal; and (7) average processing times for initial authorization requests and appeals. These data should inform efforts to refine and improve the OPD prior authorization program, such as additional provider exemptions or suspension of prior authorization process or services, as well as be thoroughly evaluated before implementing the proposed requirements on additional services.

4. Premature Effective Date

CMS proposes to implement prior authorization for an additional OPD service on or after March 1, 2023. If CMS proceeds with implementing prior authorization for the new service 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

[17] AMA, Consensus Statement on Improving the Prior Authorization Process (2018), available at https://www.amaassn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensusstatement.pdf.

authorization. **Additionally, we reiterate our significant concerns with increasing administrative burdens for physicians and their staff in the wake of the COVID-19 crisis.** We anticipate that physicians and hospitals will face a long road to recovering financial stability even after the official end of the public health emergency, and we urge CMS to seriously weigh the potential harms to both patients and clinicians of imposing additional administrative tasks on our health care system during this difficult and unprecedented time.

D. Rural Emergency Hospitals (REH): Payment Policies, Conditions of Participation, Provider Enrollment, Use of the Medicare Outpatient Observation Notice, and Physician Self-Referral Updates

Recommendation:

- The AMA generally supports the proposed payment for REHs, including the additional five percent payment to REH, and calls on CMS to similarly provide for added reimbursement for physicians who provide services to patients in the REHs. The AMA calls for CMS to closely monitor and to report through existing cost reporting on whether a sufficient share of revenue to the REH, which includes the monthly facility payment, is being directed to outpatient care.

1. Rural Emergency Hospitals (REH) Payment Policies

In this proposed rule, CMS continues from its REH Conditions of Participation (CoP) proposed rule to propose REH payment policies and other directives. CMS proposes to define "REH services" as all covered outpatient department services that would be paid under the OPPS, and to exclude services that may be provided in outpatient departments that are not paid under the OPPS (such as laboratory services and outpatient rehabilitation therapy services). Once a facility receives the REH designation, CMS proposes to pay for REH services equal to the payment for OPPS services, with an additional five percent. CMS proposes to limit beneficiary copayment for services to 20 percent of the OPPS payment amount; the additional five percent paid to an REH would not factor into the beneficiary copayment. While an REH would need to be able to perform certain outpatient department services as a part of its Conditions of Participation, those OPD services (such as laboratory services or post-hospital extended care services) that fall outside of the definition of REH services would not be eligible for the additional five percent payment. Services not defined as REH services would be paid for according to their established, respective schedules—not under OPPS. CMS also proposes to pay a monthly REH Facility Payment that, starting in 2024, will increase by the hospital market basket percentage increase.

The AMA generally supports the proposed payment for REHs. The AMA has long advocated for adequate payment for its physicians, and supports the need for hospitals to receive adequate payment as well. As evidenced in its proposed rule, CMS recognizes that the health needs of those who live in rural areas will not be met with the closure of rural hospitals and critical access hospitals (CAHs). The AMA applauds CMS for quickly realizing the downward trend as it related to hospital closures in rural communities, and for taking actions including providing additional financial resources to bolster the system. The AMA has highlighted the struggles of addressing health in rural communities and has advocated for policies to help address the burdens borne by rural hospitals and rural physicians, such as workforce shortages (including a lack of specialists), diminished patient volumes, Medicare payment and ultimately, financial distress and practice and facility closures. The COVID-19 pandemic further stressed the rural health system and has forced many institutions to reconsider how to operate efficiently with some deciding to close. Our rural hospitals, rural providers, and rural patients deserve a more stable system to address these systemic issues and to strengthen the health of rural communities.

Under the proposed payment system, REHs will receive an additional 5 percent payment above the OPPS. The additional 5 percent is funded by the Federal Supplementary Medical Insurance Trust Fund under section 1841 and will have no impact on OPPS budget neutrality. While the AMA believes this is the right approach—to not pit REHs again, the other institutions under a budget neutral system—we must highlight that physician payment has not been treated as fairly. Under existing statutory budget neutrality requirements, any MPFS changes cannot increase or decrease expenditures by more than $20 million in a year. The CY 2023 MPFS proposed rule again threatens physicians with steep payment reductions which stem from new policies proposed by CMS for services provided in non-office settings (i.e., hospital, emergency medicine, nursing facility and home visits). While supporting the REH payment proposal in this proposed rule, the AMA renews our strong call for CMS to prevent the steep budget neutrality cuts pending in the proposed rule.

As we note the additional 5 percent payment to REHs, the AMA calls on CMS to similarly provide for added reimbursement for physicians who provide services to patients in the REHs. The additional 5 percent payment to REHs will not reach physicians and other clinical providers who are paid under the MPFS. We have highlighted the challenges with recruiting, retaining, and incentivizing physicians in rural areas, and additional payment to REH physicians would help address this issue. We ask CMS to create an add-on modifier or code for physician claims, analogous to CMS' proposal to create an REH-specific payment flag on REH claims, and to pay an additional 5 percent for each CPT billed by physicians and clinicians in REHs. This additional 5 percent payment could be treated similarly to the additional OPPS payment under the statute meaning, it would not impact budget neutrality, and would not factor into the Medicare beneficiary copayment.

Regarding the REH monthly facility payment that CMS has proposed to be $268,294 per REH per month, the AMA encourages CMS to codify the associated reporting requirement under 42 CFR 419.92(b)(3) for an REH receiving the additional monthly facility payment which requires the REH to maintain detailed information on how it has used the monthly facility payments. The AMA calls for CMS to closely monitor and to report through existing cost reporting on whether a sufficient share of revenue to the REH, which includes the monthly facility payment, is being directed to outpatient care.

The statute which establishes REHs precludes administrative or judicial review of CMS' implementation of all of the REH program provisions. The AMA believes this creates a precarious position for CMS and for REHs, recognizing that the new program will likely be subject to future review and possible revisions. Aspects of the program such as the REH monthly facility payment, other payment provisions, and the Conditions of Participation, are examples of program provisions that may warrant future review. The complete "hands-off" approach to a new program is a highly unusual move, one that does not foster a transparent, accountable, and equitable system. The AMA urges CMS to not codify this section at this time.

2. REH Conditions of Participation

The AMA submitted comments to the CMS proposed REH Conditions of Participation on August 29, 2022.[18] The AMA supports the goals of the Proposed Rule to ensure equitable access to high quality care in rural communities and understands the importance of the proposed rule as rural hospitals continue to close, leaving vast care deserts. The AMA offered comments which included the importance that an experienced physician be included in the governing body and serve as the medical director of the REH,

[18] On July 6, 2022, the proposed health and safety standards titled "Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital CoP Updates" were published at 87 FR 40350.

the appropriate use of telemedicine in REHs with the employment of local physicians, and requirements around REH emergency services

3. REH Provider Enrollment

In order to be an REH, CMS proposes that the same enrollment provisions applicable to other providers and suppliers must be met. For existing CAHs or small rural hospitals converting to an REH, CMS proposes to require Form CMS-855A for change of enrollment and also proposes to waive the application fee. Whereas CMS ordinarily requires the termination of an existing Medicare enrollment and enrollment as a new provider or supplier type, here CMS describes the "conversion" of a CAH or small rural hospital to an REH to justify a less involved process for the status change. CMS proposes to categorize REHs at a limited level of risk where they would not have additional screening requirements.

The AMA recognizes the conversion of CAHs or small rural hospitals to REHs is unique, and in the interest of implementing the program by January 1, 2023, and the close nexus of the existing and new facilities, the AMA supports the provider enrollment policies as proposed.

4. Use of the Medicare Outpatient Observation Notice by REHs

REHs are not required to provide required notification under the NOTICE Act, known as the Medicare Outpatient Observation Notice (MOON). Although not routine for Medicare beneficiaries to receive services at an REH for more than 24 hours, CMS recognizes there may be instances a beneficiary's encounter at an REH exceeds 24 hours. For those rare instances, CMS solicits comments on the potential need to notify Medicare beneficiaries of their status as outpatients when exceeding 24 hours and whether the MOON is most appropriate notice to communicating this information.

The AMA recognizes the importance of beneficiaries understanding their cost-sharing obligations for outpatient observation services. In an emergency hospital, and especially in an REH, it may be very difficult to determine the ultimate diagnosis, the associated and specific laboratory tests, exams, and other interventions. The emergency bill, composed of both physician fees and facility fees, are often complicated for a beneficiary to fully understand. Taken together, the AMA encourages CMS to emphasize that a Medicare beneficiary should be stabilized and an REH should fulfill its EMTALA obligations before a MOON is provided.

5. Physician Self-Referral Updates

Rural communities already face a dearth of providers and specialists, and under the current Stark laws against physician self-referral, beneficiaries could have severe limitations on access to REHs. As currently written, the physician self-referral laws could inhibit access to medically necessary designated health services furnished by REHs that are owned or invested in by physicians (or their immediate family members) and thwart the underlying goal of safeguarding or expanding such access. Therefore, CMS proposes an "REH exception" to the Stark laws that would create a new exception for ownership or investment interests in an REH and would revise certain existing exceptions so they are applicable to compensation arrangements where an REH is involved.

The AMA supports CMS' creation of an REH Stark exception. The AMA dissuades CMS from imposing unnecessary burdens on annual reports (such as a detailed description of the identity of each owner of or investor in the REH) and discourages any requirements for public advertising or posting of physician ownership arrangements. Beneficiaries are always able to inquire about such arrangements and when they

do, it should be provided to them. The AMA agrees that in order to use the proposed REH exception, the entity must be enrolled in Medicare as an REH.

E. OPPS Payment for Software as a Service

Recommendations:

- The AMA does *not* think that CPT codes 0649T, 0722T, and 0724T should be considered "certain services" that are packaged under the regulation and recommends that CMS allow for separate payment of these important services without creating C-codes.
- The AMA commends CMS for seeking to understand the costs associated with innovative AI technology. Identifying these costs is critically important in ensuring Medicare beneficiaries and clinicians can access these kinds of services. Although resource costs such as practice expense are accounted for differently in the OPPS payment system, it is important that the direct practice expense included in the CPT code is not only considered for payment when a service is provided in physician offices under the MPFS but is also considered as a resource cost when APC assignments are determined under the OPPS payment system.
- The AMA believes the FDA, not CMS, is best positioned to evaluate an AI product's potential for introducing inappropriate bias into clinical decision making, especially bias which could influence outcomes for minoritized groups, and that such evaluation should be incorporated into the requirements to be met by AI developers seeking authorization to market.

1. CY 2023 Proposal for Software as a Service (SaaS) Add-on Codes

The AMA would like to thank CMS for reviewing and assigning new technology APCs to the following CPT category III codes:

- 0648T *Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; single organ*
- 0721T *Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging*
- 0723T *Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session*

The AMA does not support the CMS proposal to establish HCPCS codes, specifically, C-codes, to describe the following CPT category III add-on codes. CMS states that the codes do not meet their definition of add-on codes within the OPPS payment system and that establishing C-codes will allow the services to be paid separately under the OPPS system:

- 0649T *Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure); single organ (List separately in addition to code for primary procedure)*

- 0722T *Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)*
- 0724T *Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)*

While the AMA acknowledges the OPPS policy of packaging payment for add-on codes into the associated diagnostic imaging service, the AMA points out that this is a convention specific to the CMS OPPS system. Add-on designation by the CPT Editorial Panel simply means that the add-on code must be reported with the primary procedure. In fact, the add-on code structure ensures appropriate payment for additional work after accounting for any efficiencies that may result from the services being performed together. The purpose of add-on codes in the CPT code set is not to package the service into the primary procedure, but rather to "add-on" a service that requires additional work apart from the primary procedure with which it is reported. The introductory material in the CPT codebook describes the add-on code concept in the following way: "Add-on codes describe additional intra-service work associated with the primary procedure." Designation as an add-on code by the CPT Editorial panel does not imply that the service is of lesser value.

The AMA agrees with CMS that the SaaS procedure is the same regardless of whether it is furnished with or without the imaging service and that the payment for SaaS procedures, when billed concurrently with the acquisition of the images, should be equal to the payment for the SaaS procedures when the service is performed using prior imaging. However, the AMA believes that the existing CPT add-on codes 0649T, 0722T and 0724T can be used for separate payment by CMS in the OPPS system. The regulations under 42 CFR 419.2(b)(18) require packaging of "certain services described by add-on codes." CMS is not required to package all services described by add-on codes, rather only "certain services." The AMA does *not* think that CPT codes 0649T, 0722T, and 0724T should be considered "certain services" that are packaged under the regulation and recommends that CMS allow for separate payment of these important services without creating C-codes. This approach would be highly preferable to CMS' proposal to establish C-codes and would avoid the confusion and complexity introduced to the system when C- or G-codes are created to solve a perceived problem even though applicable CPT codes exist.

2. Comment Solicitation on Payment Policy for SaaS Procedures

The AMA appreciates that CMS has begun to recognize SaaS procedures as separately payable under the OPPS. The AMA has also taken notice of the increasing number of "…FDA approved or cleared "machine learning" or "AI" clinical software programs…" In response, the AMA, as the voice of physicians, supports innovation that is aligned with the AMA House of Delegates policies and principles and is focused on driving improved health equity, improved privacy safeguards for patients and physicians and ensure transparency and validity in critical areas of health care including coding and payment for AI. We urge CMS to engage with stakeholders like the AMA to identify common terminology across the payment systems so that physicians can better understand CMS' coverage and payment of AI technologies.

Previous limitations in the terminology used in the CPT code set became an urgent priority in recent years due to the rapid pace of innovation and FDA clearance of increasingly sophisticated AI products, which go well beyond what was being described 20 years ago when computer aided detection (CAD) products

were first described for use in the radiology section of the CPT code set. The AMA recognized a need among stakeholders in the CPT Editorial Panel process for consistent terminology to better understand how AI medical services fit into the CPT code set. In response to this need for guidance the CPT Editorial Panel developed a framework for AI terminology. While the AI taxonomy may not address all the questions that CMS has posed in this rule, it could prove helpful to CMS as the agency determines the appropriate payment approach for SaaS procedures included in the OPPS system. In September 2021, the CPT Editorial Panel accepted the addition of *Appendix S: AI taxonomy for medical services & procedures*[19] and the appendix became effective for stakeholder guidance in developing coding for AI on January 1, 2022.

The CPT Editorial Panel created *Appendix S: AI taxonomy for medical services & procedures* in order to categorize the functionality of AI by using terminology that describes the impact on the work of the physician. In this way the terminology is used to separate out what the machine does and what the physician does to produce discrete and differentiable code descriptors. Because CPT codes describe the work of physicians and other qualified health care professionals, the approach is focused on how AI augments the professional service, and it may prove useful as CMS seeks to understand when the analysis is distinct from the professional service paid under the PFS. Appendix S outlines three categories for AI applications:

- Assistive: The work performed by the machine for the physician or other QHP is assistive when the machine detects clinically relevant data without analysis or generated conclusions. Requires physician or other QHP interpretation and report.
- Augmentative: The work performed by the machine for the physician or other QHP is augmentative when the machine analyzes and/or quantifies data in a clinically meaningful way. Requires physician or other QHP interpretation and report.
- Autonomous: The work performed by the machine for the physician or other QHP is autonomous when the machine automatically interprets data and independently generates clinically meaningful conclusions without concurrent physician or other QHP involvement. Autonomous medical services and procedures include interrogating and analyzing data. The work of the algorithm may or may not include acquisition, preparation, and/or transmission of data. The clinically meaningful conclusion may be a characterization of data (e.g., likelihood of pathophysiology) to be used to establish a diagnosis or to implement a therapeutic intervention. There are three levels of autonomous AI medical services and procedures with varying physician or other QHP professional involvement:

    - Level I. The autonomous AI draws conclusions and offers diagnosis and/or management options, which are contestable and require physician or other QHP action to implement.
    - Level II. The autonomous AI draws conclusions and initiates diagnosis and/or management options with alert/opportunity for override, which may require physician or other QHP action to implement.
    - Level III. The autonomous AI draws conclusions and initiates management, which require physician or other QHP action to contest.

The following table included in the AI Taxonomy is meant as a summation and visual display of the definitions introduced in the AI Taxonomy:

[19] Available at https://www.ama-assn.org/system/files/cpt-appendix-s.pdf.

Service Components	AI Category: Assistive	AI Category: Augmentative	AI Category: Autonomous
Primary objective	Detects clinically relevant data	Analyzes and/or quantifies data in a clinically meaningful way	Interprets data and independently generates clinically meaningful conclusions
Provides independent diagnosis and/or management decision	No	No	Yes
Analyzes data	No	Yes	Yes
Requires physician or other qualified health care professional interpretation and report	Yes	Yes	No
Examples in CPT code set	Computer-Aided Detection (CAD) Imaging (77048, 77049, 77065-77067, 0042T, 0174T, 0175T)	Continuous glucose monitoring (CGM) (95251), external processing of imaging data sets	Retinal Imaging (92229)

The AMA commends CMS for seeking to understand the costs associated with innovative AI technology. Identifying these costs is critically important in ensuring Medicare beneficiaries and clinicians can access these kinds of services. Costs for AI vary based on the individual application and the business model of the associated technology company. This is true across services, specialties, types of practice and patient cohorts. As such, determinations about cost will require individual per-code or per-encounter analysis. Different types of resource costs associated with AI technology include licensing agreements, per-service analysis fees and subscription fees. In some cases, components of the service are performed by a data processing center. The AMA has found that many AI applications and software can be accounted for as a direct practice expense within the practice expense (PE) component of CPT codes. For example, CMS has acknowledged that the AI analysis performed on retinal imaging in CPT code 92229 is a direct practice expense because it is directly attributable to a specific patient and incurred for each patient. Although resource costs such as practice expense is accounted for differently in the OPPS payment system, it is important that the direct practice expense included in the CPT code is not only considered for payment when a service is provided in physician offices under the MPFS but is also considered as a resource cost when APC assignments are determined under the OPPS payment system.

3. *Solicitation of comments regarding bias in software*

The AMA commends CMS for "seeking comments on how we could encourage software developers and other vendors to prevent and mitigate bias in their algorithms and predictive modeling." AMA policy supports the development of thoughtfully designed, high-quality, clinically validated health care AI that is:

- designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
- transparent;
- conforms to leading standards for reproducibility;
- identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities, including when testing or deploying new AI tools on vulnerable populations; and
- safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.

When developed with these principles in mind and incorporated into clinical practice appropriately, we believe that innovative technology including products incorporating AI can help improve quality of care and increase health equity.

However, we note that many of these products are novel and not yet in widespread use so their impact on quality of care or health equity is not yet entirely clear. While we believe these products can be used to provide higher quality of care to a greater number of patients, we strongly support CMS' and other regulators' interest in gathering the data necessary to calculate the performance and impact of innovative technology moving forward. Given that the approaches to design and implementation, as well as the underlying data provenance, will vary by necessity, it will be important to gather additional evidence on the development and impact of the use of specific technologies.

Advancing equity in health requires the understanding and acceptance of the harmful impacts of historical and contemporary racism on our individual and collective ability to strive for and achieve a reality in which we all have the resources, conditions, opportunities, and power to thrive and achieve optimal health. The AMA is strongly committed to achieving these goals and addressing related issues, including the potential of AI to introduce inappropriate bias into clinical decision making.

The AMA is greatly concerned with the potential for software and AI to introduce bias into the medical system when these products are not developed with a comprehensive data set or do not provide a clear description of the limitations of an application. Algorithms are only as good as the data on which they are trained and operate and can be subject to bias arising from several directions and due to many causes: limitations in the geographic origins and ancestral representativeness of the data collected; missing data; small sample sizes; the implicit biases and inaccurate or inexperienced judgments of clinicians; or differential care delivered in different clinical settings to different populations of patients. As a result, technical solutions to mitigate bias before, during, or after an algorithm processes data may not be sufficient to ensure that an algorithm benefits patients as intended. Instead, there must be a focus on ensuring the data used to train algorithms are free from bias, including inappropriate reliance on race or ethnicity.

Therefore, it is our belief that the best way to control for bias is during algorithm conceptualization and development, including ensuring appropriate and unbiased data are used for training. While potential bias can be discovered and ameliorated after the product is in use, ideally developers will have a comprehensive product development plan in place that helps ensure it is free of inappropriate bias throughout the total product lifecycle and, most importantly, before it is marketed. We follow with interest the progress being made to develop tools to detect algorithmic bias and anticipate that market authorization and favorable coverage decisions will in time require use of such tools by developers.

We applaud CMS' commitment to understanding these issues. The AMA believes the FDA, not CMS, is

best positioned to evaluate an AI product's potential for introducing inappropriate bias into clinical decision making, especially bias which could influence outcomes for minoritized groups, and that such evaluation should be incorporated into the requirements to be met by AI developers seeking authorization to market. Products that are found to potentially introduce bias should not be granted marketing authorization nor should they be covered by CMS.

F. Organ Acquisition Payment Policy

Recommendation:

- The AMA strongly supports CMS' proposal to include as organ acquisition costs the costs for donor management when death is imminent.

The AMA supports the proposals in the Proposed Rule that would authorize additional surgeons to determine whether an organ is usable and those provisions that would allow costs incurred prior to the death of a donor to be reimbursable. However, we have serious concerns about CMS' proposed modifications of the cost reporting rules related to research organs, which may significantly increase the costs of critical transplant research and incentivize OPOs to discard organs that are not suitable for transplantation rather than making these organs available to researchers. We are also concerned that the proposed exclusion of the purchase price of organs in the statistics used to allocate a hospital's General and Administrative costs would treat organ acquisition costs differently from other purchased items and services and would result in significant Medicare payment reductions that would adversely impact patient care.

G. Request for Comment: A Potential Future Specialty Centered Approach for the *Ambulatory Surgical Center Quality Reporting* (ASCQR) Program

Recommendation:

- While the AMA generally supports the concept of allowing ASCs to tailor their quality measurement and improvement efforts to those procedures more frequently treated at the facility, we urge CMS not to consider implementing or adapting the MIPS MVPs for other quality programs since much work is still needed.

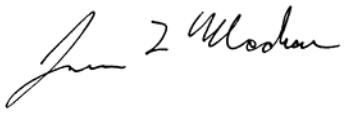
The AMA agrees with CMS' overarching goal of the ASCQR Program goal to have an up to date, comprehensive set of quality measures for widespread use to promote informed decision making regarding clinical care and quality improvement efforts in the ASC setting. However, while we generally support the concept of allowing ASCs to tailor their quality measurement and improvement efforts to those procedures more frequently treated at the facility, we urge CMS not to consider implementing or adapting the MIPS MVPs for other quality programs since much work is still needed. We believe that the current design is not geared toward improving patient outcomes around an episode, condition, or other public health priority and requires significant redesign before it is implemented even in MIPS.

It is our understanding that MVPS are intended to more broadly represent value with cost and quality captured within a clinical concept or procedure. The questions that CMS poses for the ASC Quality Reporting Program appear to have a greater focus on creating sets of related measures similar to the MIPS specialty sets, which enable the selection of more appropriate quality measures. If so, this would be a more appropriate direction but would also require further thoughtful consideration.

CMS must also ensure that any measure considered for a specific quality program has undergone robust testing for that setting and level of accountability and it must be coordinated with the measure stewards. The absence of robust testing to ensure that it is feasible for ASCs to implement each measure as specified with reliable and valid scores produced at the facility level increases burden on health care teams while simultaneously setting them up for poor and inaccurate reflections of the quality of care they provide. This scenario continues to occur with the inclusion of measures such as ASC-10 (Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps–Avoidance of Inappropriate Use) and ASC-11 (Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery), which were developed as clinician-level measures and never tested for use by ASCs. To our knowledge the vast majority, if not all, of the measures included in Tables 73-75 have not be tested for the ASC setting and it is imperative that CMS ensure that all measures included in a quality program are demonstrated to be feasible, reliable, and valid with close collaboration with the measure stewards.

We thank you for the opportunity to provide input on this Proposed Rule. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD