October 5, 2020

The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1734–P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via online submission at www.regulations.gov

RE: CMS-1734-P – Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

I am pleased to submit the following comments on behalf of the Ambulatory Surgery Center Association (ASCA) in response to the Centers for Medicare & Medicaid Services' (CMS) Proposed CY 2021 Revisions to Payment Policies under the Medicare Physician Fee Schedule (MPFS) and updates to the Quality Payment Program (QPP).

ASCA represents the interests of the more than 5,800 Medicare-certified ambulatory surgical centers (ASCs) nationwide. ASCs are located in every state and offer a high-quality, convenient and low-cost choice for Medicare beneficiaries who do not require hospitalization after surgical or diagnostic procedures. We appreciate the opportunity to comment on a few of the proposed provisions that affect ASC clinicians and the Medicare patients they serve.

Physician Fee Schedule

Payment Rate Revisions Due to Budget Neutrality

ASCA joins the wealth of healthcare stakeholders with serious concerns about the drastic decrease in the physician conversion factor (CF). The 10.6 percent reduction from the 2020 CF can be directly traced to budget neutrality adjustments tied to impending updates to evaluation and management (E/M) services. The increases to the E/M work relative value units (RVU) finalized in the CY 2020 MPFS, coupled with the zero-sum nature of statutory budget neutrality,

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means that specialties will experience a wide range of impacts. Specialties that do not furnish a large proportion of high-level E/M visits, including many of surgical specialties that operate in ASCs, are in line for substantial payment cuts.

The COVID-19 pandemic has caused significant disruption to the healthcare industry, particularly those physicians who furnish elective surgeries, and the effects of the pandemic will likely be felt into 2021 and beyond. Mandated elective surgery stoppages in spring 2020, as well as the need for enhanced safety protocols and understandable patient hesitation, caused a precipitous drop in procedure volume compared to normal years.[1] Although many ASCs have been able to resume elective surgeries, payment cuts of 5 percent or greater to specialties such as ophthalmology, gastroenterology and orthopedic surgery may be crippling in an already tenuous economic environment. This will undoubtedly hamper Medicare beneficiary access to necessary care. A recent study found that disease progressions due to delayed treatment of cancers, including colorectal cancer, could cost as much as $50,000 per year[2]. ASCs provide roughly 50 percent of colonoscopies to Medicare beneficiaries each year.

ASCA recognizes that the budget neutrality provisions of the MPFS are statutory, and therefore CMS could not unilaterally waive budget neutrality via proposed rulemaking. However, these are drastic times and CMS and the Department of Health and Human Services (HHS) should explore every regulatory avenue available to ensure the continued availability of health services for Medicare beneficiaries. **CMS and HHS should use authorities granted under the ongoing public health emergency (PHE) to implement the scheduled office visit increases but waive budget neutrality requirements in an effort to mitigate financial stress and preserve patient access to care.** CMS and HHS should also engage Congress in an effort to prevent drastic payment cuts to any health provider during the PHE.

Global Surgical Packages

ASCs do not receive a technical payment for E/M services furnished under Medicare, and as such, these visits are seldom, if ever, performed in ASCs. However, E/M visits are an essential part of the preoperative process and have a direct relationship to optimal patient and procedure referral in the ASC. ASCA joins the many organizations disappointed with CMS' continued decision not to apply Relative Value Scale Update Committee (RUC) recommended updates to office/outpatient E/M codes furnished as part of a global surgical package.

As other stakeholders have noted, this decision could have serious, detrimental consequences on payments for E/M visits furnished as part of a surgical package relative to other standalone E/M visits. Failure to update payments for certain E/M codes creates unfair payment differences between surgical specialties and other physician types for providing the same services, in direct violation of the Medicare statute that prohibits CMS from paying physicians differently for the same work. This decision also ignores the recommendation of the RUC, which represents all medical specialties and voted overwhelmingly (27to 1) in April 2019 that full relative value unit (RVU) increases should be incorporated into global code packages[3]. In fact, the medical

[1] Tenet Health reported that United Surgical Partners International (USPI) same-facility surgical cases were down 71.4 percent in March 2020.

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6738320/

[3] https://www.ama-assn.org/system/files/2019-07/ruc-voting-office-visits-final.pdf

stakeholder community at large has been united in recommending that CMS incorporate the revised E/M values into visits bundled as part of global surgical packages.

For these reasons, ASCA implores CMS to finalize a policy that applies RUC-recommended changes to E/M visits furnished as part of global surgical packages. ASCA supports the American Medical Association's physician and health professional workgroup dedicated to analyzing E/M coding and payment issues and hopes that CMS will continue to consult surgical specialties when considering changes to reimbursement policy.

Quality Payment Program

Merit-Based Incentive Payment System (MIPS)

MIPS Value Pathways

In comments submitted on the CY 2020 MPFS proposed rule, ASCA expressed appreciation for CMS' desire to create new approaches to move physicians to value-based payments. ASC-based clinicians are generally not ideal candidates for traditional alternative payment models (APMs) despite delivering high-quality, cost-efficient care. ASCA agrees that moving toward models that are flexibly structured around clinical specialties and bring together focused, value-based measurements should remain the goal of the Quality Payment Program (QPP).

Given the disruption caused by the COVID-19 pandemic, ASCA supports CMS' decision to delay implementation of the MIPS Value Pathways (MVP) framework until the CY 2022 rulemaking cycle. The additional time will allow refinement of the initial set of MVPs and implementation policies, as well as allow traditional MIPS scoring to reach its statutorily designed scoring mechanisms. CMS should balance the desire for simplification with the confusion that might arise from layering a new framework on top of current requirements.

ASCA supported the four guiding principles put forth in the CY 2020 proposed rule to define MVPs and continues to believe that site of service should be considered an essential part of any comparative performance data so that patients can best evaluate the highest quality, most cost-effective site for their care.

While supporting the spirit behind the newly proposed fifth guiding principle (*MVPs should support the transition to digital quality measures*), ASCA continues to have concerns about how clinicians with limited access to electronic health record (EHR) technology may be treated in the new framework. ASC-based clinicians and clinicians in many other vital medical specialties have limited access to EHRs and other health information technology that could be used to satisfy interoperability requirements. This fact is reflected in a statutory exemption from the MIPS Promoting Interoperability (PI) performance category. Therefore, it is troubling that CMS is proposing to develop MVPS in the 2022 MIPS performance period by incorporating the entire set of PI measures. Development of MVPs in this manner may dissuade ASC-based clinicians, for whom MVPs would otherwise be an ideal value-based payment structure, from participating. Mandating certified EHR technology (CEHRT) usage as part of MVPs will directly contradict CMS' proposed development criteria for MVP appropriateness, namely whether the measures are reportable by multiple specialties and whether they capture the care settings of the clinicians

being measured. **ASCA urges CMS to consider MVP development criteria that take into account those clinicians who may not be able to satisfy electronic reporting requirements.**

ASCA requests that CMS take a slow approach to MVP design and implementation and looks forward to CMS stakeholder engagement in designing this new framework for future payment years. At a minimum, CMS must expand on how the MVP framework and the current four category performance scoring system would interact while transitioning to reporting through MVP pathways. It is also unclear how the MVP framework would align with the statutory payment adjustments under the MIPS program.

Establishing the Performance Threshold

Provisions in the Bipartisan Budget Act of 2018 gave CMS discretion in setting the performance threshold up to the 2024 MIPS payment year. ASCA has appreciated CMS' desire to create a smooth transition to the time when the performance threshold is statutorily required to reflect overall mean or median final scores of the MIPS-eligible clinician population. This desire was reflected in performance thresholds of 3 points, 15 points, and 30 points in the first three years of the MIPS program. In the CY 2020 MPFS proposed rule, CMS proposed a performance threshold of 45 points for the 2022 MIPS payment years (based on CY 2020 reporting) and an expected threshold of 60 points for the 2023 payment year (based on CY 2021 reporting). These were based on needing a stepwise ramp to an estimated, statutorily mandated performance threshold of 74 in the 2024 MIPS payment year.

ASCA is pleased that CMS has re-examined its performance threshold in light of the ongoing COVID-19 pandemic and is now proposing a performance threshold of 50 points for the 2022 MIPS payment year. As noted in the rule, disruptions due to the PHE will likely make it difficult for many clinicians, especially those in small practices, to reach the performance threshold. Negative payment adjustments due to low performance scores are now possibly severe (-9 percent) and CMS should seek to reduce any further payment cuts in the already uncertain health care environment. Final rule changes to the proposed 2023 MIPS performance threshold should only be downward to ensure greater clinician flexibility. Therefore, if CMS calculates revised estimates of the performance threshold for the 2024 MIPS payment year that information should only be incorporated if it gives clinicians greater reporting flexibility in the 2021 reporting period.

ASCA continues to be concerned about ASC-based clinicians' ability to meet the performance threshold and avoid negative payment adjustments. As referenced in the PI performance category comment below, ASC-based clinicians have a disproportionate share (65 percent) of their overall performance score determined by the Quality category. There are undeniably fewer combinations of performance scoring that will allow ASC-based clinicians to reach increasingly high performance thresholds. This fact is exacerbated by the overall reduction in Quality measures available and increasing potential payment adjustments. This creates undue burden and disadvantages for those clinicians and groups operating in a lower cost, higher quality setting. ASCA requests that CMS consider mechanisms to provide scoring relief for those clinicians and groups burdened to reach a given performance threshold due to category reweighting.

Small Practice Bonus

In the CY 2018 Quality Payment Program Final Rule, CMS finalized a policy by which small practices—practices consisting of 15 or fewer clinicians—would receive 5 bonus points added to their overall performance score. In the CY 2019 Final Rule, CMS finalized a proposal to transition the small practice bonus to an additional 3 points in the Quality performance category, rather than the overall performance score.

ASCA opposed moving the small practice bonus to the Quality performance category and the bonus reduction from 5 to 3 points. Reducing the available bonus and loading the bonus points on the Quality performance category significantly dilutes the support CMS strives to provide to small practices challenged by QPP participation. This problem only increases as the performance threshold increases with each payment year. By CMS' own estimation, small practices (1–15 clinicians) are more than twice as likely to receive a negative payment adjustment as practices with 25–99 clinicians and almost six times as likely to receive a negative adjustment as practices with more than 100 clinicians. **ASCA requests that CMS re-evaluate the small practice bonus and return it to additional points added to a clinician's overall performance score.**

Promoting Interoperability Performance Category

Pursuant to Sections 4002 and 16003 of the 21st Century Cures Act (Pub.L. 114-225), clinicians who furnish "substantially all" of their services in ASCs are exempt from the Promoting Interoperability (PI) performance category due to lack of access to certified electronic health record technology (CEHRT). This causes the PI category to be weighted 0 percent for ASC-based clinicians, and the proportionate scoring weight transferred to the Quality performance category. Based on CMS' proposed weights for the 2020 performance period, this reweighting means that Quality measures will account for 65 percent of the scoring weight for ASC-based clinicians.

Loading weights onto the Quality performance category in this manner means that the quality metrics (values and distribution) have a disproportionate, and potentially detrimental, impact on overall performance score. As the federal government looks to cut healthcare costs, eligible clinicians should be encouraged to take cases to the lower-cost, high-quality ASC setting instead of being penalized for using ASCs. ASCA recommends that CMS devise a more equitable reweighting methodology for clinicians covered under an EHR-exemption.

Advanced Alternative Payment Models (A-APMs)

Physician Focused Payment Models and Opportunities for Surgical Specialties

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Physician Focused Payment Model Technical Advisory Committee (PTAC) and tasked it with providing comments and recommendations to the HHS Secretary on physician payment models. The PTAC is intended to respond to the concern that there are limited APM opportunities for the majority of MIPS-eligible clinicians by facilitating the Secretary's review process of proposals for physician focused payment models (PFPMs). The PFPMs process can potentially increase the

Advanced APM opportunities for ASC-based clinicians and other clinicians with limited Advanced APM opportunities. Considering the potentially onerous requirements of MIPS reporting as a result of performance category reweighting (described in previous sections), the ability to participate in the Advanced APM track would give ASC-based clinicians greater flexibility in their Medicare reimbursements.

This CY 2020 proposed rule contains no mention of the PTAC or further development of PFPMs. CMS has previously signaled a long-term desire to transition clinicians from MIPS to Advanced-APM models. This goal will not be realized without an expansion of Advanced-APM models which encompass a wider range of medical specialties and sites of service. Stakeholders will continue to be discouraged from creating new models via the PTAC process unless HHS and CMS make a commitment to a more open, collaborative process in which models are ultimately accepted for testing and implementation. ASCA recommends that CMS, in collaboration with the PTAC, set clear processes and timelines for testing and ultimately integrating new Advanced APMs into the QPP. ASCA recommends that CMS, and its sub-agencies such as the Center for Medicare & Medicaid Innovation, develop clear guidance documents and tools to better stimulate development of robust proposals designed to include the wide range of surgical specialties that are performed in the ASC environment.

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ASCA appreciates CMS' acknowledgment that all settings of care and practices of all sizes are essential to providing high quality, efficient care. We value the Agency's willingness to listen to our concerns as we strive to give our members the ability to continue providing provide high-quality patient care. We look forward to continuing to work with you and your staff. If you have any questions, please contact Kara Newbury at knewbury@ascassociation.org or 703.636.0705.

Sincerely,

William Prentice
Chief Executive Officer