September 06, 2022

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1770-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Via online submission at https://www.regulations.gov/document/CMS-2022-0113-1871

Re: CMS-1770-P – Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Dear Administrator Brooks-LaSure:

The Ambulatory Surgery Center Association (ASCA) submits the following comments in response to the Centers for Medicare and Medicaid Services' (CMS) Proposed CY 2023 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 6,000 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 proposed provisions that affect ASC clinicians and the Medicare patients they serve.

PHYSICIAN FEE SCHEDULE (PFS)

Conversion Factor

Health care professionals and related organizations are aligned in expressing concern over the expiration of the Protecting Medicare and American Farmers from Sequester Cuts Act 3 percent increase to the CY 2022 conversion factor (CF). Although Congress would again need to step in

to rebalance the CF, CMS should be concerned as Medicare beneficiaries risk losing access to essential health services if the provider cuts take effect.

According to the Surgical Care Coalition, Medicare surgical professional reimbursement could face as high as an 8.5 percent cut in 2023[1] due to a combination of the proposed 4.5 percent CF cut and pending cuts stemming from the Pay-As-You-Go (PAYGO) Act of 2010 that could be as high as 4 percent. These cuts are in addition to the mandatory 2 percent across-the-board sequester reductions that resumed as of July 1, 2022. There is no doubt that reimbursement reductions this drastic, on top of inflationary pressures in the healthcare economy, put Medicare beneficiaries at risk of losing access to critical surgical procedures. In particular, provider cuts may have an outsized effect on beneficiaries in rural areas or from historically underserved populations, directly opposing this administration's commitment to prioritizing care for those populations.

ASCA urges CMS to work with Congress to extend the 3 percent increase to the conversion factor and implement long-term fixes for budget neutrality components of Medicare payment systems that adversely affect providers and beneficiary access to care.

Potentially Misvalued Codes

In this rule, CMS responds to a commenter that nominated six cataract surgery codes (CPT codes 65820, 66174, 66982,66984, 66989, and 66991) as well as nine retinal procedure codes (67015, 67036, 67039, 67040, 67041, 67042, 67043, 67108, 67113) as potentially misvalued due to the lack of an established non-facility payment rate for the global 90-day procedures. Although CMS notes that a number of these codes were just evaluated in last year's MPFS final rule and no non-facility rate was established, the Agency still suggests that the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) consider re-surveying the nominated codes.

While ASCA recognizes CMS' desire for cost savings and is encouraged by the Agency's desire to consider policies that would encourage migration of services, especially surgical procedures, to lower-cost settings, we have serious concerns about the safe performance of these procedures in the physician office environment. These concerns were raised in 2015 when CMS considered assigning a non-facility Practice Expense (PE) Relative Value Unit (RVU) for cataract surgery and they remain valid today. CMS' top priority should be patient safety, and we join others in the ophthalmic surgery community that have deep concerns regarding the lack of a regulatory

[1] https://www.surgicalcare.org/2022/08/01/surgical-care-coalition-and-over-100-medical-organizations-urge-congress-to-stop-pending-medicare-cuts-that-will-impact-millions-of-seniors/

framework to ensure cataract patients would experience the same quality of care in an office as they currently do in hospital outpatient departments (HOPDs) and ASCs.

In the proposed rule, CMS notes that the nominated codes in question are "complex surgical eye procedures… [that] require dedicated spaces…such as a well-lighted and sterile surgical theater, specific eye surgery equipment and possibly clinical staff and other medical personnel trained to assist in these surgeries and the patient's immediate post-surgery recovery." ASCA agrees with this assessment; the modern cataract surgery operating room (OR) is a carefully designed environment that includes phacoemulsification machines with or without femtosecond laser devices, operating microscopes, delicate microsurgical instruments and sterilization systems that often have been tailored to the microsurgical setting.

A safe physical environment is comprehensively regulated in surgical sites through the hospital Conditions of Participation (CoP) and the ASC Conditions for Coverage (CfC). These regulations outline the requirements that hospitals and ASCs must satisfy to perform surgery, including infection control protocols, physical plant standards and staffing requirements. Attention is directed to emergent care needs, including proper patient monitoring equipment, medical gases (including oxygen), properly equipped crash carts (including defibrillators) and all necessary airway and medication needs. By contrast, office-based surgical centers are neither Medicare-certified nor state licensed, and office accrediting standards fall well short of the criteria necessary for an ASC or HOPD to achieve "deemed status" with Medicare from those same accrediting organizations. The under-regulated, non-standardized nature of care within the office-based environment is directly antithetical to CMS' aim of providing safe, high-quality care to its beneficiaries.

A recent survey by the Outpatient Ophthalmic Surgery Society (OOSS) offers a demographic profile of the typical Medicare cataract patient and supports the need for these procedures to be performed in a well-regulated surgical environment. OOSS reviewed more than 10,000 cataract cases from 217 ophthalmic ASCs and found that a majority of patients (57 percent) were over the age of 70. Further, OOSS found that 94 percent of patients presented with one of five comorbidity conditions (hypertension, cardiovascular disease, cerebrovascular disease, pulmonary disease, endocrine disease or cancer) and 90 percent of patients presented with at least two of the conditions.

ASCA does not support the establishment of a non-facility payment rate for the nominated codes in question.

Clinical Labor Pricing Updates

In the CY 2022 MPFS Final Rule, CMS finalized a proposal to update clinical labor pricing over a four-year period. ASCA had heard concerns from its specialty society partners about this

policy and submitted comments requesting that CMS reconsider. Pausing the update process would give the Agency time to address concerns from office-based specialty providers and allow for stabilization of physician reimbursement overall at a time when several other policies (cuts to the conversion factor, sequester, PAYGO, evaluation and management updates) are causing compounding reimbursement cuts.

As with many payment policies within Medicare, the issue seems to arise not from the clinical labor pricing update itself but rather from budget neutrality. United Specialists for Patient Access (USPA) estimated in 2021 that the actual impact of clinical labor pricing updates on reimbursement for many providers, including vascular surgeons, could be as significant as negative 11 percent. Reimbursement cuts of this magnitude will have implications on the availability of certain office-based specialty procedures to Medicare beneficiaries. There is also the downstream risk of making independent physician practices financially unstable and accelerating the trend of consolidation towards corporate entities and large health systems. For these reasons, ASCA again requests that CMS temporarily freeze the clinical labor pricing updates.

Global Surgical Packages

ASCs do not receive a technical payment for E/M services furnished under Medicare so 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 to an 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 and 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 (27–1) in April 2019 that full relative value unit (RVU) increases should be incorporated into global code packages[2]. In fact, the medical 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

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

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.

Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

ASCA has historically supported proposals that expand the ability of Medicare beneficiaries to receive colorectal cancer screening. ASCA supported Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116-260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests and its implementation in CY 2022 rulemaking. The CAA adopted a modified version of the Removing Barriers to Colorectal Cancer Screening Act, legislation that ASCA has supported for years, ensuring that if a scheduled screening colonoscopy becomes therapeutic, the Medicare beneficiary will not face a copayment.

ASCA supports the policies proposed in this year's MPFS proposed rule, namely aligning Medicare with recently updated recommendations by the United States Preventive Services Task Force (USPTF) that colorectal cancer screenings begin at age 45[3]. According to a USPFT analysis, lowering the screening age from 50 to 45 is estimated to result in both fewer colorectal cancer cases and deaths[4].

ASCA also supports the proposal to expand the definition of colorectal cancer (CRC) screening to include a screening colonoscopy following a positive stool-based test. Last year, ASCA requested that CMS consider this policy change and we are pleased to see the Agency enact a change that closes a loophole that has been penalizing beneficiaries with cost-sharing after a non-invasive stool-based test reveals abnormal results.

MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)

Transition from MIPS to MVPS

In previous comments, ASCA expressed appreciation for CMS' desire to create new approaches to move physicians to value-based payments. That said, 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 significant disruption caused by the COVID-19 pandemic, ASCA supported CMS' decision to delay implementation of the MIPS Value Pathways (MVP) framework. ASCA is supportive of the movement from traditional MIPS

[3] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening
[4] https://www.ncbi.nlm.nih.gov/books/NBK570833/

to the MVP framework. ASCA will defer comments on specific MVPs to the clinicians and specialty organizations with expertise to propose relevant measures and activities. However, ASCA does have general comments on the MVP Guiding Principles, the timeline of MVP implementation and clarifications on category reweighting for ASC-based clinicians.

In comments submitted to the CY 2021 MPFS Proposed Rule, ASCA expressed concern about the fifth MVP Guiding Principle, "MVPs should support the transition to digital quality measures." These concerns persist but are outlined more specifically later in these comments in response to the Advancing to Digital Quality Measurement Request for Information (RFI).

ASCA is pleased to see CMS propose a long, phased transition to move clinicians from traditional MIPS to mandatory MVP reporting. Given that traditional MIPS just reached maturity this year, it is appropriate to give clinicians maximum time to adjust to a new value-based payment structure. Even if the MVP framework is more advantageous to clinicians and patients than traditional MIPS reporting, it is still a new structure that will have significant implications on reimbursement. CMS should not hesitate to reassess the timeline after seeing data from the first year of MVP voluntary reporting in CY 2023.

ASCA strongly supports inclusion of ASC-based clinicians into the proposed "special status" codified definition. Clinicians who provide substantially all their services in ASCs should not be penalized for lack of access to health information technology, a view clearly shared by Congress given their inclusion of Section 16003 in the 21st Century Cures Act (exempts ASC-based clinician from penalties under Meaningful Use and subsequently Promoting Interoperability). CMS did not make it clear in the proposed rule whether ASC-based clinicians, as defined under the "special status" definition, will still have their Promoting Interoperability scores reweighted in the new MVP scoring methodology as is currently the case in traditional MIPS. CMS should make these reweights clearer in the final rule and future rules, as they do for small practices that face similar challenges accessing electronic health record technology.

Continuing to Advance to Digital Quality Measurement in Physician Quality Programs—Request for Information

While we support the goal of moving to all-digital quality measures (dQM) by 2025, we have serious concerns about the ability of ASC-based Medicare providers to submit such measures. While the Office of the National Coordinator of Health Information Technology (ONC) estimates that at least 86 percent of office-based physicians and 96 percent of acute care hospitals are currently using an EHR, we estimate that ***at most*** 50 percent of ASCs are using an EHR.[5] Additionally, many of those ASCs with EHRs are likely using inpatient products that are

[5] This estimate is based on a data from Definitive Healthcare, a 2021 survey of ASCA members and estimates from ASC-focused EHR vendors.

ill-fitted to the operational needs of an ASC. ASCs did not receive any federal funding for EHR adoption in the HITECH Act of 2009 and should not be penalized for slower adoption of health information technology (health IT).

Both Congress and CMS have recognized the lack of EHR availability in ASCs. There is no federal requirement for ASCs to implement an EHR, and ASC-based clinicians (those clinicians who furnish 75 percent or more of their covered services in an ASC) are exempt from the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS). While ASCs are subject to the policies finalized in the ONC's 21st Century Cures Act Final Rule, that rule contains several exceptions for sites of service with limited access to electronically stored health information. For example, ASCs are not responsible under Information Blocking for any health information not stored in electronic format.

Given the current lack of health IT in ASCs it is likely that a transition to EHR-based quality reporting would provide a considerable burden for many clinicians working primarily in ASCs. It would also provide an inaccurate picture of care quality provided in ASCs as compared to offices and hospitals that have had years to integrate health IT components into their clinical and administrative processes. ASCA has strong concerns about moving to dQMs by 2025. CMS should consider ASC stakeholder feedback before implementing policies that may penalize ASCs. ASCA has an ongoing working relationship with staff at ONC that can serve as a foundation for such stakeholder discussions.

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ASCA appreciates CMS' acknowledgement that all settings of care and practices of all sizes are essential to providing high quality, efficient care to Medicare beneficiaries. We value the Agency's willingness to listen to our concerns as we strive to support our members in providing 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