



October 2, 2020

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Baltimore, MD 21244-8016

RE: 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 (CMS-1734-P)

Dear Administrator Verma:

The American Society of Breast Surgeons (ASBrS) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) input on the calendar year (CY) 2020 Medicare Physician Fee Schedule and Quality Payment Program proposed rule. ASBrS, the primary leadership organization for surgeons who treat patients with breast cancer and benign breast diseases, is committed to continually improving the practice of breast surgery by serving as an advocate for those who seek excellence in the care of breast patients. Founded in 1995, the Society now has more than 3,000 members throughout the United States and in 35 countries around the world.

The comments below are intended to assist CMS in its policymaking with the goal of ensuring patient access to quality care provided by breast surgeons and appear in the order in which CMS addresses them in the proposed rule.

Medicare Physician Fee Schedule Payment Policies

Telehealth and Other Services Involving Communications Technology

ASBrS is appreciative of the steps the Agency has taken to ensure patient access to care in the unprecedented COVID-19 public health emergency (PHE) in which we find ourselves. We believe that the flexibilities implemented during the PHE regarding telehealth have helped to highlight the opportunities that new technology has brought in our abilities to reach patients remotely. At the same time, as CMS contemplates telehealth policy in a post-PHE environment, we request that the Agency move thoughtfully and cautiously to ensure that the quality of patient care is maintained while we increase access to services and that reimbursements accurately value the resources required for the services that have been furnished via telehealth.

As part of this cautious approach, ASBrS recommends that CMS:

- Continue to cover audio-only services for the PHE but going forward re-evaluate the payment levels associated with those services if CMS extends coverage
- Provide clarity on billing and documentation guidance for audio-only services if CMS extends coverage of these services
- For telehealth services generally, reconsider, in consultation with the CPT Editorial Panel and the AMA RUC, the valuation of services furnished via telehealth vs. in-person to ensure that resource and time assumptions are truly comparable if CMS continues to make comparable reimbursements for services regardless of whether the service is provided remotely

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic

1. *Inherent Complexity Add-On Code (GPC1X)*

As part of CY 2020 rulemaking, CMS finalized the creation of a new, single G-code for use to reflect increased complexity in an office and outpatient E/M visits with the following descriptor:

GPC1X (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*)

In discussing this already finalized policy, CMS restated its assertion that the Agency created the code because “*the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits.*” CMS also acknowledged, however, the feedback it continues to receive regarding lack of

clarity around the code and the utilization assumptions that CMS makes to determine expected spending in CY 2021 related to use of the code.

As we stated previously, we appreciate CMS' effort to ensure that payments accurately reflect the resources required to treat complex patients, particularly given the treatment decisions that breast cancer patients must navigate with their surgeons. At the same time, we are concerned that this newly conceived G-code continues to be in need of more thorough vetting. It is still unclear whether CMS' intended use of the code would truly result in the code being used in conjunction with most all office/outpatient visits without regard to resource use during the visit. Therefore, ***ASBrS requests that CMS delay implementation of GPC1X for increased complexity (or any similar code) and allow for the CPT Editorial Panel to review and define the code parameters and a subsequent AMA RUC review for appropriate valuation.*** We remain concerned that CMS has proceeded with implementation of this code even though its original rationale for implementation of this code has evaporated. In CY 2019 rulemaking when CMS first proposed the concept of an add-on code for inherently complex E/M visits, CMS stated that it was motivated to do so *"to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits."* Yet when CMS abandoned its proposal for the single payment rate for levels 2 through 5 visits, CMS still moved forward with the creation of an inherent complexity code, creating confusion about its use and CMS' rationale for implementation.

In the event CMS proceeds with implementation of the code on January 1, 2021, ***ASBrS urges CMS to provide additional guidance on use of the code and the documentation requirements needed to submit a claim using the code.*** In this year's proposed rule, CMS describes several clinical disciplines in which it envisions utilization of the code. Regarding use of the code in specialty care, CMS states,

HCPCS add-on code GPC1X could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals.

We believe that this description inherently aligns with the type of service and care that surgeons provide to breast cancer patients as they navigate their treatment options and recovery. For instance, breast surgeons possess specialized clinical skills to diagnose and treat patients with breast cancer. The role of the breast surgeon is to utilize his or her knowledge, skills, and experience to provide truly multi-disciplinary collaborative patient care including patient education, expectations, and shared decision-making. Most often this requires the breast surgeon to consult with a team of practitioners including radiologists, radiation oncologists, medical oncologists, genetic counselors, physical therapists, rehabilitation physicians, social workers, and patient education specialists to synthesize an ideal individualized treatment plan of care for each of our patients. However, it is unclear to our members whether there would be additional documentation requirements to submit a claim for this

code given that this is precisely the type of care that breast surgeons provide to their patients and would already be documented in the medical record.

2. *Revaluing Services Analogous to Office and Outpatient E/Ms: Global Services*

As part of CY 2021 rulemaking, CMS makes proposals to increase the values of several services that it cites as being closely tied to the values of the office and outpatient E/M visit codes. However, CMS yet again fails to adopt the RUC recommendations to make commensurate increases to global services for the office visits that are bundled into those 10- and 90-day packages. In numerous separate instances, CMS extends increases based on the office and outpatient E/M codes to end-stage renal disease monthly capitation payment services, transitional care management services, maternity care services, assessment and care planning for patients with cognitive impairment, initial preventive physical examination and initial and subsequent annual wellness visits, emergency department visits, behavioral healthcare services, and therapy evaluations. CMS even goes so far as to state that it is increasing the valuation of therapy evaluations based on the office and outpatient E/M increases even though the therapy evaluation codes “do not specifically include, were not valued to include, and were not necessarily valued relative to, office/outpatient E/M visits.” Yet CMS neglects its own precedent from 1997, 2007, and 2011 by failing to make the RUC-recommended increases to global services, even though those CPT codes have a direct relationship to office and outpatient E/M services.

For the following reasons, ***ASBrS again urges CMS to reverse course and implement the RUC recommendation to extend the value changes in office and outpatient E/M visits to global codes.*** First, we believe that CMS’ statements that its decision was based on concern over the number of post-op visits included in 10- and 90-day global codes is an inappropriate rationale to make an across-the-board arbitrary payment policy. In using this rationale, CMS inappropriately conflates two different issues: (1) the relativity of the resource-based relative value system; and (2) the services that are considered “typical” in a 10- and 90-day global code. CMS has mechanisms for revaluing potentially misvalued codes that are based on data and stakeholder input. Here, CMS has decided that it will forgo these mechanisms and instead abandon the relativity of the entire Medicare Physician Fee Schedule because of a belief that the agency keeps repeating, but fails to support with data that can accurately result in revaluation of the codes. Second, this is a drastic departure from past CMS policy when there has been a significant revaluation of the E/M code set. Recognizing the equivalent work in stand-alone office visits and visits included in 10- and 90-day globals, CMS has always ensured that increases in value for visits in the global period were made commensurately with increases to office and outpatient visits including in 1997 as part of the first Five-Year Review, in 2007 under the third Five-Year Review, and in 2011 when the elimination of consultation codes created budget neutrality adjustments to office visits. ***ASBrS urges CMS to follow its past policy to ensure that values of codes that are derivative of the wRVUs of the office and outpatient E/M are updated accordingly by adopting the RUC recommendation to extend the updates to 10- and 90-day globals.*** This is not only consistent with past CMS policy but would ensure that CMS creates consistency in its approach to increasing services related to office and outpatient E/Ms as it did in this year’s proposed rule for the services listed above.

In not making commensurate increases to globals, CMS states that it does not “make changes to the valuation of the 10- and 90-day global surgical packages to reflect changes made to values for the office/outpatient E/M visit codes while we continue to collect and analyze data on the number and level of office/outpatient E/M visits that are actually being performed as part of these services.” First, the Congressional mandate for CMS to collect data on global services was issued in 2015. The data collection and analysis has extended almost six years: a period of time that is unreasonable, particularly when the Agency has begun to use the ongoing analysis to justify payment cuts.

Second, this data collection exercise should not be used as an excuse for the agency not to update the value of services bundled into the global codes, since it is not the *value* of the services that CMS is gathering data on, but rather the *number* of services provided. Furthermore, it is disingenuous for the agency to assert that the almost six-year data collection means that increases to globals should be halted across the board, given that the agency recently agreed with and implemented AMA RUC recommendations for certain surveyed and revalued global services with packaged E/M visits. If there was concern about the accuracy of the number of visits, CMS could propose codes for the list of Potentially Misvalued Services. But for those codes that have undergone a recent survey and revaluation, there is no reasonable argument that CMS should not extend the office and outpatient E/M increases proportionally based on the office visits packaged into those global services. CMS’ decision to not extend the increases for even those services calls into question the overall rationale that CMS provides for extending these increases for some services that are related to office and outpatient E/Ms and not to global services that have packaged office visits in their values.

Valuation of Specific Codes for CY 2021

Modified Radical Mastectomy (CPT 19307). ASBrS thanks CMS for accepting the AMA RUC work RVU recommendation of 17.99 for CPT 19307 (*Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle*) as well as the recommendations for the associated direct PE inputs. We believe that the RUC process provides a thoughtful, data-driven vehicle for determining the appropriate values for services. While we do not always agree with the outcomes themselves, ASBrS strongly supports the process and is therefore supportive of the RUC as the most appropriate venue for determining the values of services in a manner that relies on the best-available data and that is intended to preserve the integrity and relativity of the entire system with the input of the clinicians providing the services being valued. Therefore, we again thank CMS for accepting the AMA RUC work RVU recommendation for CPT 19307 and strongly urge the Agency to follow its own precedent by accepting the RUC recommendations to extend the office and outpatient E/M wRVU increases to the office and outpatient visits included in 10- and 90-day globals.

Merit-Based Incentive Payment System (MIPS) Policies

Cost Performance Category

The ASBrS appreciates CMS's ongoing work with clinical stakeholders to develop more focused episode-based cost measures. ASBrS members served on the Wave 2 Oncologic Disease Management Clinical Subcommittee (CS), and one of our members led the smaller workgroup that produced the draft cost measure titled, "Lumpectomy, Partial Mastectomy, Simple Mastectomy." Despite our involvement, we continue to have concerns with aspects of the measure development process, including a rushed and inadequate field-testing period which prevented CMS from gathering meaningful input.

We continue to be concerned that only 3 of the 18 episode-based cost measures proposed for 2020 have been endorsed by the NQF. Of the 8 measures developed during Wave 1, only 3 were reviewed and eventually endorsed by the NQF Cost and Resource Use Committee. The other 5 did not pass muster with the Scientific Methods panel and were unable to move on for formal evaluation by the Cost Committee yet are currently being used in MIPS. Similarly, none of the Wave 2 measures, including the Lumpectomy, Partial Mastectomy, Simple Mastectomy measure, have yet been considered by the NQF. It is concerning that CMS is moving ahead with using these measures for accountability when the Measures Application Partnership (MAP) provided conditional support for use of these measures pending NQF endorsement. In light of these ongoing issues, **ASBrS does not support CMS's proposal to increase the weight of the Cost Category for the 2021 performance year from 15% to 20%, while simultaneously decreasing the weight of the Quality category.** CMS should maintain the current weight of the Cost category for 2020.

CMS also should remain flexible with this category for the next few years as it continues to further refine and test existing cost measures and conducts additional education and outreach so that clinicians can better understand how to use the data produced by these measures. Clinicians should only be held accountable for costs that they can directly control. If no such measures exist, or do not produce a sufficient number of cases, then the cost category should be re-weighted to 0%.

We also strongly urge CMS to continue to make improvements to the field-testing period, such as extending the timeline to access the reports and provide feedback. While we appreciate that Acumen recently made some updates to improve the field-testing process, such as extending the review period to 5 weeks for Wave 3 compared to 4 weeks for previous waves, we still believe this timeframe is too rushed to ensure meaningful feedback from working clinicians, particularly at a time when clinicians have limited bandwidth given the COVID-19 pandemic. Finally, we recommend that CMS conduct better and more frequent education and outreach to ensure clinicians understand how to interpret the measure specifications and feedback report data.

Quality Performance Category: Topped Out Quality Measures

The ASBrS continues to be very concerned with CMS's topped out measure policies, including achievement point caps and eventual removal from the program. While we recognize the need to focus on areas where gaps in care persist, we are concerned that:

- The accuracy of topped out measure determinations is challenged by shifting MIPS requirements from year to year.
- Topped out measures may reflect performance of only a portion of clinicians who self-select the measure because of expected high performance rather than true performance across all eligible clinicians.
- Removal of certain topped out measures could lead to unintended consequences if declining performance becomes difficult to track over time.

We urge CMS to conduct more thorough analyses of factors potentially influencing topped out performance to ensure more accurate determinations. For example, CMS should consider factors such as whether performance varies by group versus individual reporting, by practice setting, by geography, by volume of cases, or by physician experience with quality reporting. Topped out measure determinations must also account for the importance of the measure, as well as consider the number of other measures available to a particular specialty. We thank CMS for ultimately maintaining measure #264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer in both the 2020 and 2021 MIPS performance year despite topped out performance. This demonstrates CMS' appreciation for the need to ensure that specialties have a sufficient number of relevant measures in the program. ***At the same time, we would like to see more thorough and transparent analyses by CMS when making determinations about topped out measures.***

We also remind CMS that it is costly and time-consuming for specialty societies to develop new measures to replace topped out measures—especially smaller specialties such as ours. These challenges are now compounded by financial strains and clinical care disruptions related to the COVID-19 PHE. For example, professional society budgets are strained, making measure development a lower priority. Additionally, abnormal clinical service volumes make it difficult to adequately test measures at a level and in a timeframe required by CMS. ***We request that CMS take these ongoing challenges into account when considering topped out measures for removal over the next few years.***

ASBrS appreciates the opportunity to provide input on the provisions contained in the proposed rule. We look forward to working with you to ensure that Medicare policies support patient-centered care and continue to provide the appropriate incentives to drive quality improvement. If you have any questions, please contact Sharon Grutman, Manager, Advocacy, Communications, & Quality Initiatives at sgrutman@breastsurgeons.org.

Sincerely,



Jill Dietz, MD

President