AMERICAN SOCIETY OF PLASTIC SURGEONS®
THE PLASTIC SURGERY FOUNDATION™

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September 10, 2018

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1693-P
Mail Stop C4-26-05
7500 Security Blvd,
Baltimore, MD 21244-1850

Via Electronic Submission: http://www.regulations.gov

Re: File Code-CMS-1693-P; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Saving Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule for the Physician Fee Schedule for CY 2019, published in the July 27, 2018 *Federal Register*.

ASPS is the largest association of plastic surgeons in the world, representing more than 7,000 members and 94 percent of all American Board of Plastic Surgery board-certified plastic surgeons in the United States. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and cancer reconstruction. ASPS promotes the highest quality patient care, professional and ethical standards, and supports education, research, and public service activities of plastic surgeons.

Outlined below are several key areas of concern in relation to this proposed rule.

Evaluation and Management (E&M) Documentation Guidelines

In this proposed rule, the Agency has outlined several changes to E&M documentation, with a focus on New and Established office/outpatient visit codes 99201-99215. The primary goal of the proposal is to reduce administrative burden so that practitioners can instead focus on the patient. By allowing providers to choose, as an alternative to the 1995 or 1997 framework for documentation, to use either medical decision making or time as a basis to determine the appropriate level of E&M visit, the Agency hopes to reduce administrative burdens.

ASPS appreciates the work the Agency has undertaken to address the unwieldly documentation guidelines. Allowing doctors to spend more time with patients by simplifying documentation is laudable; however, we are concerned with the narrow focus of this proposal to include only office/outpatient

visits and not other E/M visits; the aggressive timeline the Agency has identified for implementation of these changes; and the estimates about how much time this will save clinicians given the quick proposed implementation and the likelihood that other payers will not so quickly adopt similar proposals leading to having to document differently for similar visits that get submitted to different payers.

Physicians will need more than the two months between the final rule and proposed implementation date to be educated on and adapt to the changes in documentation for some, but not all services they provide. We also fear that the proposed documentation changes, if implemented without further analysis of the unintended consequences, may result in increased fodder for spurious malpractice suits.

Many plastic surgeons remain inexperienced in the use of electronic medical records (EMR); however, we are concerned that the incredibly short timeline proposed will not be sufficient for vendors to modify or design EMR technology to ensure correct capture of a limited range of E&M services. Additionally, we are concerned that varying the methods of potential clinical documentation between providers (i.e. guidelines AND medical decision making AND time) may limit the kind of information available in, and for sharing amongst EMR systems further hampering efforts to achieve interoperability.

We would be remiss to not also point out that non-Medicare payers will need adequate time to consider and implement, often through contracting, similar policy on E&M documentation. Barring that, physicians may be forced to alter data collection and documentation, based on payer. Alternatively, physicians may simply continue to document E/M visits as they have had to in the past, resulting in no burden reduction at all.

Respectfully, we urge CMS to delay this proposal, and spend the next year working with the physician community to ensure any changes to the documentation guidelines will improve rather than further complicate the data collection processes used by the typical medical practice.

Simplifying Payment Amounts

The Agency has indicated the most important distinctions between the kinds of visits furnished to Medicare beneficiaries are not well reflected by the current E&M visit coding. To rectify this, a single payment rate for level 2 through level 5 E&M visits has been proposed. A single set of Relative Value Units (RVUs) (one for new patients and one for established patients) has also been proposed. In addition, CMS has proposed add-on "G" codes to account for additional resources to address complexities inherent to different types of care.

While we appreciate the concern that payments for services should be appropriate, we are concerned that any mandate to report one or more "G" codes to signal the use of additional resources will create a significant amount of administrative burden for practices; immeasurably so on the small practice.

CMS should consider that many physicians that are employed by hospitals and health systems have RVU based contracts and a proposal that consolidates the RVU levels for E/M visits into a single RVU rate could have potential widespread, unexpected consequences, some of which will be financially positive, some of which will be financially negative, but none of which will be based on an accurate assessment of the resources involved with delivering care. While the idea of simplifying the coding process is quite appealing, the lack of input the Agency sought from the AMA's Relative Value Update Committee (RUC) panel as to this proposal is troubling. As the only multispecialty workgroup dedicated to identifying the resources required to provide physician services, the RUC would seem to be the logical starting point for

any discussion about changes to RVUs. We are aware, as attendees at the AMA RUC meetings, that a workgroup has been formed to offer alternatives to the Agency's proposed coding structure for New and Established patients. As such, we ask that the Agency delay implementation of their proposal and instead work with the AMA to identify and validate alternative payment and documentation processes that might be better suited to meet the goals of reducing administrative burdens, decreasing the need for unnecessary documentation and ensuring physicians can deliver high quality care without fear of increased audit and liability risk.

Multiple Same-Day Service Payment Reduction

CMS has proposed to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable visit. It was only based on subsequent conversations that the physician community learned that the CMS plan for implementing this policy was to add the office/outpatient E/M codes to the Multiple Procedure Payment Reduction (MPPR) for surgery list. CMS did not state in the text of the rule that this was how it planned to implement the policy and only mentioned "modifier 25" and "0-day" globals, which created confusion about how to respond to what CMS has proposed. Because of the lack of clarity in the rule on how CMS would implement this policy, we believe that CMS cannot finalize the proposal.

In addition, from a policy standpoint, we believe that CMS should abandon this proposal. If CMS adds the office/outpatient E/M visits to the MPPR for surgery list, it will inevitably include the processing of a reduction on claims where the E/M is billed with the use of modifier 25 (and in some same day cases, modifier 57). According to Current Procedural Terminology (CPT) guidelines, modifier 25 is used to indicate a **significant, separately identifiable, and medically necessary E&M service** provided on the same day as a procedure. Providing medically necessary, separate, and distinct services on the same date of service allows physicians to provide effective and high-quality care. This can save patients a return visit and improve outcomes. The CPT guidelines specifically state that separate, distinct services should be reimbursed appropriately and in accordance with established coding conventions and guidelines, whether used on the same date or different dates

As such, we are puzzled to see the Agency has proposed to introduce payment reductions for the lesser service when both an E&M and procedure are billed the same day. Although CMS has indicated it believes this proposal is an extension of the MPPR for surgery policy already in place, we respectfully remind the Agency that the existing MPPR for surgery policy was crafted recognizing efficiencies/overlap in work can be gained when two or more ***procedures*** are performed during the same encounter.

Furthermore, we remind the Agency that at AMA meetings over the past several years, CMS and the medical community have worked to remove the overlap in the physician work and practice expense for procedures commonly performed during the same encounter as an office visit. It is our belief that any overlap has already been accounted for in the valuation of procedures performed in the office setting. By introducing additional reductions in payments, the Agency appears to be unjustly reducing fees for physicians committed to providing timely, quality care.

As such, we respectfully urge CMS to not implement this proposal and instead, work with specialty societies and the AMA RUC to continue the work being done to ensure the accuracy of the value of physician services, including E&M services performed the same day as a procedure.

Updates on Global Surgery Data Collection

Section 523 of MACRA required CMS to implement a process to collect data on the number and level of postoperative visits and use these data to assess the accuracy of global surgical package valuation. Since July 1, 2017, CMS has required practitioners in groups with 10 or more practitioners in nine states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island) to use the no-pay CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package), to indicate that an E&M service was performed during a postoperative period for reason(s) related to the any of the 293 procedures the Agency identified as high utilization or high dollar.

In this proposed rule, the Agency notes that compliance with the reporting for the first six months has been varied, with noticeable trends by specialty, type of procedure and by state, and seeks suggestion as to how to encourage reporting to ensure validity of the data without imposing undue burden.

ASPS and other medical specialty societies invested significant time and effort into educating our members on the need to report post-operative visits. We have created web pages, held educational sessions, and sent reminder notices based on our understanding of the mandate. Yet, by our count, CMS held just one National Provider call (in April 2017) to provide education to physicians and a quick review of Medicare Administrative Contractor websites would seem to indicate they have not provided much in the way of education or training on this issue either.

Without a concentrated educational effort by all parties, any data collected in the first six months is suspect. It is not reasonable for CMS to rely on it as an indication of a lack of furnished visits, but rather, it instead should be viewed as a policy in need of additional education and training. ASPS has serious reservations that the data collected throughout CY 2019 could even be used to set policy, unless the Agency significantly increases outreach and training on the need for accurate reporting of post-operative visits, and even if improvements were made, the data is only shedding light on frequency not level of visit.

At a minimum, we respectfully request CMS conduct a more in-depth analysis of the dataset after an additional six months of time has elapsed.

Updates to the Quality Payment Program

ASPS appreciates the work CMS has done to address concerns previously raised about the functionality of the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models. The Agency has shared many new options in this proposed rule, and we respectfully offer the following observations.

Quality Component of MIPS

Tiering Quality Measures

CMS is proposing to change the scoring of the quality performance category in the future and put forward several options in this proposed rule. One suggestion is a tiered approach based on the "value" of a measure (gold, silver, bronze). Highest tier ("gold") measures would include outcome measures, composite measures, or measures that address high priority areas. Middle tier ("silver") measures

would include process measures that are directly related to outcomes and have a demonstrated performance gap. Lowest tier ("bronze") would include standard of care or topped out process measures. Points for achievement would be rewarded based on tier; the higher the tier, the more points can be rewarded. Additionally, clinicians that choose top-tier measures would be required to submit fewer measures. Restrictions could potentially be put on how many low tier measures that could be reported, or requirements added for a certain number of high tier measures to be reported.

ASPS agrees with CMS that not all measures are created equal. We have previously pointed out that current methods for profiling physicians based on the scoring of the quality component of MIPS may produce misleading results, and that there are significant differences between measures that are linked to outcomes and low bar process measures. However, ASPS believes there still is a place for high quality, evidence-based process measures. It is not always feasible to create an outcome measure - some facets of care are just not in the control of the physician and improving processes still can improve care. Although it does seem like the proposed system would add extra complexity to an already complicated system, and might lead to multiple issues if certain specialties never have any "gold" measures and thus, remain at an automatic scoring disadvantage, we applaud the Agency's recognition that higher bar process measures do matter.

Additionally, measures with no case mix adjustment, or those restricted to narrow subsets of the population may continue to produce invalid assumptions about the generalizability of the quality of care provided. As such, we encourage CMS to authenticate any tiering system (e.g., how and where the cut points are made), ensuring the final product is statistically validated and does not continue to misclassify the quality of any given measure or the provider who works hard to report it.

Finding relevant measures is especially challenging for the surgical specialties. Most measures available are aimed at primary care physicians and/or cardiologists. Even measures that do affect surgical outcomes, like the tobacco screening measure, are extremely difficult for surgeons to report with the 2-visit requirement and global billing periods.

Benchmarking

Benchmarking is another challenging issue for new measures in which there is limited member uptake. The minimum sample size of 20 physicians reporting 20 cases has been difficult to achieve for rarer procedures, especially when our MIPS eligible members are those in small practices, not large academic institutions.

We ask for more flexibility in minimum reporting cases or perhaps 10 physicians and 10 cases as the minimum for small practices as well as more flexibility on the creation of benchmarks which may take more than one year for specialists with limited numbers of quality measures. ASPS also advocates for considering data from non-MIPS eligible clinicians in the determination of benchmarks when QCDRs can provide such data.

Topped Out Measures

Beginning with the 2019 performance period, CMS is proposing to begin incrementally removing process measures from the program. We remind the Agency that there are data to show that when we stop measuring something, performance decreases and as such, suggest the Agency investigate creation of a "legacy" measure set - akin to the surgical checklist, where there could be a composite set of formerly topped out measures (e.g. VTE prophylaxis, prophylactic antibiotics (giving and discontinuing). We also suggest that the Agency consider being more flexibile in evaluating measures for surgeons and in creating benchmarks over longer periods of time to encourage surgeons to participate in quality reporting.

Also, CMS has not provided data on topped-out measures with a breakdown by specialty. If each nearly topped out measure could be looked at across specialties to know whether a certain specialty actually performs much lower on a measure than others, perhaps there would be more value in retaining the measures for certain specialties with new benchmarks, or allowing specific QCDRs to re-tool the measures for their own use if they are an under-performing specialty.

Improvement Activities (IA) Component of MIPS

Beginning with the 2019 performance period, CMS is proposing six (6) new improvement activities; proposing to modify five (5) existing activities and to remove one (1) existing activity for the CY 2019 performance period and future years.

The majority of IA activities are targeted to primary care which makes it very difficult for surgeons to participate. Few of the newly proposed activities are relevant to our specialty. It is difficult for smaller societies to design and propose these, and perhaps larger organizations including PCPI and the SQA could work together to create these for surgeons. However, the deadline for new activities is extremely early in the year, which presents a hardship.

Promoting Interoperability (PI)

CMS has continued to provide incentives for the adoption, implementation, upgrade and meaningful use of Certified Electronic Health Record Technology (CEHRT) in the implementation of MIPS. The Agency's willingness to modify multiple requirements under the Medicaid Meaningful Use Measures is welcomed; as is the desire to align the requirements of the Promoting Interoperability performance category with the requirements of the Medicare Promoting Interoperability Program for eligible hospitals. However, we note with some dismay that the Agency is unable to modify the certification requirements of an EHR for CY 2019.

While the number of new and unique 2014 edition products may be declining, there remain a significant number of legacy systems in use. As we have shared in previous comment letters, the costs associated with upgrading to the 2015 edition of CEHRT can be prohibitive for many solo providers, even though the administrative burdens associated with an upgrade may be lessened. Recognizing that 40% of physicians are not affiliated with a hospital, or have other access to 2015 editions of CEHRT, we respectfully request the Agency use their considerable influence with Congress to ensure hardship

exemptions for performance year 2019 include a carve-out for those clinicians without access to 2015 CEHRT.
Of note, during the previous reporting year nearly all of the ASPS MIPS eligible surgeons were in practices of 15 or fewer clinicians, exempting them from PI reporting. We respectfully ask CMS to reconsider the proposal of reweighting the PI category into Quality instead of the final score as was the case in Year 2. Due to the 45% weighting of the Quality category, this change in how the small practice bonus is applied only adds 1.35 points to the final score instead of 3 points, a 55% reduction in hardship exemption relief. This means small practices will be burdened with more time spent reporting Quality data than their peers, who do use electronic health systems, to make up for their inability to achieve points through PI. This undermines the Agency's good intention to promote "Patients over Paperwork".

Additionally, we would encourage CMS to work with the Office of the National Coordinator to ensure any open application programming interfaces (APIs) recognize and include surgical information. Although 2015 Edition CEHRT offers enhanced functionalities, such as APIs, there are currently very few applications that are relevant to surgical specialists, which prevents them from really taking advantage of these improved functionalities and limits the incentive to invest in system upgrades.

Scoring Methodology

CMS indicates they have heard from many stakeholders that the current scoring methodology under MIPS is complicated and difficult to understand, but appears to link the confusion over scoring to the multiple measures a clinician might choose from within a performance score. Surgical specialties such as ours support CMS maintaining a diverse set of measures, which provide our members with more relevant reporting options and allow them to engage in the program more meaningfully. For the 2021 MIPS payment year, the Agency intends to build on the scoring methodology finalized for the transition years, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. This "simpler, more flexible, less burdensome structure," will allow MIPS eligible clinicians to put their focus back on patients.

Yet, we note with frustration that the proposed rule devotes over 100 pages to describing the scoring methodology for MIPS participation in 2019. For physicians in small practices, who are often reluctant to purchase electronic health systems and rely instead on manual data entry, successful participation in the MIPS program continues to be an impossible reach. The Agency also needs to study and better understand the difference between manual and electronic benchmarks, which impacts comparative quality trending.

CMS Licensing Agreements

Beginning in CY 2019, CMS indicates QCDRs submitting measures for MIPS will have to enter into a licensing agreement to allow for the use (without modification) of any submitted and approved measures at no cost to other QCDRs.

ASPS strongly opposes the proposal to require QCDR licensing agreements with CMS to allow open access for other QCDRs to submit data on proprietary QCDR measures for purposes of MIPS as a condition of the 2019 QCDR application. Currently medical societies have the responsibility to create, license, and update their quality measures that involve the expertise and limited time of their physician members and costly resources. Shared measures between societies are created using stewardship

processes to protect the integrity of the measures, often including legally binding use of Memoranda of Understanding. ASPS believes CMS does not have the authority to allow open sharing of measures with or without modification outside of these agreements especially when there is no oversight of the e-measure specification by software vendors. We respectfully ask that CMS allow medical societies to continue to protect the integrity and intellectual property of their quality measures and their specifications. We also ask CMS commit to monitor vendors in their creation of electronic measure specifications. We strongly oppose the requirement to attest to this new regulation as a condition of submitting our QCDR application, before the final rule is even released. At a minimum, this regulation should be deferred to the 2022 payment year (2020 QCDR application) and thorough vetting of the new process with input from all QCDRs over the course of the next year.

Quality Reporting Deadline Changes

The CMS mandate to have QCDRs live on January 1 creates a challenge for physician professional membership organizations and the vendors they work with since CMS doesn't approve MIPS measure specifications until Dec 27, giving less than one week between release and the expectation to be able to accept data. On a recent QCDR call, CMS staff stated that the measures did not have to be finalized, but the QCDR needed to be able to accept data. It is our belief that CMS is not fully aware of how manual data are captured in a QCDR. For ASPS, as well as several other societies with whom we spoke, the only data collected relate directly to measure specific questions. We would be more than willing to demonstrate this process, which might help CMS understand the difficulties in operationalizing this requirement. We ask either that MIPS measure specifications are approved more quickly for the upcoming year or that this date be moved for live reporting until March 1.

Eligibility timelines are also a challenge. The fact that a clinician might be eligible from Jan 1-Sept 30 and then find out Oct 1 that they are no longer eligible is frustrating. This is less of an issue in 2019 if the opt-in proposal is finalized.

There has been discussion on changing the QCDR self-nomination period from September 1-November 1 to July 1-September 1 with a January 1 data collection start, essentially moving the timeline back two months, which will allow for additional review time and discussion of measures between CMS and QCDRs. This creates a burden for measure developers that have multi-year timelines and processes for new measure development based on the November 1 submission date. This could delay measures currently in production for up to one year. It also does not give enough time to gather data on provisional measures, especially for new enrollees.

Advanced Alternative Payment Models (APMs)

ASPS notes with disappointment the lack of Advanced APMs in the market that focus on reconstructive procedures. The lack of transparency on the number of plastic surgeons enrolled in Advanced APMs, combined with cost-prohibitive access to claims data continues to limit the creation of and participation in this option of the QPP.

Regulatory Impact

Almost half of all plastic surgeons work in single or small group practices. We are pleased to see that the Agency recognizes, as we do, that these providers are small businesses and can be significantly impacted by fluctuations in reimbursement for services they provide. We are cautiously optimistic that the 1% increase in reimbursement the Agency predicts for plastic surgeons in CY 2019 will in fact be recognized.

Conclusion

ASPS appreciates the opportunity to offer these comments, and we look forward to working with CMS to ensure reimbursement is fair and adequate. Should you have any questions about our comments, please contact Catherine French, ASPS Director of Health Policy, at cfrench@plasticsurgery.org or at (847)981.5401.

Sincerely,

Jeffrey Janis, MD
President, American Society of Plastic Surgeons

cc: Lynn Jeffers, MD – ASPS Board Vice President of Health Policy & Advocacy
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