AMERICAN SOCIETY OF PLASTIC SURGEONS®
THE PLASTIC SURGERY FOUNDATION™

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June 27, 2016

Andrew Slavitt – Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Hubert H. Humphrey Building, Room 445-6
Washington, DC 20201

Submitted Electronicaly Via: http://www.regulations.gov

Re: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule (CMS-5517-P)

Dear Acting Administrator Slavitt:

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to provide comments on *the Centers for Medicare and Medicaid Services (CMS) Proposed Rule on Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models* published in the May 9, 2016 *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. ASPS promotes the highest quality patient care, professional and ethical standards, and supports education, research, and public service activities of plastic surgeons.

Rescinding the sustainable growth rate was an outstanding achievement. While we applaud the work of the Agency to stabilize fee updates through 2019, we are deeply invested in ensuring any value-over-volume reimbursement schematic will not create barriers to delivering necessary care for plastic surgeons enrolled in the Medicare program. Outlined below are several key areas of concern in relation to this proposed rule.

Quality Payment Program (QPP) – General Concerns

The Agency has proposed a January 1, 2017 start date for the QPP. ASPS believes this timeline to be too aggressive, especially considering the amount of education and software updates that will be required for successful participation. We respectfully ask that CMS move forward with a performance year of 90 days in year one, making reporting beyond 90 days ***optional***, gradually increasing reporting requirements to 180 days by year three and to 365 days by year five. We base this request in part on the results of a recently survey of the Healthcare Information and Management Systems Society (HIMSS)

members, where only 3% of the respondents indicated their organization is highly prepared to make the transition to QPP.[1]

Additionally, we believe the Agency's regulatory impact analysis is incorrectly low. Based on member feedback, we believe the impact on small, solo providers is grossly understated, which could create unintended consequences for Medicare beneficiaries. As stewards of a program developed to ensure patients with the lowest incomes and in the most remote areas have access to care, we respectfully remind the Agency that every day, 10,000 US citizens become Medicare-eligible. By 2030, one out of every five people will be over the age of 65. ASPS is concerned that patients in rural areas, especially those requiring procedures, will experience access issues when new graduates as well as solo practitioners determine an urban, salaried employment arrangement is the only way to escape increasing administrative burdens and rising overhead costs necessary to comply with Medicare reimbursement programs.

ASPS is extremely disappointed to learn that CMS plans to delay the implementation of "virtual groups" as a reporting option for clinicians. Members of such a group, while located in different geographic areas, could join efforts and resources to ensure successful participation in the QPP. While we recognize the Agency has a desire to "get it right" and is requesting additional time to ensure technological infrastructure is in place prior to launch of such a program, we believe that by adjusting the QPP reporting period, the Agency would not only provide clinicians with the necessary additional time to prepare, but could itself ensure rulemaking processes are incorporated into the virtual reporting system and operationalized accordingly. We believe a July 1 start date for virtual groups is within reach for the Agency, and as such, respectfully request CMS to reconsider their stance on the start date for virtual group reporting as well as the deadline for registering as a virtual group in year one of the MIPs program.

Finally, one of our most longstanding frustrations is the ongoing withhold of funding for measure development. As the Agency is well aware, measure development takes significant time and significant resources. As the Agency is also aware, there are critical measure gaps, particularly for small specialty groups like plastic surgery. ASPS is, along with the rest of organized medicine, gravely concerned that CMS has ignored the drumbeat of calls to focus first on measure development. You simply cannot build a program whose primary thrust is fostering and rewarding quality if you do not have the means to measure.

We are calling, once again, on CMS to release the funding allocated under Section 102 of MACRA. Develop criteria for which entities will be eligible for the funds, ensure that the measure development expertise of specialty societies is recognized in those criteria, and release the funds. These funds could be being used right now to gain ground in an essential area where we are desperately behind. While the promise of technical assistance from CMS is a start, ASPS is concerned that disbursement of measure development funding to state agencies will be problematic, as they will be unable to develop measures of value to all clinicians, regardless of specialty.

Instead, ASPS would urge the Agency to begin allocating funds directly to physician-led organizations and their clinical experts who are best suited to develop measures useful to their specific members. In addition, clinical data registry activities and the development of specialty-focused alternative payment models are best developed by a specialty society. Thus far, and in part due to a lack of information from CMS, we are unsure the Agency appreciates the gravity of the change the QPP system will have to specialty providers. MACRA represents a significant transformation in the Medicare program, and we

respectfully remind the Agency that in order for the QPP to succeed, it is critical to not incorporate known flaws from previous performance measurement systems into this new model.

Exclusions from MIPS

CMS proposes that a new Medicare-enrolled eligible clinician—defined as a professional who first becomes a Medicare-enrolled eligible clinician within the PECOS during the performance period for a year and who has not previously submitted claims as a Medicare-enrolled eligible clinician either as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier—not be treated as a MIPS eligible clinician until the subsequent year and the performance period for such subsequent year.

Furthermore, CMS proposes that the definition of a MIPS eligible clinician does not include MIPS eligible clinicians who are below the low-volume threshold selected by the Secretary for a given year, and is proposing to define those who do not exceed the low-volume threshold as an individual MIPS eligible clinician or group who, during the performance period, has Medicare billing charges less than or equal to $10,000 *and* provides care for 100 or fewer Part B-enrolled Medicare beneficiaries.

While the wording in the proposed rule for this section of the rule used double negatives on several occasions, it appears that unless the Agency intends to evaluate each clinician individually, the above guidelines will almost certainly exclude clinicians participating as a Group. This is especially problematic for plastic surgeon groups, who may treat only one Medicare eligible patient in a year, but will most certainly exceed the $10,000 in billed fees for reconstructive care. Should the Agency continue to assert that a provider must see less than 100 patients *and* bill less than a specific dollar amount of billed services to be excluded under the low volume threshold, we would ask that a value that does not unfairly exclude surgeons be contemplated by the Agency. We recommend raising the fees component to $30,000. Specifically, we request that a MIPS eligible clinician would be excluded from participation in the MIPS if an individual MIPS eligible clinician has Medicare billing charges less than or equal to $30,000 and provides care for 100 or fewer Part B-enrolled Medicare beneficiaries. For a group, we recommend that CMS multiply the suggested exclusion based on the number of eligible clinicians in a group. For example, if a group of two eligible clinicians would be excluded from participation in the MIPS the group has Medicare billing charges less than or equal to $60,000 (2 x $30,000) and provide care for 200 (2 x 100) or fewer Part B-enrolled Medicare beneficiaries).

Specific Concerns - Merit-based Incentive Payment System (MIPS)

The QPP consists of two tracks – The Merit-based Incentive System (MIPS) and Alternative Payment Models (APMs). MIPS was introduced as a "fresh-start and streamlined" approach to measuring quality. ASPS was hopeful that improvements would be incorporated into this new quality reporting program, allowing more solo-practitioners to participate effectively. We were disappointed to learn that, under the proposed rule, the Agency is proposing four components of MIPS and is viewing each as a separate program, requiring distinct measures, scoring methodologies, and requirements for each component. As written, we believe this proposal will create significant complexity in the program as a whole, add to confusion and, ultimately, minimize participation by clinicians who will begin to opt out of the Medicare program altogether, rather than be penalized for their lack of understanding and training. Without significant education by the Agency and specialty societies, we fear the MIPS program will not be able to

deliver on its goal of improving quality and lowering costs. Outlined below are several key areas of concern with the MIPS program as proposed.

Quality Performance Component of MIPS

ASPS was pleased to learn that the Agency has proposed short-term solutions to address "gaps" in the quality performance component of MIPS and was especially grateful to learn that CMS recognized that there are limited Plastic Surgery-specific measures available under PQRS and for proposed for inclusion under MIPS. We strongly support CMS' proposal to allow those Eligible Clinicians reporting under specialty measures to report on less than the proposed minimum of 6 measures. However, we request that CMS provide additional details on the scoring methodology for Eligible Clinicians reporting on fewer than 6 measures under the specialty measure set proposals and ensure that in those scenarios, Eligible Clinicians are still eligible for the maximum number of potential points under the Quality performance category.

In addition, because the proposed rule provided no information on how CMS will engage specialty providers in the creation of additional measures of value to specialties, we request further information from the Agency on how ASPS and other specialties might be able to work together to brainstorm, finance, and develop additional quality metrics. Ideally, this information would be shared prior to publication of the final rule.

We would be remiss however, to not remind the Agency that it has been a challenge for specialty providers to meet the 50% reporting threshold required under the current PQRS program, and as such, are concerned that the proposed higher thresholds, which the Agency proposes to set at 80 to 90%, depending on the reporting mechanism, will continue be difficult to reach. As such, we respectfully request the Agency share more information on how it arrived at the proposed thresholds, provide a statistical rationale for proposing a substantial increase in administrative burden, and what assistance it can provide to ensure those thresholds will not limit clinicians from achieving the necessary data quotients for each submission mechanism.

Additionally, while we appreciate the proposal to remove "case minimums," without additional information on the process the Agency intends to use to incorporate new measures into the quality category, it is difficult for ASPS to evaluate the long-term negative impact MIPS will have for plastic surgeons. We would encourage the Agency to share more information on the process it intends to use to evaluate newly proposed measures and during their analysis, to focus less on process oriented measures and instead strive to develop measures to validate optimal outcomes.

With regards to "topped-out" measures, ASPS believes there is value in retaining the measures to assess long term performance and appreciates the Agency's proposal to maintain certain topped-out measures. However, while some measures may seem topped out, we do not believe CMS should assign a lower weight to these measures as we believe there is still significant value in these measures. Improvements in care may be quickly lost if even a small gap widens. As an example, a gap of even 2

percent could significantly impact a large number of Medicare beneficiaries on a measure such as pre-operative care antibiotics. Without long term tracking, clinician and patient behaviors may change and it may become impossible to know when or how gaps in care have widened. By limiting the maximum number of points a clinician may earn for measures the Agency has identified as "topped-out," ASPS is concerned this proposal will disincentive participation by clinicians with a limited number of measures to choose from.

We are also concerned about CMS' arbitrary decision to maintain some topped out measures and to remove others. For example, CMS proposes to remove PQRS 22: Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures) rather than maintain it and subject it to its proposed limited scoring methodology. While we do not support the modified scoring methodology that CMS proposes to adopt at this time, we do believe that CMS should apply a consistent policy of retaining ALL topped out measures, at least in the initial years of MIPS.

Lastly, ASPS is concerned about benchmarks based on legacy data, including historic PQRS participation. As the Agency is well aware, many specialties did not successfully participate in the early years of the PQRS program. Our review of the MACRA statute indicates that it does not mandate a two-year look back, and as such, we believe the Agency may inadvertently penalize participants in the MIPS program by proposing to base benchmarks solely on past performance of providers other than those we would consider specialty-specific peers.

Resource Use Performance Component of MIPS

The Agency's proposal to derive resource use scores based on claims information appears promising at first glance. However, the lack of details on the methodology it will use could be problematic, especially if clinicians are penalized for situations over which they have no control. We remind the Agency that phone calls and email used to ensure patients receive all necessary services are not compensated under the Medicare program, and as such, the totality of care coordination may not be adequately reflected on claims. Additionally, comparing measures for subspecialties with their "peers" in the broader specialty may negatively impact the subspecialist, who often will treat the more complicated patients. Removing comparisons by specialty will further complicate scoring, as this does not "level the playing field," but instead attempts to compare care for unique and complicated conditions to care for routine services. Without more information on CMS strategy for the implementation of patient relationship codes and for attributing costs accounted for under episodes of care, we are unable to accurately assess the impact this resource use proposal will have on small and solo providers.

Because of the limited number of condition or procedure episodes that have been created, and the proposal to wait until November 2016 to post current and future measures for this component of the MIPS program, ASPS respectfully requests that at a minimum, the Agency set the Resource Use score at less than 10% of the total score in the first years of the MIPS program. Additionally, we urge the Agency to consider an incremental or phased-in approach for the Resource Use category, staging the implementation across several years based on group size given the increased difficulty of assigning costs to smaller practices or solo practitioners. Therefore, we oppose CMS' proposal to increase the weight of the resource use performance category to 15 percent of the CPS for the 2020 MIPS payment adjustment. Ideally, the Agency would implement this component of MIPS similar to the process used

under the Value-Based Modifier program and began analyzing resources in groups of 100 or more providers, followed by groups of ten or more, and finally, evaluating groups of less than ten. In this way, we believe small and solo providers will not be negatively impacted by this component of the MIPS program in the early years by resource use measures that are largely inapplicable to small practices.

Clinical Practice Improvement Activities (CPIA) Component of MIPS

MACRA defines the term "Clinical Practice Improvement Activity" as any activity that relevant eligible professional organizations and other stakeholders identify as one that improves clinical practice or care delivery and is likely to result in improved outcomes.

ASPS is puzzled to learn the Agency has not included Continuing Medical Education (CME) as a CPIA activity. CME has long been recognized as a means by which clinicians can demonstrate that they are engaging in Continuing Professional Development (CPD) to maintain the knowledge, skills, and practice performance, all leading to optimal patient outcomes. As such, we urge CMS to add CME and CPD activities as measures in the CPIA category.

Additionally, we urge the Agency to re-evaluate the two-tiered scoring for this component of MIPS. It appears that many of the activities the Agency has included for scoring are more often performed by primary care versus specialty care, and the use of “high” versus “medium” activities complicates any scoring. ASPS is especially troubled to see that only one QCDR measure was included in the high activity list and request that the Agency be much more transparent on how it determines what constitutes high or medium activities.

Advancing Care Information Performance Component of MIPS

While still focusing on the use of electronic health records (EHR), the Agency had indicated prior to publication of the proposed rule that clinicians would have some choice in the measures that reflect how they use an EHR in their practice.

The meaningful use program, intended in part to improve communication between medical entities, was onerous and financially burdensome for many small group and solo providers. Unfortunately, ASPS finds the proposal to place a strong emphasis on interoperability, information exchange and security – all of which many small and solo practice providers cannot control due to a lack of IT staff or proper training. The proposal also continues to includes aspects of a pass-fail scoring system, including reporting on at least one patient for each of the measures in the objectives that require a numerator and denominator. This is especially concerning for us, as not all of the measures are applicable to specialty care.

ASPS is concerned that the proposed attestation process will be unsurmountable for small and solo providers, many of whom may not be able to adequately attest to anything beyond basic IT related questions. We respectfully remind the Agency that the attestation does not measure interoperability. This proposal places a heavy administrative burden on the provider versus the vendor. The proposed implementation date for attestations is also problematic, as vendors may themselves not be ready to attest to data blocking, IT surveillance, and ONC Review requirements the Agency has yet to make public. We urge the Agency to reconsider any proposal that perpetuates a system where the focus is on system reporting versus the actual performance of the clinician.

Additionally, we note with dismay that the Agency proposes yet another complex scoring system for this component of the MIPS program, scoring both participation and performance. Requiring clinicians to

report on meaningful use measures in both the CPIA and ACI categories adds to the complexity and confusion inherent in the MIPS program.

At a minimum, ASPS requests the Agency develop education and technical assistance for providers and vendors and include an option to limit any clinician's reporting period to 90 days. Because EHRs have not yet saved costs for small practices they continue to be seen as a financial burden for providers already struggling with economic viability. As such, we also respectfully request the Agency re-evaluate its proposal for EHR hardship exemptions. A null or no value scoring in this component of the MIPS program would result in other categories being weighted differently, and will most likely prevent a clinician from obtaining a high composite score.

Use of Qualified Clinical Data Registries (QCDRs)

MACRA requires the Secretary to encourage the use of QCDRs in carrying out MIPS, and ASPS was encouraged by the Agency's proposed goal of expanding the capabilities of a QCDR, allowing for a stronger picture of the overall quality of care provided.

ASPS believes greater incentives will encourage adoption of this technology and along with other specialty societies, appreciate the opportunity to create measures specific to our members. We are concerned however, that any proposal to assign unique identifiers and limit the sharing of non-MIPS measures will inhibit reporting by a broad spectrum of clinicians. As such, we ask for clarification on granting permission for use of society-specific measures by other clinicians. Additionally, the proposed "rigorous" CMS approval process for measures may also become problematic, as will the Agency's proposal to require yearly re-qualification of each registry.

We also question the Agency's proposal to set the submission threshold for QCDRs higher than that for claims and would encourage the publication of qualifying entities prior to November 1, 2016 if the Agency intends to move forward with its proposal to recognize only those QCDRs with a requisite number of participants reported on or before January 1, 2017.

MIPS Composite Performance Scoring

Under CMS's proposed scoring policies, a MIPS eligible clinician or group that reports on all required measures and activities could potentially obtain the highest score possible within the performance category, presuming they performed well on the measures and activities they reported. A MIPS eligible clinician or group who does not meet the reporting threshold would receive a zero score for the unreported items in the category. The MIPS eligible clinician or group could still obtain a relatively good score by performing very well on the remaining items, but a zero score would prevent the MIPS eligible clinician or group from obtaining the highest possible score.

MACRA mandates that clinicians are provided timely, confidential feedback on their performance in the Quality and Resource use performance categories. These two components of MIPS will account for 60% of the composite score, with the Agency proposing to provide feedback by July 1, 2017.

To ensure MIPS eligible clinicians or groups have adequate time to address any inconsistencies in the remaining 40% of the performance categories, ASPS urges the Agency to enhance the proposed feedback process, providing real-time feedback to clinicians on each of the four components of MIPS. ASPS recognizes the Agency is relying on information technology (IT) systems to ensure success of their mission to improve quality and costs. Our members will certainly appreciate the Agency's proposal to

allow for informal reviews of a composite score, but we respectfully remind CMS that an informal review could help minimize any negative impact to the Agency as well as the clinician. In the spirit of continuous improvement, we request the Agency reconsider its proposal to disallow appeals of any decisions made during an informal review, especially in year 1 of the MIPS program. IT systems, especially those with recent upgrades to address program changes, can have anomalies or unwanted adverse effects. Secondary reviews may help identify systematic issues before they become insurmountable.

We would also encourage timely publication of processes and procedures – ideally prior to publication of the MACRA Final Rule. A transparent process, publicized in advance of the start date of the MIPS program, will only increase the public's trust. The inclusion of real-life examples of the composite scoring methodology would also be viewed as valuable by clinicians.

Posting of MIPS Scores via Physician Compare

In this proposed rule, CMS indicates it will publicly report an eligible clinician's MIPS data on a public website, in an easily understandable format, sharing information regarding the performance of MIPS eligible clinicians or groups reimbursed under MIPS.

ASPS appreciates the opportunity the proposed rule offers to review and correct data and recognize that data under appeal and review will not be publicly reported until a review is complete. However, we request that the review process begin 90, rather than 30 days in advance of the publication of new data. Furthermore, we request technical details of the appeal process be shared directly with societies, as we are typically the first to receive questions from our members on the appeals process.

APMs and Advanced APMs

MACRA provides a 5% annual lump sum payment to physicians who participate in qualified APMs, proposed to be referred to as Advanced APMs, at certain threshold levels and exempting them from MIPS. It also requires the Agency to move 70% of revenue to APMs.

While the Agency recognizes there will be a limited number of Advanced APMs effective January 1, 2017, ASPS is puzzled to understand why the Agency is proposing to introduce standards that, if implemented as proposed, would severely limit the participation of clinicians, including plastic surgeons, in the APM program. At a minimum, we would encourage the Agency to make specialty models a priority in the APM program and to develop approval processes that will ensure the timeframe from submission to approval is routinely less than 24 months.

Additionally, in the instances where participation in an Advanced APM Entity leads to the determination of Qualified Participant (QP) status for the participation Eligible Clinicians, because any bonus is proposed to be delivered to the TIN of the Advanced APM Entity rather than to the individual clinicians billing under that TIN, we would ask the Agency to support fair distribution of bonus funds to all participants in an APM.

Posting of APM Scores via Physician Compare

CMS has proposed to indicate via Physician Compare on eligible group or individual clinician profile pages when they are participating in an APM or Advanced APM. When relevant and possible, the clinician or group would be linked to their APM data. ASPS appreciates the Agency's proposal to move slowly on integrating this data on the website, not only because the APM concept is new to consumers,

by also because the average level of health literacy will necessitate thoughtful, clear and unambiguous explanations of the information.

Summary

In closing, ASPS appreciated the opportunity to offer these comments, and we look forward to working with CMS to ensure reimbursement is fair and adequate. We encourage the Agency to expedite publication of the MACRA final rule to ensure clinicians and societies have adequate time to review, validate, and provide education prior to January 1, 2017.

Should you have any questions about our comments, please contact Catherine French, ASPS Health Policy Manager, at cfrench@plasticsurgery.org or at (847)981.5401.

Sincerely,

David H. Song, MD, MBA, FACS
President, American Society of Plastic Surgeons

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1. http://www.healthcarefinancenews.com/news/ony-3-or-providers-feel-ready-pay-value-himss-survey-finds