Medicare Red Tape Relief Project

Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date: August 25, 2017

Name of Submitting Organization: American Society of Plastic Surgeons

Address of Submitting Organization: 444 E Algonquin Road
Arlington Heights, IL 60005

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Priority Issue # 1 / 6

Statutory ☐ **Regulatory** ☒

Please describe the submitting organization's interaction with the Medicare program:

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. The Society's members care for patients with private insurance and for Medicare beneficiaries. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients, including the treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and cancer.

Short Description: CY 2018 Updates to the Quality Payment Program (CMS-5522-P)

Summary:

MIPS: General

The fragmented nature of the MIPS scoring system is challenging for many clinicians. ASPS remains concerned that the limited exposure that many small practices may have gained under the 2017 "Pick your Pace" reporting strategy may not translate into heightened institutional knowledge. In addition, the proposed process for scoring "topped out" quality measures will add to the scoring confusion, and the Advancing Care Information (ACI) too closely resembles the "all-or-nothing" approach that was problematic for many clinicians under the Meaningful Use program. . Year 1 was plagued with constant change as new requirements and clarifications to the program were noticed almost weekly, sometimes daily. Year 2 will be the first true year of stability for MIPS and it is important for the Agency to recognize that physicians will still face considerable challenges as they work to comply with the program.

Virtual Groups

CMS introduced the concept of virtual groups to encourage small practices to participate in MIPS. Many plastic surgeons work in solo practice or in groups of less than five, so the "virtual groups" reporting option could alleviate many of the systems and staffing concerns that have presented solo provides from reporting quality measures. However, the proposed process of implementation and

scoring for virtual groups is confusing and complicated for physicians looking to utilize this option. The need for a unique identifier for Virtual Groups may also be a show-stopper for many clinicians. ,

Physician Compare

The MIPS program is just entering its second year, and ASPS is concerned that public reporting of data may be premature as the results from the first program year will not be available before April 2018. ASPS is also concerned that the proposed preview period may not be long enough for clinicians to accurately validate the Agency's data against their own information due to confusing scoring methodologies.

Alternative Payment Models

Specialists, including plastic surgeons, are frustrated by the lack of APM participation options available for specialists, especially as the intent of MACRA was to move physicians away from traditional fee-for-service and into payment models that better focus on cost and quality.

Related Statute/Regulation: MIPS Final Rule (starting with calendar year 2017): 81 FR 77008-77831
Calendar Year 2018 Updates to MIPS (Proposed Rule): 82 FR 33950-34203

Proposed Solution:

MIPS: General

The Agency should delay scoring the "Cost" component until educational efforts have been offered to physicians. CMS should also reconsider the maximum number of bonus points a clinician might earn under the ACI, considering the Agency's goal of incentivizing the use of Health IT during the 2018 performance year. There is also a need to expand the definition of IA's to include participation in clinical registries and continuing medical education (CME) to support physicians reporting.

Virtual Groups

The complexities of implementing the use of virtual groups and its respective scoring may create a barrier for clinicians looking to participate, making it difficult to complete all necessary steps and feedback loops prior to the December 1, 2017 deadline for 2018 participation. ASPS has asked the Agency to consider launching this participation option as a "pilot program" and extend the application deadline to mid-year 2018. Additionally, we encouraged CMS to recognize the need for some scoring latitude for Virtual Groups in 2018, including no more than a 90-day reporting period for each of the three scored components of MIPS. CMS should provide timely educational opportunities for those clinicians interested in learning more about this new participation option prior to and throughout the 2018 calendar year. Moreover, specialty societies are in a unique position to connect physicians with similar practices, regardless of geography. As such, we believe CMS should utilize medical specialty societies as partners in connecting interested clinicians into possible virtual groups, and in the development of educational materials.

Physician Compare

While the "Pick Your Pace" option was a creative way to encourage participation, flexible participation options need to be extended into future years to reduce the burden of quality reporting for office-based clinicians. ASPS also encourages CMS to share comparative data on quality performance with both providers and the public. In addition, we request the Agency increase the transparency of their scoring process before results are shared with the public or reported through the Physician Compare website. We also ask that before publicizing any data, CMS provide educational opportunities for

clinicians to further their comprehension of the purpose and the measures reported on the Physician Compare website.

Alternative Payment Models

While ASPS recognizes the time and resources necessary to validate proposed APMs as well as Advanced-APMs, we encourage CMS to commit additional staff and funding necessary to lessen the timeline currently in place for review and consideration of newly proposed APMs.

NOTE: The American Society of Plastic Surgeons submitted comments to Administrator Verma on this proposal on August 21, 2017.

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Priority Issue # 2 / 6

Statutory ☐ **Regulatory** ☒

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Short Description: The Development of Quality Measures

Summary:

Streamlining Measure Selection

CMS has previously requested that specialty medicine provide recommendations on how to streamline the review and selection of quality measures for programs such as the Quality Payment program (QPP), with the goal of identifying opportunities to release measures and/or measure specifications earlier than November 1st of each year. There is still room for improvement in this area.

Furthermore, the Qualified Clinical Data Registry (QCDR) measure review period is often difficult to navigate as there is inconsistent feedback and decisions on measures submitted by specialty medicine, as well as a lack of transparency regarding the rationale for these decisions. Specialty medicine societies, including ASPS, also face unrealistic timelines during this process and are provided with little to no feedback when measures are rejected.

Creating Specialty Measure Sets

While we appreciate the Agency's goal to identify gaps in current measure sets, specialty providers are acutely aware of the lack of actionable measures in the existing quality programs and believe that efforts need to focus on not only filling measure gaps in certain clinical areas, but also improving the current set of available measures. Plastic surgery is often forced to report on measures that are not

critical to the procedure or care provided, but instead require physicians to comply with a regimented checklist that does not take specialty care into account.

New measures specific to specialty care must be created. Yet the Agency has not consulted the specialty societies when working to develop measure sets or incorporate measures into Specialty Measure Sets. For example, the Agency recently added eight additional measures to the Plastic Surgery measure set, all without input from ASPS. Measure 402 (Tobacco Use and Help with Quitting Smoking) specifically addresses evaluation and management services provided to adolescents 12 to 20 years of age during a Primary Care visit. As such, this measure is hardly relevant to plastic surgery care nor an indication of quality of care.

Without additional funding, many small specialty societies, including ASPS, will be unable to shoulder the costs associated with developing measure sets specific to their members. Furthermore, ASPS is concerned that the amount of time necessary to develop representative evidence-based guidelines and measures, especially given the rigor of the proposed development process, will create an insurmountable obstacle for those working to meet this goal.

Funding for New Measure Development

Through the creation of new specialty specific measures, plastic surgeons and other specialty care providers will be able to successfully participate in the MIPS program.

Utilizing the QCDR for Data Collection

EHR vendors have demanded substantial amounts of money to incorporate quality measures into their products, and providers have often been unable to pay the high cost of incorporating specialty specific quality measures via an EHR. Even with the Agency's dedicated efforts to address gaps in practice, barriers created by the EHR vendors will continue unless CMS acts to reduce these barriers or incentivizes the reporting of specialty measures through the QCDRs. Numerous specialty societies have invested a considerable amount of time and money to develop registry reporting tools, which can often be used in place of Health IT systems, yet the Agency does not recognize the full capability of these registries.

Related Statute/Regulation:

Call for Quality Measures: MIPS Final Rule (starting with calendar year 2017): 81 FR 77137- 77155

QCDR Measures: MIPS Final Rule (starting with calendar year 2017): 81 FR 77158

Specialty Measure Sets: MIPS Final Rule (starting with calendar year 2017): 81 FR 77161

Proposed Solution:

Streamlining Measure Selection

ASPS suggests that the Agency maintain current measures longer, as yearly fluctuations in measures only cause more confusion among physicians. Increased uniformity will lessen the burden and volume of incorporating yearly updates and the resulting last minute reshuffling of information included in a society specific Quality Clinical Data Registry (QCDR) application, as well as the changes necessary to update the QCDR infrastructure. If possible, the new measures/specifications should be publicized earlier in the calendar year, perhaps in a proposed rule.

ASPS recommends that the Agency develop standardized processes for reviewing quality measures. This process should include notice of timeframes for determination and feedback, as well as an outlined appeals system.

Creating Specialty Measure Sets

ASPS implores the Agency to work more closely and on an ongoing basis with specialty societies when altering the specialty specific measure sets, as specialty societies offer key insights into the relevance of these measures. As cited previously, CMS created the plastic surgery specific set without soliciting input from ASPS and included a measure that was completely irrevlevant to our physicians. Measures are of no value when they address services not typically provided by the clinician, and a specialty society can assist the Agency in identifying those measures most relevant to their discipline. While it may seem as though providers would prefer a wide variety of measure options, a measure set's true size is actually limited to the number of usable measures it contains. As such, we respectfully ask CMS to re-evaluate every measure assigned to a specialty specific measure set to ensure clinicians regularly provide the care described by the measure.

Funding for New Measure Development

ASPS strongly encourages the Agency to immediately provide additional information on the funding opportunities created under MACRA that are earnmarked for the creation of additional measures. This funding was intentionally included within MACRA so that specialty medicine organizations can develop measures for their members, yet little to no information about the funding has been released to the public.

Utilizing the QCDR for Data Collection

ASPS encourages CMS to look beyond EHR vendors as the only mechanism to collect and report social, psychological or behavioral data, and respectfully reminds the Agency that specialty society QCDRs can be a valuable, low cost alternative for collecting unique health IT data. The use of a QCDR has previously been identified as a valid alternative for the collection of uniform data to evaluate specified clinical processes, quality and outcomes. Registries may be the only valid option for reporting specialty specific quality measures for many providers. We encourage the Agency to better recognize the value that clinical data registries bring to health care by incentivizing the use of QCDRs into future reporting requirements and recognizing their use in place of current EHR meaningful use requirements.

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Priority Issue # 3 / 6

Statutory ☐ **Regulatory** ☒

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Short Description: Obstacles to Data Collection

Summary:

Burdensome Reporting Requirements

CMS regularly releases new requirements on data collection, which are often burdensome for physicians and often unattainable for even medium size practices. Furthermore, the requirements are not necessarily based on clinical standards of care.

The 2017 proposed rule for the Physician Fee Schedule is a prime example of a circumstance that could have been avoided if only CMS had solicited direct input from impacted specialties from the start instead of after the rule was drafted. In this proposed rule the Agency created a pilot program requiring physicians to report pre- and post-operative evaluations via the use of "G" codes based on place of service, complexity of patient and the completion time. As introduced, these "G" codes would have required reporting of care in 10 minute increments. The volume of responses from surgical societies was strongly against this proposal, as there is no way practice management systems can capture and report services based on a multiplier of 10 minutes. Moreover, there are no studies that indicate that 10 minutes is the standard time measurement for tracking physician care.

The time necessary to compile rationale as to how the proposed policy would impact clinicians, as well as time to create educational materials for members was significant. CMS provided no rationale for

creating a set of G codes with a 10-minute time standard. The Agency ultimately retracted this proposal, but only after surgical societies dedicated a significant amount of time and resources to demonstrate the large administrative burden that would have been imposed by the CMS proposal. Finally, after months of discussions following the released proposal, the specialty societies successfully persuaded CMS to finalize a proposal to report post-operative evaluations via an existing CPT code (although that policy is also flawed). Months of additional work could have been avoided if only the Agency had consulted with the specialties impacted prior to drafting the proposal.

Generalization of Data

Hospitals are currently asked to collect metrics that can be submitted to CMS for quality assessment, improvement and ultimately reimbursement. These metrics are often measured through analysis of ICD-10 diagnostic codes, which is problematic for certain sections of the ICD-10-CM book that lack specific codes. For example, the Surgical Site Infection (SSI) quality metric could provide detailed insight into causes for reinfection. As ICD-10 does not include codes for every type of SSI, the very general ICD-10 diagnosis codes used by plastic surgeons may also be reported by other specialists. In these instances, analysis based only on an ICD-10 code prevents the plastic surgeon from determining whether the infection was a result of his/her procedure or a procedure performed by another specialist. This lack of procedure specific data collection for the SSI measures prevents the hospital and the plastic surgeon from timely and accurate assessment of whether there is a recurring problem specific to a specialty, thus delaying implementation of an effective course of corrective action.

Health IT Obstacles

As CMS develops new regulations on physician use of health IT systems, software vendors are expected to update their programs to allow physicians to comply with the Agency's revised rules on data collection. Yet the number of requirements placed on these vendors by CMS revisions make it nearly impossible for vendors to roll out the necessary updates in a timely manner. These vendor software update delays then create challenging timelines physicians to comply with CMS rules.

Related Statute/Regulation:

Section 1848(c)(8)(B)
CY 2017 Medicare Physician Fee Schedule, 81 Fed. Reg. 80209-80225

Proposed Solution:

Burdensome Reporting Requirements

ASPS recommends that CMS detail how the Agency intends to use data collected in any new or additional processes for providers. The Agency should also work with specialty societies to see if there are opportunities to obtain this necessary data through existing avenues of data collection, instead of creating new administrative burden for providers. Most specialty society-driven data registries collect "episode of care" information (similar to what is requested in the above example).

CMS should also work within the CPT for data collection as often as possible. This allows physicians to provide robust data through fewer codes, delivered through a vehicle to which practices are already accustomed. Limiting the scope of code collection would allow physicians to participate in a manageable way while ensure CMS collects meaningful data.

Generalization of Data

ASPS recommends that the Agency accept both ICD-10 diagnostic codes ***and*** CPT procedure codes for these metrics. This will allow the Agency to collect the information needed while also allowing practitioners to more effectively utilize the data. Physicians can then use the statistics from their CPT code report to identify opportunities to improve surgical performance and outcomes. They can also

further research complications by the CPT code, as medical literature reports outcomes and analysis using these codes.

Health IT Obstacles

ASPS suggests that the Agency include providers and vendors in early discussions on changes to data collection so that both parties are able to make long-range business decisions in order to comply with the Agency's revised rules.

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Priority Issue # 4 / 6

Statutory [X] **Regulatory** [ ]

Please describe the submitting organization's interaction with the Medicare program:

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Short Description: Delay 2015 Certified Electronic Health Record Technology (CEHRT) Adoption Requirements under MIPS

Summary:

In the October 2016 final regulation for the Merit-Based Incentive Payment System (MIPS), CMS requires clinicians to adopt 2015 Edition CEHRT by the 2018 performance period and report measures comparable to Stage 3 Meaningful Use.

Related Statute/Regulation: Definition of CEHRT for MIPS: 42 CFR 414.1305
MIPS Final Rule (starting with calendar year 2017): 81 FR 77008-77831
Calendar Year 2018 Updates to MIPS (Proposed Rule): 82 FR 33950-34203

Proposed Solution:

As providers are still working to comply with the Modified Stage 2 measures while also transitioning to the new QPP, ASPS believes that adoption of the 2015 CEHRT is asking too much. Plastic surgeons and other specialists currently have few EHR options that incorporate specialty specific needs, making adoption of this technology into their clinical workflow both difficult and hugely expensive, as they must absorb the costs without receiving the clinical benefit. Furthermore, Stage 3-like measures require interoperability between systems, which is not currently available.

Therefore, ASPS strongly encourages CMS to finalize the use of technology certified to the 2014 Edition or the 2015 Edition for an EHR reporting period in 2018. We would also support allowing providers to use a combination of EHR technologies certified to the 2014 Edition and 2015 Edition to be used for an EHR reporting period in 2018, for those EPs, eligible hospitals, and CAHs that are not able to fully implement EHR technology certified to the 2015 Edition.

While the June 2017 MIPS proposal rescinds the October 2016 requirement, there is no guarantee that CMS will continue to uphold this position in the final rule for 2018 or in years to come. For this reason, this issue necessitates congressional action.

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Priority Issue # 5 / 6

Statutory ☐ **Regulatory** ☒

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Short Description: Centers for Medicare and Medicaid Services Program Integrity Initiatives

Summary:

Burdensome Requirements

CMS continues to place burdensome requirements on physicians as the Agency works to implement its program integrity initiatives. These initiatives are often duplicative and costly to physicians who work to comply with the Agency's requirements, but who ultimately face financial penalties due to technicalities or non-uniform application of requirements.

For example, CMS and its contractors conduct regular reviews, including medical record auditing. Through these various review processes, different contractors request identical information. Each request from a CMS contractor requires physician practices to utilize time and resources to comply. This is burdensome and duplicative and could be eliminated if the Agency identifies a way to share these materials across contractors.

Coverage Policies

Inconsistent Medicare coverage and payment policies are often the root cause of improper payments. Furthermore, contractors consistently fail to follow proper protocol when developing or updating coverage determinations. For example, the reimbursement for breast construction via a Latissimus Dorsi flap with the placement of a tissue expander is often subject to unique coding rules, depending

on the "black box" edits – made without stakeholder input or review – created by each of the Medicare Administrative Contractors.

Denials & Overpayments

CMS does not have sufficient safeguards to protect physicians from contractors who inappropriately deny claims or services. There is little transparency or dialogue between the contractor and the provider to help educate the contractor and CMS on why a denied claim should in fact be paid.

Related Statute/Regulation: Assorted, including: 42 CFR 421; 42 CFR 402; 42 CFR 420; Medicare Program Integrity Manual

Proposed Solution:

Burdensome Requirements

ASPS recommends that CMS streamline processes for physicians while maintaining the Agency's purpose and goals. CMS should work to consolidate the number of contractors working on a single process to ensure that the process is executed in a uniform manner and to eliminate confusion between vendors. Streamlining these processes will also reduce physician confusion over unique application requirements, producing savings for these small businesses by protecting them from financial penalties. Currently, the sheer number of applications practices must deal with are leading to small errors in areas of nuance. Those small errors are leading to penalties.

Coverage Policies

ASPS believes that the creation of local coverage and payment policies should be more transparent and should require contractors to strictly observe the Agency's requirements for soliciting comments. Contractors should be required to solicit and earnestly consider stakeholder recommendations, including those provided by specialty medical societies. These contractors must also be required to utilize a formalized notice-and-comment process for any changes to coverage and payment policies. This is an area where congressional oversight and reporting is needed.

CMS should award Medicare Administrative Contractor (MAC) contracts based on performance. That performance should be determined, in significant part, by how well a MAC adheres to local coverage determinations processes and how well a MAC executes its appeals processes used by providers for denied services rendered. If contractors fail to meet these requirements, the Agency should terminate their agreement with the service provider.

Denials & Overpayments

ASPS believes the Agency and providers would be best served if there was substantially better clinical insight involved in these coverage determinations. The Agency should utilize physicians from the same specialty to provide clinical expertise on whether the service is medically necessary. In an effort to encourage appropriate coverage determinations, penalties should be put in place for contractors who inappropriately deny claims.

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Priority Issue # 6 / 6

Statutory ☐ **Regulatory** ☒

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Short Description: CMS Engagement with Specialty Societies

Summary:

Promulgation of CPT Codes

Plastic surgery plays an active role in the American Medical Association's (AMA) CPT process. Throughout this process, specialty societies offer input in the crafting of CPT codes and revisions. CMS audits these meetings, but does not provide any feedback as the AMA and the specialty societies develop their recommendations. Instead, CMS holds all comments until after the AMA submits its final proposal; sharing the Agency's final recommendations months later when proposed rules are published.

FDA Utilization of Subject Matter Experts

The FDA utilizes subject matter experts (SMEs) to provide clinical expertise in various fields across the Agency. Yet these SMEs are often brought into the discussion at a later stage, limiting the value of their professional and clinical experience. Furthermore, specialty societies have a very limited opportunity to engage the FDA and provide clinical insight on their respective areas of expertise.

Related Statute/Regulation: The Administrative Procedure Act (APA), Pub.L. 79–404, 60 Stat. 237
Executive Order 13563 – Improving Regulation and Regulatory Review
Executive Order – Identifying and Reducing Regulatory Burdens
Executive Order 12866 – Regulatory Planning and Review

Proposed Solution:

Promulgation of CPT Codes

ASPS encourages CMS to play a more active and vocal role in the creation of CPT codes and to establish a two-way dialogue with the AMA and specialty societies. For example, following the AMA's final CPT proposal, CMS often determines that some of the AMA's recommendations are not feasible. The Agency's concerns could have been addressed during the initial discussions if CMS had an active voice during those CPT discussions, instead of just silently auditing the meeting. This would save the AMA and specialty societies considerable time and resources and would also provide CMS with a more comprehensive understanding before they make their final decision. This dialogue would allow the AMA and the specialty societies to shed light into the rationale behind these recommendations and for CMS to provide thoughtful, transparent reasons for why certain decisions are made.

FDA Utilization of Subject Matter Experts

ASPS recommends that the FDA include both the Agency's subject matter experts and specialty societies in early discussions on rule or guidance development. ASPS has enjoyed such a relationship with recent FDA draft guidance documents, with positive outcomes. Other specialty societies would appreciate the opportunity as well.