AMERICAN SOCIETY OF PLASTIC SURGEONS®
THE PLASTIC SURGERY FOUNDATION™

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June 13, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1677-P
7500 Security Blvd, Mail Stop C4-26-05
Baltimore, MD 21244-1850

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

Re: Medicare Program: Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices (CMS-1677-P)

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 on *Inpatient Prospective Payment System CY 2018 Proposed Rule* published in the April 28, 2017 *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.

Non-Covered Procedure Edits

With the advent of case-by-case coverage determinations for gender confirmation surgery, we agree with the Agency's review and updating of the list of ICD-10-PCS procedure codes impacted by existing Non-Covered Procedure edits. We hope that CMS will finalize these edits. We would be remiss to not also ask the Agency to review current policy for breast implant placement for trans females. As we are sure you are aware, in the typical patient, estrogen therapy alone does not result in what would be considered adequate growth of breast tissue. Augmentation procedures are necessary, and should be included as a reimbursable service.

We would encourage CMS to review the nuances of CPT coding for breast prosthesis, and adjust existing policy that excludes augmentation mammoplasty (CPT 19325) as a covered service for MtF patients undergoing gender confirmation surgery.

Proposed Changes to Surgical Hierarchies

The Agency is proposing to move MS-DRG 614 and 615 (Adrenal and Pituitary Procedures with CC/MCC and without CC/MCC respectively) above MRS-DRGs 622, 623 and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional, and Metabolic disorders, with MCC, with CC and without CC/MCC respectively) in the surgical hierarchy rankings within the MS-DRG GROUPER software to address an *individual* issue brought forward by a participating hospital. Based on the way in which a secondary procedure of using fat to resolve a defect post benign pituitary gland removal is reported, the MS-DRG assignment can dramatically change.

ASPS recognize the current GROUPER methodology may occasionally result in the assignment of a lower DRG when multiple procedures are performed during the same hospital stay, but reminds the Agency that MS-DRGs 622, 623, and 624 are linked to a multitude of graft and debridement procedures. We respectfully request the Agency provide an opportunity for more discussion and to also produce additional data for those surgical specialties that may be affected by sequencing changes to the above MS-DRGs in the GROUPER. ASPS is extremely concerned that the proposal put forward is made on the basis of just one clinical scenario and believe CMS should ensure a more thorough analysis of the potential impact of such a change prior to adjusting existing GROUPER logic.

Accounting for Social Risk Factors

In response to the Agency's request for feedback on whether they should account for social risk factors in the Hospital Value-Based Payment Program (HVBP), ASPS shares the following:

We concur with the strategies and considerations outlined by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) for the HVBP in its December 2016 report, *Social Risk Factors and Performance Under Medicare's Value-Based Payment Programs*. Similarly, we agree with findings described in the National Academies of Sciences Engineering and Medicine's report, *Accounting for Social Risk Factors in Medicare Payment*, which describes five social risk factors that are conceptually likely to be of importance to health outcomes of Medicare beneficiaries. The report also includes health literacy as another important risk factor which we would support.

ASPS maintains that adding social risk factors into the current risk adjustment formula offers the potential for better calibration of hospital scores and removes incentives to discourage treatment of patients who might negatively impact a hospital's performance score. This should positively impact patient access to care, as hospitals would no longer be financially rewarded for treating only patients it believes will positively impact its performance on quality and cost metrics. In addition, by providing hospital readmission rates organized by hospital patient mix using patient characteristics, patients would have access to additional information that may assist them in choosing where to seek care.

Finally, we encourage the Agency to reconsider the use of a three-year look back period historically used to calculate readmission rates as it moves forward with changes to this program. We'd also ask the Agency to be mindful of unintended consequences, such as increased reporting burdens, when implementing changes.

Physician Owned Hospitals

In this rule, the Agency is seeking public comment on the appropriate role of physician-owned hospitals in the delivery system, and how the current scope of, and restrictions on physician-owned hospitals affect healthcare delivery. Additionally, the Agency is seeking comments on the impact current policies have on Medicare beneficiaries.

Under Section 6001 of the Affordable Care Act, restrictions were placed on physician-owned hospitals (POHs). ASPS understands the concerns that prompted those restrictions, but gently reminds the Agency that POHs have been shown to provide high-quality care. Of note, and for the fifth year in a row, a POH was recognized as first in the nation under the Agency's 2017 payment year of the Value-Based Purchasing program, which rewards hospitals for delivering high quality care, adhering to best practices and improving the patient experience.

ASPS believes there is a place for POHs in the medical community's efforts to enhance care coordination and promote new healthcare delivery models and respectfully requests the Agency implement policies that complement current and future legislative proposals that might repeal bans on the growth and expansion of POHs.

Inclusion of the Quality of Informed Consent Documents for Hospital-Performed, Elective Procedure Measures

In an effort to promote more valuable care and expand the pool of measures that aim to improve patient safety, the Agency is suggesting a new measure to incentivize hospitals to improve the informed consent process for elective procedures. The list of qualifying procedures is broad, capturing 10 medical specialties and various levels of surgical invasiveness. In response to the request for feedback, ASPS can share the following:

We understand this measure was developed in conjunction with feedback from patients and patient advocates. However, based on the paucity of information provided in this rule, the process does not appear to have included significant input from the hospital or physician community. This oversight is concerning, especially since the Agency has indicated their long-term goal is to create measures focusing on shared-decision making.

As the Agency is most certainly aware, most often the informed consent discussions between a patient and surgeon occurs well in advance of any document review and signature in the hospital setting. ASPS offers its members access to an informed consent product, with documents that have been actively used for decades and modified as time has progressed. These materials represent the "best practice" model for elective plastic surgery procedures. We routinely encourage our members to include an informed consent discussion with their surgical patients pre-operatively, and we agree that the process can improve both patient comprehension and satisfaction.

However, without additional clarification from the Agency on how the physician's informed consent process can and should augment the hospital informed consent process, we have serious concerns with the potential for unintended consequences a measure such as this will create. Particular concerns include the amount of

time necessary to comply, waiting periods, seemingly unresolvable differences between volume of information desired to present and desire to limit volume of actual printed materials, reliance on written materials when it is known that many patients do not have sufficient literacy, and the impact of these mandates on interpreter services.

Additionally, ASPS is concerned that the administrative burden to coordinate informed consent activities will be especially difficult for those surgeons who do not have access to interoperable medical records. We are concerned this policy could delay not only start times, but also the date for an elective procedure. Canceled procedures may result in undue hardships to the patient, some of whom have traveled long distances.

In order to improve outcomes, we would expect a measures such as this to also require process improvement activities. Specifically, after the first round of evaluation, trained staff, ideally nurses, would be needed to provide education, with real time monitoring and continued feedback. Each hospital would need staff specifically trained to review consents prospectively, get in touch with doctors for clarifications, and make corrections. We are hopefully the Agency's final set of training materials will include process improvement activities.

Most importantly, we are concerned with the large scope of this measure. In beta testing, the Agency recognized most hospitals received low performance scores, citing "quality" as the reason for the findings. If the Agency moves forward with its plan to calculate the scores for a representative sample of *all* informed consent documents at facilities, regardless of the number of beds or the number of specialties provide care at that facility, we worry that even with "comprehensive standardized testing" the process will be anything but effective and efficient. As such, we encourage CMS to reconsider the number of specialties as well as the volume and range of services included in the first year of any informed consent measure, and to provide ample education and training well in advance of its launch.

Electronic Health Records (EHRs)

- **Electronic Clinical Quality Measures (eCQMs)**

  While we realize the eCQM proposals are directed at easing the burden for the Inpatient Quality Reporting (IQR program) and not the Meaningful Use program, we would like to thank CMS for the work it has done to lessen the burden of reporting eCQMs by decreasing the number of measures a hospital must report and reducing the number of calendar quarters for which data must be submitted for CY2018. This move provides better alignment with the EHR Incentive, and we encourage CMS to finalize this provision.

- **Certification Requirements for 2018**
  We appreciate that CMS is working with ONC to monitor the deployment and implementation status of EHR technology certified to the 2015 Edition, and that, if the Agency identifies a change in the current trends and significant issues with the certification and deployment of the 2015 Edition, it will consider flexibility in 2018. We do not believe vendors or providers will be ready to move to 2015 Edition technology and the requisite Stage 3 measures. Therefore, we strongly encourage CMS to finalize the

use 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. We would encourage CMS to also consider this level of flexibility for the Advancing Care Information (ACI) category of the Merit-Based Incentive Payment System (MIPS).

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 Health Policy Manager, at cfrench@plasticsurgery.org or at (847)981.5401.

Sincerely,

Debra Johnson, MD
President, American Society of Plastic Surgeons

cc: Lynn Jeffers, MD – ASPS Board Vice President of Health Policy & Advocacy
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Steve Bonawitz, MD – Chair, ASPS Healthcare Delivery Subcommittee
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