AMERICAN SOCIETY OF PLASTIC SURGEONS®
THE PLASTIC SURGERY FOUNDATION™

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October 2, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 1736-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments Submitted Electronically to **http://www.regulations.gov**

Re: CMS 1736-P - Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician- Owned Hospitals

Dear Administrator Verma:

The American Society of Plastic Surgeons (ASPS) is the world's largest association of plastic surgeons. Our over 7,000 members represent 93 percent of Board-Certified Plastic and Reconstructive Surgeons in the United States. ASPS promotes not only the highest quality in patient care, but also in professional and ethical standards. Our members are highly skilled surgeons who improve both the functional capacity and quality of life for patients, including treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and gender affirmation surgery. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (Proposed Rule) on the Hospital Outpatient Prospective Payment System, published August 12, 2020 in the *Federal Register (Vol. 85, No. 156 FR, pages 48772-49082).*

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

1. Skin substitutes

We appreciate CMS' continued engagement with manufacturers and stakeholders on existing Medicare OPPS/ASC payment policies for skin substitutes but would be remiss not to point out that, for almost three years, wound care providers have been awaiting information from the Agency on policy changes to the current "high/low" cost payment methodology for skin substitutes.

While we recognize the complexity of issues involved with any potential change, we respectfully ask that this become a key focus for the Agency during CY 2021. A long term, predictable approach to reimbursement will help our members make important decisions about the types of ADMs they offer and help them work with facilities to be mindful of price, handling characteristics, processing methods, and potential risks, benefits, alternatives, and consequences for their patients. We firmly believe that Medicare should be enacting policies through rulemaking that build stability and sustainability in federal health care programs. We appreciate the need for innovative payment approaches but living under

constant threat of change does not foster the program stability that Medicare beneficiaries and their health care providers need and deserve.

Additionally, as CMS moves towards including synthetic products in its description of skin substitutes, we ask that the Agency consider the unintended consequences of utilizing a single HCPCS code with a broad descriptor for synthetic skin substitutes versus product specific codes, which is the approach used for biological skin substitutes. Specifically, ASPS has concerns that products with significant range in costs could be lumped into the same HCPCS code, resulting in some products being overpaid and other products being underpaid. CMS can avoid such problems by assigning product specific HCPCS codes to each unique synthetic skin substitute, as it has done for many years for all other skin substitutes.

2. Removal of services from the inpatient-only list

The Agency is proposing to eliminate the list of services (the Inpatient Only (IPO) list) that can be done on an inpatient-only basis for Medicare patients over the next three years, beginning by removing about 300 musculoskeletal-related services in CY 2021. This would allow a wide range of services to be performed as outpatient surgery, including tumor removal/bone grafts (APC 5114); finger amputation (APC 113); Fracture/tendon repair (5112); Replantation of hand (APC 5116); and Upper extremity amputations (APC 5115).

We concur with CMS that a physician should use his or her complex medical judgment to determine the generally appropriate setting for care, but we note that the inpatient-only list was originally created to *protect* beneficiaries. Many of the musculoskeletal-related services, as illustrated by the four examples above, can be complicated, requiring care and coordination of services typically provided in the inpatient setting of a hospital. This will certainly hold true for additional procedures beyond the musculoskeletal clinical family that CMS proposes to remove from the IPO list over the next several years as well. CMS dismisses concerns from stakeholders that payers or other entities might use the lack of an IPO list to push procedures into the outpatient setting for cost reasons even if it is better for patient care that the procedure be performed in the inpatient setting and provides no safeguards regarding this concern. ASPS believes this concern is valid and warrants a more thoughtful approach than CMS has put forward. As such, we encourage CMS to thoughtfully review the range of procedures included in the first year of the proposed transition to a full elimination of the IPO list to ensure patient safety evaluation systems in the outpatient setting can adequately track and report on care coordination and health care quality outcomes for each patient. In addition, for future years where APCs must be created to absorb the performance and reimbursement of procedures in the outpatient setting for the first, we believe the Agency must have a more detailed policy for how it intends to reimburse facilities for these procedures given the lack of outpatient cost data.

Additionally, we ask the Agency to begin outreach to the Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs) immediately to ensure best practices for audits and education to providers regarding compliance with short-stay admission policies are universally adopted and communicated prior to the start of CY 2021. This will help mitigate some of the administrative burden for outpatient hospitals and surgeons performing services previously flagged as inpatient-only procedures. We believe that the moratorium on site-of-service review should be extended, and because this is such a potentially significant shift and because of concerns about payer and contractor behavior,

if CMS finalizes the elimination of the IPO list, we request that CMS extend the site-of-service review moratorium for procedures that come off the IPO list from 2 years to 4 years.

3. Hospital Outpatient (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule, CMS established a prior authorization process for certain hospital OPD services to address unnecessary increases in the volume of some covered OPD services. Recognizing that the process for the first five service categories, which include blepharoplasty and did not begin until July 2020, we were disappointed to see the Agency did not provide any initial feedback on lessons learned thus far in this proposed rule. As indicated in our previous comments about this program, immediate feedback would, we believe, lessen the administrative burden for both the OPD and surgeon. We have been made aware of instances where several Medicare Administrative Contractors (MACs) are struggling to complete prior authorizations timely and/or have erroneously denied prior authorizations.

To ensure this program works as intended, A***SPS encourages CMS to immediately implement the following items:***

- Any prior authorization forms must be standardized across all Medicare Administrative Contractors (MAC).
- Physicians should be able to submit the prior authorization requests electronically.
- Approval or denial of coverage should be determined and communicated to the physician no more than 48 hours after the receipt of the completed prior authorization form.
- Retrospective reviews and/or denials should be prohibited in all cases where a physician appropriately followed the prior authorization procedure and received approval to perform the surgery.
- A transparent appeal and/or retroactive authorization process should be included in the prior authorization procedures that are developed.

It is simply not good policy to delay analysis and feedback to those participating in this program, not to mention delay care, and we remain hopeful that CMS, along with the MACs, will, at the very least, offer educational events to share best practices with providers before the end of this year.

Summary

In summary, ASPS is hopeful that CMS will continue to work with the medical community to ensure the fee-setting process remains transparent and does not limit access to care. We appreciate the opportunity to provide these comments and look forward to working with CMS to ensure administrative burdens are reduced and reimbursement is fair and adequate. Should you have any questions about these comments, please contact Catherine French, ASPS Health Policy Director, at cfrench@plasticsurgery.org or at 847.981.5401.

Sincerely,

Lynn Jeffers, MD – President, American Society of Plastic Surgeons

cc: Greg Greco, MD - ASPS Board Vice President of Health Policy and Advocacy
Howard Levinson, MD - ASPS Board Vice President of Research
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