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June 17, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1655-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Comments to CMS-1655-P – Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports

Dear Acting Administrator Slavitt:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing in regards to CMS-1655-P.

ISASS is a global, scientific, and educational society of spinal surgeons and scientists organized to provide an independent venue to discuss and address the issues involved with surgical aspects of basic and clinical science of spinal care. Thank you for the opportunity to provide comments on the proposed rulemaking.

Proposed Additional Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years – Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure

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ISASS would like to express appreciation to CMS for refining the proposed Lumbar Spinal Fusion/Refusion Clinical Episode-Based Payment Measure in response to comments on the 2015 and 2016 IPPS rulemakings from the surgical spine community. While the proposed SFusion payment measure in the 2017 proposed IPPS rulemaking with five clinical subtypes[1] of fusions of the lumbar spine does create a less heterogeneous patient population, ISASS does not believe that the proposed SFusion hospital clinical episode-based payment measure is ready for inclusion in the Hospital Inpatient Quality Reporting (IQR) Program for the following reasons:

Diagnosis - While the proposed SFusion payment measure is limited to fusions of the lumbar spine and does account for the approach and number of levels being fused, the proposed measure does not account for the patient's diagnosis. A lumbar fusion to treat disc degeneration is different than a lumbar fusion to treat spondylolisthesis, recurrent herniated nucleus pulposus, or iatrogenic instability. Further, there may be important anatomic and clinical differences regarding the location of the lumbar fusion (L1-L2, L2-L3, L3-L4, L4-L5 and L5-S1). Indications and techniques in the upper lumbar spine are generally different from those at the lower three levels. While current coding does not distinguish between the levels fused, some ICD-10-CM codes allow for an additional level of granularity by distinguishing the lumbosacral region (L5-S1) from the lumbar region (L1-L5). Future ICD-10-CM codes could serve to more specifically identify segments of the spine within each region and could be used to further refine the patient cohort. The proposed SFusion payment measure currently looks to specified MS-DRGs and CPT® codes to trigger an episode; ISASS recommends the inclusion of ICD-10-CM codes in order to include diagnosis as the third element of the episode trigger to further homogenize the patient population.

Additionally, the circumstances under which the lumbar fusion surgery is performed should be accounted for within the measure. An emergency surgery to treat a traumatic spinal injury is much different than an elective surgery to treat a patient's long-standing degenerative condition. Further, a primary lumbar fusion surgery on a previously unoperated patient is much different than a revision surgery for a failed prior fusion (pseudarthrosis). Revision surgeries can be complicated by epidural fibrosis and scarring from the primary surgery, existing hardware from the primary surgery, increased risk of incidental durotomy, and enhanced wound care issues due to compromised vascular supply or even indolent subclinical infection. The following ICD-10-PCS codes designating lumbar fusion revision surgeries are available for hospital inpatient reporting: 0SW004Z (Revision of Internal Fixation Device in Lumbar Vertebral Joint, Open Approach) and 0SW00AZ (Revision of Interbody Fusion Device in Lumbar Vertebral Joint, Open Approach). ISASS recommends further refining the proposed SFusion payment measure to exclude trauma, multi-level deformity, and revision surgeries and include only elective primary surgeries to treat symptomatic or unstable degenerative conditions of the lumbar spine as part of the hospital clinical episode-based payment measure.

Patient Complexity – While the proposed SFusion payment measure does account for some patient complexity variables by including MS-DRGs[2] as part of the episode trigger and

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[1] i.e., Anterior Fusion-Single, Anterior Fusion-Two Levels, Posterior/Posterior-Lateral Fusion-Single, Posterior/Posterior-Lateral Fusion-Two or Three levels, and Combined Fusions

[2] See Table B-4: Spinal Fusion Episode Types within the report, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion"

incorporating patient age[3] and severity of patient illness[4], it does not appear to account for other important patient complexity variables such as sociodemographic factors, obesity, tobacco use, and population health variables which can significantly increase the complexity of obtaining a successful fusion. These factors are outside of the provider's control, add to the complexity of the case, and clearly impact patient outcomes and should be accounted for within the risk adjustment of the measure.

Services Grouped into the Episode – There is extensive discussion within the report, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" regarding the method by which services are grouped into the episode, including the development of a web-based tool for physicians consulted on development of the proposed measures to review the services eligible to be grouped into episode. However, the proposed rule and the accompanying report do not list the specific services that fall into each grouping option. Stakeholders reviewing the proposed SFusion payment measure have no information on the conditions and services being grouped into the episode and counted in the overall cost of the episode. The episode groups being developed by CMS as part of the MACRA implementation contain lists of codes that are grouped into the episode as services or sequelae. For the sake of transparency and stakeholder engagement, CMS should also include a list of services it is proposing for inclusion in each grouping option for the SFusion payment measure.

Thank you for your time and for your consideration of our comments. Again, we appreciate CMS' efforts at refining this clinical episode-based payment measure, but strongly believe there is additional work to do before the measure is finalized and included in the IQR Program. ISASS stands ready to work with CMS to further refine this measure. Please contact Liz Vogt, Director of Health Policy & Advocacy by email at liz@isass.org or by phone at 630-375-1432 with questions or requests for additional information.

Sincerely,

Morgan P. Lorio, MD, FACS
Chair, Coding and Reimbursement Task Force
International Society for the Advancement of Spine Surgery

[3] See Table C-1: Age Variables within the report, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion"

[4] See Table C-2: Severity of Illness Measures within the report, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion"