September 6, 2016

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P, PO Box 8016
Baltimore, MD 21244-8016

VIA ELECTRONIC FILING

Re: CMS-1654-P Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

Dear Mr. Slavitt:

The Spine Intervention Society (SIS), a multi-specialty association of more than 2,600 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on the Medicare Program's Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017 published in the Federal Register on July 15, 2016.

SIS appreciates the opportunity to provide input and comments to CMS and work closely with the agency in the development of the physician fee schedule rules and regulations. SIS is committed to collaborating with CMS and other health care stakeholders working to improve patient care and provide appropriate incentives to physicians to provide quality care to Medicare patients.

SIS would like to comment on the following aspects of the 2017 Physician Fee Schedule proposed rule.

- **Phase-In of Significant RVU Reductions:** SIS agrees with the CMS proposal to extend the phasing in of significant RVU reductions (20% or greater reduction in RVUs) over a period greater than a single year.

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- **Proposed Revised or New Work Relative Value Units (wRVUs) for CY 2017 Under the Misvalued Code Initiative:** SIS agrees with the proposed wRVUs for HCPCS/CPT codes 623XX5-623X12 and 77001, but disagrees with the proposed WRVUs for HCPCS/CPT codes 77002 and 77003. We recommend CMS adopt the RUC recommended values for these two codes.
- **Collection of Data Related to the Resources Used in Furnishing of Global Services:** SIS is very concerned with the methodology proposed by CMS to review and measure resources used in the provision of global services under the Physician Fee Schedule. CMS' proposal to require all providers to document post-operative patient encounters in the office setting through new G-codes represents a major burden on providers across the country. This proposal deviates from the legislative language included in the MACRA bill, which explicitly required CMS to collect data on resource use through surveys of representative samples of providers. CMS should revise their proposed methodology to be less burdensome on providers and practices, and work closely with provider associations to develop a more nuanced and simpler survey process. This will still provide the agency with enough data to determine typical post-operative resource use patterns for global period services.
- **Implementation of Appropriate Use Criteria (AUC) for Advanced Imaging Services:** SIS supports the development of evidence-based appropriate use criteria and their use by payers like CMS and within the Medicare program. We recommend CMS engage directly with physician and provider stakeholders who will be charged with the implementation of the AUC for advanced imaging services in the conditions announced by the agency in the proposed rule.

I. Phase-In of Significant RVU Reductions

In the 2017 proposed rule, CMS proposes to finalize the policy on the phase-in of significant RVU reduction for all codes not new or revised. For the 2016 Physician Fee Schedule CMS implemented a maximum of 19% reduction in a single year for all procedures not new or revised that had a total RVU reduction of 20% or greater. For the 2017 Physician Fee Schedule, CMS proposes to have the 19% reduction in total RVUs continue to be the maximum one-year reduction until the reduction is fully implemented.

SIS agrees with this proposal and supports the policy. SIS believes that significant reductions to any service can be disruptive to physicians and physician practices. By phasing in reductions and having a maximum 19% reduction in total RVUs for any year, CMS will mitigate the impact of significant reductions for physicians and practices. SIS recommends CMS finalize its proposed policy in the CY 2017 Final Rule.

II. Proposed Revised or New Work Relative Value Units (wRVUs) for CY 2017 Under the Medicare Physician Fee Schedule

SIS appreciates CMS presenting proposed relative value units in the proposed rule rather than as interim final values in the CY final year rule as had been CMS' practice in the previous calendar year Fee Schedule rules. SIS also believes that CMS should only rarely and selectively propose changes to the RUC-proposed RVUs and times. The RUC-proposed inputs reflect not only the input of practitioners providing the services in question, but the societies representing the most common providers, and the very significant and substantive scrutiny inherent in the RUC process. Unless there is compelling data to suggest the RUC recommended values are inappropriate for a service, or family of services, CMS should be cautious about applying changes. SIS also does not believe CMS should apply reverse building block methodologies or other approaches that presume the existing values and times are accurate when it is clear that often existing times and values are not accurate reflections of resources necessary to provide services under the fee schedule.

In terms of specific recommended values for CY 2017, SIS wishes to comment on the following sets of codes found in the table below.

CPT Code	Short Descriptor	2016 Work RVU	RUC Recommended RVU	Proposed 2017 Work RVU
623XX5	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance	New	1.80	1.80
623XX6	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with guidance	New	1.95	1.95
623XX7	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance	New	1.55	1.55
623XX8	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance	New	1.80	1.80

623XX9	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution) not including neurolytic substance, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance	New	1.89	1.89
623X10	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution) not including neurolytic substance, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance	New	2.20	2.200
623X11	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution) not including neurolytic substance, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance	New	1.78	1.78
623X12	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution) not including neurolytic substance, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance	New	1.90	1.90
77001	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedures)	0.38	0.38	0.38
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)	0.54	0.54	0.38
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) (List separately in addition to code for primary procedure)	0.60	0.60	0.38

Epidural Injection Codes (623XX5-623X12)

CMS reviewed a set of 6 new CPT/HCPCS (623XX5-623X12) codes for the provision of epidural injections in the back/spinal region. These codes are designed to replace a set of existing epidural injection codes that were flagged under the CMS misvalued code initiative. Stakeholders presented revised CPT code descriptors which were accepted by CPT in May 2015 and then surveyed and valued by the RUC at the October 2015 RUC meeting. The RUC accepted the 25% work RVU recommendations from the provider surveys and CMS accepted these work RVUs as reflected in the table above.

SIS agrees with the RUC and CMS recommended work RVUs for 623XX5-623X12 and recommends CMS finalize these work RVUS in the CY 2017 Medicare Physician Fee Schedule final rule.

Fluoroscopic Guidance (77001-77003)

CMS reviewed the RVUs for three existing codes for fluoroscopic guidance for central venous access, needle placement, or catheter tip procedures. These services were flagged under the Medicare misvalued code initiative and the services were reviewed by the RUC at the April 2016 meeting. In addition, several new CPT codes were created to bundle fluoroscopic guidance or existing CPT codes were revised to bundle fluoroscopic guidance. Despite that action, CMS felt compelled to propose reduced work RVUs of 0.38 for CPT codes 77002 and 77003, despite the survey results that indicated the current work RVUs of 0.54 and 0.60 respectively were the appropriate values for the services. The survey results showed no change in intra-service time for the service compared to existing inputs, yet CMS recommended reducing the values by a significant amount. Furthermore, the CMS recommended values incorrectly value 77002 and 77003 as equal to 77001 even though the set of codes is designed to reflect the differences in physician work between the three different uses of fluoroscopic guidance in relationship to the increased intensity and difficulty in placement of needles and catheters for biopsies, injections, aspirations.

SIS strongly recommends that CMS accept the RUC recommended work RVUs of 0.54 and 0.60 for HCPCS/CPT codes 77002 and 77003 and implement these work RVUs for the CY 2017 Medicare Physician Fee Schedule.

III. Collection of Data Related to the Resources Used in Furnishing Global Services

In the 2017 MPFS proposed rule, CMS outlined policies related to data collection of resources used in the provision of global services (services in the fee schedule with 010 or 090 global periods). These policies are in response to language in the Medicare and CHIP Reauthorization Act (MACRA) of 2015 which called on CMS to not implement its previously announced policy to eliminate all 010 and 090 global periods and to collect data related to the resources utilized in these services. CMS has proposed three concurrent initiatives to better identify resources used in the provision of global services. The first proposal is to create eight G-codes that all providers would be expected to report to capture inpatient, outpatient, office, and non-face-to-face post-operative patient encounters provided in a global period. The second proposal is to conduct a survey of surgeons and providers who commonly perform global services. The third proposal is to conduct field studies in a select number of sites with direct observation of practice patterns.

SIS believes the current proposal imposes far too great a burden on physicians and physician practices, in particular the imposition of reporting patient encounters through unpaid G-codes for all work done in the 10-day or 90-day post-operative period. Under the proposed policy, it is distinctly possible that a physician following a patient for 90 days will need to submit G-codes 20-50 times per patient. This represents an unnecessary burden on all physician and physician practices.

Although spine intervention physicians do not commonly use 090 global period codes, some procedures do have 010 globals and thus, spine intervention physicians would be directly affected by this proposal should it be implemented. In addition, many spine intervention physicians work in multi-specialty practices with surgeons who do commonly perform services with both 010 and 090 global periods. The CMS proposal would create a major burden on our members and our practices, and increase costs significantly.

We strongly recommend CMS revise this proposed approach to reviewing global period services and work closely with physician associations to determine a more effective and less burdensome approach to collecting data in claims based forms including the much more simplistic approach of using HCPCS/CPT code 99024 which is an unpaid reporting code for post-operative patient E/M encounters. SIS also urges CMS to choose a representative sample of physicians and not extend the requirement to all providers. CMS can gain just as statistically valid data via sampling as it can through universal, mandatory requirements.

IV. Appropriate Use Criteria (AUC) for Advanced Imaging Services

In the CY 2017 proposed rule, CMS addresses the development of a Medicare Appropriate Use Criteria (AUC) program for Advanced Imaging Services such as MRIs, CT scans, ultrasound, and other diagnostic imaging systems. CMS was mandated to develop an AUC program for Advanced Imaging as part of the Protect Access to Medicare Act (PAMA) of 2014. In the 2016 Medicare Physician Fee Schedule, CMS addressed the initial components of the program, outlining evidence-based, transparency requirements for the AUC program and establishing a process to define "provider-led entities" (PLEs) which CMS tasks with reviewing and endorsing their proposed AUC requirements for Advanced Diagnostic Imaging. In June 2016, CMS published the list of initial PLEs.

In the 2017 proposed rule, CMS announced they would not begin actual implementation of the Advanced Imaging AUC program until at least CY 2018. CMS also announced exemption criteria, and the initial list of general conditions they would include in the AUC as clinical priority areas: chest pain (includes angina, suspected myocardial infarction and suspected pulmonary embolism); abdominal pain (any locations and flank pain); headache, traumatic and non-traumatic; low back pain; suspected stroke; altered mental status; cancer of the lung (primary or metastatic, suspected or diagnosed); cervical or neck pain.

SIS supports the use of AUC as a key tool in promoting cost-effective, quality care for key clinical priority areas such as low back pain. SIS and other specialty societies that treat low back pain have developed evidence-based guidelines and AUC, and encourage CMS to closely follow these published recommendations in creating their AUC for advanced imaging. SIS is happy to share our guidelines and AUC with CMS and to collaborate with

CMS and other medical stakeholders in reviewing and finalizing the Advanced Imaging AUC.

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SIS appreciates the opportunity to provide comments and CMS' attention to these issues. We look forward to continuing to work with CMS to update and improve physician payment policies in the future.

If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@spinalinjection.org.

Sincerely,

John MacVicar, MB ChB
President
Spine Intervention Society