September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1784-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1784-P; Medicare Program; CY 2024 Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment and Coverage Policies; (August 7, 2023)

Dear Administrator Brooks-LaSure:

The International Society for Advancement of Spine Surgery (ISASS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year (CY) 2024.

ISASS is a multi-specialty association dedicated to the development and promotion of the most current surgical standards, as well as the highest quality, most cost-efficient, patient-centric, and proven cutting-edge technology for the diagnosis and treatment of spine and low back pain. The Proposed Rule includes several policy and technical modifications within the Resource-Based Relative Value Scale (RBRVS).

This letter includes ISASS recommendations and comments regarding the following:

- CY 2024 Conversion Factor
- Potentially Misvalued Codes
  - CPT code 27279
- Physician Work and Practice Expense Relative Value Unit Recommendations for CPT codes
  - Dorsal SI Joint Fusion
  - E/M Payment
    - Office/Outpatient E/M Visit Complexity Add-on Code
    - Split/Shared Visits
**CY 2024 Medicare Conversion Factor**

In the CY 2024 Proposed Rule, CMS announced an update to the Medicare conversion factor of $32.75 for CY 2024. This represents a 3% decrease from the current (2023) conversion factor of $33.88. Overall, the Physician Fee Schedule conversion factor has decreased by almost 6% just since 2022, even while many practices are still struggling to maintain financial viability due to the changes and hardships caused by the Covid-19 pandemic and the last two years of 6%+ inflation.

If the proposed conversion factor changes are implemented, most neuromodulation interventions would see dramatic reductions in total Medicare reimbursement. For instance, reducing reimbursement for non-opioid pain therapies such as spine surgery would push these patients back towards opioid-based treatment plans, which have led to the tragic opioid epidemic that continues to devastate our country. Several efficacious and cost-effective spine surgery treatments, which currently are reimbursed at marginal levels that barely cover overhead, face drastic reductions if the conversion factor were to be implemented as proposed. The same is true for intrathecal medication therapy on which people with cerebral palsy, stroke, spinal cord injury and multiple sclerosis rely. These collective reductions would represent a tremendous setback in the efforts by CMS and HHS to effectively address the opioid crisis in the United States and may inadvertently cause a resurgence of opioid prescribing.

CMS must act through the proposed rule to ensure access for Medicare patients and assist their physician partners in providing high quality, accessible care to Medicare beneficiaries by waiving all proposed physician payment reductions and instead offsetting the 6-8% real dollar loss to practices from inflation by increasing payments accordingly.

**Potentially Misvalued Codes**

**CPT Code 27279**

In the proposed rule, CMS notes they received a request from an interested party nominating CPT code 27279, Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device as potentially misvalued. The stakeholder referenced the lack of non-facility Practice Expense RVUs for 27279 and stated that the procedure can be performed safely in the non-facility setting and therefore should be updated to include non-facility inputs. Importantly, pricing in the non-facility setting would include the cost of the device(s) for 27279.

CMS, in their review of the request, notes they have concerns that this is not accurate, and that the agency is concerned about patient safety in the non-facility setting. ISASS strongly agrees with CMS regarding the lack of necessary evidence of safety for 27279 and very strongly recommends against adding non-facility inputs and payments. ISASS is composed of spine surgeons who prioritize the safest and most effective treatments for spine disorders. 27279 is an important procedure for spine patients to have access to, but it should only be performed in facility settings by trained Surgeons.
There is no clinical or programmatic benefit for Medicare patients or the Medicare program if 27279 is performed in the non-facility setting. In addition, to date, there is no clinical evidence to support the requestor’s procedural safety claims. To the contrary, the clinical evidence directly contradicts this claim. In February 2023, ISASS conducted a literature search on PubMed and Google Scholar to determine if published data was available that described cohorts of patients undergoing sacroiliac (SI) joint fusion for chronic SI joint pain in the non-facility setting. Our conclusion supported that no published article indexed in PubMed appears to describe SI joint fusion procedures taking place in an office-based setting.¹

ISASS supports that the appropriate site of service for 27279 is the surgeon’s purview, including an Ambulatory Surgery Center or the hospital setting. 27279 and 27280 have been performed by surgeons for 40+ years and surgeons with experience performing these types of spine surgeries can safely assess which type of surgical setting is most appropriate for their patients. Recently, non-surgical physicians have begun performing the less invasive procedures that are now coded as 2X000.² These non-surgical specialists do not have the same experience and perspective as surgeons and spine surgical specialties like ISASS that do not believe patients can be safely treated in office (non-facility) settings.

We commend CMS for recognizing the lack of safety data for 27279 in the non-facility setting and strongly urge CMS to reject the request to review the practice expense inputs. Although we realize that some interventional suites may be appropriate for this procedure, due to the lack of site of service differentiation from other settings reporting as non-facility, we cannot support this request. We also further urge CMS to carefully monitor utilization of 27279 in 2024 and in future years.² Utilization of 27279 by non-surgical providers such as interventional radiologists, anesthesiologists, interventional pain physicians and other interventional providers should decrease significantly with the introduction of new CPT code 2X000 for the dorsal minimally invasive SI joint fusion procedure. 2X000 describes the procedure performed by interventional specialists and 27279 describes the procedure performed by spine and neurosurgeons. If a reduction of 27279 reporting is not reflected in the claims data, CMS may consider further steps to direct providers to use the correct code as established by the American Medical Association for the corresponding procedure.

**Valuation of Specific Codes in the Physician Fee Schedule**

**Dorsal SI Joint Fusion**

CMS proposed RVUs for CPT code 2X000, *Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intraarticular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device)*. The proposed work RVU for 2X000 was 7.86. ISASS agrees with this work RVU.

ISASS also agrees with the statement in the proposed rule that CPT code 27279 does not require a resurvey or revaluation at this time since it was recently reviewed and updated. 27279 has been reviewed ad nauseum.

¹ See attached PDF submitted by Dr. Morgan Lorio February 2023
ISASS disagrees with the agency’s acceptance of the RUC recommended Practice Expense inputs for 2X000. Specifically, ISASS recommends the agency set no non-facility practice expense values for 2X000 and assign practice expense RVUs only for the facility setting. While 2X000 is not as complex a procedure as 27279, it is still a difficult procedure with the possibility of patient complications during surgery. As this is still a new procedure being performed by non-surgically trained physicians, we believe it is safer for the patient to be in a facility with the capability of effectively managing potential complications. Therefore, we support facility only practice expense for 2X000 at this time. CMS may consider reevaluating this new procedure in the coming years once data has been compiled and published supporting patient safety and efficacy in the non-facility setting of care.

ISASS would, however, support the creation and implementation of a new setting of care and pricing for interventional procedure suites. The surgical care environment provided in this setting of care exceeds the traditional non-facility settings that are utilized by providers and hence should be recognized as a distinct site of service for procedures like 2XXX0.

In regard to the non-facility practice expense RVUs, we wish to provide critical information from the perspective of the surgeon community regarding the safety implications for patients, particularly Medicare patients, which would occur from approved PE RVUS in the non-facility site of service. By way of background on this topic, ISASS has developed and maintains a Policy Statement for Minimally Invasive Sacroiliac Joint Fusion (December 2020 update) and recommends the minimally invasive lateral / trans-iliac SIJ fusion procedure (CPT 27279) for patients who meet certain criteria, based on the available evidence. Notably, based on the lack of available evidence, ISASS does NOT recommend the use of MIS dorsal/posterior SIJ procedures, at this time.

In making its recommendations, ISASS conducted a detailed review of the peer-reviewed, published evidence. In terms of the site of care, our evaluation of procedures was limited to what was discussed in the literature: facility-based procedures. Over 100 studies included reviews of patient outcomes, effectiveness, as well as safety of various SIJ procedures performed in the facility setting. We are aware of no study that describes the use of any SIJ technique, whether CPT 27279 or 2X000/0775T, in the non-facility care setting. As referenced above, this is supported by our letter from February 2023 that summarizes the December 2020 ISASS Policy Statement for Minimally Invasive Sacroiliac Joint Fusion.

**Evaluation and Management (E/M) Visits**

**Office/Outpatient (O/O) E/M Visit Complexity Add-on Code**

The Consolidated Appropriations Act, 2021 (CAA) moratorium on Medicare payment for HCPCS code G2211 Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established) will end on December 31, 2023. CMS is proposing to change the status of HCPCS code G2211 to make it separately payable by assigning the “active” status indicator, effective January 1, 2024.

ISASS has previously outlined extensive concerns with CMS implementing G2211 visit complexity code. Overall, there is a lack of clarity on the purpose, use and reporting of this code. ISASS continues
to have questions and concerns regarding the resources, typical patient, time, and definition, and reporting and monitoring of this visit complexity code.

Specifically, we have questions regarding the resources required to perform this service and believes this physician work is already described by other codes such as prolonged services (99358, 99359, and 99417), online digital management services (99421-99423), telephone E/M services (99441-99443), interprofessional telephone/internet/electronic health record consultations services (99446-99452), chronic care management services (99490, 99491, 99437 and 99439), complex chronic care management services (99487 and 99489), principal care management (99424 - 99427) or transitional care management services (99495 and 99496). Additionally, medical decision making (MDM) and/or total time on the date of the encounter addresses the care for the patient who requires unusual resources outside of the MDM Level. In fact, by selecting the code by time and then allowing the add-on code, the additional resources could be recognized in duplicate. Similarly, by selecting multiple elements of "Amount and/or Complexity of Data to Be Reviewed and Analyzed" related to ongoing care, such as ordering/reviewing tests, reviewing external notes, and discussion of management of patient with external physicians/QHP to select a level of code also duplicates complexity of service elements. We continue to assert that G2211 is duplicative of work already described in CPT and ask that CMS clarify the exact additional resources it intends to capture by creating G2211.

We are also concerned that the typical patient to receive G2211 services is not well defined. The RUC and CMS set relative valuation and resource costs based on a description of the typical patient. Is G2211 intended to describe the additional work with the most complex patients? The RUC vignettes for higher level E/M codes already described complex patients and it is unclear how G2211 as drafted differs from these enough to warrant a separate code.

We also are troubled that CMS now states that any physician or other QHP may report the service whereas CMS previously based budget neutrality assumptions on primary care physicians and specific specialties reporting the add-on with 100% of their E/M office visits. In this proposed rule, CMS clarifies that the code may not be reported when a modifier –25 is reported with an E/M service, providing limited coding clarity. CMS reiterates that this service may be appended to any E/M level. CMS went to great lengths in defining the nature of the conditions and care in the descriptors of chronic care and principal care management but fails to do so here which ISASS finds inconsistent and recommends further clarification and specification. Absent this, we believe that Medicare contractors, compliance officers and other stakeholders will face significant challenges in effectively educating and auditing health care practitioners on the proper reporting of this code.

Furthermore, CMS has not published or shared the exact methodology utilized to derive the new utilization assumptions. Therefore, inferences about the type of patient and care are further challenged and inferences are not the desired methodology to educate. Without more information on proper usage practitioners are unable to know how to best document the patient and care attributes required to report the service. CMS projected utilization estimates that 38% of all office visits will append the G2211 add-on code in the first year of implementation and then several years later, 54% of all office visits will append G2211. The CMS method to predict these precise estimates was not published. It appears that CMS excluded the claims with modifier -25 and then assumed 50% of the remaining visits would include the reporting of G2211. However, CMS should confirm its method and share this information publicly. CMS significantly overestimated the utilization upon implementation of other codes (e.g., transitional care management) and this should not be repeated.
We also note that when modifier –22 is appended to a surgical code, documentation to support the unusual additional work is required and that additional payment is not automatic. No such documentation is being required for the use of G2211 which we find problematic and inconsistent.

ISASS continues to request that CMS delay implementation of the G2211 complex care code until such time as these issues are clarified and resolved.

Split/Shared E/M Services

In the proposed rule, CMS proposes to further delay implementation of the split/shared billing changes, continuing to allow history, exam, medical decision making or time to determine who bills the visit. CMS proposes to postpone implementation of prior changes through at least Dec. 31, 2024. The prior proposal would have redefined the definition of "substantive portion" to mean more than half of the total visit time. We continue to believe that this proposal is shortsighted and does not recognize that other aspects besides visit time contribute to physician work.

Clinicians who furnish split/shared visits will continue to have a choice of history, physical exam, or medical decision making, or more than half of the total practitioner time spent to define the substantive portion, instead of using only total time.

ISASS supports this proposed delay in implementation of the split/shared billing changes and believe it benefits patients first and foremost, as well as physicians and practices alike.

Thank you for your time and consideration of ISASS comments. We greatly appreciate the opportunity to participate in efforts to more efficiently and accurately capture current spine care delivery. We commend CMS on its continued efforts to improve care quality and access.

If you have any questions on our comments, please do not hesitate to contact Morgan Lorio, MD, Chair of the ISASS Coding and Reimbursement Task Force at mloriomd@gmail.com.

Sincerely,

Morgan Lorio, MD
Chair, ISASS Coding and Reimbursement Task Force