



September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1751-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1751-P; CY 2022 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies;

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) 2022.

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 2022 Conversion Factor
- Physician Work and Practice Expense Relative Value Unit Recommendations
 - Practice Expense Labor Rate Updates
 - CPT codes 22867
 - 630XX and 630X1
 - 646X0 and 646X1
- TeleHealth Issues
- Chronic Pain Management Reimbursement

2022 Medicare Conversion Factor

In the CY 2022 Proposed Rule, CMS announced an update to the Medicare conversion factor of \$33.58 for CY 2022. This represents a 4% decrease from the current (2021) conversion factor of \$34.89.

ISASS is extremely disappointed and concerned with the drastic reduction in the Medicare Conversion Factor and strongly recommends CMS take action in the CY 2022 Final Rule to eliminate this conversion factor reduction.

If the proposed conversion factor changes are implemented, many interventions would see dramatic reductions in total Medicare reimbursement. These procedures are critically important alternatives to past devastating, epidemic opioid-based treatment plans. Several efficacious and cost-effective pain treatments are currently reimbursed at marginal levels, barely covering overhead, and now face drastic reductions if the conversion factor were to be implemented as proposed. 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 has done an admirable job in adjusting rules, regulations, and payment rates in response to the current Public Health Emergency due to the Covid-19 crisis. Yet, despite this recognition and all the efforts by CMS to increase access to care for Medicare patients, CMS is proposing the largest single reduction in payment rates to physicians and providers in many years. This is directly contrary to the efforts and the messaging by CMS. If implemented for CY 2022, this unreasonable, proposed reduction would completely undo all the success CMS and physician stakeholders have had in navigating this unprecedented health crisis. If implemented in the final rule, a -4% reduction would cause a massive access shortage as



practices reduce staff and hours to absorb the impact. This would result in less access at a time where greater access and greater flexibility is needed in caring for Medicare patients.

The reduced conversion factor constitutes a breaking of trust between physicians, CMS, and patients. Our collaboration and cooperation in overcoming these unprecedented times has been one of the few bright spots in the PHE. Reducing payments to physicians is an unfair and unacceptable response to this collaboration and risks future opportunities for cooperation. CMS should maintain their cooperation and collaboration by maintaining conversion factors and waiving budget neutrality in the fee schedule for all physicians and providers under the Medicare Physician Fee Schedule for CY 2022.

Finally, the continued downward pressure on the conversion factor continues to represent an unfunded mandate imposed on physician and physician practices at the expense of other components of the overall health care delivery system. As CMS shifts costs across components of the system, most precisely from the inpatient Part A component into the outpatient/physician Part B component, it should necessarily shift funding along with concomitant costs. However, because costs have grown while funding has not increased, a reduction in the overall conversion factor has been proposed. This has been occurring for the better part of twenty years, and if CMS appropriately funded the shifts, the conversion factor would not be facing negative adjustments. It defies logic and is profoundly unfair to all those paid under the Medicare Physician Fee Schedule and CMS owes it to all the stakeholders to take action in the next Fee Schedule to at a minimum maintain the conversion factor at the 2021 rate. **‘Robbing Peter [physicians] to pay Paul’ does not garner Peter’s support.**

Proposed Work and Practice Expense Relative Value Units

Practice Expense Labor, Supply and Equipment Updates

In the 2022 Proposed Rule, CMS recommended adjustments to practice expense (PE) inputs as a result of a revision of Clinical supply and equipment cost updates for CY 2022. This is the final year of the updated supply and equipment adjustments and has resulted in significant changes to practice expense RVUs for many services. The proposed rule indicated CMS is interested in comments on using a four-year phased implementation of the impacts in order to mitigate the drastic changes that the 2022 proposed rule entailed.

ISASS supports the phased approach and believes a four-year transition to be wise and helpful to physicians and practices. We recommend CMS finalize the transition in the final rule for CY 2022 and future years.

ISASS is also concerned with the proposed adjustment to clinical PE labor rates and their significant impact on procedures with supplies and equipment provided in the non-facility setting. If the proposed clinical labor rate updates were to be fully implemented in CY 2022 several procedures could see significant reductions in PE and total RVUs. We believe CMS



should revise the proposed update to allow for a more gradual and less drastic impact in the implementation of the updates.

To illustrate the deleterious impacts of this labor rate adjustment as proposed, CPT codes 22513, 22514, 22515, 22516 are projected to have a 20%, 22%, 22%, and 22% respectively solely as a result of this adjustment.

Shifting symptomatic patients by site-of-service with compression fractures away from the physician office to the hospitals during this 'new normal' with COVID-19 will be extremely damaging. Patient reluctance to present to the hospital for vertebral augmentation or alternatively a reluctance by the hospital to offer vertebral augmentation as treatment will only encourage a return to historic failed conservative treatment.

The consequences of a shift away from access to kyphoplasty services in an office setting includes higher incidences of death and disease, as well as more complications requiring more complex interventions later.^{1,2} Furthermore, this resultant shift will contribute to increased direct or downstream hospital-acquired costs for an already stretched health care system.

We believe CMS should revise the proposed update to allow for a more gradual and less drastic impact in the implementation of the updates and thus offset this potentially catastrophic outcome for the Medicare program and Medicare patients.

CPT code 22867

In the 2022 Proposed Rule, CMS recommended adjustments to work RVUS for CPT® code 22867, *Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*. 22867 was nominated by CMS as potentially misvalued in the 2021 Medicare Physician Fee Schedule Final Rule and was reviewed by the RUC at the January 2021 AMA RUC meeting. ISASS agreed with the agency that 22867 was misvalued and worked with other stakeholders in advising the RUC on a proposed update in value. While we appreciate the acceptance by the RUC and CMS of a new, higher value for 22867 of 15.00 work RVU from the current work RVU of 13.50, we request that CMS consider adding additional work RVUs to the adjusted value to correctly represent the physician work and intensity involved in performing 22867.

All stakeholders, including CMS, agree the current work RVU of 13.50 to be incorrect and the RUC recommendation of 15.00 work RVUs was appropriate from a RUC perspective, based

¹ Hirsch JA, Chandra RV, Carter NS, Beall D, Frohbergh M, Ong K. Number Needed to Treat with Vertebral Augmentation to Save a Life. *AJNR Am J Neuroradiol*. 2020 Jan;41(1):178-182. doi: 10.3174/ajnr.A6367. Epub 2019 Dec 19. PMID: 31857326; PMCID: PMC6975314.

² Ong KL, Beall DP, Frohbergh M, Lau E, Hirsch JA. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty "sham" trials? *Osteoporos Int*. 2018 Feb;29(2):375-383. doi: 10.1007/s00198-017-4281-z. Epub 2017 Oct 24. PMID: 29063215; PMCID: PMC6394540.



on RUC methodology. However, we encourage CMS to consider input beyond the RUC's recommendation given the evidence of incorrect valuation. ISASS has presented information and feedback on the clinical work necessary to perform this complex procedure and believe that even at 15.00 the work RVUs undervalue the work. The procedure itself includes the work of a Laminectomy, which is coded as 63047. 63047 has a work RVU of 15.37 as a stand-alone procedure which means that valuation at 15.00 for 22867 represents a clear rank order anomaly.

Therefore, we recommend the agency use a building block approach to valuing 22867 which takes the 15.37 work RVU of 63047 and adds the additional work for implantation of the interlaminar/interspinous stabilization device after the decompression laminectomy. Other lumbar spine device implant add-on codes such as 22853 have a work RVU of 4.25. When added to 63047 this would result in a work RVU of 19.62 which is also close in value to many other spinal surgery codes such as 22612 and 22630 and more appropriately places the work of 22867 relative to other similar spine surgery services.

ISASS has presented its recommendations and information that support higher work RVUs for CPT 22867. Based on these materials, ISASS recommends that CMS rely on the detailed analysis of physician work associated with the procedure, published in the *International Journal of Spine Surgery*.³ This recently published analysis of the work involved with CPT 22867 was based on an independent survey of 58 surgeons with experience performing open decompression with interlaminar stabilization (ILS) as described by CPT 22867 and experience performing open decompression laminectomy described by CPT 63047 open laminectomy. Twenty-eight surgeons responded to the survey. The survey results were there used to compare the physician work involved in the procedure with the five most common comparable procedures. A multi-linear regression analysis was then completed with comparator work RVUs as the dependent variable and estimated complexity difference as the independent variable.

“In the spirit of the Rasch analysis, the comparator CPT® code wRVUs and calculated differences were analyzed by multiple linear regression that adjusts for five relative difficulties (complexity) variables captured during the survey (mental effort, technical effort, physical effort, risk, and overall intensity). In other words, the wRVUs for CPT® 22867 was predicted by using the relative difficulty of the surveyed procedure to the most comparable procedure. The regression analysis of comparator code wRVUs (dependent variable) on the calculated differences (independent variable) estimated an intercept of 20.95.”⁴

The **new regression analysis** demonstrates that not only are the current work RVUs for CPT 22867 undervalued but that the work RVUs for CPT 22867 should be increased to 20.95 to

³ Lorio D et al. Determination of Work Relative Value Units for Management of Lumbar Spinal Stenosis by Open Decompression and Interlaminar Stabilization. *Int J Spine Surg*. 2021;15(1):1-11. doi:10.14444/8026.

⁴ Lorio D et al. Determination of Work Relative Value Units for Management of Lumbar Spinal Stenosis by Open Decompression and Interlaminar Stabilization. *Int J Spine Surg*. 2021;15(1):1-11. doi:10.14444/8026.



correctly value the physician work. See Figure 1 below showing the regression analysis results with the 0-value falling well above 20 work RVUS for the value of the physician time and effort involved in the procedure 22867 (see Figure 1 embedded below).

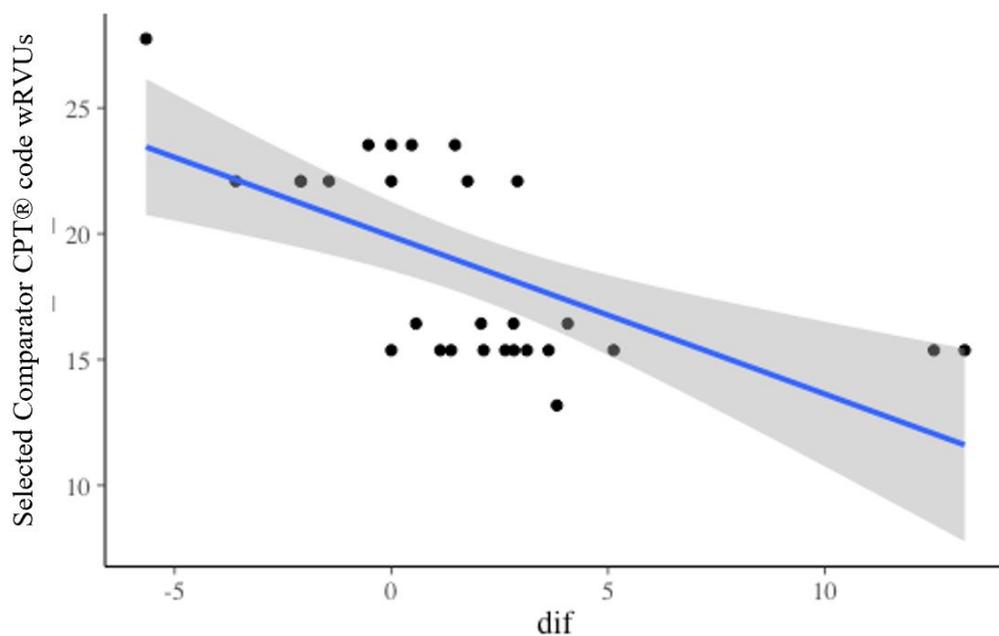


Figure 1. Results of regression analysis of estimated wRVUs of CPT® 22867.

ISASS understands that CMS may need to provide a rationale for increasing the work RVUs for CPT 22867 in the final rule. The following approaches may be considered:

- CMS can explain the procedure described by CPT 22867 includes the work of an open laminectomy, which is coded as 63047.
- CPT 63047 has a work RVU of 15.37.
- If CMS finalizes, as proposed, work RVUs of 15.00, CPT 22867 would be clearly undervalued.

In support of this added value, there is evidence from large samples of intra-service time that the intra-service work time for 22867, which the RUC surveyed at 90 minutes, is in fact greater, with a median time of approximately 110 minutes. This additional 20 minutes further supports and warrants higher work RVUS than the 15.00 proposed by CMS and the RUC.



Additional **new data** from an analysis published in *Spine*⁵ suggests far more consumption of physician work RVU by 22867 procedurally than by laminectomy 63047 alone, as indications have grown within a more complex patient population as evidenced by the excerpted study results below:

Eighty-three (83) patients from 2007-2019, which included 37 cases of single-level laminectomy as compared to 46 single level lumbar interlaminar stabilization following decompression (ILS+D). The ILS+D cohort (69 yo) was older than the Laminectomy cohort (64 yo, p=0.042) and had higher ASA grades; the ILS+D cohort, additionally, had a higher American Society of Anesthesiologists (ASA) grade of 2.59 versus the Laminectomy cohort grade of 2.17, p=0.020. The ILS+D cohort patients had (1) greater estimated blood loss (EBL) of 97.50 ml versus 52.84 ml, p=0.004, (2) longer operative time of 141.91 min versus 106.81 min, p=0.001, and (3) longer length of stay (LOS) of 2.0 days versus 1.1 days, p=0.001. ILS+D cohort had higher total perioperative complications (21.7% versus 5.4%, p=0.035) and higher ILS instrumentation complications (10.9% versus 0.0%, p=0.039) than did the Laminectomy cohort. Obviously, both Time and Intensity for ILS+D (or CPT 22867) have been erroneously misvalued, as has the malpractice RVU for this combined open procedure. Currently, Surgalign Spine Technologies, Inc (Deerfield, Illinois) is the only source for the ILS implant component (coflex™) used procedurally.

Moreover, 22867 has demonstrated **organic growth** procedurally by the emergence of lumbar interspinous stabilization following decompression (ISS+D) which is undergoing IDE trial and being coded as 22867 and reimbursed likewise. Procedural time data from the LimiFlex™ (Empirical Spine, Inc, San Carlos, CA) IDE trial (presented in part by Lavelle et al, ISASS21, Miami, FL) is summarized below in Table 1. One hundred-forty (140) procedures completed to date. Mean skin-to-skin time was 112 minutes, with mean 23-minute device implantation time. This illustrates that the bulk of the procedure is dedicated to the decompression laminectomy, and consistent with literature reports of the surgery and anesthesia time required for decompression consistent with CPT 63047. The 23-minute average device insertion time also corresponds to the additional time to insert an interbody fusion device corresponding to CPT 22853. Thus, the work RVU associated with CPT 22867 should reflect the total work of CPT 63047 and an add-on code such as 22853, as described above.

Table 1: Procedure time details from the LimiFlex™ IDE Study (minutes)

	Mean ± SD	Min.	25 th %	Med.	75 th %	Max
Skin-to-skin time	112 ± 32	59	88	105	125.25	216
LimiFlex™ implant time	23 ± 15	7	14	18	27.25	84
Total anesthesia/OR time	168 ± 39	97	139	164	191	305

⁵ Zhong J et al. Patient Outcomes After Single-level Coflex Interspinous [Interlaminar] Implants Versus Single-level Laminectomy. *Spine*. 2021 Jul 1;46(13):893-900. doi:10.1097/BRS.0000000000003924. PMID:33395022.



Please also note that **open ILS/ISS+D (CPT 22867)** performed by surgeons is NOT to be confused or conflated with **percutaneous ILS/ISS (CPT 22869)** performed by non-surgeons (Medicare Utilization data from 2019 shows 97% of claims for CPT 22869 to be performed by pain physicians). A parity model for reimbursing the combined procedure has been previously presented to CMS/OMB to rectify the gross mis-valuation of 22867 and additionally supports the increase in work RVU. Finally, ISASS points out that when a surgeon is required to halt implantation of either ILS or ISS due to intraoperative technical considerations that the decompression performed is appropriately coded alone as 63047, which is also consistent with the building block approach.

ISASS strongly recommends that CMS adopt a work RVU of 19.62 with the use of a building block methodology in the 2022 Medicare Physician Fee Schedule if they choose not to implement the RUC recommended work RVU of 15.00.

CPT codes 630XX and 630X1

In January 2021, the RUC submitted interim recommendations for new CPT add-on codes 630XX and 630X1. The RUC did not accept the revisions to the existing code family as editorial and recommended that the entire family be resurveyed. Thus, the new CPT codes 630XX and 630X1 were resurveyed with their base codes 22630, 22632, 22633, and 22634 in April 2021 for review at that RUC meeting and interim values were established for CPT codes 630XX and 630X1. The recommendations for all six codes were submitted by the AMA RUC to CMS in May. ISASS urges CMS to accept the final recommendations from the April 2021 RUC meeting for CPT codes 630XX and 630X1 for the 2022 Medicare Physician Fee Schedule.

Background

First, in discussion of the additional level code 630X1, CMS contends that “we do not agree that decompression when performed in conjunction with posterior interbody arthrodesis at the same interspace should have an anomalously high work value in comparison to other similar add-on codes that have longer intra-service times.” We would remind CMS that the valuation of decompression when combined with interbody fusion has a long history involving the use of Modifier –62.

Modifier –62 Two Surgeons: When 2 surgeons work together as primary surgeons performing distinct part(s) of a procedure, each surgeon should report his/her distinct operative work by adding modifier 62 to the procedure code and any associated add-on code(s) for that procedure as long as both surgeons continue to work together as primary surgeons. Each surgeon should report the co-surgery once using the same procedure code. If additional procedure(s) (including add-on procedure[s]) are performed during the same surgical session, separate code(s) may also be reported with modifier 62 added. Note: If a co-surgeon acts as an



assistant in the performance of additional procedure(s), other than those reported with the modifier 62, during the same surgical session, those services may be reported using separate procedure code(s) with modifier 80 or modifier 82 added, as appropriate.

In 1998, the AMA Modifier -62 Workgroup considered whether different specialties should report 22630-62 when physicians of different specialties performed different portions of this procedure. At that time, orthopedic surgeons routinely performed the interbody fusion, while neurosurgeons performed the decompression. The workgroup decided use of modifier -62 *Two Surgeons*, would undervalue the work performed, as 22630 did not include the work of a laminectomy and discectomy for decompression; 22630 only described the bone resection necessary to access the disc space to complete the interbody fusion. A decompression (63047) performed at the same level would be reported with modifier -51 *Multiple Procedures*. A National Correct Coding Initiative (NCCI) edit effective January 1, 1999, further corroborated the distinction procedurally, and noted that modifier -59 *Distinct Procedural Service*, should be used if the same surgeon was performing both procedures at the same spinal level. The combined use of the decompression and interbody fusion codes was reiterated in a January 2001 CPT Assistant Article.

In 2010, a new code combining 22630 (arthrodesis, posterior interbody technique) and 22612 (arthrodesis, posterior or posterolateral technique) was developed. When the new code 22633, *Arthrodesis, combined posterior or posterolateral and interbody fusion including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression)*, was surveyed, respondents were instructed that the procedure would **not** include the work of decompression. It was understood at this time that the work of decompression would be separately reported.

There was a misinterpretation of the combined application of these codes by payers which eventually led in 2015 to a NCCI edit, which blocked use of -59 for 63047 performed at the same level as 22630/22633. Including the work of decompression (63047) in the interbody fusion codes (22630/22633) produces a disruptive rank order anomaly in physician work values, since this inclusion was not incorporated in the RUC valuations of these codes. National spine societies uniformly opposed this NCCI edit and asked that it be overturned. A CPT Assistant article published in October 2016 offered a similar opinion to the NCCI edit, conflicting with previous CPT and CPT Assistant publications. This article was rescinded by the AMA in another CPT Assistant article published in May 2018. The efforts to correct this error eventually yielded the new interbody decompression codes, 630XX and 630X1.

The CMS proposed values of 630XX and 630X1 are considerably lower than the historical values for the codes previously used to report this physician work. The RUC recommended values are certainly not anomalously high, and in fact represent a significant decrease in valuation for these services.

630XX



In the proposed rule, CMS disagrees with the interim RUC recommendation that supports the January 2021 survey 25th percentile work RVU. The Agency suggests that an analysis of other add-on codes with similar time values indicates that this service is overvalued and instead proposes a work RVU of 3.08 based on an intra-service time ratio. The proposed value represents an unacceptable 45 percent reduction from the interim RUC recommendation as submitted. CMS is not using a valid method to propose a work RVU for CPT code 630XX by proposing a value based on an intra-service time ratio. The ratio uses the intra-service time (40 minutes) of the interim RUC recommendation and that of CPT code 63048 *Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)*(work RVU = 3.47 and 45 minutes intra-service time). ISASS strongly disagrees with CMS calculating intra-service time ratios to account for changes in time. This approach ignores magnitude estimation and is inconsistent with RBRVS principles. ISASS recommends that CMS embrace the following input from practicing physicians when: (1) valid surveys are conducted; (2) rigorous review by the specialty society committees is performed; and (3) review of magnitude estimation and cross-specialty comparison has been conducted by the RUC.

The proposed value represents an unacceptable 45 percent reduction from the interim RUC recommendation as submitted. CMS' proposed value also disregards the input of highly trained, experienced, and knowledgeable neurosurgeons and orthopedic surgeons and the RUC by proposing to base the work RVU of code 630XX on an intra-service time ratio using CPT code 63048 *Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)*. CMS claims code 63048 is a stronger reference code due to "similarities in the long descriptors, physician time, and intensity of intra-service work."

However, code 63048 is an inappropriate comparator because of differences in procedure and patient elements. Code 63048 describes performance of a decompressive laminectomy at an additional level to a base code, 63047 *Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar*. Part of the work and time involved in 63048 is that of exposure of bony and soft tissue elements of the adjacent level. The codes assessed in this survey, 630XX, do not require additional work of exposure; the exposure is completed as part of the base interbody fusion code.

Additional Decompression [CPT codes 630XX and 630X1], when required, with TLIF(PLIF) is performed via an angular oblique approach after partial facet resection resulting in an intense, surgically challenging experience (with increased potential for durotomy or neural injury) during the extended hemilaminectomy(s)/laminectomy work component, which is due



in part to asymmetric dural expansion or ballooning. The complexity of the surgical indication for TLIF(PLIF) including instability or revision, epidural fibrosis (scar), and advanced degeneration present in the elderly also technically lead to increased durotomy during the Additional Decompression.⁶ Whereas 63048 is performed after completion of 63047 which provides wide, safe posterior exposure for a more straight-forward approach procedurally. Hence, 630XX describes only the high intensity, dangerous aspects of neural element and spinal cord decompression. Therefore, these procedures, while similar, cannot be valued based upon time ratio alone.

CMS, in a meeting with the surveying spine specialty societies on 09.10.21 understandably raised questions regarding why 63048 is a much different procedure than 630XX and 630X1. We believe these details provide strong evidence in response to this concern voiced by CMS and helps explain why the CMS chosen crosswalk of 63048 is not appropriate for 630XX. Moreover, this crosswalk approach ignores magnitude estimation and is an overly simplistic approach to valuing this physician service.

Difference in patient population also argues for a difference in valuation between these codes, as discussed during the RUC assessment of 630XX. Patients undergoing 630XX are considerably more complex, with more severe pathology, than those patients undergoing 63047 and 63048. The disease process affecting patients undergoing 630XX is so severe that it requires performance of an interbody fusion, a procedure much more complex than a lumbar decompression. This may entail greater degrees of stenosis, greater extent of facet joint arthropathy, and greater degrees of degenerative change at the involved segment. This complexity is verified by survey results; while 630XX and 63048 have similar time estimates, 630XX was valued much higher by survey respondents, reflecting how the intensity and difficulty of this service is greater than 63048.

In the 09.10.21 CMS meeting with surveying spine specialty societies, CMS inquired whether the RUC surveys of 630XX included 63048 as a reference code and if not, why not. RUC processes regarding codes placed on a survey Reference Service List (RSL) precluded the inclusion of 63048 on the first survey in Fall of 2020. When the CPT Editorial Panel approved codes 630XX and 630X1 at the October 2020 CPT Editorial Panel meeting they also made editorial changes to the family of decompression codes which included CPT code 63048 (along with other ZZZ codes in the family such as 63035, Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar. The RUC process for surveys does not allow societies to list a code in a RSL that has been revised and identified as part of “a CPT family of codes” for review/reaffirmation at the same meeting. Therefore, 63048 was not included as a possible reference service for the survey reviewed in January 2021 but the RUC did accept its current values at that meeting.

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3198662/>



However, when 630XX and 630X1 were resurveyed with the parent codes of 22630, 22632, 22633, and 22634 for the April 2021 RUC meeting, 63048 was included on the reference service list because it was no longer identified as part of the tab/family of services under RUC review. Hence, survey respondents for the April 2021 meeting did have the opportunity to select 63048 as a key reference for 630XX but it was not one of the two most commonly chosen reference services. The two key reference services from the April 2021 RUC survey were CPT codes 22840, Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure) and 22208, Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); each additional vertebral segment (List separately in addition to code for primary procedure) which are both codes for highly complex, difficult and risky additional level spinal surgeries.

The fact that these two procedures were chosen by more than half the respondents while 63048 and other far less involved additional level spine surgery reference codes were not chosen strongly supports the argument that 630XX (and 630X1) are much more difficult procedures than 63048.

The RUC constructed several valid comparisons to value CPT code 630XX. The RUC compared to the key reference service code 22552 *Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)* (work RVU = 6.50 and 45 minutes intra-service time) and noted that the reference code has slightly higher intensity as anticipated for a surgical procedure and in comparison, with a lumbar procedure. The RUC also compared code 630XX to MPC code 34812 *Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision, unilateral (List separately in addition to code for primary procedure)* (work RVU = 4.13 and 40 minutes intra-service time) and noted that the MPC code involves open femoral artery exposure by groin incision and closure of the wound, typically for separately reported delivery of an endovascular prosthesis for an asymptomatic infrarenal abdominal aortic aneurysm. In comparison, exposure and closure for the survey code are performed as part of the primary arthrodesis code and the intra-service time includes higher intensity bony and soft tissue resection (typically pathologic and not normal in nature) and decompression of neural elements in immediate high-risk proximity of the pathologic anatomy. Therefore, although both codes require the same time, the physician work and intensity of 630XX is greater than 34812.

CMS notes that the proposed work RVU for CPT code 630XX falls between CPT code 19294 *Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy* (work RVU = 3.00 and 40 minutes intra-service time) and CPT code 37185 *Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological*



thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (work RVU = 3.28 and 40 minutes intra-service time). These are inappropriate comparison codes because neither reflect the complexity of 630XX. Code 19294 describes the additional soft tissue work required for delivery of radiation therapy after partial mastectomy. This code is routinely reported concurrently with a separate code for the work of the radiation oncologist. This code describes only soft tissue dissection and the physician work does not involve dissection around neural elements and around the spinal cord and dura, with greater risk for complication and major morbidity (neurologic deficit, CSF leak at the time of surgery, or hematoma potentially causing postop permanent functional loss). The physician work of code 19294 has a lower intensity than code 630XX. Similarly, code 37185 describes mechanical thrombectomy, arterial or arterial bypass graft, for second and adjacent vessels. This work does not entail risk to neural elements or to the spinal cord; it is considerably lower intensity than 630XX.

Subsequent to the January 2021 RUC meeting and based on a request from the RUC at the January 2021 meeting, the specialty societies resurveyed 630XX at the same time that the base codes-22630 and 22634 were surveyed. The RUC re-reviewed CPT code 630XX in April 2021 and recommended a work RVU of 5.70 based upon the recent survey results this time from 111 neurosurgeons and orthopedic spine surgeons. The RUC determined that the April 2021 survey 25th percentile appropriately accounts for the physician work involved in this add-on service and that the final recommendation is more accurate than the interim as it is based on the survey of the entire code family. Also, the overall experience of the survey respondents is greater for the new survey of six codes when compared to the prior survey of only the add-on codes. The RUC recommendation were for 45 minutes intra-service time and the time included in this add-on service is essentially all high-risk, higher intensity work. The lower intensity surgical exposure activities have already been completed with the base code, so the physician work of 630XX involves the actual higher intensity decompression. ISASS strongly recommends a work RVU of 5.70 as supported by the survey 25th percentile. **ISASS urges CMS to accept a work RVU of 5.70 for CPT code 630XX.**

630X1

CMS is proposing a work RVU of 2.31 for CPT code 630X1 based on an intra-service time ratio between the proposed 30 minutes of intra-service time for CPT code 630X1 and the proposed 40 minutes of intra-service time for CPT code 630XX. While the RUC recommended, on an interim basis, that CPT code 630X1 should be valued based on a direct crosswalk to CPT code 33572 with 30 minutes intra-service time as supported by the survey, CMS again uses an intra-service time ratio in justifying the proposed value. ISASS strongly disagrees with CMS calculating intra-service time ratios to account for changes in time. In contrast to the CMS process, the RUC acknowledged the robust survey results and determined that a value below the 25th percentile was appropriate given the time for code 630X1 was three-fourths that of the 630XX code.



CMS brackets its proposed work RVU for CPT code 630X1 between CPT code 43273 *Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s)* (work RVU = 2.24 and 30 minutes intra-service time) and CPT code 22870 *Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level* (work RVU = 2.34 and 30 minutes intra-service time) and notes that both of these reference codes have identical intra-service times as CPT code 630X1. Code 43273 is an add-on code designed for addition to base codes describing endoscopic retrograde cholangiopancreatography (ERCP). This procedure does not involve dissection around neural elements and the spinal cord; its only relevance to 630X1 is a comparable intra-service time. It is not an appropriate crosswalk. Code 22870, while a spine procedure, specifically does not involve decompression of neural elements or of the spinal cord, hence its intensity is much lower than 630X1. The base code which 22870 is routinely appended to CPT code 22869 *Insertion of interlaminar/ interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level*, is an outpatient code. In contrast, the base codes for 630XX and 630X1 are all inpatient codes. It is assumed that the pathology of patients undergoing codes 22869 and 22870 is less severe than those patients undergoing interbody fusion (22630/22633) with concomitant lumbar decompression (630XX and 630X1). Therefore, this CMS recommended code is also a poor crosswalk.

The RUC, however, constructed appropriate brackets for CPT code 630X1, with identical intra-service time, using comparator codes 32674 *Thoracoscopy, surgical; with mediastinal and regional lymphadenectomy (List separately in addition to code for primary procedure)* (work RVU = 4.12 and 30 minutes intra-service time) and 33924 *Ligation and takedown of a systemic-to-pulmonary artery shunt, performed in conjunction with a congenital heart procedure (List separately in addition to code for primary procedure)* (work RVU = 5.49 and 30 minutes intra-service time). ISASS notes that CPT code 32674 is a minimally invasive procedure to identify and remove lymph nodes in conjunction with a single lobe lobectomy. The technical skill and mental effort/judgment for 630X1 is greater due to the involvement and necessary protection of spinal cord and neural elements. CPT code 33924 is more intense than 630X1 and thus appropriately valued higher.

ISASS maintains that CMS is not using a valid method to propose a work RVU for code 630X1 by proposing a value based on an intra-service time ratio. Moreover, the proposed value represents an unacceptable 48% reduction from the interim RUC recommendation as submitted.

At the April 2021 RUC meeting, ISASS and other societies presented updated survey values for 630X1 which was surveyed at the request of the RUC along with its base codes 22632 and 22635. The RUC re-reviewed CPT code 630X1 in April 2021 and recommended a work RVU of 5.00 based upon the recent survey results from 111 neurosurgeons and orthopedic surgeons who are familiar with and perform spinal surgery. The RUC determined that the survey 25th percentile appropriately accounts for the physician work involved in this add-on service and



that the final recommendation is even more accurate than the interim value as it is based on the robust survey results rather than a crosswalk. The new survey, which included all six codes, elicited an intra-service time of 40 minutes that is only five minutes less than the work related to 630XX and is believed to be a more accurate reflection of the difference in work between laminectomy/ facetectomy/foraminotomy with decompression of the first segment and of an additional segment. ISASS strongly recommends a work RVU of 5.00 based on the survey 25th percentile. **ISASS urges CMS to accept the work RVU of 5.00 for CPT code 630X1.**

646X0 and 646X1: Destruction of Intraosseous Basivertebral Nerve

646X0

CMS disagrees with the RUC recommendation that supports the survey 25th percentile work RVU for CPT code 646X0. The Agency suggests that an analysis of other 10-day global codes with similar work time values indicates that this service is overvalued and instead proposes a work RVU of 7.15 based on a crosswalk to CPT code 63650 *Percutaneous implantation of neurostimulator electrode array, epidural* (work RVU = 7.15, 60 minutes intra-service time and 170 minutes total time).

It appears all these comparison codes were arbitrarily selected as CMS does not provide any clinical foundation for the comparison of the surveyed codes to the crosswalk codes. Furthermore, these comparison codes seem to have been selected solely for their similar characteristics to the Agency's desired reduction and to justify similarly chosen time ratio comparisons. ISASS recommends that CMS embrace the input from practicing physicians when valid surveys were conducted, rigorous review by the specialty society committees was performed and review of magnitude estimation and cross-specialty comparison has been conducted by the RUC.

ISASS also disagrees that the proposed crosswalk to CPT code 63650 serves as a more accurate valuation for CPT code 646X0. The crosswalk is clinically inappropriate because the work of 646X0 has a much closer comparator in the actual performance of the procedure in 22514 and 22513.

Rather, ISASS supports its recommendation for code 646X0 with solid comparisons to the key reference service codes 22514 *Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar* (work RVU = 7.99, 45 minutes intra-service time and 150 minutes total time) and 22513 *Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic* (work RVU = 8.65, 50 minutes intra-service time and 155 minutes total time).



22514 and 22513 were by far the most commonly chosen reference codes by survey respondents, with 55 of 58 respondents choosing one of these codes. 63650 was also on the survey Reference Service List and respondents who perform the procedure had the opportunity to distinguish between the clinical relevance of the services and relative resources. Only 1 of the 58 respondents choose 63650 as their key reference service suggesting it is not a clinically appropriate or relevant comparator for the work and resources required to perform 646X0.

We also believe the surveyed intra-service time of 60 minutes for performing BVN ablation of the first two vertebral bodies to be on the very low end of possible mean or median times. This is because recognized and accepted impedance issues per vertebral body (1) occur (secondary to local vasculature or bone density) halting the procedure in a percentage of BVN lesions per vertebral body and (2) thus increase the **active (not static)** intra-service RFA work step component. Kyphoplasty does not incur lesion impedance (the combined effects of ohmic resistance and reactance). Impedance issues when they occur, do not occur as an incidental singular event. However, they may occur multiple times requiring much more additional physician work effort, including removing and cleaning/drying the RFA probe and then meticulously reinserting the RFA probe using additional image guidance, each time this occurs. The net result is that the survey time quoted of 15 minutes for the localized intra-osseous bipolar RFA step is much greater, as a single case entails a minimum of two BVN lesions adjacent to the disc or two vertebral bodies. An additional level would similarly be affected involving an additional vertebral body if adjacent or contiguous and two additional bodies if discontinuous.

Thus, BVN ablation clearly takes longer to perform than either of the kyphoplasty procedures, as the precision for tunneling through hard bone into the vertebral body (VB) and reaching the loci of the BVN is greater than just entering the vertebral body to perform vertebral augmentation. The average age of patients in published studies approaches 50 years old, and this population has denser bone than that encountered with kyphoplasty. In addition, the risk of complication from BVN ablation is greater as the consequences of a complication with BVN ablation are orders of magnitude greater (paralysis, severe and irreversible pain). These factors make the work involved in performing BVN ablation clinically far more complex and intense (i.e. the pucker factor is much higher with BVN ablation than with kyphoplasty).

To assist CMS with better understanding the differences between the BVN ablation procedure and Kyphoplasty, please see Attachment 1-Step-by-Step Pictorial Depiction of BVN Ablation Procedure. We also offer the following step-by-step description in table 1 below.

Table 2

Steps	BVN Ablation	Kyphoplasty
1	Patient receives general anesthesia (moderate sedation is rare with BVN Ablation)	Patient receives general anesthesia or moderate sedation

2	Patient turned prone on radiolucent table – all extremities are appropriately padded and the eyes inspected	Patient turned prone on radiolucent table – all extremities are appropriately padded and the eyes inspected
3	C-arm brought in to visualize the spine in AP/LAT/OBL to ensure that vertebral bodies (VBs) to be treated can be visualized. Requires rotation of the imager to square the VB in both views to ensure appropriate guidance into the VB	C-arm brought in to visualize the spine in AP/LAT to ensure that vertebral bodies (VBs) to be treated can be visualized.
4	Back prepped and draped – wider than usual for pedicular procedures due to the more lateral approach to entry	Back prepped and draped - usual region
5	First VB selected – imagine intensifier rotated to oblique for facet view to assist with entry into the lateral aspect of the pedicle	VB to be treated is lined up. AP & Lateral view.
6	Skin entry point identified and infiltrated with 1% lidocaine using a 25-gauge 1-1/2 inch needle	Skin entry point identified and infiltrated with 1% lidocaine using a 25-gauge 1-1/2 inch needle
7	22-gauge 5-inch spinal needle is used to anesthetize the track to the pedicle and periosteum and to confirm the introducer cannula trajectory	
8	Skin incision made	Skin incision made
9	8-gauge introducer cannula assembly (ICA) introduced through the skin, subcutaneous tissue and paraspinal muscle until bony contact is made.	11-gauge Jamshidi needle is advanced to the origin of the pedicle
10	Position checked in the AP and Lateral plane with fluoroscopy.	Position checked in the AP and Lateral plane with fluoroscopy.
11	The ICA is malleted to advance through the pedicle - traversing posterolateral to anteromedial to enter the VB as close to the medial wall of the pedicle without breaching. Advancement is checked by rotating the C-arm between AP and Lateral.	Jamshidi is advanced thru the pedicle with a small mallet in the middle of the pedicle. Checked with C-arm between AP and Lateral
12	The trocar tip is advanced into the posterior VB leaving the introducer cannula (IC) in the pedicle.	Advance to the VB body.
13	The trocar is removed and the Curved Cannula (CC) Assembly (CCA), with the nitinol J-stylet inserted into the IC.	Stylet is removed, guidewire inserted.

14	Trajectory of the CCA is checked in the lateral view making sure that the direction is to the target of the basivertebral nerve (BVN).	Introducer Cannula is passed over the guidewire to the VB.
15	The CCA is malleted advancing it in 2 mm increments into the VB and adjustments made to trajectory to make sure that the CCA is going to hit target.	With the channel made, the balloon is inserted. Position checked in the AP and Lateral
16	Target in the lumbar VB is 30-50% from the posterior wall and at the equator of the VB.	Steps 5 - 15 may be repeated for the contralateral side
17	Target in S1 is 50% from the posterior wall and 40% from the superior endplate.	The balloon(s) is inflated checking its position in AP and Lateral
18	The CCA is advanced to pass the mid-point as seen on the AP view.	With cavity created the balloon(s) is deflated and removed.
19	The stylet is removed.	Using bone fillers, the PMMA is inserted thru the pedicle(s)
20	The bipolar radiofrequency probe is connected to the generator and inserted into the IC to reach the target.	The PMMA hardens in less than 10 minutes.
21	The PEEK sleeve (part of the CC) is retracted to expose the RF tip.	Instruments are removed and surgical wound repaired.
22	AP view is obtained to ensure that the tip bisects the spinous process.	Patient returned to the supine position and general anesthesia is reversed.
23	The generator is turned on and energy applied for a total of 15 minutes at 85 degrees Celsius. When an impedance issue occurs (>17%), lesioning is halted. The RF probe is removed and cleaned/dried, then reinserted to reach the target and lesioning resumed after AP image view confirms bisection of target; this step may need to be repeated multiple times to complete lesion and will necessarily require much more than 15 minutes to actively apply energy for a total of 15 minutes so as to complete lesion.	
24	Steps 5 - 23 are repeated at each and every VB that requires treatment.	
25	Instruments are removed and surgical wound repaired.	
26	Patient returned to the supine position and general anesthesia is reversed.	



ISASS also compared 646X0 to other 010 global period codes including CPT code 31239 *Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy* (work RVU = 9.04, 60 minutes intra-service time and 168 minutes total time) which has the same intra-service time and similar post-operative visits of 0.5 99238 discharge visit and 1-99213 office visit and similar total time. ISASS believes 646X0 to be slightly more intense in its work than this endoscopy procedure, but otherwise very similar in nature.

The CMS recommended work RVU actually creates a significant rank order anomaly with 22513 and 22514 at the proposed work RVU of 7.15. 646X0 takes more time to perform, as the specialty RUC survey validated, and is a more complex procedure. 646X0 involves thermal destruction of the basivertebral nerve inside lumbar and sacral vertebrae thus achieving the desired pain relief for patients which is complex work performed through advanced equipment inside hard bone as opposed to 22513 and 22514 which, while also performed inside a vertebral cavity involves the insertion of a balloon, which is not as complex or intense. Yet, the CMS work RVU for 646X0 would be significantly less than the work RVU for 22513 and 22514. This is clinically incorrect and will lead to inappropriate and inaccurate allocation of Medicare resources and reimbursement.

ISASS strongly recommends a work RVU of 9.75 based on the survey median and entreats CMS to embrace the input from practicing physicians when: (1) valid surveys are conducted; (2) rigorous review by the specialty society committees is performed; and (3) review of magnitude estimation and cross-specialty comparison has been conducted by the RUC. ISASS urges CMS to accept a work RVU of 9.75 for CPT code 646X0.

646X1

CMS disagrees with the RUC recommendation of the survey 25th percentile work RVU for CPT code 646X1 of 4.87. However, the Agency states they believe that “the relative difference in work between CPT codes 646X0 and 646X1 is equivalent to the recommended increment of -3.38 RVUs.” CMS is proposing a work RVU of 3.77 for CPT code 646X1 based on the “recommended increment” of 3.38 RVUs, below the proposed work RVU of 7.15 for CPT code 646X0. While the RUC takes changes in work and time carefully into account, the RUC recommended value of 4.87 for CPT code 646X1 was not arrived at for the purposes of establishing an absolute difference in value. As stated above, the value was the survey value from the RUC survey and it is not methodologically based or consistent with other more valid methodologies used to determine work RVUs.

CMS states its belief that “the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity.” This, however, does not achieve relativity and instead has the appearance of seeking an arbitrary value from the vast array of possible mathematical calculations, rather than seeking a valid, clinically relevant relationship that would actually preserve relativity.



The RUC utilized robust survey data and numerous supporting reference codes to determine the recommended value of 4.87 for the new add-on code. The RUC compared CPT code 646X1 to key reference service code 22515 *Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)* (work RVU = 4.00 and 30 minutes intra-service time). The RUC also compared code 646X1 to the second key reference service code 22552 *ArthrodeISASS, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure)* (work RVU = 6.50 and 45 minutes intra-service time). The RUC determined that 646X1 is appropriately bracketed by the two key references services.

In addition, the RUC also compared CPT code 646X1 to other ZZZ global period codes and noted that there are several ZZZ codes with 60 minutes of intra-time and similar work RVUs. Specifically, CPT code 61799 *Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure)* (work RVU = 4.81 and 60 minutes intra-service time) and CPT code 63103 *Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (eg, for tumor or retropulsed bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure)* (work RVU = 4.82 and 60 minutes intra-service time) are spinal/cranial procedures with similar amount of physician work and identical intra-service times.

Given this volume of similarly valued ZZZ codes with similar times, the RUC recommended work RVU of 4.87 is clearly appropriately rank ordered. The CMS proposed work RVU on the other hand creates a major rank order anomaly, not only with these services, but in particular with 22515 at a work RVU of 4.00 despite having an intra-time of 30 minutes, half of 646X1's intra-service time.

ISASS strongly recommends a work RVU of 4.87 based on the survey 25th percentile for this add-on code. We believe this work RVU maintains the appropriate relativity between the add-on (646X1) and the base code (646X0) for BVN Ablation.

Practice Expense

We appreciate that CMS is proposing the RUC recommended direct PE inputs without refinements.



Telehealth and Other Services Involving Communication Technologies

During the COVID-19 PHE, pursuant to authority granted in the CARES Act, CMS waived the geographic and site of service originating site restrictions for Medicare telehealth services, allowing Medicare beneficiaries across the country to receive care from their homes. These flexibilities remain in effect through December 31, 2021. In the proposed rule, CMS does not propose to permanently extend these waived restrictions in the PFS stating that it lacks authority to make this adjustment. However, CMS does propose to maintain some telehealth adjustments including expanding the number of services that can be billed as telehealth. ISASS fully supports this extension of the PHE status and all related statutory and sub-regulatory changes affected by the PHE emergency authority.

In the proposed rule, CMS is not proposing to continue current coverage and payment for Medicare audio-only visits for all services except mental health services after the conclusion of the COVID-19 PHE. ISASS supports the current coverage policies and payment rates for audio-only visits for all services, not just mental health services, and strongly encourages CMS to extend the current coverage and payment rates for a minimum of two years after the end of the PHE or December 31, 2023. We believe this 24-month extension is particularly necessary for Medicare patients as there will be a significant period even after the PHE lapses during which Medicare patients will likely benefit from full access to all non-face-to-face services including audio-only visits. We believe the current payment rates to be appropriate as the provider work for audio-only patient visits is completely equal to in-person or audio-video patient encounters particularly so for Medicare patients who often are only employing audio services, reside in locations with limited internet connectivity, and not using smart technologies with audio-video programming. We do support the proposal to cover mental health services delivered via audio-only technology and applaud the agency recognizing the importance of allowing of maintaining and possibly expanding access to the services for patients in need of them. We do, however, believe the rationale provided in the proposed rule can and should be expanded to all office E/M services in the final rule.

Chronic Pain Management Reimbursement

In the proposed rule, CMS is soliciting comments on whether it should create separate coding and payment for chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether these services are already appropriately recognized in the payment system. CMS cites multiple federal reports that urge better support for person-centered pain management, including the 2016 National Pain Strategy and the 2019 HHS Pain Management Best Practices Inter-Agency Task Force Report. It also notes the intersection between the problems with pain care and the worsening epidemic of drug overdose deaths, primarily due to illicitly manufactured fentanyl, other synthetic opioids, and methamphetamine. CMS also notes that untreated and inappropriately treated pain may translate to increased Medicare costs as more patients experience functional decline,



incapacitation, and frailty.

ISASS is grateful to the agency for their long overdue recognition of the opportunity to address the opioid crisis, which has devastated untold number of American and Medicare beneficiaries, by actively incentivizing alternate chronic pain management treatments. This approach appropriately recognizes the real clinical need for pain management services. It also seeks to rebalance the treatment options way from opioid based prescriptions to repeated and prolonged treatment through mental health and chronic pain relief. ISASS members have been at the front lines in responding to the opioid crisis for our patients and believe that it is absolutely appropriate and necessary to provide separate and/or additional reimbursement for these services. CMS has in recent years provided payment through G-codes and modifiers for providers who are treating patients with multiple chronic conditions and patients transitioning from inpatient treatment to outpatient/home based treatment and we recommend the agency create G-codes similar to the chronic care management codes that can be billed by pain management and mental health providers for chronic care for patients with severe pain as a condition.

ISASS applauds this move and stands ready to assist the agency in the development of coding and reimbursement options for providers like our members who care for this specific patient population. We look forward to collaborating with the agency and other stakeholders in this process.

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 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,

A handwritten signature in black ink that reads "Morgan F. Lorio MD". The signature is written in a cursive style.

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