

8735 W. Higgins Rd. Ste. 300 Chicago, IL 60631 Phone 847/375-4714

Fax 847/375-6424

Web site: www.neuromodulation.org

September 26, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1715-P; CY 2020 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (August 14, 2019)

Dear Administrator Verma:

The North American Neuromodulation Society (NANS) 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) 2020, published in the August 14, 2019 *Federal Register (Vol. 84, No. 157 FR, pages 40482-41289)*.

NANS is a multi-specialty association of more than 1,600 physicians dedicated to the development and promotion of the highest standards for the practice of neuromodulation procedures in the diagnosis and treatment of the nervous system, including neurosurgeons, orthopedic spine surgeons, anesthesiologists, physiatrists, psychologists, urologists, and neurologists. We are committed to working with CMS and other stakeholders to promote the highest quality, most efficient, patient care for patients dealing with chronic neuromuscular pain.

Today we are faced with an opioid crisis in America, but we also have millions of Americans who suffer with chronic pain. These patients need access to opioid alternative treatments, including interventional pain management treatments which are appropriate and effective treatment for a variety of chronic pain conditions. Decisions in the proposed rule will significantly impair some patients from accessing these treatments. We recommend CMS follow the recent HHS Opioid Task Force's guidance which specifically directs HHS agencies to encourage non-opioid pain management treatments and help patients access critical and efficacious non-opioid treatments. Assigning inappropriately low work and practice expense RVUs to non-opioid options such as injections, nerve ablation procedures, pain reservoir analysis and refill are contrary to this effort. All these pain services are clinically efficacious alternative to opioids for pain management. While the agency should always strive for fair and appropriate payment for physician services, the role these procedures

¹ https://www.whitehouse.gov/opioids/

can play in diverting patients from using opioids for pain management, makes an even more compelling case to ensure appropriate payment and access to these services.

In the proposed rule, CMS discusses proposals to address the opioid crisis indicating that they recognize this to be a national health issue, but your emphasis must be beyond the establishment of new codes for treatment and counseling for substance use disorders. Addressing the opioid crisis is a critical priority that falls upon CMS as well as physicians who treat patients with substance abuse disorders or patients who are at risk for them, such as those with chronic pain. That is why some of the proposed changes which could have a detrimental effect on patient access to certain interventional treatments must be carefully reviewed by CMS, we urge you to take our comments and concerns seriously given the current opioid issues in this country. CMS has named September, Pain Awareness Month and states in the September MLN Network Newsletter, "CMS is committed to reducing opioid misuse by promoting person-centered care that encourages safe and effective pain management including opioid and non-opioid pain treatments." We strongly encourage CMS to recognize that services like interventional pain therapies are one of the key treatment options for patients with pain that does not involve opioid prescriptions and helps reduce pain in Medicare patients. Furthermore, the Opioid Taskforce has also emphasized the importance of providing fair reimbursement to providers who are on the front lines treating pain and trying to help control the Opioid crisis.

This letter includes NANS recommendations and comments regarding the following:

Valuation of Specific Codes

- A. Proposed Valuation of Specific Codes for CY 2020
 - 1. Electronic Analysis Pain Pump Pump-PE Only
 - 2. Genicular Nerve Treatment Codes
 - 3. Sacroiliac Nerve Treatment Codes
 - 4. Somatic Nerve Treatment Codes

Payment for Evaluation and Management (E/M) Services

- A. Evaluation and Management (E/M) Office Visit Services
- B. Office Visits Included in Surgical Global Payment

Physician Billing Privileges Under Medicare

Proposed Valuation of Specific Codes For CY 2020

Analysis of Pain Pumps (PE Only, CPT codes 62367-626370)

CPT codes 62367, Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill; 62368, Electronic analysis of pro Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status,

drug prescription status); with reprogramming; 62369, Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill and 62370, Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)

These services were flagged by the RUC's Relativity Assessment Workgroup (RAW) because some of the services were originally surveyed and valued by a different specialty than the typical specialty in 2016. The RAW recommended that societies review the practice expense (PE) inputs only for the four codes. Several societies presented the PE inputs at the April 2018 RUC meeting. However, NANS was not part of that review and presentation. Had we been, our advisors would have identified several issues with the proposed RUC times which we feel are inaccurate and do not properly represent the work involved in managing these intrathecal drug delivery systems. In addition we are very concerned with the potential for these changes in reimbursement to create further issues for access to this treatment and possible safety concerns. Over the years as CMS has ratcheted down reimbursement for this service more and more providers have ceased to provide this service for patients due to the high labor intensity for the doctor and his/her staff, the high risk of managing intrathecal medications, which can be life threatening if managed improperly or hastily, and the progressive decreased reimbursement for this service inconsistent with the true intensity and risk for the physician. Further loss of access will certainly follow these unjustified proposed cuts and will only lead to increased systemic opioid use by patients with chronic pain. This is directly contrary to the recommendations of the 2019 HHS Task Force which specifically directs HHS agencies to encourage proper reimbursement for pain management treatments/services.²

We believe the RUC and CMS, while attempting to follow their procedures and processes, either were not aware or did not fully consider the impacts of their actions. Specifically, the RUC and CMS applied significant reductions to clinical labor inputs for CPT 62367 and 62368 because these services are billed more than 50% of the time with Evaluation and Management office visit services. While this may be the case, the underlying rationale-that clinical staff times are redundant do not apply to these services. Neuromodulation physician offices provide these services to patients every day, and the time spent by clinical staff is not duplicative and is not captured by any accompanying Evaluation and Management codes. The work done for 62367 and 62368 are additive to office visits and should not have clinical labor inputs reduced. We recommend that CMS use the current (2019) Practice Expense inputs and not adopt the proposed reductions for 2020.

We also believe the clinical labor time assigned to CPT codes 62369 and 62370 for clinical staff time during the procedure ("intra-service") should not be set as the same time as the time assigned for physician intra-service work. This is not how these services are provided in practice where the clinical staff spend significant amounts of time before and after the physician provides his/her services in the actual provision of the services. The previous practice expense settings of 50, and 52 minutes, clinical staff intra-service time are accurate and consistent with actual practice patterns and should not have been subject to arbitrary reductions. Analysis of pain pump prescription refills requires significant amount of very meticulous work from the doctor and staff. In the case of intrathecal Baclofen or high dose morphine, a missed refill could cause life threatening withdrawal. Each patient has to be tracked for refill dates, chart reviewed before

² IBID

ordering to look for changes from the doctor, prescriptions need to be written, and then transmitted to a pharmacy. When medications are received, these need to be recorded and double-locked per Drug Enforcement Agency (DEA) regulations, and then when taken out and dispensed the staff must inform and assist the patient in collecting their signatures. And that is all work done in advance of the actual pump refill. The refill requires work and specific expertise to be performed properly, an incorrect refill such as a pocket fill (when the medications are placed into the pump pocket rather than the pump accidentally) has an extremely high morbidity and a significant mortality rate. After the refill any and all waste must be disposed of properly; these are extremely potent solutions of medications and the doctor and clinical staff must maintain strict control. This amount of work occurs for every patient encounter and should be recognized in the RVUs assigned to these services.

We implore CMS to restore the inputs from the 2019 fee schedule for 2020. Restoration of the 2019 clinical labor inputs and practice expense RVUs are critically important to assuring uninterrupted access to this vital non-oral opioid treatment. Not taking this action will undoubtedly imperil patient safety and have deleterious effects on some of the most-needy pain and spasticity patients including those patients with severe cancer pain, Multiple Sclerosis, Cerebral Palsy, and other chronic pain states for which pain pump access allows for a higher quality of life and better health for patients.

Genicular Injection and RFA (CPT Codes 64640, 64XX0, and 64XX1)

In May 2018, the CPT Editorial Panel approved the addition of two codes to report injection of anesthetic and destruction of genicular nerves by neurolytic agent: 64XX0 (*Injection(s)*, anesthetic agent(s) and/or steroid; genicular nerve branches including imaging guidance, when performed), and 64XX1 (Destruction by neurolytic agent genicular nerve branches including imaging guidance, when performed). These codes as well as another code in the family, codes 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) were reviewed and discussed at the October 2018 and January 2019 RUC meetings.

This procedure is extremely important in the management of patients with chronic knee pain secondary to severe Osteoarthritis of the knee, who can't have a Total Knee Replacement or don't want a major surgery with the associated risk and rehabilitation, and those unfortunate patients who have undergone a total knee replacement but still have pain. In fact, these patients have few other choices other than chronic opioids. Genicular nerve denervation offers an excellent, efficacious, and much more inexpensive alternative. Even prescribed opioids for a 6-12-month duration (the duration of effect of Geniculate RF ablation therapy) would be more costly to Medicare and is worse for patients (and society) due to the attendant risk of opioid addiction. Other treatment options including neuromodulation therapies (DRG stimulation and Peripheral Nerve Stimulation) are significantly more expensive and invasive. While we also advocate for patients to have access to these treatments for recalcitrant chronic knee pain, we also recognize that less costly and less invasive therapies should be tried first. Improper payment for genicular nerve denervation may lead some physicians to skip this treatment option, opting for more expensive and more invasive therapies.

Work RVU Recommendations

64XX1 (Destruction by neurolytic agent genicular nerve branches including imaging guidance, when performed)

Code 64XX1 (Destruction by neurolytic agent genicular nerve branches (includes image guidance, when performed) is a new code that describes destruction of 3 different nerve branches (superomedial, inferomedial, and superolateral genicular nerve branches) at three locations (adjacent to the periosteum on the medial aspect of the tibia, and at both the medial and lateral aspects of the femur) in order to achieve analgesia for the respective knee.

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64XX1	N/A	2.62	2.50

Code 64XX1 will be a new code in 2020 so there is no current value for this code. The RUC recommended a wRVU of 2.62. CMS is proposing to reduce it to 2.50 wRVUs.

CMS is basing this value on an intra-service time ratio in relation to an existing code in this family of services, CPT code 64640. CMS compared the RUC recommended wRVU, intraservice and total times of CPT codes 64XX1 and 64640 to derive their proposed wRVU of 2.50 by calculating the intra-service time ratio between these two codes, which is a calculated value of 1.25. CMS multiplies this ratio with the RUC recommended work RVU of 1.98 for CPT code 64650, which results in a calculated value of 2.48. This value, CMS states, is nearly identical to the RUC survey 25th percentile value of 2.50 for code 64XX1.

As previously stated, NANS strongly disagrees with CMS' intra-service time ratio methodology in general as well as for the specific circumstance to value code 64XX1. It has been a longstanding position of CMS that treating all components of physician time (pre-service, intraservice, post-service and post-operative visits) as having identical intensity is incorrect and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. NANS is very troubled by this methodology and how the agency has approached valuation of other codes surveyed by NANS for CY 2020 in this proposed rule. CMS seems to have randomly selected various methodologies in proposing values for different codes versus seeking a valid, consistent, transparent and accepted methodology to preserve relativity. Over the years the methodologies used by the RUC (namely, magnitude estimation, survey data and clinical expertise) have been the primary method when developing work values for physician services. We urge CMS not to abandon this approach.

The agency also used code 11622 (Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 1.1 to 2.0 cm) as a reference code to support its proposed value. It has a wRVU of 2.41 and similar time to code 64XX1. NANS disagrees with the reference code. As previously discussed in this letter, reference codes should be similar in both time as well as in clinical similarity. CPT code 64XX1 describes the destruction of three different nerve branches at three locations to provide analgesia for the respective knee and code 11622 which describes

excision of a malignant lesion of trunks, arms or legs. The physician work required for 64XX1 is more intense in that it is the destruction of three different nerve branches and if performed incorrectly would have the potential to produce irreversible tissue damage to other motor or sensory nerves in the vicinity of the knee.

During its deliberations the RUC considered these issues and in identified a crosswalk more appropriately aligned code 64XX1. RUC selected code 11642 (*Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 1.1 to 2.0 cm*) which is also a multi-points of comparison (MPC) code. While the time associated with 11622 and 11642 is similar, code 11642 is an excision on the face, ears, eyelids, nose, lips, which is a more delicate area in which precision is required and it is more intense and complex to complete. The RUC concluded and NANS agrees that 11642 is a more appropriate crosswalk than the one proposed by CMS.

NANS urges CMS to accept a wRVU of 2.62 for code 64XX1.

For the remaining two codes in the family, CMS is proposing the RUC-recommended wRVU recommendations. CMS is proposing 1.98 wRVUs (25th percentile survey value) for CPT code 64640 and the RUC-recommended wRVU of 1.52 (25th percentile survey value) for CPT code of 64XX0. NANS is pleased that CMS is supporting the RUC recommendations for these two codes.

NANS urges CMS to finalize these proposed wRVU values of 1.98 wRVUs for code 64640 and 1.52 for code 64XX0.

Practice Expense Recommendations

CMS is proposing refinements to the RUC recommended direct PE inputs for code 64XX1.

For code 64XX1, CMS is proposing to refine the quantity of the supply item SD011 cannula (radiofrequency denervation) (SMK-C10) from 3 to 1. CMS does not believe that the use of 3 of this supply item would be typical for the procedure as the nerves would typically be ablated one at a time using this cannula, as opposed to ablating three of them simultaneously. NANS wishes to clarify to the agency that 64XX1 procedure requires simultaneous ablation of the three genicular nerves. This is standard practice and was therefore the way in which the survey respondents would have completed the survey. We believe CMS may be basing their time and equipment assumptions on the cooled Radiofrequency (RF) cannula provided by a single manufacturer/supplier. The cooled RF cannula costs approximately \$600-\$1,000 per kit, but accounts for only 20% of the market share for this procedure as we understand. CMS needs to include with the PE reimbursement coverage for the multiple cannulas used when performing multiple simultaneous lesions with hot RF or the cost of the coolief equipment @\$.... CMS is also proposing to refine the equipment time for the equipment item radiofrequency kit for destruction by neurolytic agent equipment from 141 minutes to 47 minutes. The equipment time recommendation was predicated on the use of 3 of the SD011 supplies for 47 minutes apiece and CMS is refining the equipment time to reflect their supply refinement to 1 cannula. The same concept as above applies here as well. Three individual kits are required to do this work simultaneously.

NANS urges CMS to accept the RUC practice expense input recommendations for code 64XX1 including 3 units of supply item SD011 and 141 minutes associated with equipment item radiofrequency kit for destruction by neurolytic agent.

Radiofrequency Neurotomy Sacroiliac Joint (CPT Codes 6XX00, 6XX01)

In September 2018, the CPT Editorial Panel created two new codes to describe injection and radiofrequency ablation of the sacroiliac joint with image guidance for somatic nerve procedures.

Work RVU Recommendations

CMS is proposing the RUC-recommended wRVU of 1.52 for code 6XX00 (Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)) and the RUC-recommended wRVU of 3.39 for code 6XX01 (Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)). NANS is pleased that CMS is proposing to accept the RUC wRVU recommendations for these codes.

NANS urges CMS to finalize the proposed wRVUs of 1.52 for code 6XX00 and 3.39 for code 6XX01.

Practice Expense Recommendations

CMS is proposing refinements to the RUC recommended direct PE inputs for code 6XX00 and 6XX01.

CMS is proposing to refine the quantity of supply item SC028 *needle*, 18-26g 1.5-3.5in, spinal, from three to one for CPT code 6XX00. CMS agrees that the service being performed in CPT code 6XX00 would require a spinal needle but propose that the use of three such needles would be atypical. This code describes four separate injections of three sacral levels. Four separate needles are required to inject the dorsal rami of L5 and the lateral branches of S1, S2 and S3. While the original RUC recommendation indicates only 3 needles are needed, this was an error and should in fact be 4 needles. Standard practice is to place the four needles, then simultaneously inject.

Additionally, CMS is proposing to refine the quantity of supply item SD011 cannula (radiofrequency denervation) (SMK-C10) from four to two for CPT code 6XX01. CMS does not believe that the use of four cannula would be typical for the procedure, as the reference code currently used for destruction by neurolytic agent contains only a single cannula. The agency believes that the nerves would typically be ablated one at a time using this cannula, as opposed to ablating four of them simultaneously. Similar to the injection code (6XX00), the radiofrequency ablation of the nerves innervating the sacroiliac joint requires four cannulas for simultaneous ablation of the four nerves. The cannulas are placed one at a time and then all 4 nerves are lesioned simultaneously to shorten the duration of the procedure. As with the injection codes, this is standard procedure and the physicians surveying this code accounted for the decrease in time accordingly. Again, we believe CMS may be basing their pricing on products that use cooled RF. However, these cannulas cost much more than the standard hot RF cannulas which is

what the societies and the RUC based their recommendations on. As with the Genicular Nerve codes described above, if CMS is basing their per procedure quantity estimates on cooled RF, the PE for this code would have to be significantly increased to reflect the use of this equipment (approximately \$600-\$1,000 per cannula). However, we believe it is more consistent with standard CMS approaches for valuation to reflect the supplies used in the majority of SI joint nerve RF ablations procedures which is 4 hot RF cannulas and not a single (coolief) cannula as proposed.

NANS urges CMS to accept the corrected RUC PE input recommendations for code 6XX00 including 4 units of supply item SC028 and the RUC PE input for code 6XX01 of 4 units of supply item SD011.

Somatic Nerve Injection Code Family (CPT Codes 64400, 64408, 64415, 64416, 64417, 64420, 64421, 64425, 64430, 64435, 64445, 64446, 64447, 64448, 64449, and 64450)

The Somatic Nerve Injection Code family describes the injection(s) of an anesthetic agent(s) and/or steroid into a nerve plexus, nerve, or branch; reported once per nerve plexus, nerve, or branch as described in the descriptor regardless of the number of injections performed. This code family was recently reviewed at the request of the Editorial Board of the *CPT Assistant* to clarify the code definitions and improve the understanding of the appropriate reporting of the code family. The new code family was approved at the May 2018 CPT Editorial Panel meeting and surveyed for the October 2018 RUC meeting.

Work RVU Recommendations

NANS was very disappointed that CMS has proposed to reject the RUC work RVU (wRVU) recommendations for 12 of the 18 codes in this family which recently went through a vigorous survey process. In developing these recommendations, the RUC took a comprehensive approach which included consideration of robust survey data; input from clinical experts; and maintenance of appropriate relativity within the code family and throughout the fee schedule. In developing specific recommendations, the RUC considered: anatomic location of each nerve, whether the service is typically performed in an office or facility setting, the typical approach used by the dominant specialty to access the nerve and whether the service involves continuous administration via placement of a catheter. NANS does not believe the agency took these critical factors into account when developing their proposals.

NANS is also concerned over the agency's overall approach to developing proposed values for this family of codes.

• Harvard vs RUC Survey Data: The first issue has to do with the consideration of time and other data related to these codes. This family of codes includes many Harvard-based codes. These are codes that have never been surveyed; time is not based on a direct measurement and the basis for the current valuation is unknown. The family also includes codes that have been surveyed by the RUC and for which there is a documented rationale for the current value of the code. Throughout its review of this family CMS has equated the imputed time from Harvard data with the more reliable RUC survey time. This is a flawed methodology. Historically, RUC survey data has been viewed as a more accurate measurement of time versus Harvard time. On a related issue, while it has been a long-standing policy of the agency that a reduction in time does not equate to a one to one reduction of wRVU values, CMS has seemed to apply this approach to this family.

Selection of Crosswalks and Reference Codes to Establish Values: Historically the selection of crosswalks or reference codes are based not only on similar intra-service time but also clinical similarity. Clinical similarity refers to the complexity, intensity and risk of the procedure. Throughout this family, CMS has selected reference codes where intra-service time seems to be the only similarity and where there clearly is no clinical similarity to the two procedures. As an example, in one instance for a surveyed code which is performed predominately in the facility setting as part of post-operative pain management after major surgery, CMS selected a relatively simple procedure performed in the office setting generally performed by a non-physician health practitioner.

NANS has significant concerns with this approach and believes it has resulted in a significant and inappropriate undervaluation of these services. NANS strongly believes the evidence-based RUC recommendations are more appropriate and urge CMS to finalize the RUC recommendations for this entire family.

Summary Table: Somatic Nerve Injection Code Family

Code #	2019 wRVUs	Current Data Source	RUC Rec.	Basis for RUC Rec.	2020 Proposed wRVU	Basis for 2020 Proposed wRVU
64400	1.11	Harvard	1.00	 Survey data (25th percentile) Reference code 	0.75	 Time ratio methodology Reference code
64415	1.48	RUC- 2009	1.42	 Survey data (25th percentile) Reference code 	1.35	Time ratio methodologyReference code
64416	1.81	RUC- 2008	1.81	 Survey data (25th percentile) Reference code 	1.48	 Time ratio methodology Reference code
64420	1.18	Harvard	1.18	 Survey data (25th percentile) Reference 	1.08	 Time ratio methodology Reference

Code #	<u>2019</u> <u>wRVUs</u>	Current Data Source	RUC Rec.	Basis for RUC Rec.	2020 Proposed wRVU	Basis for 2020 Proposed wRVU
				code		code
64421*	1.68	Harvard	0.60	• Crosswalk	0.50	 Time ratio methodology Reference code
64425	1.75	Harvard	1.19	 Survey data (25th percentile) Reference code 	1.00	Maintain rank order in the family
64430	1.46	Harvard	1.15	 Survey data (25th percentile) Reference code 	1.00	Maintain rank order in the code family
64445	1.48	RUC- 2009	1.18	 Survey data (25th percentile) Reference code 	1.00	Maintain rank order in the code family
64446	1.81	RUC- 2008	1.54	• Crosswalk	1.36	 Time ratio methodology Reference code
64448	1.63	RUC- 2008	1.55	• Crosswalk	1.41	 Time ratio methodology Reference code
64449	1.81	RUC- 2008	1.55	• Crosswalk	1.27	Time ratio methodologyReference

Code #	2019 wRVUs	Current Data Source	RUC Rec.	Basis for RUC Rec.	2020 Proposed wRVU	Basis for 2020 Proposed wRVU
						code

^{*} Note, the code definition of 64421 is changing in 2020. It is going from an XXX code to an add-on code that is reported with the base code of 64420.

By the agency's own admission, the time ratio methodology used by CMS throughout the evaluation of this code family is not consistent with their overall approach to valuing codes. Additionally, applying this method to codes that have not been previously surveyed (Harvard) and comparing that time to RUC survey time is a completely flawed methodology.

64400 Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie,

ophthalmic, maxillary, mandibular)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64400	1.11	1.00	0.75

Code 64400 describes injection of the trigeminal nerve. The typical patient presents with a normal neurologic exam but reports headaches that include pain in one or more branches of the trigeminal nerve (ophthalmic, maxillary, or mandibular). Code 64400 is currently a Harvard-valued code that has not been previously surveyed. This means that the time was merely extrapolated and not measured directly. The rationale for the basis of the current value is unknown.

The current value for code 64400 is 1.11 wRVUs. The RUC recommendation reduced it to 1.00 wRVUs and CMS is proposing to further reduce it to 0.75 wRVUs. This represents a 25% reduction from the RUC recommended value. The agency's rationale for this reduction is that the intra-service time decreased from 37 to 6 minutes (84 percent reduction) and the RUC-recommended total time decreased from 69 to 20 minutes (71 percent reduction) for CPT code 64400. CMS is basing its recommendation of 0.75 wRVUs on a crosswalk to code 64450 (*Injection(s)*, *anesthetic agent(s)*; *other peripheral nerve or branch*) which CMS indicates has a similar intra-service time. However, injection of the trigeminal nerve branches is significantly more difficult with much greater risk. The risk of complication for an injection in the facial region is much greater than the concomitant risk of injecting nerves in the torso or extremity regions which are the most common locations for 64450.

NANS believes the agency's rationale is flawed and that the proposed crosswalk to 64450 is inappropriate.

In developing its rationale for a proposed value for this code, CMS is comparing intra-service time for a Harvard-based code to times from a RUC survey. As we stated in our introductory comments, this is a flawed methodology. Typically, Harvard time is not based on a direct measure of the service while the RUC surveys are a survey of time specific to the code. NANS believes it is always inappropriate to compare Harvard time to RUC time.

CMS also supports its proposed value with a crosswalk to code 64450. Crosswalks are an effective methodology to assign value in a relative value system. That said, as discussed in our introductory comments to this section crosswalks are only appropriate if the codes are similar in intra-service time and are clinically similar (*e.g.* complexity, intensity and risk). The anatomical location of the injection determines the clinical complexity, intensity and risk of the procedure. Codes 64400 and 64450 are not clinically similar. Code 64450 is not specific to a nerve target and is used when a more specific code is not available. The typical patient for 64450 is described as a patient experiencing a chronic burning pain and a tingling sensation in the plantar aspect of their right foot. A clinically similar service to 64450 is code 20553 (*Injection(s)*; *single or multiple trigger point(s)*, 3 or more muscles) which has RUC intra-service time of 10 minutes and is valued as 0.75 wRVUs. In contrast, code 64400 describes an injection of the trigeminal nerve which is inherently more complex than injecting the plantar aspect of the right foot, the typical patient for the 64450 vignette, which 78 percent of survey respondents to a survey for 64450 found to be accurate.

The RUC's recommendation for code 64400 was based on survey data and a crosswalk to a more appropriate crosswalk.

In recommending 1.00 wRVUs, the RUC based this recommendation on the 25th percentile of the dominant specialty reporting the code (neurology). The RUC decided to take this subset approach which is atypical but used in this circumstance because although neurology is the top performing specialty, they represented fewer survey responses than anesthesiology. Neurology is 47 percent of the 2017 Medicare claims whereas anesthesiology is only 10 percent of the claims. NANS believes this is an appropriate approach to take in this circumstance. We would note, that if the RUC would have based its recommendation on the 25th percentile of all survey respondents the recommended value would have been higher than 1.00 wRVUs.

The RUC also strongly supported its recommendation with comparison to CPT code 31575 *Laryngoscopy, flexible; diagnostic* (wRVU = 0.94, intra-service time of 5 minutes, total time of 24 minutes) and MPC code 36620 *Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous* (wRVU = 1.00, intra-service time of 7 minutes, total time of 17 minutes). NANS believes that these are appropriate reference codes that are both clinically similar (complexity, intensity and risk) as well as have similar in intra-service time.

NANS urges CMS to accept the RUC recommendation of 1.00 wRVUs for code 64400.

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Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64415	1.48	1.42	1.35

Code 64415 describes the injection of the brachial plexus. The typical patient presents with persistent, debilitating pain interfering with the ability to complete daily activities. This code was previously surveyed by the RUC in 2009.

The current value for code 64415 is 1.48 wRVUs. The RUC recommendation reduced it to 1.42 wRVUs and CMS is proposing to further reduce it to 1.35 wRVUs. This represents a 5% reduction from the RUC recommended value. CMS indicates that their recommendation is based on their "...time ratio methodology..." although they do not provide details on the methodology. While intra-service time for this code did decrease from the current 15 minutes to 12 minutes with the most recent survey, reducing the value based just on reduced intra-service time would be inconsistent with current CMS policy. CMS' longstanding position is that, "...we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs." This is reiterated 18 separate times in the CY 2020 Proposed Rule including with this code, however it was disregarded when proposing an alternate valuation method.

CMS also supported its recommendation by a reference to CPT code 49450 (*Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injections(s), image documentation and report)*, which has a wRVU of 1.36 and similar intra-service and total time values to CPT code 64415. NANS believes this rationale is flawed and does not believe the crosswalk is appropriate. Code 49450 was surveyed twelve years ago in 2007.

The RUC's recommendation for code 64415 was based on survey data and with additional support with other reference codes. The RUC recommendation was based on the 25th percentile work RVU and careful review of all of the underlying clinical attributes of the procedure.

The RUC also strongly supported its recommendation with comparison to code 64612 *Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)* (wRVU = 1.41, intra-service time of 10 minutes, total time of 41 minutes) and code 30903 *Control nNANSI hemorrhage, anterior, complex (extensive cautery and/or packing) any method* (wRVU = 1.54, intra-service time of 15 minutes, total time of 39 minutes). Both of these codes are more recently surveyed than 49450 which is another reason that makes these more accurate and appropriate comparison. Code 64612 was surveyed in 2012 and code 30903 was surveyed in 2016. We believe code 64612 is a code more clinically similar making it a strong reference code for 64415. The intensity and risk of an injection of a facial nerve described by 64612 more closely resembles 64416 than the reference code selected by CMS, code 49450.

NANS urges CMS to accept the RUC recommendation of 1.42 wRVUs for code 64415.

64416 Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)

Code#	2019 wRVU	RUC	2020 Proposed
		Recommended	wRVU
		wRVU	

64416	1.81	1.81	1.48

Code 64416 describes the injection of the brachial plexus with continuous infusion by catheter. The typical patient presents with persistent, debilitating pain interfering with the ability to complete daily activities. This code was previously surveyed by the RUC in 2008.

The current value of the code is 1.81 wRVUs. The RUC recommended maintaining the current value. CMS proposes to reduce the value to 1.48 wRVUs. While the overall time for the code did decrease from 60 minutes to 49 minutes, the current survey resulted in the same intra-service time of 20 minutes as the original survey from 2008. NANS believes this consistency in intra-service time provides support for maintaining the current value of 1.81 wRVUs.

CMS disagrees with the RUC recommendation based on their previously mentioned but not clarified time ratio methodology. The agency bases its proposed value for the code by bracketing it between code 62270 (*Spinal puncture, lumbar, diagnostic*), which has a wRVU of 1.37, identical intra-service, and similar total time to CPT code 64416 and CPT code 91035 (*Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation*), which has a work RVU of 1.59, identical intra-service, and near identical total time values to CPT code 64416.

NANS believes this rationale is flawed and that the crosswalk is not appropriate. CMS proposed value is 18 percent lower than the RUC recommendation, creates rank order in the family and results in an inappropriately low IWPUT of 0.0451. Code 64416 is typically performed in a facility setting. In contrast code 91035 is typically performed by in the office setting. While the intra-service time may be similar, it is very clear that the intensity of these two procedures are not similar. The clinical intensity of a gastroesophageal reflex test (code 91035) is less than injection of the brachial plexus with continuous infusion by catheter (code 64416). Code 91035 is not an appropriate reference code for code 64416. We also find 62270 to be problematic. While it is typically performed in a facility setting, 62270 is a diagnostic procedure while 64416 is therapeutic and an inherently more intense service.

In contrast to the agency's analysis, the RUC recommendation was based on the 25th percentile wRVU and careful review of all of the underlying clinical attributes of the procedure.

The RUC also strongly supported its recommendation with comparison to code 32554 *Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance* (work RVU = 1.82, intra-service time of 20 minutes, total time of 56 minutes).

NANS urges CMS to accept a wRVU of 1.81 for code 64416.

64420 Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64420	1.18	1.18	1.08

Code 64420 describes the injection of the intercostal nerve. The typical patient presents with persistent, debilitating pain. A trial of intercostal nerve block is scheduled to relieve her pain and improve her function. The code is reported once per level regardless of the number of injections performed. Code 64420 is currently a Harvard-valued code that has not been previously surveyed. This means that the time was merely extrapolated and not measured directly. Nor is the rationale for the basis of the current value known.

The current value for code 64420 is 1.18 wRVUs. The RUC recommended maintaining that value but CMS is proposing to reduce it to 1.08 wRVUs. This represents an 8.5% reduction from the RUC recommended value. Similar to previous codes CMS indicates that their recommendation is based on their "...time ratio methodology..." CMS also establishes the proposed value by referencing code 12011 (Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less), which has a wRVU of 1.07, similar intra-service, and total time values to code 64420.

NANS believes the agency's rationale is flawed and that the proposed crosswalk to 12011 is inappropriate.

We reiterate our opposition to comparing RUC survey time to Harvard time. As we previously stated, Harvard time is not based on a direct measure of the service while the RUC surveys are a survey of time specific to the code. NANS believes it is always inappropriate to compare Harvard time to RUC time. The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based, therefore it is invalid to compare the current time and work to the surveyed time and work.

Also, as previously stated, while crosswalks are an effective methodology to assign value in a relative value system, they are only appropriate if the codes are similar in intra-service time and are clinically similar in complexity, intensity and risk. These codes are not clinically similar. The typical patient for code 12011 presents with facial abrasions and cuts and requires simple repair of superficial wounds. The complexity, intensity and risk of code 64420, in which describes the injection of the intercostal nerve to address persistent debilitating pain, is greater than 12011.

The RUC's recommendation for code 64420 was based on survey data and comparison to other codes in the fee schedule. The RUC recommendation was based on the current wRVU which is supported by the 25th percentile wRVU from robust survey results, as well as careful review of all underlying clinical attributes of the procedure.

The RUC also strongly supported its recommendation with comparison to code 49082 Abdominal paracentesis (diagnostic or therapeutic); without imaging guidance (wRVU = 1.24, intra-service time of 10 minutes) and code 32562 Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break-up of multiloculated effusion); subsequent day (work RVU = 1.24, intra-service time of 10). NANS believes that these codes are more clinically similar to code 64420 than 12011 and provide more appropriate references.

NANS urges CMS to accept a work RVU of 1.18 for CPT code 64420.

64421 Injection(s), anesthetic agent(s) and/or steroid; intercostal nerves, each additional level (List separately in addition to code for primary procedure)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
+64421	1.68	0.60	0.50

Code 64421 is currently a Harvard-valued code 0-day global code. This means that the time was merely extrapolated and not measured directly. Nor is the rationale for the basis of the current value known. The code has been revised for 2020 and becomes an add-on code to be reported with base code 64420. A ZZZ global period has been assigned to the new code.

The current value of the code is 1.68 wRVUs. The RUC recommended decreasing it to 0.60 wRVUs and CMS is proposing to further reduce it to 0.50 wRVUs. Similar to their rationale for the base code 64420 and other previous codes CMS indicates that their recommendation is based on their "...time ratio methodology..." CMS also establishes the proposed value by referencing code 15276 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)), which has a wRVU of 0.50 and identical intra-service and total times to code +64421.

This methodology of comparing Harvard, which is not based on survey data, to RUC survey time is inappropriate and inconsistent with agency policy. In contrast, the RUC recommendation is derived from an appropriate direct work value crosswalk from 64421 to CPT code 77063 *Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)* (wRVU = 0.60, intra-service and total time of 8 minutes). The RUC noted that although the survey code involves somewhat more intra-service time, both services require a very similar amount of physician work.

NANS believes this is a more appropriate comparison and we urge CMS to accept a wRVU of 0.60 for code 64421.

64425 Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64425	1.75	1.19	1.00

Code 64425 describes the injection of the ilioinguinal, iliohypogastric nerves. The typical patient presents with persistent, debilitating pain and a trial of ilioinguinal /iliohypogastric nerve block is scheduled to relieve pain and improve function. Code 64425 is currently a Harvard-valued code that has not been previously surveyed. This means that the time was merely extrapolated and not measured directly. Nor is the rationale for the basis of the current value known.

Code 64425 is currently valued at 1.75 wRVUs, the RUC recommended a value of 1.19 wRVUs and CMS is proposing to further reduce it to 1.00 wRVUs. CMS only indicates that they disagree

with the RUC recommendation and they are proposing to reduce the value in order to maintain rank order. While CMS identified codes to bracket the proposed value, they do not provide a direct crosswalk to support this value.

In contrast, the RUC recommendation is supported by the 25th percentile wRVU from robust survey results, as well as careful review of all underlying clinical attributes of the procedure.

The RUC also strongly supported its recommendation with comparison to CPT code 49082 *Abdominal paracentesis (diagnostic or therapeutic); without imaging guidance* (wRVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes) and code 32562 *Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break-up of multiloculated effusion); subsequent day* (work RVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes). We would note that the recent survey for code 64425 resulted in 11 minutes intra-service time. NANS believes that the crosswalks identified by the RUC are reasonable and appropriate.

NANS urges CMS to accept a wRVU of 1.19 for CPT code 64425.

64430 Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64430	1.46	1.15	1.00

Code 64430 describes the injection of the pudendal nerve. The typical patient presents with persistent, debilitating pain and a trial of pudendal nerve block is scheduled to relieve her pain and improve her function. The code is reported once per nerve regardless of the number of injections performed. Code 64430 is currently a Harvard-valued code that has not been previously surveyed. This means that the time was merely extrapolated and not measured directly. Nor is the rationale for the basis of the current value known.

CMS indicates that they disagree with the RUC-recommendation of 1.15 wRVUs and are proposing a wRVU of 1.00, to maintain rank order among comparable codes in the family. They also indicate that the survey resulted in a reduction in intra-service time from the current time. We once again note that it is inappropriate and inconsistent with agency policy to compare RUC survey time to Harvard time which was not measured directly.

In contrast the RUC recommendation was based on the current work RVU which is supported by the 25th percentile work RVU from robust survey results, as well as careful review of all underlying clinical attributes of the procedure.

The RUC strongly supported its recommendation with favorable comparison to code 49082 Abdominal paracentesis (diagnostic or therapeutic); without imaging guidance (wRVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes) and code 32562 Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break-up of multiloculated effusion); subsequent day (wRVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes). We further note that the recent survey for code 64430 resulted in 10 minutes intra-

service time. NANS believes that the crosswalks identified by the RUC are reasonable and appropriate.

NANS urges CMS to accept a wRVU of 1.15 for code 64430.

64445 Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64445	1.48	1.18	1.00

Code 64445 describes the injection of the sciatic nerve. The procedure is typically used for pain management in the recovery room. The code is reported once per nerve regardless of the number of injections performed. This code was previously surveyed by the RUC in 2009.

The code is currently valued at 1.48 wRVUs, the RUC recommended reducing the value to 1.18 wRVUs and CMS is proposing to further reduce it 1.00 wRVUs maintain rank order among comparable codes in the family. While CMS identifies reference codes to bookend this proposed value, they do not provide any direct crosswalks. NANS was disappointed with this proposal and finds the agency's rationale to be extremely flawed. The agency did not provide any clear rationale for the proposing the specific value of 1.00 wRVUs.

In contrast, the RUC recommendation is supported by the 25th percentile work RVU from robust survey results, as well as careful review of all underlying clinical attributes of the procedure. The RUC strongly supported its recommendation with favorable comparison to code 67810 *Incisional biopsy of eyelid skin including lid margin* (work RVU = 1.18, intra-service time of 13 minutes, total time of 27 minutes) and code 32562 *Instillation(s)*, via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break-up of multiloculated effusion); subsequent day (work RVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes). We further note that the recent survey for code 64445 resulted in 10 minutes intra-service time. NANS believes that the crosswalks identified by the RUC are reasonable and appropriate.

NANS believes the reduced value of the RUC recommendation from the current value sufficiently accounts for the reduction in intra-service time from the previous RUC survey (15 minutes intra-service time) in comparison to the current RUC survey (10 minutes intra-service time).

NANS urges CMS to accept a wRVU of 1.18 for CPT code 64445.

64446 Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)

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64446	1.81	1.54	1.36

Code 64446 describes injection of the sciatic nerve with continuous infusion by the catheter. It is typically used to manage post-operative pain and facilitate rehabilitation. The service is typically performed in a facility setting. The code was previously surveyed by the RUC in 2008.

The code is currently valued at 1.81 wRVUs. The RUC recommended reducing the value to 1.54 wRVUs and CMS proposes further reducing the value to 1.36 wRVUs. CMS is basing this value on their previously mentioned, although never clarified, time ratio methodology and reference to CPT code 51710 (*Change of cystostomy tube; complicated*), which has a near identical wRVU of 1.35 and similar intra-service and total time values to code 64446.

The RUC recommendation is derived from an appropriate direct work value crosswalk from 64446 to code 30903 *Control nNANSI hemorrhage, anterior, complex (extensive cautery and/or packing) any method* (work RVU = 1.54, intra-service time of 15 minutes, total time of 39 minutes). Both services have identical intra-service time and total time and involve an identical amount of physician work.

NANS believes the reduced value of the RUC recommendation from the current value reflects sufficient recognition of the reduction in intra-service time from the previous RUC survey (20 minutes intra-service time) in comparison to the current RUC survey (15 minutes intra-service time).

NANS urges CMS to accept a wRVU of 1.54 for code 64446.

64448 Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64448	1.63	1.55	1.41

Code 64448 describes injection of the femoral nerve with continuous infusion by catheter. It is typically used to manage post-operative pain and facilitate rehabilitation. The service is typically performed in a facility setting. The code was previously surveyed by the RUC in 2008.

This code is currently valued at 1.63 wRVUs, the RUC recommended reducing it to 1.55 wRVUs and CMS is proposing to further reduce it to 1.41 wRVUs. CMS is basing this value on their previously mentioned, although never clarified time ratio methodology and reference to CPT code 27096 (*Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed*), which has a work RVU of 1.48 and similar intra-service time and total time values to CPT code 64448. While these are both injection procedures, they are not clinically similar in intensity, complexity and risk. We would note that 27096 is performed in the physician office setting nearly 50% of the time while in contrast code 64448 is performed in the facility setting almost 100% of the time. The CMS

proposal is further flawed as it compares 64448 to 27096, with 1.48 wRVU, while proposing just 1.41 wRVUs for 64448, a code that is by all comparators much more complex than the proposed reference code.

In contrast, the RUC recommendation is based on a crosswalk to code 62322 *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 (wRVU = 1.55, intra-service time of 11 minutes, total time of 39 minutes). The survey code involves somewhat more intra-service time whereas both services only differ on total time by 1 minute and require a very similar total amount of physician work. The RUC also supported its recommendation with MPC code 57452 *Colposcopy of the cervix including upper/adjacent vagina;* (wRVU = 1.50, intra-service time of 15 minutes, total time of 40 minutes). NANS believes this is a much more robust and appropriate rationale than the one proposed by CMS.

NANS urges CMS to accept a wRVU of 1.55 for CPT code 64448.

64449 Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64449	1.81	1.55	1.27

Code 64449 describes injection of the lumbar plexus, posterior approach with continuous infusion by catheter. The service is typically used to manage post-operative pain and facilitate rehabilitation. It is typically performed in a facility setting. The code was previously surveyed by the RUC in 2008.

Code 64449 is currently valued at 1.81 wRVUs, the RUC recommended reducing it to 1.55 wRVUs and CMS proposes further reducing it to 1.27 wRVUs. CMS is basing this value on their previously mentioned, although never clarified time ratio methodology and reference to CPT code 11755 (*Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)*), which has a wRVU of 1.25 and similar intra-service and total times to CPT code 64449. NANS has similar concerns with this reference code that we had with the reference code for code 64448. Code 64449 is used to manage post-operative pain after major surgery, and it includes infusion by catheter. The service is typically performed in a facility setting. In contrast code 11755 is a biopsy of a nail unit and is typically performed by in the office setting. While the intra-service time may be similar, it is very clear that the intensity of these two procedures is not at all similar. Code 11755 cannot serve as an appropriate reference code for code 64449.

In contrast, the RUC recommendation is based on a crosswalk to CPT code 62322 *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

(wRVU = 1.55, intra-service time of 11 minutes, total time of 39 minutes). The survey code involves somewhat more intra-service time whereas both services only differ on total time by 1 minute and require a very similar total amount of physician work. NANS believes this is a much more accurate and appropriate rationale than the one proposed by CMS.

NANS urges CMS to accept a wRVU of 1.55 for code 64449.

Practice Expense Recommendations

For codes 64400, 64415, 64417, 64420, 64425, 64430, 64445, 64447 and 64450. CMS is proposing a refinement to the clinical activity time for CA011, *provide education/obtain consent*. CMS is reducing the time associated with this activity from the RUC recommended 3 minutes to 2 minutes. The agency states that the rationale for this refinement is that the standard time for this activity is 2 minutes.

NANS disagrees with this rationale. The RUC PE Subcommittee does not have a standard time allocated for this clinical activity. For clinical activity CA011, the RUC PE Subcommittee guidelines instruct specialty societies to "Include only the additional education/consent activities not included in the pre-service period" for this clinical activity. Since the standard for 000-day global services in the pre-service period for this activity, CA004, *Provide pre-service education/obtain consent*, is zero minutes, specialties involved in submitting PE recommendations for these codes explained that 3 minutes of time is needed, which the PE Subcommittee accepted. The societies explained that the time is required because of the potential complications associated with injections and the need to review aftercare instructions.

NANS urges CMS to accept the RUC recommendation of 3 minutes for clinical activity CA011, provide education/obtain consent codes 64400, 64415, 64417, 64420, 64425, 64430, 64445, 64447, and 64450.

Payment for Evaluation and Management (E/M) Outpatient and Office Visit Codes (99201-99205, 99211-99215

Work and Practice Expense RVUs

In the 2020 Proposed Rule, CMS accepted RUC recommended adjustments to Work and Practice Expense RVUs for Evaluation and Management services in the Outpatient/Office setting-CPT codes 99201-99215. The set of codes reviewed have had revisions made for CPT 2021 and CMS proposes to adopt the new CPT descriptors and recommended work RVUs for the Medicare Physician Fee Schedule starting in Cy 2021.

NANS does not agree with the recommended work and PE RVU changes and does not believe that there should be changes to the time or value of the office visit E/M codes. While we appreciate CMS's attempts to reduce the workload for physicians, we are not convinced that eliminating the need for certain levels of documentation will be in the best interests of patient care. Documentation is required for medicolegal reasons and insurance requirements and while CMS is providing relief in the area of E/M documentation, this will not completely eliminate the burdens on physician's for certain levels of documentation.

We note that the impetus to make changes to E/M coding came from CMS as a way to reduce

physician burden. We appreciate that CMS has already gone a long way to reduce burden with policy changes. For example, for 2019 CMS reduced the amount of work necessary for documentation by allowing ancillary staff to enter information that is reviewed by the physician and signed rather than entered or re-entered by the physician. For 2021 the proposed new coding system will also rely on medically appropriate H&P documentation or time rather than the current system. This potentially will also reduce physician burden. However, the burden of documentation, which includes the documentation of a patient's history, physical examination findings, and specific testing requires data entry in order to ensure coverage for testing (MRI, CT, etc.) and/or treatment (injections, surgery, etc.) for the purposes of documenting medical necessity. The documentation requirement for non-E/M services still remains extremely high and has not been adequately incorporated into the proposed payments for E/M services, nor is this extra work incorporated in the current payments for the non-E/M services.

In light of this, we believe the survey of the revised codes was premature. We urge CMS to delay consideration of the survey time and values that were recommended by the RUC.

Global Surgical Packages

In addition to the RUC-recommendations regarding physician work, time, and practice expense for office E/M visits, the RUC also recommended adjusting the work RVUs for codes with a global period to reflect the changes made to the work RVUs for office E/M visits. Procedures with a 10- and 90-day global period have postoperative visits included in their valuation and each global procedure has at least one-half of an E/M visit included in the CMS time/work file.

CMS mistakenly states that the visits in the global package codes are not directly included in the valuation. Rather, the work RVUs for procedures with a global period are generally valued using magnitude estimation.

We agree that RUC survey methodology uses magnitude estimation to develop work RVU recommendations that are relative to other codes in the physician fee schedule. However, the basis of the fee schedule—the work done during the Harvard study—is a building block method that used time and intensity that was directly surveyed and/or extrapolated to develop the initial work RVUs in the first fee schedule in 1992. The RUC's method of "magnitude estimation" has consistently identified and used component comparisons of pre, intra, and post times along with number and level of visits to assess relativity. The RUC also uses total time (including total E/M time) to compare relativity between codes with different global periods.

To maintain the relativity, which was established in 1992, CMS has twice (1998 and 2007) adjusted the work RVUs and time for global codes to account for adjustments to work and time for office visit E/M codes. The issue that CMS raises in this rule regarding MACRA legislation to review the number and level of visits in global codes is not related to maintaining relativity across the fee schedule based on current data in the CMS work/time file.

By failing to adopt all the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC)-recommended work and time values for the revised office visit E/M codes for CY 2021, including the recommended adjustments to the 10- and 90-day global codes, CMS improperly proposes to implement these values in an arbitrary, piecemeal fashion.

It also violates the basic operating payment methodology in the Medicare Physician Fee Schedule and implies that the same work done by different types of physician and for different reasons have different value. We do not believe CMS intends this, however, if global payments are not adjusted, CMS opens the door to specialty-based payments for services which could lead to a wholesale revaluation of all services in the MPFS based on the "value" of each specialty type. This would be unsustainable and have profoundly negative impacts on patient care.

It is highly inappropriate for CMS to move forward with the proposal to not apply the RUC-recommended changes to global codes. If CMS finalizes the proposal to adjust the office/outpatient E/M code values, the agency <u>must also</u> apply these updated values to the global codes. It is imperative that CMS take this crucial step. Without an adjustment of global periods, CMS will affect all of the following:

- Disrupt the relativity in the fee schedule: Applying the RUC-recommended E/M values to stand-alone E/Ms, but not to the E/Ms that are included in the global surgical package since the inception of the fee schedule, will result in disrupting the relativity between codes across the Medicare physician fee schedule. Changing the values for some E/M services, but not others, disrupts this relativity, which was mandated by Congress and established in 1992 and refined over the past 27 years. Indeed, since the inception of the fee schedule, E/M codes have been revalued four times in 1993 (through refinement after implementation of extensive E/M coding changes, 1997 (after the first five-year review, 2007 (after the third five-year review) and 2011 (after CMS eliminated consult codes and moved work RVUs into the office visit codes) and when payments for new and established office visits were increased, CMS also increased the bundled payments for these post-operative visits in the global period.
- *Create specialty differentials:* Per the Medicare statute, CMS is prohibited from paying physicians differently for the same work, and the "Secretary may not vary the…number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician." Failing to adjust the global codes is tantamount to paying some doctors less for providing the same E/M services, in violation of the law.
- Run afoul of section 523(a) of MACRA: CMS points to the ongoing global code data collection effort as a reason for not applying the RUC-recommended changes to office visit E/M codes to global codes. In addition, the agency states that it is required to update global code values based on objective data on all of the resources used to furnish the services included in the global package. These arguments conflate two separate issues. The issue that CMS raises regarding MACRA legislation is not related to maintaining relativity across the fee schedule based on current data in the CMS work/time file. In fact, section 523(a) specifically authorizes CMS to make adjustments to surgical services, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project.
- Ignore recommendations endorsed by nearly all medical specialties: The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) to recommend that the full increase of work and physician time for office visits be incorporated into the

³ 42 U.S. Code §1395w-4(c)(6).

global periods for each CPT code with a global of 10-day, 90-day and MMM (maternity). The RUC also recommends that the practice expense inputs should be modified for the office visits within the global periods.

We believe review and implementation of any changes to the office visit E/M codes is premature given the extensive coding changes and flawed survey process. However, if CMS chooses to move forward with office visit E/M increases, we urge CMS to incorporate the changes into the work, time, and practice expense for global codes to maintain fee schedule relativity.

Medicare Billing Privileges

CMS' proposed 2020 Medicare Physician Fee Schedule includes substantial changes to the rules for obtaining and maintaining Medicare billing privileges. This proposed action is in the section describing proposed changes to the enrollment of opioid treatment programs (OTP), CMS has inserted what at first glance may appear to be an innocuous one-paragraph statement applying enrollment approval and revocation rules for opioid treatment programs to <u>all</u> physicians and other eligible professionals. This change would apply to physicians and other eligible professionals in OTP and non-OTP settings. Revocation or denial action could be taken against physicians and other eligible professionals in solo practice or who are part of a group or any other provider or supplier type."). We are specifically concerned with the lack of recourse and the legal rights provided to the healthcare provider. While we understand the need for CMS to control fraud and abuse, we believe this rule could also be used to improperly punish physicians based on an inquiry where the physician is ultimately exonerated. There must be a pathway that allows for timely appeal options for physicians and with some level of protected rights. We are particularly concerned with the amount of unilateral control that will be granted to CMS over this process while providing providers with limited to no rights for appeal.

The proposed rule would allow CMS to revoke the Medicare billing privileges of any physician who has "been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of healthcare with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm."

In taking this action, CMS has arguably introduced some of the most significant and substantial changes to the rules for obtaining and maintaining Medicare enrollment, since the rules were first established in 2006. We believe this is an error and could have profoundly negative impacts on patient access and physician involvement with Medicare. Furthermore, the proposal undermines the critical role played by state licensing boards and represents a federal usurpation of state level regulatory activities. We do not agree that there is a need for this action. These proposed changes will not only affect specialty physicians (often in short supply) and eligible professionals working in areas where there are health professional shortages, but also physicians and other nonphysician practitioners working in hospital enrolled group practices providing ER coverage and other needed services. It would also impact professionals providing medical direction and attending physician services in nursing facilities. In addition, a Medicare revocation leads to a mandated cross-termination of participation in Medicaid and other federal payer programs. In short, this new denial and revocation authority will affect far more physicians and other eligible

professionals than the "high risk" Medicare-enrolled opioid treatment programs for whom these new revocation and denial bases were reportedly introduced.

We strongly urge CMS to retract the proposal in the final rule.

In summary, we appreciate the efforts of CMS in improving and updating the Medicare Physician Fee Schedule. We particularly appreciate and applaud CMS' commitment to incentivizing non-opioid treatment options in order to reduce the scale of the opioid crisis facing this country. For this reason, we strongly encourage CMS to facilitate chronic pain patient access to opioid alternative treatments, including interventional pain management treatments which are appropriate and effective treatment for a variety of chronic pain conditions. Assigning inappropriately low work and practice expense RVUs to non-opioid options such as injections, ablations, pain reservoir analysis and refill are contrary to this effort. All these pain services are clinically efficacious alternative to opioids for pain management. While the agency should always strive for fair and appropriate payment for physician services, the role these procedures can play in diverting patients from using opioids for pain management, makes an even more compelling case to ensure appropriate payment and access to these services.

We also believe it is critical that CMS adopt revised global period RVUs if they move forward with implementing increases to office visit Evaluation and Management codes (99201-99205, 99211-99215) in CY 2021. Lastly, we encourage CMS to revoke the proposal to remove Medicare billing privileges without adding greater transparency and appeal processes for physicians having their privileges reviewed.

Thank you for your time and consideration of NANS 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 Chris Welber, NANS Executive Director, at cwelber@neuromodulation.org.

Sincerely,

B. Todd Sitzman, MD, MPH

B. Toll Sitzman, M.

President

North American Neuromodulation Society (NANS)



David Kloth, MD Senior Advisor NANS, Past President NANS

Dadhaenpo

David Provenzano, MD Co-Chair NANS Advocacy and Policy Committee

Jason Pope, MD

Co-Chair NANS Advocacy and Policy Committee

Corey Hunter, MD,

NANS AMA CPT Editorial Panel CPT Advisor, Member NANS Board of Directors

Dawood Sayed, MD,

NANS AMA CPT Editorial Panel Alternate CPT Advisor

Damean Freas, MD,

NANS RUC Advisor

amean WE Freas

Peter Pahapill, MD,

NANS RUC Alternate Advisor

Michael & Feory 100

Michael Leong, MD Member, NANS Advocacy and Policy Committee Chair, NANS Legislative Fellowship Program