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September 28, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1734-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1734-P; CY 2021 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies;

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) 2021.

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 pain and other conditions that can be with targeted electrical, chemical and biological technologies to the nervous system in order to improve function and quality of life.

This letter includes NANS recommendations and comments regarding the following:

- **CY 2021 Conversion Factor**
- **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

- **TeleHealth Issues**
- **Scope of Practice Issues**

2021 Medicare Conversion Factor

In the CY 2021 Proposed Rule, CMS announced an update to the Medicare conversion factor of \$32.26 for CY 2021. This represents an 11% decrease from the current (2020) conversion factor of \$36.09. This adjustment reflects a budget neutrality adjustment for changes in relative values for individual services, with significant increases in relative values for office and outpatient Evaluation and Management (E/M) services (CPT codes 99201-99215) and the fact that CMS opted to maintain budget neutrality which because of the E/M increases necessitates the large conversion factor reduction.

NANS is extremely disappointed and concerned with the drastic reduction in the Medicare Conversion Factor and strongly recommends CMS take action in the CY 2021 Final Rule to eliminate this conversion factor reduction. The most appropriate action would be to not implement the proposed increases in E/M codes. As noted in more detail below, NANS believes the RUC recommended RVUs, which were accepted by CMS in the proposed rule to be incorrect and recommends maintaining current RVUs for the E/M codes at their 2020 RVU rates. However, if CMS chooses to move forward with the changes in E/M RVUs, NANS believes it is essential that CMS take action to waive budget neutrality by maintaining the CY 2020 conversion factor for CY 2021. Many practices are struggling to maintain financial viability due to the changes and hardships caused by the Covid-19 pandemic and their closure would significantly impact access to care to CMS covered patients.

If the proposed conversion factor changes are implemented, most pain interventions would see dramatic reductions in total Medicare reimbursement. These procedures are critically important alternatives to opioid based treatment plans which have led to the tragic opioid epidemic that continues to devastate our country. Several efficacious and cost-effective pain treatments which currently are reimbursed at marginal levels that barely cover overhead face drastic reductions if the conversion factor were to be implemented as proposed. 62323, Lumbar or sacral (caudal) interlaminar epidural injection(s); with fluoroscopy would see a 9% reduction in total payment; 62325, Cervical or thoracic continuous interlaminar epidural injection(s), with fluoroscopy would see a 11% reduction (injections in the cervical and thoracic region carry increased risks as seen in closed claims analysis); 63650 and 63655, Implant neuroelectrodes would be reduced by 7.5%; 64450, Other peripheral nerve or branch would be reduced 9.2%; and 64633, Destruction cervical/thoracic facet joint by neurolytic agent and 64635, Destruction lumbar/sacral facet joint by neurolytic agent would be reduced by 7.5%. In short, 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. CMS in fact, proposes to expand the PHE status into 2021 in the proposed rule and recognizes the severe negative impact on physician and physician practices in terms of increased costs and reduced reimbursements.

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 and if implemented for CY 2021 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 -11% reduction would cause massive shortage of access as practices reduce staff and hours to absorb the impact. This would result in less access at a time that greater access and greater flexibility is needed in caring for Medicare patients.

The reduced conversion factor also represents 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 2021.

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

Work and Practice Expense RVUs

In the 2021 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 until physicians are educated and there is more experience with the new coding system. Only then can we obtain reliable feedback and information regarding the time and work involved.

We note that the impetus to make changes to E/M coding is a good faith attempt to reduce physician burden. We appreciate that CMS has already gone a long way to reduce burden with policy changes. For example, in 2019 and 2020, 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 could also reduce physician burden. We would like to point out to CMS the inconsistencies in their efforts at reducing administrative burden; CMS recently proposed other policies, like adding prior authorization for spinal cord stimulation in the 2021 Proposed OPPTS/ASC Payment System Rule, a policy that would offset the benefits of other efforts like reduced E/M documentation 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 the purposes of medical necessity and for purposes of medical liability

documentation. Even if CMS reduces its H&P documentation requirements, lawyers and courts will still expect proper medical documentation. In addition, this documentation is essential in post-payment reviews where medical necessity is being questioned. Therefore, the documentation requirements for non-E/M services will still remain extremely high and has not eliminated by the current proposals by CMS., This extra work is also not incorporated into payments for other non E/M services.

In light of this, we believe the survey of the revised codes was premature as the survey did not allow physicians to integrate the reduced time and effort as a result of the documentation changes. We urge CMS to delay consideration of the survey time and values that were recommended by the RUC and consider a possible resurvey and revaluation only after physicians have adapted and incorporated the new guidelines and requirements.

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 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 should also apply these updated values to the global codes. It is imperative that CMS take this crucial step.

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.

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 as Health and Human Services Secretary Azar recently extended the PHE declaration through October 23, 2020. In the proposed rule, CMS does not propose to permanently waive these restrictions in the PFS stating that it lacks authority to make this adjustment. However, CMS does propose to extend the PHE through the end of the calendar year in which the PHE ends, or December 31, 2020. NANS fully supports this extension of the PHE status and all related statutory and sub-regulatory changes affected by the PHE emergency authority.

We support Medicare telehealth services which have been dramatically expanded during the COVID-19 PHE and in the proposed rule, CMS has proposed to permanently keep several codes that were temporarily added to the Medicare telehealth list, including the prolonged office or outpatient E/M visit code and certain home visit services. CMS also proposes to keep additional services, including certain emergency department visits, on the Medicare telehealth list until the end of the calendar year in which the PHE ends to allow more time to study the benefit of providing these services using telecommunications technology outside the context of a pandemic. This new Category 3 would provide a basis for adding or deleting services from the Medicare telehealth list on a temporary basis where there is likely clinical benefit, but where there is not yet sufficient evidence available to permanently consider the services under Category 1 or 2. NANS supports the use of the category 3 category and the efforts to make adding services to the Telehealth services list more flexible and responsive. We believe there are numerous services and procedures not currently approved for telehealth that would be beneficial to add, and believe easing barriers is critical to providing safe and effective care for Medicare patients.

Telehealth Visits

CMS seeks comment on whether it is appropriate to maintain the COVID-19 PHE flexibilities which allow physicians and NPPs to perform required visits for nursing home residents via telehealth using two-way, audio/visual communications technology. CMS also proposes to allow more frequent follow-up Medicare telehealth visits for nursing home residents, allowing a

Medicare telehealth visits to be covered once every 3 days instead of once every 30 days. This is intended to put more autonomy in the hands of clinicians to decide the frequency of necessary visits via Medicare telehealth, and to afford nursing home residents more care if necessary. NANS supports this proposal and believes it is essential to maintaining care for Medicare patients in Nursing Facilities.

In the proposed rule, CMS is not proposing to continue current coverage and payment for Medicare audio-only visits after the conclusion of the COVID-19 PHE stating CMS does not have the authority to permanently waive the requirement for two-way, audio/video communications. The proposed rule does, however, ask for comments on whether the current payment rates should be extended beyond the expiration of the PHE or December 31, 2021 and if so, for how long. NANS supports the current coverage policies and payment rates for audio-only visits 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. By continuing to treat phone encounters as less work, it actually discriminates against many patients who are very elderly, infirm, and/or live in underserved areas.

SCOPE OF PRACTICE and RELATED ISSUES

CMS' policies on scope of practice continue from Executive Order 13890, which modifies supervision requirements and unjustifiably expands the scope of practice for many different health care providers in Medicare. CMS believes "physicians, NPPs, and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure ..." and proposes policies from that position. NANS is extremely concerned that in many cases, the Executive Order 13890 will result in sub-standard care for Medicare patients and not only reduce quality of care, but also lead to more costs in the near future as patients require more intensive physician interventions that could have been avoided under physician care, as opposed to Non-Physician Provider (NPP) care.

Teaching Physician and Resident Moonlighting Policies

In the proposed rule, CMS stated it is considering whether the teaching physician and resident moonlighting policies enacted during the COVID-19 PHE should be extended on a temporary basis (that is, through December 31, 2021 if the PHE ends in 2021) or whether the flexibilities should be made permanent. During the COVID-19 PHE, CMS allowed the teaching physician to satisfy supervision requirements using audio/video real-time communications technology to direct the care furnished by a resident, and to review the services furnished by the resident during or immediately after a visit, remotely. CMS pays for the interpretation of diagnostic radiology and other diagnostic tests when performed by a resident as long as the teaching physician is present through audio/video real-time communications technology. CMS also permits a teaching

physician to direct a resident during psychiatric service using audio/video real-time communications technology.

NANS supports the waiving of in-person requirements and supports the extensions of the waivers.

Supervision of Diagnostic Tests by Certain NPPs

Effective January 1, 2021, CMS is proposing to amend the basic rule under the regulation at § 410.32(b)(1) to allow NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice. Prior to the COVID-19 PHE, physicians, NPs, CNSs, PAs, certified nurse-midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) who were treating a Medicare beneficiary for a specific medical problem could order diagnostic tests when they used the results of the tests in the management of the beneficiary's specific medical problem. However, generally only physicians were permitted to supervise diagnostic tests. In the May 1st COVID-19 IFC, CMS permitted, during the COVID-19 PHE, PAs, NPs, and certain other NPPs to supervise diagnostic tests. CMS is proposing to make this supervision practice permanent. CMS is also proposing to permanently eliminate the requirement that a general level of physician supervision is necessary for diagnostic tests performed by a PA.

NANS strongly urges CMS to not allow PAs to perform and supervise diagnostic tests without direct physician supervision. While all PAs have some training and experience with performance of diagnostic tests, none have the extensive training that physicians do and they are simply not fully qualified to perform the tests with no supervision. Allowing diagnostic testing by PAs will reduce quality of care for Medicare patients, and increase costs to the Medicare patients in the form of increased testing much of which is likely not medically necessary. And with more testing, there will inevitably be more treatment done, much of which will be of limited efficacy. We believe physician supervision and performance of diagnostic tests is extremely critical to maintaining the health and well-being of Medicare patients and strongly oppose allowing PAs to perform unsupervised testing. We also note that CMS may not be even fully aware of specific state regulations, as the proposed rule ask for comments on what state rules and laws are relevant and applicable. Given that the agency is not sure of how their proposals would be offset or impacted state-to-state, we believe it is premature to move forward with the proposal. We urge CMS to revise the diagnostic testing proposal for Calendar Year 2021 and beyond in order to promote the highest quality care for Medicare patients.

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, MBA, NANS Executive Director at cwelber@neuromodulation.org.

Sincerely,

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Peter Konrad, MD
President
North American Neuromodulation Society (NANS)

A handwritten signature in black ink, appearing to read "David Provenzano". The signature is bold and cursive, with a prominent "D" and "P".

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

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Joshua Rosenow, MD
Co-Chair
NANS Advocacy and Policy Committee

A handwritten signature in black ink, appearing to read "David Kloth". The signature is cursive and somewhat stylized, with a long horizontal stroke at the end.

David Kloth, MD
Senior Advisor
NANS Advocacy and Policy Committee