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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-1736-P; CY 2021 Proposed Rule Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals

Dear Administrator Verma:

The North American Neuromodulation (NANS) appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (*Proposed Rule*) on the revisions to Medicare policies under the Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Payment Systems 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 neuromuscular pain.

This letter includes NANS recommendations and comments regarding the following:

- **Pre-Approval for Neurostimulator Implantation and Cervical Fusion**
- **Payment for 340b Drugs**
- **Elimination of the Inpatient Only Procedure (IPO) List**
- **Site Neutral Payment Policy**

Pre-Approval for Neurostimulator Implantation and Cervical Fusion

Last year, CMS finalized a proposal to establish a process through which hospitals must submit a prior authorization request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for processing. The change applied to five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.

This year, the agency proposes to expand prior authorization requirements for two additional services: implanted spinal neurostimulators and cervical fusion with disc removal to curb what they state may be unnecessary utilization.

NANS strongly disagrees with this proposal and the rationale provided by the agency. We strongly urge CMS to not apply the prior authorization requirement to both of these procedures as this requirement creates an improper and unnecessary burden on physicians and physician practices. This is in direct opposition to numerous other CMS initiatives to decrease administrative burdens for medical practices and is redundant to already existing National Coverage Decisions (NCDs) and Local Coverage Decisions (LCDs) that exist for Spinal Cord Stimulation.[1]

We dispute the CMS claim that prior authorization will reduce unnecessary utilization. There is evidence that prior authorization has little impacts on unnecessary authorization but mostly causes a delay in appropriate care (leading patients toward alternative pain relief options like opioids).[2] There is not sufficient evidence that utilization is increasing at significant rates for these procedures (for example, CPT code 63650, Implant Neuroelectrodes, saw only a 1% increase in Medicare utilization from 2018 to 2019 and 63655 saw a decrease in Medicare utilization, 22610, Cervical Fusion saw only a 2% increase in utilization), but there is considerable evidence to illustrate the costs for patients and practices from prior authorization policies used by private payers.[3][4][5]And even to the extent utilization is increasing, there are multiple factors that could affect utilization changes such as innovation, awareness, payment policy, legislative policy and clinical factors.

For example, Karrison et al in a 2009 study found that when time spent in acquiring prior authorization is converted to dollars, they estimated that the national time cost to practices of

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[1] Centers for Medicare and Medicaid Services. NCD 160.7 Electrical Nerve Stimulators.

[2] Morley, C. P., Badolato, D. J., Hickner, J., & Epling, J. W. (2013). The impact of prior authorization requirements on primary care physicians' offices: report of two parallel network studies. *The Journal of the American Board of Family Medicine*, *26*(1), 93-95.

[3] Casalino, L. P., Nicholson, S., Gans, D. N., Hammons, T., Morra, D., Karrison, T., & Levinson, W. (2009). What Does It Cost Physician Practices To Interact With Health Insurance Plans? A new way of looking at administrative costs—one key point of comparison in debating public and private health reform approaches. *Health Affairs*, *28*(Suppl1), w533-w543.

[4] American Board of Pain Medicine. Second Annual Survey of Pain Medicine Specialists Highlights Continued Plight of Patients with Pain, And Barriers to Providing Multidisciplinary, Non-Opioid Care. Article. 2019. http://abpm.org/component/content/article/296

[5] American Board of Pain Medicine. Second Annual Survey of Pain Medicine Specialists Infographic. 2019. http://abpm.org/uploads/files/abpm%20survey%202019-v3.pdf .

interactions with plans is at least $23 billion to $31 billion each year.[6] Furthermore, Morley et al. reaffirmed that preauthorization is a measurable burden on physician and staff time.[7] This financial burden and cost has only increased in the ensuing seven to twelve years and we believe this cost to be an unnecessary and unjustified burden for physicians performing neurostimulator implantation procedures.

Other studies have confirmed and added to the body of evidence showing the detrimental impact of prior authorization burdens to patient access.[8] A 2019 AMA survey that prior authorization efforts add 14.4 hours of staff time per week to their workload with 30% of respondents reporting to have a Full Time Employee (FTE) dedicated to prior authorization. The same survey found the prior authorization burden to have increased significantly over the past 7 years, with 86% of respondents reporting increased prior authorization costs to their practice in the previous five years.[9] A study from the Cleveland Clinic estimated their annual costs for prior authorization activities to exceed $10 million a year.[10]
We also strongly disagree with the agency's contention that neurostimulator implantation procedures are not efficacious. To the contrary, numerous studies have found that spinal cord stimulation is highly efficacious; especially if offered early in the disease process[11], . Rivzi and Kumar found "*that efficacy of SCS treatment is time dependent with success rates exceeding 80% if implantation occurs within 2 years of symptom onset, compared with 15% for patients whose implants happened 20 years after the onset of pain [6–9]."*[12]*We are concerned that prior authorization process will eventually lead to delay in care for Medicare Beneficiaries thereby increasing the cost burden for managing their chronic pain syndromes. Furthermore studies have demonstrated that a longer delay from chronic pain to spinal cord stimulation results in higher healthcare resource utilization.*[13]

Indeed, SCS is a key alternative to opioid prescription for the management of pain symptoms and reducing access to this non-opioid alternative will only increase opioid prescriptions and opioid dependence and ultimately result in higher addiction rates, higher costs to Medicare and to society as a whole. SCS has been shown to prevent, stabilize or decrease the use of opioids. In addition, earlier consideration of SCS before escalated opioid use has the potential to improve clinical outcomes.[1415] Studies have demonstrated that prior authorization creates specifically negative impacts for non-opioid pain procedures and that these increased delays and denials have led to increased opioid prescription rates.[16] We urge CMS to follow the recommendation of

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[6] Health Affairs, 28, no.4 (2009):w533-w543 What Does It Cost Physician Practices To Interact With Health Insurance Plans? Theodore Karrison and Wendy Levinson Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra,

[7] Morley, C. P., Badolato, D. J., Hickner, J., & Epling, J. W. (2013). The impact of prior authorization requirements on primary care physicians' offices: report of two parallel network studies. *The Journal of the American Board of Family Medicine*, *26*(1), 93-95

[8] Casalino, L. P., Nicholson, S., Gans, D. N., Hammons, T., Morra, D., Karrison, T., & Levinson, W. (2009). What Does It Cost Physician Practices To Interact With Health Insurance Plans? A new way of looking at administrative costs—one key point of comparison in debating public and private health reform approaches. *Health Affairs*, *28*(Suppl1), w533-w543.

[9] https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf

[10] https://www.ama-assn.org/practice-management/sustainability/inside-cleveland-clinic-s-10-million-prior-authorization-price

[11] Deer TR, Grider JS, Lamer TJ, et al. A Systematic Literature Review of Spine Neurostimulation Therapies for the Treatment of Pain. *Pain Med*. 2020;21(7):1421-1432. doi:10.1093/pm/pnz353

[12] Rizvi S, Kumar K. Spinal cord stimulation for chronic pain: the importance of early referral. *Pain Manag*. 2014;4(5):329-331. doi:10.2217/pmt.14.34

[13] Sharan AD, Riley J, Falowski S, et al. Association of Opioid Usage with Spinal Cord Stimulation Outcomes. *Pain Med*. 2018;19(4):699-707. doi:10.1093/pm/pnx262

[14] Sharan AD, Riley J, Falowski S, et al. Association of Opioid Usage with Spinal Cord Stimulation Outcomes. *Pain Med*. 2018;19(4):699-707. doi:10.1093/pm/pnx262

[15] Adil SM, et al. Impact of Spinal Cord Stimulation on Opioid Dose Reduction: A Nationwide Analysis. *Neurosurgery.* nyaa353. August 31, 2020.

[16] https://www.ama-assn.org/practice-management/sustainability/prior-authorization-nonopioid-pain-care-prolongs-patient

their Pain Taskforce[17] and increase access to SCS and other similar non-opioid treatments. Requiring prior authorization of SCS does the exact opposite of what CMS' own medical and public health officials have urged and represents a massive cost to society, patients, and providers, without offering anything other than overestimated cost savings.[18]

We believe it is essential to continue to increase access to non-opioid pain treatment and spinal cord stimulation is an especially important alternative to opioid prescriptions.[19] We urge CMS to revise their proposal to decrease access to SCS through the imposition of a costly and burdensome prior authorization process.

Payment for 340b Drugs

In the proposed rule, CMS adopted a policy to pay average sales price (ASP) minus 22.5 percent for 340B-acquired drugs, including when furnished in nonexcepted off-campus provider-based departments (PBDs) paid under the Physician Fee Schedule (PFS). In last year's rule, CMS acknowledged the ongoing litigation relating to the lower payment amount, including a district court ruling that the agency exceeded statutory authority in adjusting the payment rate for 340B drugs. In early August 2020, the U.S. Court of Appeals for the District of Columbia Circuit reversed the lower district court's ruling and held that CMS in fact, reasonably interpreted the Medicare statute as authorizing the rate reductions under a "general adjustment authority" with the purpose "to reimburse hospitals for their acquisition costs accurately."

CMS conducted a survey to gather data on hospital acquisition costs for 340B drugs following the court ruling that found that CMS acted beyond its statutory authority but also acknowledged that CMS might base the payment amount of average acquisition cost when survey data are available. Based on the results of this survey of hospital acquisition costs for 340B drugs, CMS is now proposing the pay for 340B drugs for CY 2021 and subsequent years at ASP minus 34.7 percent, plus an add-on of 6 percent of the ASP. This results in a net payment rate of ASP minus 28.7 percent for 340B drugs. For biosimilars, CMS is proposing to set net reimbursement at ASP minus 28.7 percent of the biosimilar's ASP, not minus 28.7 percent of the reference product's ASP.

NANS believes the 340B program is essential to helping providers stretch limited resources to better serve their vulnerable communities in the safety net. Conti et al in 2019 concluded that estimated profits that hospitals derived from administering 340B-discounted drugs to Medicare patients are small compared with respective operating budgets[20].

In our opinion, the recent CMS proposal of paying all 340B drugs at a net payment rate of ASP (average sale price) minus 28.7 percent would adversely affect Medicare beneficiaries access to certain non-opioid based pain management medications which have been critical in battling the opioid epidemic. This potential increase in the cost of drug procurement and disbursement may

I. [17] Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations published May 9, 2019

[18] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49.

[19] Adil SM, et al. Impact of Spinal Cord Stimulation on Opioid Dose Reduction: A Nationwide Analysis. *Neurosurgery.* nyaa353. August 31, 2020.

[20] Conti, R. M., Nikpay, S. S., & Buntin, M. B. (2019). Revenues and Profits From Medicare Patients in Hospitals Participating in the 340B Drug Discount Program, 2013-2016. *JAMA network open*, *2*(10), e1914141-e1914141

force providers to revert back to using highly potent and addictive opioid class of medication to manage chronic pain in Medicare beneficiaries.

We urge CMS to revise their proposed changes to the 340b program to continue to allow hospitals full access to a full array of drugs to help in the fight against opioid addiction.

Elimination of Inpatient Only Procedure (IPO) List

The Inpatient Only (IPO) List was created to identify services that require inpatient care because of the invasive nature of the procedure, the need for postoperative recovery time or the underlying physical condition of the patient. CMS stated in the proposed rule that they concluded that the list is not necessary to identify services that require inpatient care because of changes in medical practice, including new technologies and innovations. As a result, beginning in 2021, CMS proposes to eliminate the IPO list over three calendar years, starting with the removal of 300 musculoskeletal-related services in 2021. CMS also proposed a three-year period of implementation with different procedures phased out across the three years.

NANS is opposed to the proposed elimination of the Inpatient Only List and asks CMS to revise their proposal to maintain the IPO list as is for CY 2021 and beyond. We believe the IPO list helps maintain a standard of safety and quality for Medicare patients by keeping more complicated procedures limited to the inpatient setting where patients recovering can be ensured more intensive post-operative care and monitoring for potential complications from intensive procedures and care. If there are specific procedures that are felt to be safely performed in Outpatient settings, CMS already has a process by which stakeholders can apply to remove services from the IPO list. CMS has annually moved procedures off of, or onto, the IPO list, and we believe this process has served providers, facilities, and most importantly, patients well by ensuring safe and appropriate follow-up care for intensive procedures on at-risk patients. We do not believe it is necessary to move away from this process at this time and urge CMS to delay any elimination of the IPO list for CY 2021 and beyond.

Site-Neutral Payment Policy for Clinic Visits

As finalized in the CY 2019 OPPS/ASC final rule, CMS completed the implementation of the two-year phase-in of applying the Medicare Physician Fee Schedule (MPFS) rate for the clinic visit service (G0463 – Hospital outpatient clinic visit for assessment and management of a patient) when provided at an off-campus PBD and reimbursed under OPPS. This clinic visit is the most common service billed under OPPS and typically occurs in the physician's office. CMS instituted the proposal based on its authority to restrict unnecessary increases in the volume of covered services.

In September 2019, a federal district court sided with hospital plaintiffs, ruling that CMS lacked statutory authority to implement the change. However, on July 17, 2020, the U.S. Court of Appeals for the District of Columbia Circuit ruled in favor of CMS, holding that the agency's regulation was a reasonable interpretation of the statutory authority to adopt a method to control unnecessary increases in the volume of the relevant service. In light of this recent court ruling, CMS will continue the site-neutral policy in 2021. CMS has not released information on how or

whether it will address reprocessing 2019 claims that were previously reprocessed at the higher OPPS rate.

While NANS understands that CMS has statutory authority to implement site-neutral payment policies, NANS does not believe the policy is correct and efficacious for CY 2021 at a minimum. Imposing site-neutral payments for E/M visits would impact the financial status of many outpatient facilities across the country at a time when outpatient facilities have taken a disproportionate negative impact due to closures of outpatient facilities and elimination of elective procedures during the Covid-19 PHE. Imposing greater reimbursement reductions on facilities because of site-neutrality requirements will lead to more furloughed or eliminated staff positions, more delays in necessary services, and reduced access to outpatient care. We would urge CMS to continue to provide fair and reasonable reimbursement for facilities for CY 2021 and throughout this period of Covid-19 related impacts. CMS should delay any site-neutral payment policies at least for a period of at least an additional year after the end of the PHE period which would be well after CY 2021.

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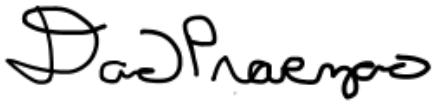
Thank you for your time and consideration of NANS comments. We greatly appreciate the opportunity to participate in efforts to more efficiently and accurately capture current care delivery. We commend CMS on its continued efforts to improve care quality and access. If you have any questions on our comments, please do not hesitate to contact Chris Welber, MBA, NANS Executive Director, at cwelber@neuromdoulation.org.

Sincerely,

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



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