

October 5, 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: 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 undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to thank you for 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. Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring access to appropriate, effective, and responsible treatments.

The *Proposed Rule* includes several policy and technical modifications within the Resource-Based Relative Value Scale (RBRVS). This letter includes our recommendations and comments regarding the pre-approval for neurostimulator implantation.

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 implanted spinal neurostimulators to curb what they believe may be unnecessary utilization.

Our societies strongly disagree with this proposal and the rationale provided by the agency. **We strongly urge CMS not to apply the prior authorization requirement to neurostimulation procedures as this requirement creates an improper and unnecessary burden on physicians and physician practices.** We also dispute the CMS claim that prior authorization will reduce unnecessary utilization. There is evidence that prior authorization merely results in delays in appropriate care. There is no evidence that utilization is increasing at significant rates for these procedures, but there is considerable evidence to illustrate the costs for patients and practices from prior authorization policies used by private payers.

For example, Karrison *et al.* found that when time spent in acquiring prior authorization is converted to dollars, national time cost to practices of interactions with plans is at least \$23 billion to \$31 billion each year.¹ This financial burden and cost has only increased in the ensuing twelve years and we believe this cost to be an unnecessary and unjustified burden for physicians performing neurostimulator implantation.

Other studies have confirmed and added to the body of evidence showing the detrimental impact of prior authorization burdens to patient access. A 2019 AMA survey found that 64% of patients surveyed experienced at least a one-day delay in scheduling and another 26% experienced delays of three or more days -- with 91% of respondents experienced delays in necessary care. Of physicians surveyed, 24% reported that a delay related to prior authorization led to adverse patient events and 16% reported hospitalizations directly attributable to prior authorization. Furthermore, the same study found that prior authorization efforts add 14.4 hours of staff time per week to their workload with 30% of respondents reporting that their practice has a Full Time Employee (FTE) dedicated to prior authorization. The same survey found the prior authorization burden to have increased significantly over the past seven years, with 86% of respondents reporting increased prior authorization costs to their practice in the previous five years.² A study from the Cleveland Clinic estimated their annual costs for prior authorization activities to exceed \$10 million a year.³

These studies apply to the neurostimulator procedures identified by CMS in the proposed rule and demonstrate that imposing these burdens will result in unnecessary delays for patients in accessing these critical procedures.

We also strongly disagree with the agency's contention that neurostimulator implantation procedures are overutilized or somehow not efficacious. To the contrary, numerous studies have found that spinal cord stimulation (SCS) is highly efficacious. Rivzi and Kumar found "*that efficacy of SCS treatment is time dependent with success*

¹ 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,

² <https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf>

³ <https://www.ama-assn.org/practice-management/sustainability/inside-cleveland-clinic-s-10-million-prior-authorization-price>

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.”⁴

Indeed, neurostimulation is a key alternative to opioid prescription for the management of pain symptoms. 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. 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.⁵ **We urge CMS to follow the recommendation of their Opioid Taskforce 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 will incur a massive cost to society, patients, and providers, without offering anything other than overestimated cost savings.

We believe it is essential to continue to increase access to non-opioid pain treatment and SCS is a very important alternative to opioid prescriptions. We urge CMS to revise their proposal to decrease access to neurostimulator implantation through the imposition of a costly and burdensome prior authorization process.

Thank you for your time and consideration of our 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 Belinda Duszynski, Senior Director of Policy and Practice at the Spine Intervention Society, at bduszynski@SpineIntervention.org.

Sincerely,

American Academy of Pain Medicine

American Academy of Physical
Medicine and Rehabilitation

American Society of Anesthesiologists

American Society of Neuroradiology

American Society of Spine Radiology

North American Neuromodulation
Society

North American Spine Society

Society of Interventional Radiology

Spine Intervention Society

⁴ 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

⁵ <https://www.ama-assn.org/practice-management/sustainability/prior-authorization-nonopioid-pain-care-prolongs-patient>