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August 18, 2021

Elizabeth Richter
Action Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention:
Mail Stop 1753-P; C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code 1753-P; CY 2022 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 Richter:

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:

- **403b Drug and Biologics Reimbursement and Chronic Pain Management Medication**
- **Reinstatement of the Inpatient Only Procedure (IPO) List**
- **Revision of ASC Allowed Procedures List**

403b Drug and Biologics Reimbursement

In the proposed rule, CMS reviewed their 2021 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."

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[1].

In our opinion, the current policy of paying a net payment rate of ASP (average sale price) minus 22 percent has adversely affected Medicare beneficiaries access to certain medications especially non-opioid based pain management medications that have been critical in battling the opioid epidemic.

We therefore strongly support and appreciate the agency's proposal to pay these drugs specifically at ASP +6 and believe this change will improve beneficiary access to these non-opioid pain management medications at a critical time in the battle against rising opioid addiction and the resulting costs to patient's health and well-being.

We urge CMS to finalize the policy on non-opioid pain management medication for CY 20222 and going forward.

Reinstatement and Review 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 are reversing the policy enacted in 2021 to eliminate the IPO list and allow all services on the IPO list to performed in outpatient facilities. The current policy called for a three-year integration period during which dozens of procedures from the IPO list would be allowed in the outpatient setting each year until complete elimination of the IPO list would take effect after three years. In the 2021 rule, CMS concluded that the list is not necessary to identify services that require

[1] 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

inpatient care because of changes in medical practice, including new technologies and innovations.

NANS was opposed to the proposed elimination of the Inpatient Only List and asked 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 did not believe it was necessary or wise to move away from this process at this time and urged CMS to delay any elimination of the IPO list for CY 2021 and beyond and therefore, we support the current proposal to move all 300+ services previously scheduled to be removed back to the IPO list as proposed.

The 2022 proposed rule also asked for comments on whether CMS should proceed with annual reviews of services eligible for the IPO list and NANS believes such an annual review is in fact advisable and recommends CMS reestablish this annual review policy. This would allow for nomination of services on the IPO list to be removed, but only with thorough and careful consideration. We believe such an approach provides important safety and quality standards for Medicare patients, while continuing to allow procedures that can be done safely and effectively in the outpatient and ASC settings to be reimbursed in those settings and not be "crowded" out by demand for services that are currently best suited for inpatient care.

Despite our support for the change, NANS is troubled by the significant shift in policy and believe the abruptness will lead to confusion and frustration for physicians and patients alike. We are hopeful that CMS will avoid such major changes in consecutive years going forward.

ASC Allowed Procedures List

In the proposed rule, CMS reviewed its policies on procedures and services allowed in the Ambulatory Surgical Center setting. The agency is proposing for 2022 to remove over 250 services that were added to the ASC covered services list for 2021 but the agency now believes should not be allowed in the ASC setting or at a minimum should be further reviewed against stated criteria for approval. NANS is supportive of a measured, deliberate, and transparent process for approving services for the ASC setting. We believe such an approach can help protect patient safety and reduce risks of hospitalization and serious complications. We also believe it is critical that the decision-making process be collaborative with the guidance of physicians in particular driving approval of procedures for the ASC. Physicians are best equipped to make clinical evaluations of the safety of procedures in each setting and we are pleased that CMS is considering a procedure level review that allows stakeholders to critically measure the pluses and minuses for each procedure reviewed.

Despite our support for the change, NANS is troubled by the significant shift in policy and believe the abruptness will lead to confusion and frustration for physicians and patients alike. We are hopeful that CMS will avoid such major changes in consecutive years going forward.

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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@neuromodulation.org.

Sincerely,

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