AMERICAN ACADEMY OF
OTOLARYNGOLOGY-
HEAD AND NECK SURGERY

September 27, 2019

SUBMITTED VIA ELECTRONIC MAILING

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
P.O. Box 8016
Baltimore, MD 21244-8013

[Submitted online at: https://www.regulations.gov/comment?D=CMS-2019-0109-0002]

Re: CMS 1717-P Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Dear Administrator Verma:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on the "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals" published in the Federal Register on August 9, 2019. Our comments will address the following issues within the proposed rule: 1) price transparency 2) prior authorization 3) vagus nerve stimulation, and 4) establishing CPT code 31298, 31634, and 31647 as permanently office-based procedures.

I. Price Transparency

For CY 2020, CMS is proposing to increase hospital price transparency through a number of policy changes. Included in this transparency initiative is a requirement that hospitals disclose to patients whether the physicians are hospital staff or whether they are contracted to the hospital. Additionally, the proposal requires that hospitals disclose whether the physicians will bill the patient's separately and if they are in-network for the patient. Patients should be able to receive quality care

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without having to worry about receiving additional bills. **The AAO-HNS strongly supports proposals that increase hospital and insurance price transparency.**

We share CMS's view that increased transparency could help address the issue of "surprise" medical bills. Despite efforts to determine that a provider is within their insurer's network, patients may still receive unanticipated medical bills which are a surprise to both the patient and their primary provider. The average family cannot afford these unexpected bills, in addition to their already unbearable out-of-pocket costs. These unanticipated bills are often incurred because patients do not have any way of determining in advance every provider who will be involved in their care. This is especially true in emergency situations or when surgical complications occur.

The healthcare delivery system is complex, and patients should not have to navigate it without consumer protections. While Congress is currently debating a number of legislative proposals to address surprise medical bills, **the AAO-HNS commends CMS for taking steps to increase hospital price transparency and reduce the incidence and impact of surprise medical bills.**

II. Prior Authorization

For CY 2020, CMS is proposing to impose a prior authorization requirement for a new subset of services to ensure that these procedures are only billed when medically necessary. Prior authorization is often used by payers as a mechanism to reduce health care spending. Even though this is purported to lead to lower costs, evidence shows that this is not the case. On average, ENT physician offices complete more than 40 prior authorizations per week with the average approval time taking between two and seven days. **Excessive prior authorizations do not curb healthcare expenditures, but instead cost patients time and money in addition to delaying their care.**

The timeframe that CMS is proposing to complete prior authorization reviews is of particular concern. In the proposed rule, CMS or its contractor would issue a decision (affirmative or non-affirmative) within 10 business days. These timeframes potentially endanger patient safety and should be reduced.

III. Vagus Nerve Stimulation

For CY 2020, CMS is seeking comment on whether the LivaNova VNS Therapy System for TRD meets the newness criterion. The AAO-HNS believes that while there have been technical improvements in the LivaNova VNS system, this technology does not meet the newness criteria. Instead, it is our understanding that this represents a natural progression of an existing system. We have significant concerns over the marked increase in pricing for this product. The advance in technology, in of itself, should not qualify under the "newness criteria". Rather this is an expected advance of existing technology.

IV. Establishing Certain CPT Codes As Permanently Office-Based

For CY 2020, CMS is proposing to designate three CPT codes commonly performed by otolaryngology-head and neck surgeons as permanently office-based. These three codes, 31298 (nasal/sinus endoscopy, surgical, with dilation (eg balloon dilation); frontal and sphenoid sinus ostia), 31634 (bronchoscopy, rigid or flexible, including fluoroscopic guidance ,when performed; with balloon occlusion with assessment of air leak, with administration of occlusive substance eg fibrin glue if performed) and 31647 (bronchoscopy, rigid or flexible, including fluoroscopic guidance ,when performed with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial

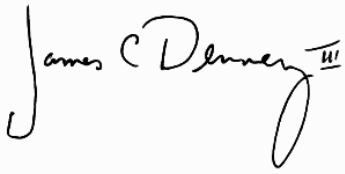
valve(s), initial lobe). The otolaryngology community already utilizes well-defined criteria to guide the selection of the appropriate site of service based on the procedure and individual considerations unique to each patient. We strongly support that the determination of how to best provide adequate and timely care to a Medicare beneficiary should fall under the purview of the patient-surgeon relationship.

CMS performed their annual review of the surgical procedures for which ASC payment is made to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. The agency's review of the CY 2018 volume and utilization data resulted in the identification of three covered surgical procedures that they believe meet the criteria for designation as office-based. The data indicate that the procedures are performed more than 50 percent of the time in physicians' offices. The AAO-HNS is supportive of the ongoing trend to migrate procedures from the hospital outpatient setting to the ambulatory surgical center to the physician office when appropriate and safe. We continue to advocate that our members have the flexibility to perform these services in the setting most clinically appropriate for the patient. **The AAO-HNS supports establishing CPT codes 31298, 31634 and 31647 as permanently office-based procedures, and urges that CMS finalize this policy for implementation in the HOPPS/ASC 2020 Final Rule.**

Conclusion

The AAO-HNS appreciates the opportunity to provide comment and recommendations regarding these important policies on behalf of our members. We look forward to working with CMS as it continues its efforts to reduce regulatory burdens for providers and improve patient access to quality care. If you have any questions or require further information, please contact healthpolicy@entnet.org.

Sincerely,



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