AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY

August 29, 2012

SUBMITTED VIA ELECTRONIC MAIL AND REGULAR MAIL

Marilyn Tavenner, RN
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1589-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) Payment System for CY 2013

Dear Acting Administrator Tavenner:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on the "Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations" published in the *Federal Register* as a proposed notice on July 30, 2012. Our comments will address the following issues, in the order in which they appear in the proposed rule: (1) Updates affecting the OPPS Payments; (2) OPPS payment for drugs and biological; (3) OPPS payment for hospital outpatient visits; (4) Clarification of supervision requirements in the OPPS; (5) Hospital outpatient quality reporting program; (6) ASC 2013 proposed payment rates; (7) ASC quality reporting program.

I. UPDATES AFFECTING 2013 OPPS PAYMENTS

In the proposed rule, CMS proposes utilizing the geometric mean cost of services within an Ambulatory Payment Classification (APC) to determine relative payment weights for services. This is a drastic change from the former methodology, used since the inception of the OPPS in CY 2000, which relied on the median costs of services to establish relative weights for services. If finalized, this proposed policy would impact many Otolaryngology based APCs. In some cases, the change results in significant decreases to payment for services within a given APC. Some examples include:

APC	CPT Code	Code Descriptor	Proposed Payment Reduction in 2013
0074	31570	Laryngoscope w/vc inj	-10.6%
0074	31576	Laryngoscopy with biopsy	-10.6%
0074	31578	Removal of larynx lesion	-10.6%
0074	31235	Nasal/sinus endoscopy dx	-10.6%
0074	31237	Nasal/sinus endoscopy surg	-10.6%
0074	31238	Nasal/sinus endoscopy surg	-10.6%
0072	31231	Nasal endoscopy dx	4.4%
0072	31233	Nasal/sinus endoscopy dx	4.4%
0072	31511	Remove foreign body larynx	4.4%
0072	31513	Injection into vocal cord	4.4%

The Academy is concerned about the potential impacts of this policy change. As indicated in the examples above, Otolaryngology APCs will incur both deep reductions in reimbursement, as well as increases in some instances. We understand that modifying a key methodology within a payment system, such as using the median rather than the geometric mean to calculate cost to charge ratios (CCRs), will result in some APCs being more impacted than others. ***Despite this, the Academy urges CMS to carefully monitor the impact of this policy change over the next several rulemaking cycles to ensure there is not an overtly negative impact to any one medical specialty or APC as a result of using the geometric mean to calculate CCRs. In the event CMS identifies any APCs that appear to incur extreme reductions in one calendar year (i.e. more than 10%), or APCs that are incurring repeated reductions over several years due to this new methodology, we encourage CMS to identify those APCs through the annual rulemaking process and allow specialties to submit public comments, or present at an APC panel meeting whichever occurs first, in order to stabilize payment for any APC that is penalized repeatedly by reductions to the APC's payment rate.***

II. OPPS PROPOSED PAYMENT FOR DRUGS AND BIOLOGICALS IN 2013

AAO-HNS is pleased that CMS has proposed an increase to reimbursement for drugs and biologicals without pass through status, to ASP + 6% in CY 2013. ***We believe this new methodology proposed by CMS much more accurately reflects the actual costs incurred by hospitals in providing and administering drugs and biologicals, therefore we strongly urge CMS to finalize the rate of ASP + 6% for 2013. We believe this rate is a more accurate representation of hospitals true costs in providing and administering these drugs and biologicals.***

III. OPPS PAYMENT FOR HOSPITAL OUTPATIENT VISITS

Under current policy, when a Medicare beneficiary presents to the hospital for care the physician must decide whether to admit them as an inpatient or treat them as an outpatient. Inpatient services are paid under Medicare Part A, while outpatient services are paid under Medicare Part B. Occasionally, when a physician admits the patient for inpatient care, a reviewing body such as a MAC, RAC, or CERT will review the claim and deny it as not reasonable and necessary under the Social Security Act (SSA). In these cases, hospitals may rebill a new inpatient claim for a limited set of Part B services that were furnished to the patient and refer to it as "Inpatient Part B" or "Part B Only" services. They may also bill Medicare Part B for any outpatient services that were provided to the patient during the 3-day payment window prior to the admission of the patient.

Once the patient is discharged, however, the hospital cannot change their status to outpatient in order to submit an outpatient claim. If they wish to change the status, it must be done prior to discharge and the patient, provider, and utilization review committee must agree with the status change decision. The reason for this restriction is due to potential liability for the beneficiary. Specifically, beneficiaries that are admitted as inpatients pay a onetime deductible for all services provided during their first 60 days in the hospital. Beneficiaries are not asked to pay for self-administered drugs or post-acute skilled nursing facility (SNF) care that may be required. These costs are covered by Medicare, so long as the beneficiary was in the hospital as an inpatient for 3 days. Outpatients, however, are required to pay a copayment for each individual outpatient service and self-administered drugs and SNF care are not covered by Medicare Part B.

In the CY 2013 rule, CMS requests public input on several areas of this policy. Specifically, how they might go about providing more clarity and guidance to providers and beneficiaries regarding observation care. The Academy is pleased to be able to provide comment on the various inquiries made by the Agency and will respond to them in the order they appear in the proposed rule:

1) How might CMS improve current instructions on when a patient should be admitted as an inpatient?

The Academy strongly supports clarification by CMS regarding when a patient should be admitted to the hospital as an inpatient. ***In this regard, we recommend that CMS implement a bright line rule regarding when a patient is an "inpatient" that is clear and understandable by physicians, staff, and beneficiaries. We continue to believe that a physician's care in the facility is the same, regardless of a patient's designation as an inpatient or outpatient, and as such we believe that the physician, using his or her clinical judgment, should be allowed to make the decision whether to admit a patient to the hospital. We urge CMS to increase the transparency of patient status for both patients and physicians and implement an appropriate payment policy for both outpatient and short inpatient hospital stays that is consistent across both sites of service.***

2) Is it permissible for CMS to redefine "inpatient" using length of stay or other variables as the parameters, in conjunction with medical necessity?

The Academy believes defining an "inpatient" based on length of stay, or using other variables, would be extremely useful. ***We therefore recommend that CMS automatically define anyone who has received care in the facility setting for more than 48 hours as an inpatient.*** Once the patient's care has extended beyond that time threshold, they would then be designated as a hospital inpatient and all care leading up to that point should then be rolled into the inpatient care and counted towards the three day window required for coverage of self-administered drugs or post-acute skilled nursing facility (SNF) care after discharge from the facility. The only exception to this rule should be where there is evidence that the patient was mis-managed or that necessary care was delayed in order to reach the 48 hour time threshold for admittance as an inpatient. This would benefit the beneficiary because it is clearer regarding what their financial obligations are under both patient designations. This is information we believe patients have the right to know in real time during their stay. It's also helpful to the physician in cases where they know their patients will require follow up care at an SNF or otherwise, and they want to ensure that the necessary steps are taken so the patient will have the appropriate follow up care, and that it's covered by Medicare, once they are discharged.

3) Whether CMS should cap the amount of time a beneficiary can receive observation services as an outpatient?

Again, the Academy believes a policy that caps the amount of time a beneficiary can receive observation services as an outpatient would be useful as it would provide clarity for providers and beneficiaries. For example, if both providers and patients know that they can only be "observed" as an outpatient for 48 hours, physicians would be able to estimate the necessary length of stay, and care, the beneficiary requires, as well as whether they will need follow up care at an SNF. If it is determined they do need follow up care, this bright line rule will allow the physician to admit them right away so that the 3 day admission threshold for self-administered drugs and post-acute SNF stays is met and the patient receives the necessary, post-discharge care covered by Medicare for inpatients.

4) Whether the use of clinical measures or prior authorization would be useful requirements for payment of an admission?

The Academy strongly opposes any policy requiring prior-authorization before admitting a patient. To require prior-authorization prior to admission to the hospital as a condition of payment would only add to the administrative burden for physicians and hospital staff when admitting a patient to the hospital. In addition, given that beneficiaries being admitted to the inpatient facility are typically some of the sickest beneficiaries, or those requiring the most care, it makes little sense to further complicate and delay the admission process for the patient by requiring prior-authorization. ***Therefore, we do not think such a policy would be in the best interest of patient care, and urge CMS not to implement any prior authorization requirements for admission to the hospital.***

IV. CLARIFICATION OF SUPERVISION REQUIREMENTS IN THE OPPS

AAO-HNS applauds CMS's decision to hold rural hospitals harmless in regards to compliance with supervision rules relating to the provision of outpatient therapeutic services, such as speech language pathology. The Academy also supports CMS's proposal to establish an independent advisory review process for consideration of stakeholder requests for assignment of supervision levels, other than direct supervision, for specific outpatient hospital therapeutic services. CMS proposes in 2013, to refer questions about supervision of specific services to the Ambulatory Payment Classification (APC) Panel.

While we generally support this proposal by CMS, we are concerned that because the APC Panel is only convened once during the rulemaking process this policy change may result in only one opportunity for public stakeholders to weigh in with CMS on modifications to supervision rules. ***Therefore, we urge CMS to ensure that if this proposed policy is put into place within the final OPPS 2013 rule that they also allow additional administrative avenues beyond the APC Panel meeting for the public to comment on any proposed modifications to supervision rules for diagnostic or therapeutic services.***

V. HOSPITAL QUALITY REPORTING PROGRAM

AAO-HNS is committed to improving the quality of care through the application of measurement into continuous quality improvement programs. We have worked closely with the the Physician Consortium for Performance Improvement, to shape and develop a series of measures for many Otolaryngology – Head and Neck Surgery diseases and diagnosis. AAO-HNS supports the use of outcomes measures and recognizes they are more difficult to implement and require risk adjustment. While we understand the science of performance measurement is moving effectively in this direction, ***we support a combined approach to utilizing both process and outcomes measures. Process measures, such as those developed utilizing evidence in the form of clinical practice guidelines, are valuable in understanding gaps in the delivery process and they are an important tool in the overall improvement continuum. We strongly support the alignment of measures across Medicare programs using standardized measures that are clearly applicable to, and agreed upon by, a given specialty and have been endorsed by consensus organizations, such as the National Quality Forum.***

We recognize that where multiple payment systems use different measures and varying applications of the measures, physicians are often confused by conflicting information regarding their quality performance and associated quality of care that is communicated to beneficiaries. In an effort to ease this confusion for providers who may practice in the hospital outpatient, inpatient, or ASC setting, ***we strongly encourage CMS to align the measures and reporting requirements for the various quality programs. In addition, we urge CMS to work to streamline the timeframe and approval process for quality measures physicians can report as part of these quality programs.*** As we stated in our comments on the Medicare Physician Fee Schedule NPRM, the alignment of the approval process for quality measures available for reporting, such as those endorsed by National Quality Forum (NQF), AMA-Physician

Consortium for Performance Improvement (PCPI), specialty societies and CMS would greatly increase the number of measures applicable to Otolaryngologists and boost participation in all Medicare quality reporting programs.

VI. ASC 2013 PROPOSED PAYMENT RATES

a. Updates to the ASC Payment System

CMS proposes an update to the ASC payment system for CY 2013 of 1.3%. The Academy appreciates this proposal to update the ASC payment system, but remains concerned that in the event the 2% sequestration cuts take effect in 2013, that this would result in an overall negative update for ASCs, which are already paid at a reduced rate compared to the hospital outpatient setting. This disparity in payment is attributable to the use of the consumer price index methodology in the ASC rather than a market basket update methodology which is used in the OPPS. ***Due to concerns regarding payment rates for services rendered in an ASC, we urge the Agency to consider other update methodologies for future rulemaking that may bring more parity to reimbursement for services provided in both the hospital outpatient and ASC setting. Specifically, we respectfully request that CMS align payments in the ASC setting with those in the OPPS.***

b. Proposed Surgical Procedures Designated as Office Based

Within the proposed rule, CMS proposes to designate nasal endoscopy procedures (31295, 31296, and 31297) as office based in 2013 when performed in the ASC setting. This means these services will be paid, for the technical component, at the lesser of the ASC payment or the MPFS Practice Expense (PE) RVU.

While the Academy understand that this has been CMS' longstanding policy regarding reimbursement for services designated as "office based" in the ASC setting, we remain concerned that this policy does not render adequate payment for some services performed in an ASC. ***Specifically, we believe that patients at higher risk are more frequently seen in the ASC setting, and we encourage CMS to consider this in future rulemaking and rate setting for ASC procedures that are designated as "office based".***

VII. ASC QUALITY REPORTING PROGRAM

CMS is proposing that beginning October 2012 ASCs will be expected to report claims-based measures for quality reporting purposes. Data reported between October 1, 2012 and December 31, 2012 will be used to calculate 2014 payment. Similarly, data reported in 2013 will be used to calculate payment in 2015. ASCs must submit data on the claims-based quality measures by including the appropriate Quality Data Code (QDC) on their Medicare claims to avoid a -2% penalty to their payments in 2014.

While the Academy is supportive of quality reporting and programs that encourage the provision of the highest quality care to beneficiaries, we remain concerned about several aspects of the impending ASC Quality Reporting Program (ASCQR). Specifically, we are concerned that many providers and ASCs are unaware of the October 2012 rollout date for this program. There has been very limited information and a severe lack of communication to ASCs, beyond annual rulemaking, about the deadline for this program. ***Based on this lack of communication and education to ASCs, the Academy respectfully requests that CMS delay implementation of this program until at least January 1, 2013, to give providers and ASCs time to prepare to properly report on the proposed quality metrics. In addition, delaying until the first of the year in 2013 would provide a less confusing timeline for rolling out the program and would allow the first year of penalties in 2015 to be based on reporting for a full calendar year, rather than a three month window in 2012 which will not accurately reflect the quality of care provided by ASCs because they will not be ready to report, and do not have enough time to get up to speed prior to October 1, in order to comply.***

Further, we encourage CMS to continue their work to align the measures and reporting requirements across all quality programs within the Medicare payment programs. ***As such, we recommend that CMS align the measures for ASC reporting with those of other quality programs and encourage the Agency to continue expanding the measure sets so that Otolaryngologists and other specialists have a meaningful opportunity to report on measures that accurately reflect the quality of care they provide to their patients.***

Conclusion

The American Academy of Otolaryngology—Head and Neck Surgery appreciates the opportunity to provide comment and recommendations regarding these important policies on behalf of our members. If you have any questions or require further information, please contact Jenna Kappel, MPH, MA, Director of Health Policy at jkappel@entnet.org or 703-535-3724.

Thank you.

Sincerely,

David R. Nielsen MD

David R. Nielsen, MD, FACS
Executive Vice President and CEO