



**AMERICAN ACADEMY OF
OTOLARYNGOLOGY—
HEAD AND NECK SURGERY**

October 19, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0044-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—
Stage 2

Dear Ms. 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 final rule **Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2**. Our comments focus on the Core and Menu Measures and Objectives and the proposed options for reporting Clinical Quality Measures (CQMs). The AAO-HNS represents over 12,000 physicians in the United States who diagnose and treat disorders of the ears, nose, throat, and related structures of the head and neck. The medical ailments treated by this specialty are the most common that afflict all Americans, old and young, including hearing loss, balance disorders, chronic ear infection, rhinological disorders, snoring and sleep disorders, swallowing disorders, facial and cranial nerve disorders, and head and neck cancer.

The Academy and its members are highly supportive of adopting robust and applicable electronic health records (EHRs) into their practice to improve quality of care and enhance patient safety. We are also appreciative of CMS' attempt to more closely align the EHR Incentive Program with other quality initiatives such as the E-Prescribing (eRx) Incentive Program, Physician Quality Reporting System (PQRS), and Accountable Care Organizations (ACOs). We also applaud the new elements such as the batch file process for groups reporting as individuals, all of which are designed to help reduce the burden placed on physicians and their staff when switching to an office based EHR system.

Despite these improvements, the Academy feels the stringent program requirements with high satisfaction thresholds will continue to hinder health information technology (HIT) adoption. According to the Government Accountability Office (GAO), within Otolaryngology, only 14.1 percent of all eligible physicians were awarded EHR Incentive payments in 2011. We feel allowing for greater flexibility to meet meaningful use requirements will spur the adoption of HIT and move the country closer to the desired outcome for the Medicare/Medicaid EHR incentives.

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While the Academy supports a staged approach to the EHR meaningful use incentive program, we believe that this approach must take into account the current technological realities and the additional financial and administrative costs that will be incurred by physicians to meet all of the program requirements. Further, we believe that a system should be developed where CQMs are designed, easily translated into EHRs, and the calculations of the measures and reporting of the measures is automatic.

Stage 2 Core Objectives:

CPOE Requirement: In the proposed rule, CMS included a measure for Computerized Physician Order Entry (CPOE) for more than 60 percent of medication, laboratory, and radiology orders created by a licensed professional. The Academy commented that this was too steep an increase from the Stage 1 requirement of 30 percent to the Stage 2 requirement of 60 percent. The Academy recommended that CMS remove the laboratory and radiology requirements during the EHR reporting period and decrease the proposed threshold for medication orders to only require one laboratory and one radiology order are entered electronically. In the final rule, CMS reduced the number of lab and radiology orders to 30 percent created by the Eligible Provider (EP) during the reporting period. ***We appreciate CMS' recognition of the steep increase between Stage 1 and Stage 2 and the subsequent reduction in the requirement's measurement. However, we believe it is not reasonable for clinicians to have to collect all this information at the point of care, and recommend that CMS remove the laboratory and radiology requirements during the EHR reporting period. We also urge CMS to decrease the proposed threshold for medication orders to only require one laboratory and one radiology order are entered electronically.*** Because physicians are very involved in seeing patients and performing surgery, they often do not have time to fill out forms for radiology and labs, and instead, rely on assistants to fill them out. It will be important in the future for lab and radiology orders to be received by CPOE, but this is not attainable currently. ***As such, we believe the status of "no orders" should be allowed as a positive value in the numerator. The decision not to order tests is still an order decision. If physicians are given credit for not ordering tests, then it will not only reduce the number of unnecessary tests, but there will also be an incentive for physicians not to order tests, in general.***

Electronic Prescribing (E-prescribing): In the proposed rule, CMS proposed to increase the requirement to include more than 65 percent of orders transmitted as e-prescribing. The Academy expressed concern that many specialty physicians will not be able to meet this level of e-prescribing, and instead, suggested CMS reduce the threshold for EPs to generate and transmit permissible prescriptions electronically to 50 percent. ***We applaud CMS' decision to reduce the e-prescribing threshold to 50% in the final rule. We believe this is a more attainable level of e-prescribing for specialty physicians such as Otolaryngology- Head and Neck Surgeons.***



Record Demographics: CMS finalized the requirement to include listing the patient's preferred language in the demographics, which we feel is potentially problematic, especially for small offices which make up a majority of the Otolaryngology-Head and Necks practices. ***We support the inclusion of recording some information to capture for quality of care purposes, such as gender identity, disability status, and preferred language, but this should be optional for physicians to record given that some small practices will not have the capability to provide interpreter services. Our understanding is that providing interpreter services is not required for Medicare Part B services. We request CMS provide clarification on this matter. We also recommend that EPs only be required to meet a 60 percent threshold, rather than the 80 percent indicated by CMS.***

Record Smoking Status for Patients: ***The Academy appreciates CMS's inclusion of the recording of smoking status for patients 13 years or older. We believe this is an important issue because tobacco use is the leading cause of preventable death in this country, responsible for more than 400,000 deaths each year. However, as noted in our comments on the proposed rule, the Academy again recommends moving this requirement from the core set, and instead, including it in the clinical quality measures (CQMs).***

Implement Clinical Decision Support: CMS finalized the requirement for EPs to implement five clinical decision support interventions related to four clinical quality measures (CQMs), as well as enable and implement the functionality for drug-drug and drug-allergy interaction checks. ***The Academy thanks CMS for decreasing the number of CQMs in the threshold, but believes that the requirement to implement five clinical decision support interventions related to four CQMs would still be very challenging for specialists, including otolaryngologists, who may not need to implement so many clinical decision support interventions for their particular patient populations given the type of care they provide.***

CMS notes that if none of the CQMs are applicable to a EPs scope of practice, the EP should implement a clinical decision support intervention that he or she believes will be effective in improving the quality, safety, or efficacy of patient care. The Academy is involved in developing measures, based on our clinical practice guidelines approved by the society, and moving them through the National Quality Forum (NQF) approval process, but this takes an extensive amount of time. The measures will then need to be incorporated into the EHR system which leads to an additional expense for Otolaryngologists. ***Therefore, the Academy continues to emphasize that the clinical decision support requirement is not an appropriate core criteria for specialists. Further, the Academy maintains our position that the number of CQMs required should be two. Since CMS has moved forward with the requirement for four CQMs, the Academy recommends where no CQM is applicable, that CMS allows the EP to implement a CQM that has been approved by a specialty society and is under review for endorsement by the NQF. For***



example, the Academy strongly urges CMS to include a set of quality measures focusing on adult sinusitis for use by otolaryngologists. These measures (listed below), were developed by the AMA-Physician Consortium for Performance Improvement (PCPI) with the support of the AAO-HNS Foundation (AAO-HNSF) and we believe should be included as measures that would meet the CQM threshold criteria.

Incorporate Clinical Lab-Test Results into EHR as Structured Data: We agree with CMS that lab tests results should be incorporated into EHR as structured data but that should not be required until EMRs have evolved to the point where this is happening automatically. As we stated in our comments on the proposed rule, the idea to ask clinicians to manually enter non-structured data into a structured format is extremely inefficient. ***Manually entering non-structured data into a structured format is fraught with many dangers, most notably, the errors that will be made in entering the data. If it cannot be incorporated as structured data, then it should be left as unstructured data and an exclusion given.***

Because there is no requirement for labs to electronically interface with all types of EHRs, there is no incentive to invest in the infrastructure or to make labs compatible with EHR for a low volume user. The Academy has also found that otolaryngology practices that have adopted EHRs, or who are preparing to purchase an EHR, in many cases do not buy the lab interface because it is cost-prohibitive for the small amount of labs the practice orders. It is our understanding that if you are an organization that is a high volume user of labs, the labs themselves will often subsidize the cost of the interfaces, but in most cases this does not apply to the otolaryngology community. We are additionally concerned our members will not be able to get their EHR certified because of the requirement of a lab interface. It is essential that a functional Nationwide Health Information Network (NwHIN) is created before this measurement is required. This way, a physician has to interface with the NwHIN, and the labs and hospitals are required to do the same, at which point everything will be compatible. Until then, it is prohibitive and counterproductive to implement this requirement. ***Therefore, the Academy believes that otolaryngologists should not be prevented from meeting meaningful use criteria by their failure to purchase a costly laboratory interface or module until such time as costs to do so become more manageable for small practices. The Academy recommends that CMS re-examine the measure and criteria and remove it from the health IT functionality measures.***

Send Reminders to Patients: CMS finalized the requirement for an EP to send a reminder to more than 10 percent of all unique patients, who prefer to receive a reminder, who have had an office visit with the EP within the 24 months before the beginning of the EHR reporting period. While we appreciate and are supportive of CMS' goal of increased patient engagement in Stage 2, we are concerned that this measure will be difficult for specialists to meet. For example, it would not make sense for an Otolaryngologist to send reminders to patients with a more acute,



time-limited condition, such as acute otitis or patients undergoing surgery. **Therefore, as stated in our comments on the proposed rule, the Academy urges CMS not to include sending patient reminders as a requirement.**

Provide Patients with Electronic Access to their Health Information Allowing Patients to View, Download, or Transmit their Health Information: The Academy supports CMS's proposed objectives to provide patients with an electronic copy of their health information and also believe patient engagement is essential to quality healthcare; however, **we continue to oppose CMS's measure that requires physicians to provide patients the ability to view their health information within 4 days of the information being available to the practice, and requiring 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) to view, download or transmit to a third party their health information. The "4 business day" time limit is arbitrary, fails to recognize that physician practices are not typically open 24 hour a day, and fails to appreciate that some information should only be provided to patients during a face-to-face encounter.** Four business days is significantly under the 30 days allowed under HIPAA for providing an electronic copy of health information, and would be an inordinately short period of time to provide "new" test results and information that have not already been discussed with the patient. It is important that our members have more time to discuss certain results, especially if the results involve bad news or complex treatment options, in person or over the phone to allow for necessary discussion and questions. We also feel this truncated time frame could raise serious liability concerns for physicians.

At the very least, since CMS has decided to finalize the criteria under this measurement, physicians should have the option of disclosing only appropriate information. Physicians and patients are in the best position to determine what records are needed and when they are needed. Also, it is unclear whether circumstances that allow providers to refuse to provide copies under HIPAA have been recognized in the rule. We also object to the requirement that five percent of all unique patients view, download, or transmit their health information. **It is unfair to penalize physicians for actions outside of their control, such as patient behavior. The Academy recommends CMS should remove this provision from the requirement.**

Clinical Summary Provided to Patients: We are also apprehensive about the requirement for physicians to automatically provide clinical summaries for more than 50 percent of office visits within one business day. This appears to be an overly burdensome requirement. In addition, we are concerned about potential liability where these clinical summaries are provided automatically (that is, without obtaining the patient's authorization) and contain sensitive information. **The Academy recommends that physicians should only be required to provide patients with an electronic or printed copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request.** All patients



who request a copy of their health information should be provided either an electronic or printed copy, within a reasonable period of time, in accordance with federal and/or state law. In previous comments, the Academy expressed concern that a note which is unsigned or unreviewed by a physician may be viewed by a patient. ***We request that CMS clarify that the note should be reviewed and signed by the physician prior to providing the information to the patient and that the rule provide an adequate amount of time for the physician to do so.***

EP Performs Medication Reconciliation when Receiving a Patient: CMS originally proposed to include the requirement that the EP perform medication reconciliation for more than 65 percent of all transitions of care where the patient is transitioned into the care of the EP. In our comments, the Academy noted that the threshold for this requirement was too high to be universally and routinely applied to specialists. The Academy recommended CMS change the requirement from 65 percent to 50 percent, maintaining the Stage 1 requirement in Stage 2, which CMS took into account and finalized. ***The Academy applauds CMS' efforts to accept the Academy's comments regarding the prohibitive nature of the 65 percent threshold into consideration and maintain the Stage 1 requirements.***

Provide Summary Care Record for Each Transition of Care and Referral: In the final rule, CMS states that (A) the EP who transitions or refers their patient to another setting of care, or provider of care, provides a summary of care record for more than 50 percent of transitions of care and referrals; and (B) the EP that transitions or refers their patient to another setting of care, or provider of care, electronically transmits using CEHRT to a recipient or where the recipient receives the summary of care record via exchange facilitated by an organization that is a Nationwide Health Information Network (NwHIN) Exchange participant, or in a manner that is consistent with the governance mechanism the Office of the National Coordinator (ONC) establishes for the NwHIN sender of a summary of care record for more than 10 percent of transitions of care and referrals. In the final rule, CMS adds the requirement that (C) the EP must satisfy one of the following: Conducts one or more successful electronic exchanges of a summary of care record with a recipient using technology to receive the summary of care record that was designed by a different EHR developer than the sender's CEHRT; or conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

CMS removed the proposal to limit the numerator for measure (B) to only count electronic transmissions which conform to the transport standards proposed for adoption by ONC, and instead provides for exchanges with in the NwHIN. We agree with the concerns CMS stated in the final rule regarding the limitations of this measurement and applaud CMS for reducing the threshold and addressing concerns regarding the organizational and vendor limitations. However, many of our concerns still exist, and we believe this measure should not be implemented until there is a common system in place. Not all certified systems are compatible for sharing data, making it difficult to meet (A) and (C). Therefore, it will force independent providers



to adopt whatever software the local hospital system is using. Thus, the computer software could and would be used to force independent providers to align with a hospital system, driving them out of private practice. Likewise, networks could exclude providers who are affiliated with another network. This measure is a laudable long-term goal, but until a common data transfer is available, it should not be implemented. ***The Academy recommends that measure (B) should not be adopted or implemented until a National Health Information Network is functional, or until a common data transfer protocol such as Continuity of Care Record (CCR) or Continuity of Care Document (CCD) is adopted. The CCR and CCD are standards and are included in the vendor certification criteria. However, they provide minimal data. A more robust standard for data sharing needs to exist. Therefore, the Academy believes the state of electronic health records is not yet prepared to meet this requirement.***

Submit Electronic Data to Immunization Records: This requirement by CMS includes the successful ongoing submission of electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice. The Academy is concerned that in the rule, CMS places the onus on providers to determine whether or not a relevant Public Health Authority (PHA) has the capability to accept electronic data. This greatly increases the burden placed upon providers and their staff. CMS also indicates that any EP is excluded from meeting the requirement if the EP does not administer any of the immunizations to any of the populations for which data is collected by the jurisdiction's immunization registry or immunization information system during the EHR reporting period, etc. ***The Academy believes that otolaryngology-head and neck surgeons meet this exclusion, and therefore, this requirement does not apply to our specialty. In our comments submitted in the proposed rule for this exclusion, we asked for clarification on the specialists CMS intends to include in the exclusion to the requirement. Once again, we seek clarification from CMS regarding the specialists CMS will exclude from this requirement.***

Use Secure Electronic Messaging to Communicate with Patients on Relevant Health information: In the final rule, CMS finalizes a new measure to include a secure message sent using the electronic messaging function of EHR by more than 5 percent of unique patients seen by the EP during the EHR reporting period. CMS reduced this measure from 10 percent in the proposed rule to 5 percent in the final rule and the Academy appreciates CMS' recognition of our concerns regarding this objective. ***However, the Academy believes this should read "secure message was available to be sent" and not "sent". The measure should be that the functionality is enabled, and there should be no threshold for the number of messages sent. This measure, as written, assigns responsibility to the physician for actions beyond his control, i.e. patient participation. Although the intended goal of increased patient participation is admirable, we believe it is unfair to penalize physicians for actions outside of their control, such as patient behavior.***



Stage 2 Menu Objectives:

Make Imaging Results Available through EHR: CMS reduced the threshold of this measure from 40 percent to 10 percent in the final rule. ***The Academy appreciates CMS' response to the concerns of physicians such as Otolaryngologist-Head and Neck Surgeons and subsequent reduction of the threshold.*** The Academy also appreciates CMS removing scan from the measure and allowing physicians to use the capabilities and standards of CEHRT. The Academy believes it is important to have the images incorporated into the electronic medical record and agrees with CMS that the sharing of images should be removed as a requirement for this measure until there is a functional national network that allows the capability.

Provide Electronic Syndromic Surveillance Data to Public Health Agencies: CMS sets the measurement for this objective as successful ongoing submission of electronic syndromic surveillance data from EHR to a public health agency for the entire EHR reporting period. We understand that one of the exclusions applies where the EP is not in a category of providers that collect ambulatory syndromic surveillance information on their patients during the EHR reporting period. As CMS states in the final rule, the Centers for Disease Control (CDC) will not be issuing the guide until spring of 2013 which determine which categories of EPs would not collect such information. ***Therefore, we recommend that CMS delay this requirement until after the CDC publishes the guide so that physicians will know which categories are included in the guide.***

Cancer Registry Reporting: CMS finalizes a new measure to include the successful ongoing submission of cancer case information from EHR to a cancer registry for the entire EHR reporting period. This would include Classification of Malignant Tumors (TNM) and Staging information. This is beneficial for those Otolaryngologists who are Head and Neck specialists and treat cancer patients. However, if Otolaryngologists do not treat cancer patients, and cannot participate in the Cancer Registry reporting, they should be excluded from this measure. ***Therefore, the Academy supports this new measure with the understanding that those physicians who are able to participate may use this measure, but those physicians for whom the measure is not applicable are exempt from the requirement.***

Non-Cancer Registry Reporting: This measure includes the EPs capability to identify, and report, specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice. This would include a temporal bone registry. This is beneficial for those Otolaryngologists who treat patients who have temporal bone diseases. However, if Otolaryngologists do not treat cancer patients and they cannot participate in the Non-Cancer Registry reporting, they should be excluded from these measures, as is suggested above regarding with the Cancer registry reporting. ***Thus, the Academy***



supports this new measure with the understanding that those physicians who can participate should be required use this measure, but those physicians for whom the measure is not applicable are exempt from the requirement.

Clinical Quality Measures (CQMs) for EPs in CY 2014:

In the proposed rule, CMS included two reporting options for consideration for CY 2014, Option 1 and Option 2. Option 1 includes two alternatives: 1a and 1b. Option 2 included Medicare EPs who submit and satisfactorily report PQRS measures under the PQRS EHR reporting option using certified EHR technology would satisfy their CQM reporting requirement under the Medicare EHR incentive program.

The Academy appreciates CMS providing numerous options for comment. In comments on the proposed rule, the **Academy requested the availability of both options 1 and 2 to allow Otolaryngologists the opportunity to participate in the program, while we continue to develop specific clinical quality measures. We continue to believe having the two options available allows flexibility.**

In the final rule, CMS finalized two reporting options. Under the first, EPs will report 9 CQMs covering at least 3 domains. Under the second, EPs will submit and satisfactorily report CQMs under the PQRS EHR reporting option using CEHRT. We appreciate CMS providing flexibility to specialists in reporting CQMs via two different options. By providing two options, CMS will to increase the probability that Otolaryngologist- Head and Neck Surgeons will be able meet the CQM criteria.

However, many of these measures are heavily weighted toward primary care and preventive medicine, which make it difficult for specialties such as otolaryngology, to report CQMs. Further, the reporting requirements suggest that an EP can report CQM with zero denominators. Many Otolaryngologists-Head and Neck Surgeons will be forced to report zero values for several of the measures, which significantly undermine the utility of the process. We believe reporting the Clinical Quality Measures is important, but for specialists, is very difficult. **The Academy recommends where no CQM is applicable, that CMS allows the EP to implement a CQM that has been approved by a specialty society and is under review for endorsement by the NQF, such as the sinusitis measures set mentioned previously. The Academy is involved in developing measures approved by the society and receiving approval from the NQF, but this is a very time-consuming process. The addition of CQMs approved by specialty societies and under review by the NQF would allow otolaryngologists- head and neck surgeon, such as a set of quality measures focusing on adult sinusitis for use by otolaryngologists, would help otolaryngologists- head and neck surgeons report the measures.**

Conclusion:

The American Academy of Otolaryngology—Head and Neck Surgery appreciates the opportunity to provide these comments and recommendations on behalf of our members. We feel Electronic Health Records are an important part of our common



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goal to increase the quality of care and safety of our patients, and by working with organizations such as the Academy, we can help to ensure the success of the Meaningful Use program. If you 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
Executive Vice President and CEO