

May 7, 2012

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: Comments to 4 CFR Parts 412, 413, and 495; file code CMS-0044-P: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2 submitted on May 7th through the Federal eRulemaking Portal at <http://www.regulations.gov>

The over 157,000 members of the American Dental Association (ADA) have confidence in their ability to deliver safe and effective quality dental care and rely on the strong ADA commitment to the development and use of voluntary consensus standards for dentistry. The ADA is a national and international leader in the development of consensus standards and guidelines for materials, instruments, equipment, digital devices, and health information technology software impacting the safety and health of the public and the practice of dentistry.

The ADA is actively engaged in the development and maintenance of vocabularies critical both for clinical health information exchange and for the population of data in the electronic health record. For example, the ADA's Code on Dental Procedures and Nomenclature, which is included in the ADA's Current Dental Terminology (CDT), is a vocabulary that is a named HIPAA standard for use in electronic administrative transactions for dental claims. The ADA's leadership role with regard to standards was also recognized by the HIPAA legislation naming the ADA as an entity to be consulted when the HHS Secretary is considering adoption of a new or modified HIPAA administrative simplification standard. The ADA is the only professional association so named.

The ADA also developed a subset of the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) called the Systematized Nomenclature of Dentistry (SNODENT). SNODENT is a clinical terminology that was designed for use in the electronic health and dental records environment. The ADA is working to harmonize the SNODENT code set with SNOMED CT through the National Library of Medicine and the International Health Terminology Standards Development Organization (IHTSDO). As SNOMED CT is a recognized code set and will be the basis for EHR development and certification, it is ADA's opinion that being fully interoperable with SNOMED CT makes SNODENT the only choice for a clinical vocabulary required for dental systems.

In 2008, at the request of CMS, the ADA established the Dental Quality Alliance (DQA) to develop performance measures for oral health care. The DQA is an organization of major stakeholders in oral health care delivery that uses a collaborative approach to develop oral

health care measures. The DQA has identified several performance measures and is now engaged in conducting validity and reliability assessments of these measures. Measures developed by the DQA will be specified both for claims-based data sources as well as for electronic health records.

The DQA should continue to be recognized by HHS as the convening organization for the development of quality measures for dentistry. Quality measures developed by the DQA should be recognized as the dental quality criteria for use in HHS regulations.

As with informatics standards, the ADA is also renowned as a leader in product certification. Dentists and consumers have long recognized the ADA Seal of Acceptance as an important symbol of a dental product's safety and effectiveness. For more than 125 years, the ADA has sought to promote the safety and effectiveness of dental products. The first Seal of Acceptance was awarded in 1931. In 1984, President Ronald Reagan gave the Association a certificate of commendation for the outstanding self-regulatory efforts of its Seal program.

Dentistry is increasingly involved in the delivery of patient care in complex multidisciplinary cases. For example, a patient about to undergo cancer chemotherapy may require a diagnostic consultation with a cardiologist to rule out treatment modifications due to a heart condition and with a general practice dentist to rule out care for dental conditions that may complicate the cancer care or result in an adverse outcome if untreated. Whether the dental components of the EHR are run as an EHR Module or as one component of an integrated Complete EHR, we firmly believe that the required unique dental content should be fully included in the overall EHR implementation solution.

The ADA is committed to improving the nation's oral health through public education and through legislative advocacy to strengthen funding for dental services provided through public health programs. As the authoritative voice for dentistry, the American Dental Association response offers the following comments regarding 4 CFR Parts 412, 413, and 495; file code CMS-0044-P: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2 beginning with the two clinical quality measures proposed for oral health and then addressing other provisions within the proposed rule:

Page 13749 – Table 8 – Clinical Quality Measures Proposed for Medicare and Medicaid Eligible Professionals Beginning with CY:

Proposed measure NQF 1335: Children who have dental decay or cavities.

Description: Assesses if children aged 1–17 years have had tooth decay or cavities in the past 6 months.

As endorsed by NQF, this measure is specified for use with the National Survey of Children's Health and based on computer-assisted telephone interviews of parents. The question on the survey is "To the best of your knowledge, did [child] have decayed teeth or

cavities within the past 6 months?” Thus, this measures the caregiver’s knowledge of disease activity/ treatment received. If the endorsed measure specification is to be directly re-tooled to develop an e-measure, its reliability and validity when used through an EHR is highly questionable. Conducting patient surveys to collect subjective data on this measure, then recording and transmitting the data through an EHR, requires much system development and clinical workflow change. As endorsed, the measure is not specified for use with clinical patient data. However, if the intent is to use the concept to capture data from clinical examination through an EHR for those patients who visited a provider, the reliability and validity of the measure will depend on re-specifying the concept for use with clinical data obtained in the workflow of the EHR entries. Considerations such as type of providers, eligibility criteria for inclusion of subjects in the denominator, and data elements to record caries within the health record need to be clearly specified for use in the EHR. We recommend supporting the concept of reporting children with active caries/caries rates through the use of an EHR, as ascertained from a clinical evaluation by a dentist.

Proposed measure NQF 1419: Primary Caries Prevention Intervention as Part of Well/III Child Care as Offered by Primary Care Medical Providers (PCMP).

Description: The measure will a) track the extent to which the PCMP or clinic (determined by the provider number used for billing) applies fluoride varnish (FV) as part of the Early Periodic Screening Diagnosis and Treatment (EPSDT) examination and b) track the degree to which each billing entity’s use of the EPSDT with FV codes increases from year to year (more children varnished and more children receiving FV four times a year according to ADA recommendations for high-risk children).

As endorsed by NQF this measure is designed to account only for fluoride varnish applications performed in conjunction with EPSDT/well child visits by primary care physicians. FV can be applied at sick child visits or a separate visit for preventive oral health services. If the data source is directly from an EHR, the type of data elements that will be incorporated to identify both FV application and risk status must be specified. Currently there is much debate on acceptable indicators for classifying risk. The definition of the numerator is unclear. Does the numerator report the number of FV applications or the number of children receiving FV applications? The definition of the denominator will need to be clarified or revised to reflect a definition of increased risk for tooth decay based on data elements available within the EHR. We recommend supporting this measure if these discrepancies are addressed. Also note that this measure is specific to primary care physicians and will not capture fluoride varnish application by dental care providers. Additional value could be obtained by a measure which determines whether children who are seen in primary care providers’ settings and who are determined to be at elevated risk for caries are subsequently referred and obtain care from a dentist in a timely matter.

Page 13710 – proposed EP objective: generate and transmit permissible prescriptions electronically (eRx) – OTC medicines: The proposed measure for this object is that more than 65% of all permissible prescriptions written by the EP are compared to at least one

drug formulary and transmitted electronically using Certified EHR Technology. CMS notes that there are challenges to the electronic prescriptions for controlled substances, including more restrictive state laws and the availability of products both for providers and pharmacies that include the functionalities required by the Drug Enforcement Agency's interim final rule on electronic prescriptions for controlled substances. CMS also proposes to continue to define prescription as the authorization by an EP to dispense a drug that would not be dispensed without such authorization, and encourages public comments on CMS's assumption that over-the-counter ("OTC") medicines will not be routinely prescribed. The ADA notes some dentists may have difficulty meeting the proposed measure because they may prescribe relatively more controlled substances than certain other EPs, so the challenges noted by CMS are more likely to disqualify dentists from achieving meaningful use. The ADA also notes that more practitioners are likely to prescribe the OTC medicines that they recommend for patients who have Flexible Savings Accounts so that the OTC medicine or drug will be a qualified medical expense. Therefore, the ADA urges CMS to lower the measure, at least with respect to practitioners who prescribe a specific level of controlled substances, and to define prescription to include OTC medicines.

Page 13712 – proposed EP objective: record demographics – disability status: The NPRM encourages public comment on the burden and ability of including disability status for patients as part of the data collection for this objective and on the burden that collection of this data might impose on EPs, how to define the concept of disability status, and whether the option to collect disability status for patient should be captured under the objective to record demographics. Disability status is a legal conclusion reached by applying criteria developed under applicable federal or state legislation. Disability status is meaningless in the context of collecting demographic data, because, with the possible exception of patients who are receiving Social Security Disability benefits, or who have received reasonable accommodations for a disability at work, a patient with a medical condition may not consider himself or herself "disabled," particularly if the condition is not relevant to the services provided by the EP. For example, a patient with cancer in remission, which may qualify as a disability under the Americans with Disabilities Act, may disclose the information in a health history form, but may not think to disclose this condition as a "disability" when providing demographic information. The expansion of the definition of disability in the Americans with Disabilities Act Amendment Act of 2008 further complicates the issue of who is and is not disabled, and who may consider themselves disabled. CMS states that recording disability status for certain patients can improve care coordination. However, patients with disabilities that are relevant to care coordination would likely discuss them with the doctor recorded in a patient's health history or not as an unspecified "disability" in demographic information. Moreover, a patient's disability may involve diagnosis of substance abuse or other mental health condition. Such information may be protected under various state and federal laws, and it is unclear how an EP may comply with such laws while collecting disability status information and presumably acting on it to coordinate care. Because of this lack of clarity and inconsistency, the information generated by including disability status as an element of demographic data would be meaningless and EPs are likely to be confused as to how to

collect, protect, and use this information. The ADA urges CMS not to include disability status as an element of demographic data.

Page 13712 – proposed EP objective: record demographics – proposed measure: The proposed measure for demographics is more than 80 percent of all unique patients seen by an EP during the reporting period have demographics recorded as structured data. The NPRM notes that “if a patient declines to provide one or more demographic elements, this can be noted in the Certified EHR Technology and the EP or hospital may still count the patient in the numerator for this measure.” The ADA urges CMS to clarify that if a patient refuses to provide any demographic elements, that the EP can note this in the Certified EHR Technology and count the patient in the numerator for this measure.

Page 13713 – proposed objective – record smoking status for patients 13 years old or older: Because smoking is not the only form of tobacco use with harmful health effects, we recommend substituting “tobacco use,” rather than “smoking status,” for this objective throughout the document. Dentists are often the first health care providers to see the effects of smokeless tobacco use, which may start as early as kindergarten or first grade (e.g., 21% reported among Northern Plains Indian kindergartners (<http://www.cdc.gov/mmwr/preview/mmwrhtml/00001287.htm>), and 36% among rural 1st graders (<http://www.ncbi.nlm.nih.gov/pubmed/10146841?itool=EntrezSystem2.PEntrez>)).

Page 13718 – proposed objective: provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP: In discussing the accessibility of this data, CMS notes that “providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations. The ADA notes that the Department of Justice released an Advanced Notice of Proposed Rulemaking, Nondiscrimination on the Basis of Disability; Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations, on July 26, 2010 but has not yet issued an NPRM or a final rule. The ADA urges CMS not to include the accessibility of electronic information a requirement for meaningful use until the Department of Justice clarifies the standards for accessibility.

The proposed measure would include a requirement that “more than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives), view, download, or transmit to a third party their health information. CMS invited comment on the proposed measure for this objective and whether the 10 percent threshold is too high or too low given the patient’s role in achieving it. The ADA believes that the threshold is too high because of the patient’s role in achieving it. It is unclear how many dental patients would be interested in viewing information about their dental care online, downloading it, or transmitting it to a third party. If such interest is lacking, an EP dentist may be prevented from achieving meaningful use through no fault of his or her own—indeed, a dentist who communicates effectively with patients may be penalized when his or her

patients are satisfied that they understand their dental health and treatment and see no need to go online to view their health information. The ADA urges CMS to not require a percentage of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a third party their health information.

Page 13729 – proposed objective: use secure electronic messaging to communicate with patients on relevant health information: The proposed measure for this objective depends on patients' actions, choices, and preferences: "a secure message was sent using the electronic messaging function of Certified EHR Technology by more than 10 percent of unique patients seen by the EP during the EHR reporting period. The ADA believes that the threshold is too high due to the patient's role in achieving it (see previous comment). Moreover, certain dentists may treat a substantial number of patients who prefer not to, or cannot, communicate with the dentist electronically (for example, they may prefer an appointment reminder postcard to an electronic message, or they may not own a computer). To the extent that individuals who do not own or use a computer fall within certain demographic groups, this threshold may operate against the interests of EPs who care for individuals in those groups. Therefore, the ADA urges CMS to not require a percentage for this measure.

Page 13779 – administrative review process – filing requirements – filing deadlines: Under the proposed rule, a meaningful use appeal must be filed no later than 30 days from the date of the demand letter or other finding that could result in the recoupment of an EHR incentive payment. An incentive payment appeal must be filed no later than 60 days from the date the incentive payment was issued or 60 days from any Federal determination that the incentive payment calculation was incorrect. Any amendment must be filed no later than 15 days after the initial appeal filing deadline.

Page 13787 – proposed revisions and clarifications to the Medicaid EHR Incentive Program – Medicaid professionals program eligibility – calculating patient volume requirements: The NPRM includes several proposals to provide greater flexibility in EPs' patient volume calculations. The ADA supports CMS's goal of providing greater flexibility in calculating EPs' patient volumes and urges adoption of the proposed revisions. In particular, the ADA supports and strongly urges CMS to adopt the following proposal in the NPRM:

We propose to expand the current definition of "encounter" to include any service rendered on any one day to an individual 'enrolled' in a Medicaid program. Such a definition would ensure that patients enrolled in a Medicaid program are counted, even if the Medicaid program did not pay for the service (because, for example, a third party payer paid for all of the item or service or the service is not covered under Medicaid. ... We expect this change would increase the number of eligible providers who qualify for the Medicaid EHR Incentive Program, particularly those serving children. ... We understand that multiple providers may submit an encounter for the same individual ... We clarify that it is acceptable in these and similar circumstances

to count the same encounter for multiple providers for purposes of calculating each provider's patient volume when the encounters take place within the scope of practice.

The ADA notes that Medicaid pays for relatively few dental items and services, particularly for adult patients, and believes that the proposed expansion of the definition of "encounter" would enable more dentists who treat Medicaid beneficiaries to participate in the Medicaid Incentive Program. The ADA urges CMS to adopt this proposed change and to clarify that if a dentist treats a patient who is a Medicaid beneficiary that treatment constitutes an "encounter" for purposes of the Medicaid EHR Incentive Program, whether or not the dental item or service provided to that patient is covered by Medicaid.

General Comment

In addition, to the above comments, the ADA supports incorporating diagnostic clinical terminology designed specifically for the dental records environment. Inclusion of diagnostic information is essential to follow outcomes of care and generate robust quality measures. As mentioned previously, the ADA developed a subset of the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) called the Systematized Nomenclature of Dentistry (SNODENT). SNODENT is a clinical terminology that was designed for use in the electronic health and dental records environment. The ADA is working to harmonize the SNODENT code set with SNOMED CT through the National Library of Medicine and the International Health Terminology Standards Development Organization (IHTSDO). As SNOMED CT is a recognized code set and will be the basis for EHR development and certification, it is ADA's opinion that being fully interoperable with SNOMED CT makes SNODENT the only choice for a clinical vocabulary required for dental systems.

We appreciate the opportunity to comment on the proposed rule 4 CFR Parts 412, 413, and 495; file code CMS-0044-P: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2. If there are questions concerning these comments, please contact Dr. Frank Kyle in the ADA Washington, DC Government and Public Affairs Office at 202-789-5175 or by e-mail at kylef@ada.org.

Sincerely,

 

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