TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

March 15, 2010

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-0033-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-0033-P
RIN 0938-AP78
Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule (Vol. 75, No. 8), January 13, 2010

Dear Ms. Frizzera:

Texas Medical Association (TMA) appreciates the opportunity to comment on the above-referenced Medicare and Medicaid electronic health record incentive program proposed rules.

TMA is a private voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, its mission is to "Improve the health of all Texans." Its almost 45,000 members practice in all fields of medical specialization. It is located in Austin and has 119 component county medical societies around the state.

TMA has a keen interest in health information technology. In fact, one of its priority strategies is to "Increase Texas physicians' understanding, adoption, and appropriate utilization of vital information technologies, to support efficiency, efficacy, and quality-of-care measurement." TMA believes federal stimulus incentives and meaningful use guidelines, if implemented appropriately, are crucial to the success of nationwide EHR adoption. TMA appreciates the time and dedication of Centers for Medicare & Medicaid Services and Office of the National Coordinator staff in crafting the proposed rules. TMA offers the following comments on the Notice of Proposed Rule Making on Meaningful Use, as published in the Federal Register on January 13, 2010.

Sincerely,

William H. Fleming III, MD
President, Texas Medical Association

Joseph H. Schneider, MD, MBA
Chair, *ad hoc* Committee on Health Information Technology

Overarching Comments

Place the Emphasis on Patient Safety Rather than Meeting Specific Targets

TMA is concerned about the "unintended consequences" of EMRs, particularly in hurried implementations. A 2009 TMA survey reported that 33% of respondents experience new types of errors and find these to be major dissatisfiers with their EMRs. New types of errors are now well-known but the EMR industry still has no mechanisms for handling these systematically. We strongly encourage the development of a national "no-fault" reporting system for errors and near-misses that occur through the use of EMRs. The ability of a physician to report EMR safety issues to such a system should be a part of the criteria for achieving Meaningful Use in 2013.

All-or-Nothing Approach to Incentives (Proposed Rule 42 CFR §495.6(a))

Under proposed §495.6(a), CMS requires eligible professionals (EPs) to meet **all** objectives and associated measures of the Stage 1 criteria in order to qualify for receipt of an incentive payment (with an exception for Medicaid EPs who adopt, implement or upgrade certified EHR technology in their first payment year). TMA opposes the use of this "all-or-nothing" approach for physicians attempting to participate in the incentive program.

Physicians interested in technology have likely already made the step towards adoption of electronic health records. The physician population that needs to be reached now consists largely of those physicians who are less technically savvy and those who may face significant challenges to EHR adoption (both from a financial and a practical perspective). An all-or-nothing approach, as currently contemplated by the proposed rules, lacks needed flexibility in its application and fails to recognize the challenges that much of the physician population faces in moving towards EHR adoption. TMA recommends that CMS allow the opportunity for progression to encourage wide-spread adoption of EHRs and to acknowledge the wide variations in size and capabilities of physician practices throughout the nation.

Need for Prompt Payment of Incentives (75 Fed. Reg. 1910; Preamble, d. "Form and Timing of Payment") and Need for Timely Performance Feedback

In the preamble to the proposed rules, CMS states that it proposes "that payments be made on a rolling basis, as soon as [it ascertains] that an EP has demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment." 75 Fed. Reg. 1910. TMA encourages CMS to be mindful of the need to provide incentive payments in a timely manner and, if possible, to provide timely performance feedback.

Physicians participating in the Physician's Quality Reporting Incentive (PQRI) program do not receive incentive payments until at least nine months after information submission. Additionally, feedback is not available to physicians until the incentive payment is provided. CMS reported that only 53% of those participating in the 2007 PQRI program received incentive payments. Further, the Medical Group Management Association (MGMA) conducted a survey which indicated that 67% of respondents were not satisfied with the PQRI program. Only 48% of the respondents were able to gain access to feedback and 36.5% could not download the file. Understandably, these statistics cause physicians to be concerned that issues with receipt of feedback and timeliness of incentive payments demonstrated in the PQRI program will be repeated in the meaningful use incentive program.

Improving Quality, Safety, Efficiency, and Reducing Health Disparities

Stage 1 Objective: Documentation of Progress Notes (Proposed 42 CFR §495.6)

In the list of Stage 1 objectives for incentive payments, proposed rule 42 CFR §495.6 fails to include a requirement for the eligible professional to document a progress note for each encounter. In the preamble to the Notice of Proposed Rule Making (NPRM), CMS expressly notes its consideration of a progress note requirement and then summarily rejects the inclusion of such a requirement for Stage 1. *See* 75 Fed. Reg. 1855. The stated rationale for this decision is that "documentation of progress notes is a medical-legal requirement and a component of basic EHR functionality, and is not directly related to advanced processes of care or improvements in quality, safety, or efficiency." *Id*.

TMA recommends that CMS reconsider this decision and opt to include progress notes in the Stage 1 objectives when promulgating in its final rule. TMA contends that the failure to include clinical progress notes will further fracture the

medical record exchange by omitting this highly-useful data set. Progress notes provide significant information about the patient that is not captured elsewhere in the structured EHR, including differential diagnoses. Failure to include progress notes in Stage 1 will also have the effect of continuing to permit illegible handwritten records. The resulting hybrid systems (part electronic, part paper) will result in fragmentation of the patient's chart, especially in hospitals, and create serious safety problems.

TMA strongly supports the statement of the HIT Policy Committee that "without a requirement for progress notes, physicians may continue to document patient encounters on paper, which would significantly impede the goals of improving quality of care and care coordination. Furthermore, eliminating this requirement would obviate the need for vendor products to be certified to accommodate inclusion of progress notes."

Finally, while it is fair to exclude some parts of the chart from the data exchange requirement, mainly because of bandwidth issues/data size, there is no justification for omission of simple text, such as progress notes.

Stage 1 Objective: Computerized Provider Order Entry (Proposed 42 CFR §495.6(d)(1))

1. Types of Orders Encompassed in the CPOE Objective (Proposed 42 CFR §495.6(d)(1)(i)

In 42 CFR §495.6(d)(1), CMS proposes the inclusion of "use [of] computerized provider order entry (CPOE)" as a Stage 1 objective for eligible professionals. TMA recommends that CMS provide more specificity with regard to defining the types of orders that must be entered as discrete data for outpatient physicians as part of the Stage 1 criteria.

TMA notes that the contribution of CPOE to improvement of safety or coordination of care varies widely depending on the type of order that must be entered. In the outpatient setting, many orders do not need to be entered into the EHR. For example, orders that instruct a nurse or a medical assistant to take a specific action (e.g., wound dressing instructions or "notify MD if..." orders) take a significant amount of time to build into an ambulatory EHR and require tedious workflow redesign; however, these orders do not improve safety or coordination of care nearly as much as medication or lab orders.

Additionally, some EHRs track referral orders, but these orders may not necessarily need to be entered in the EHR's ordering system. Since the safety aspect for referral orders stems from the ability to track these orders, requiring an EHR order may in some cases add redundant work. Other orders based on protocols may be done without an EHR-entered order, such as performing initial vital signs, checking O2 stats or performing tests specific to patient condition/presentation such as a rapid strep test, glucometer reading or urine dipstick.

TMA recommends that CMS strictly focus on three types of outpatient physician orders in 2011: med orders (e-prescribing), lab orders, and imaging orders.

2. CPOE Measures (Proposed 42 CFR §495.6(d)(1)(ii))

In proposed 42 CFR §495.6(d)(1)(ii), CMS establishes the measure for CPOE at 80 percent of all orders. TMA is opposed to the use of an 80 percent measure specifically, as well as the use of percentages as a measure of CPOE in general.

TMA strongly encourages CMS to revisit the CPOE measure. The currently-proposed 80 percent measure is simply too high to be reasonable at this time. Further, any percentage-based measure would present significant operational challenges if applied with respect to CPOE.

Specifically, it should be noted that most EHRs have the ability to track and tabulate the number of computerized orders **actually** entered by a physician; however, many EHRs do not track of the number of paper-based orders. In other words, the EHR itself may not establish the denominator required for the percentage-based measure. Thus, the use of a percentage-based measure would burden the physician with the task of manually gathering the information to account for his paper-based orders. To address this concern, TMA recommends that CMS base the CPOE measure on a more straight-forward count of orders entered by the physician (rather than on a percentage of all orders).

Stage 1 Objective: Inpatient CPOE Measures (Proposed 42 CFR §495.6(e)(1))

In proposed 42 CFR §495.6(e)(1)(i), CMS establishes the Stage 1 objective for eligible hospitals or CAHS to use CPOE for orders (any type) directly entered by an authorizing provider. Additionally, 42 CFR §495.6(e)(1)(ii) sets the measure for CPOE at 10 percent for all orders. TMA recommends that CMS eliminate inpatient CPOE requirements for 2011 for safety reasons. Achieving 10 percent is not the problem; however, this will result in incomplete sets of patient paper orders in the patient's chart (the remaining 90 percent) unless: (1) CPOE orders are printed or (2) 100 percent of physicians are converted to reviewing orders electronically rather than on paper. Neither is practical or safe. Finding a unit that does not have patient transfers in or out and doing 100 percent CPOE might be a way to achieve an average 10 percent goal, but there are very few of these in general hospitals.

Stage 1 Objective: Record Smoking Status (Proposed 42 CFR §495.6(c)(7)(i) and (ii))

In proposed 42 CFR §495.6(c)(7)(i), CMS establishes the objective of recording the smoking status for patients 13 years or older. Additionally, the proposed measure for this objective is that at least 80 percent of all unique patients 13 years old or older seen by the eligible professional have "smoking status" recorded. CMS states in the preamble that it limited this requirement to patients 13 years old or older, because they "do not believe this objective is applicable to patients of all ages and there is not consensus in the health care community as to what the appropriate cut off age may be." See 75 Fed. Reg. 1855.

TMA notes that the objective, as currently drafted, would not capture the smoking exposure of individuals under 13. Thus, TMA recommends that clinicians record the smoking status of the patient **and** the smoking status of caretakers in the home for minors. Every patient (regardless of age) has the potential to encounter the risk of second-hand smoke. By expanding the objective to include the exposure of individuals under 13, a more accurate record of the patient's exposure to smoke would be created for **all** age groups.

Stage 1 Objective: Plot and Display Growth Chart (Proposed 42 CFR §495.6(c)(6)(i)(C))

In proposed 42 CFR §495.6(c)(6)(i)(C), CMS establishes the objective of plotting and displaying growth charts for children 2 to 20 years old. TMA recommends modifying this objective to provide that the EHR must calculate and record growth percentiles, in addition to providing a growth chart. TMA notes that the requirement to "plot a growth chart" is an unnecessary and costly feature if the practice does not treat children. EHRs should be permitted to be marketed without growth charts but their use for children should be contraindicated. Also, this requirement is vague, unless the specific standard types of growth chart are specified. In the past, some EHRs have used crude graphing techniques and labeled them as growth charts.

Stage 1 Objective: Clinical Quality Measure Reporting (Proposed 42 CFR §495.6(d)(3)(i) and (ii)

TMA urges CMS to allow physicians some leeway on the number and form of clinical quality measures to report on during Stage 1 of the incentive program. Currently, many EHRs are not configured to enable easy reporting on most or all of the proposed quality measures. Further, as CMS acknowledges in the preamble to the proposed rules, CMS does "not anticipate that HHS will complete the necessary steps for [CMS] to have the capacity to electronically accept data on clinical quality measures from EHRs for the 2011 payment year." 75 Fed. Reg. 1870. Thus, CMS proposes that physicians and other eligible professionals "use an attestation methodology to submit summary information to CMS on clinical quality measures as a condition of demonstrating meaningful use of certified EHR technology." *Id.*

Given the aforementioned issues with early reporting of clinical quality measures, TMA recommends that for 2011, the focus should be on the adoption/implementation of EHRs. Focusing on adoption/implementation of EHRs would encourage more widespread use of EHRs. TMA notes that there is a "digital divide" between early adopters of EHRs and those that have delayed implementation for legitimate reasons, such as cost and workflow interruption. While early adopters may welcome the reporting of quality measures, those that most need to be enticed to EHR adoption will be repelled by the reporting requirement.

TMA, therefore, recommends that CMS significantly scale down the reporting of quality measures for 2011 and defer to 2012 or 2013 many of these measures (with pilots for the submission of a very small subset of selected measures in 2011). Physicians should be allowed leeway to select which measures are most meaningful to their practice to report on during stage one.

Stage 1 Objectives and Measures: Core Measures Regarding Children, Including Recording of Immunizations (Proposed 42 CFR §495.6 generally and Proposed 42 CFR §495.6 (c)(15)(i) and (ii))

TMA encourages CMS to ensure that the set of core measures is more inclusive of children so that child health does not lag in terms of becoming electronic. Children comprise one-third of the patient population. Thus, record-keeping related to issues affecting children should not be overlooked. The measures proposed are highly adult-oriented. Pediatric specialists have no specified requirements, since it is inappropriate in most cases to apply the adult measures to pediatrics. Useful measures that would have high value, such as reporting and retrieving newborn screening data and tracking follow-up are not included even though current processes for handling these tests are primitive in many places and constitute a significant safety risk and expense.

TMA acknowledges, however, and supports proposed 42 CFR §495.6(c)(15)(i), as currently drafted, with its objective of having the "capability to submit electronic data to immunization registries and [actually submitting] where required and accepted." Additionally, TMA supports the corresponding measure of proposed 42 CFR §495.6(c)(15)(ii) that the physician "performed at least one test of certified EHR technology's capability to submit electronic data to immunization registries."

Demonstration of Meaningful Use Criteria (Proposed 42 CFR §495.8)

Proposed Rule 42 CFR §495.8 requires the physician to make certain attestations of satisfaction of the applicable objectives and associated measures. As CMS acknowledges, there are "still some Meaningful Use objectives and associated measures (Set B) where reporting may require EPs to manually gather the information necessary to report numerators and denominators or to take additional steps before attesting that the objective has been met." *See* preamble regarding Information Collection requirements at 74 Fed. Reg. 1948. CMS further estimates that it would only take physicians one hour to gather the information and report the result for each of these measures. *Id*. TMA believes that this requirement will be more labor and time-intensive than CMS' estimate.

The proposed use of numerators and denominators will require significant manual calculations on the part of physicians since many EHRs will not generate automated reports that can capture all of the orders, lists, results, conditions, and other health-related information that must be tabulated. TMA, therefore, recommends that CMS remove numerators and denominators for the first year of reporting. Percentage threshold reporting should only be required when EHRs generally have the ability to automatically and easily calculate all metrics that are required to be reported.

Improve Care Coordination

HIE Infrastructure and Functionality (75 Fed. Reg. 1870)

TMA recommends a stronger and earlier emphasis on Health Information Exchange (HIE) infrastructure, which needs to be well defined and standardized. CMS recognizes that HIE infrastructure is not widely available and states "we are cognizant that in most areas of the country, the infrastructure necessary to support the electronic exchange of structured information is not yet currently available. For that reason, we excluded the electronic exchange of structure information from many Stage 1 objectives or set relatively low performance thresholds for measures that do rely on the electronic exchange of structured data." 75 Fed. Reg. 1870.

This phased approach risks enticing many providers and hospitals into striving to attain meaningful use while leaving the question of real, ubiquitous interoperability unsolved by the current measures. This "toe-dipping," three-tier approach will not work. It may even exacerbate the problem by showing Medicare providers more regulations with little innate value, given the piecemeal functionality being proposed. This approach is expensive for physicians and may cause many practices to delay implementation while awaiting further developments. TMA recommends that HHS/ONC define a robust HIE protocol, in terms of data structure formats, so that a healthcare internet protocol can emerge among the entities that comply with meaningful use by building the roads and bridges for the rest of the healthcare infrastructure to follow.

Additionally, TMA recommends that the proposed rule be revised to be more specific in defining the "rules of the road" in developing HIE structures. Various clinically-relevant data elements are required to be released within set time periods. This is good, but needs further definition. Structured formats need to be specified (SNO-MED, CCR, HL7,

etc.) with a tie-in to a regulatory body charged with ongoing policy revisions in the future. If the requirement is merely to release, but with no specified format, perverse incentives are created for proprietary networks and silos to compete and purposely confound their data, thereby making it more difficult for competing HIEs to utilize. If no public-domain protocols are specified, HIE development will continue to be in silos, and interoperability will never form.

TMA also recommends that ONC provide clarification on how data inconsistencies in data pushed to HIEs should be reconciled. Failure to do this will result in meaningless aggregations of data that patients and physicians will find frustrating. Currently many HIEs simply accept data that is inconsistent, even to the point of accepting the illogical situation of "No Known Drug Allergies" and allergies to specific medications. Problem list aggregation and many other patient-specific fields suffer from a similar problem. Errors such as "Cancer" when "Rule Out Cancer" was intended are difficult, if not impossible, to eliminate. Unless there is a standardized approach as to how to handle these issues, they will create frustration and HIEs eventually be increasingly ignored because of this.

Improving Population and Public Health

TMA recommends that CMS define data exchange standards explicitly for use in public health reporting. Public health reporting gives CMS an entry point to legitimately enter and direct the HIE protocols debate. The federal and state governments have legitimate public health roles, including population-based medical issues and responses to disasters. Having medical data standards makes a lot of sense in these terms. The public health infrastructure provides a timely and appropriate way for CMS to define data exchange standards and not just assume they will emerge when more stakeholders are using EMRs.

Engage Patients and Families

Stage 1 Objective: Provide Patients with Timely Electronic Access to Their Health Information (Proposed 42 CFR §495.6(d)(6)(i))

In proposed 42 CFR §495.6(d)(6)(i), CMS establishes the objective of providing patients with timely electronic access to their health information (including diagnostic test results, problem list, medical lists, and allergies) within 96 hours of the information being available to the EP. Further, proposed 42 CFR §495.6(d)(6)(ii) establishes the measure of at least 10 percent of all unique patients seen by the EP being provided with timely electronic access to their health information.

TMA recommends that the aforementioned objective regarding patient electronic access to health information be required, but the measures in the 2011 requirements should encourage experimentation with meeting patient needs rather than set a percentage. Providing electronic access of health information to the consumer is a very important goal; however, the cost and work involved for each physician to achieve this through his own EHR is not insignificant. The future model of consumer access to their health information probably will be changing dramatically over the next few years, so physicians should be encouraged to experiment with different approaches rather than build out one set approach that may be obsolescent. There needs to be greater focus on developing and using internet and HIE infrastructure for PHI access. Physicians are required to provide access, including in electronic format, to EHRs under HITECH §13405(e). Although it is clear that physicians must comply with the aforementioned requirements of HITECH, for Stage 1, TMA recommends allowing physicians to decide whether or not to provide electronic access to their patients within the 96 hour time frame specifically required under proposed 42 CFR §495.6(d)(6)(i).

Eligible Providers and Hospital-Based Physicians (Proposed 42 CFR §495.4)

Under the Health Information Technology for Economic and Clinical Health (HITECH) Act, hospital-based physicians are excluded from participating in the meaningful use incentive program. The statute, however, permitted CMS to define "hospital-based." CMS defined "hospital based" under the proposed rules as "an EP (as defined under this section) who furnishes 90 percent or more of his or her covered professional services in the CY preceding the payment year in a hospital setting. A setting is considered a hospital setting if it is identified by the codes used in the HIPAA standards transactions that identify the site of service as an inpatient hospital, outpatient hospital, or emergency room." *See* Proposed 42 CFR §495.4.

TMA encourages CMS to ensure that physicians who work in hospital-based outpatient clinics be considered eligible for participation in the incentive program. Physicians who work in hospital-based outpatient clinics do not always use

the hospital EHR for clinic visits. Instead, they may use a separate ambulatory EHR. Sometimes these ambulatory EHRs are "purchased" by the hospital entity and may even be an integrated component of the inpatient EHR. However, in many cases they are completely separate EHR products, and in all cases the implementation involves a focused, expensive, and separate implementation/optimization effort from the inpatient implementation. In many healthcare systems the inpatient EHRs are implemented and the ambulatory departments are void of an EHR due to the involved costs, resource needs, and complexity. Outpatient physician groups must exert significant time and energy to plan and execute strategies for successful EHR adoption to improve quality of care. Physicians in hospital-based outpatient clinics need incentives, like other physicians.

Additionally, TMA encourages CMS to ensure that physicians in academic centers that provide services in an outpatient clinic be considered eligible for participation in the incentive program. Physicians in academic centers are the primary mentors for the next generation of physicians who, as their practices grow and mature, will ultimately determine how quickly and how far the curve is bent toward the adoption and meaningful use of EHRs. It is conceivable that training our young physicians in the successful, meaningful use of EHRs could be the primary driver of a transformation of medical practice over the next few decades (through an expanded desire and use of health information technology by these clinicians at the grassroots level). Such training cannot take place in academic centers without robust, effectively implemented ambulatory EHRs. Academic center physicians need to be supported in this effort.

TMA also recommends that CMS allow physicians in hospital-based clinics to participate by using place of service code 22. Physicians in hospital-based clinics could participate in the incentive program by using place of service code 22 (outpatient facility, also called facility fee). This would still make in-house physicians such as hospitalists, anesthesiologists and emergency physicians (who use place of services codes 21 or 23) ineligible.

E-Prescribing (Proposed 42 CFR §495.6(d)(2)(ii)

In proposed 42 CFR §495.6(d)(2)(i), CMS establishes the Stage 1objective of generating and transmitting permissible prescriptions electronically (eRx). The measure for this objective is that at least 75 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology. *See* 42 CFR §495.6(d)(2)(ii). TMA contends that CMS' proposed level of e-prescribing (i.e., 75 percent) should not be required. Instead, physicians should meet the 2010 state average of prescriptions done electronically, or the recommended 75 percent, whichever is lower. Many pharmacies (30% in Texas) still do not accept e-prescribing and there are currently no plans in place to increase pharmacy participation. In addition, patient preference is variable because e-prescribing does not give the patient a paper confirmation and some are afraid that it will be lost in the system. Finally, e-prescribing pilot programs have done very poorly because of refill issues and other problems; thus, patient resistance exists.