TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

May 29, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3

Dear Acting Administrator Slavitt,

The Texas Medical Association ("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, our maxim continues in the same direction: "Physicians Caring for Texans." TMA's diverse physician members practice in all fields of medical specialization.

On behalf of our more than 48,000 members, TMA appreciates this opportunity to offer comments on the above-referenced proposed rules relating to Medicare and Medicaid Programs; Electronic Health Record Incentive Program — Stage 3.

It is important for the Centers for Medicare & Medicaid Services ("CMS") to understand the undue burden the meaningful use program places on physicians. In review of the HITECH Act that enabled the meaningful use program, it is TMA's understanding that Congress did not intend for CMS to implement a program that became so stringent the industry could not use it effectively for care improvement. Analysis of CMS data[1] indicates that approximately 29 percent of Texas physicians involved in active patient care participated in the Medicare meaningful use program. Only 20 percent of those participating remain with the program. These figures are abysmal and very telling of the value of the program. TMA surveyed physician participants in Texas, and the primary reasons physicians are not continuing with the program are:

- Protocols are cumbersome (52 percent);

[1] *See* CMS Data and Program Reports, Medicare Electronic Health Records Incentive Program, available at: www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html (last visited May 28, 2015).

- Not improving patient care quality (38 percent); and
- Not worth effort, resources, cost (36 percent)[2]

Physicians offered the following comments about their experience that reflect the sentiments of many:

- "The criteria are too onerous, and despite my wishes, I am not able to fulfill the requirements."
- "Too expensive. Meaningful use does not help with patient care; in fact, it takes staff and physician time away from patient care."[3]

While physicians acknowledge the help towards the capital investment required to adopt electronic health records ("EHRs"), they generally realize that the meaningful use program does not improve care quality, patient safety, or practice efficiency. The continuous and excessive vendor fees required to ensure ongoing compliance with meaningful use criteria are egregious. Physicians have time and again reported to TMA that they have found value in maintaining and using electronic health records; however, the meaningful use requirements are crippling.

**Overarching Recommendations**

1. **CMS report success of the meaningful use program to Congress now that 70 percent of office-based physicians use EHRs. TMA also respectfully requests that CMS recommend that Congress sunset the meaningful use program. The Office of National Coordinator ("ONC") should then use the foundation set by the meaningful use program to focus on value-based initiatives.**

2. Setting Stage 3 requirements is premature until assessment of these measures and performance under Stage 2 are complete. TMA strongly encourages CMS to collect and consider comments submitted in response to the Stage 3 proposed rules but wait to adopt any of the Stage 3 proposed rules until the implementation of such rules is necessary and there is proven value in doing so. This may mean waiting to implement Stage 3 until 2018 or later.

3. TMA strongly recommends that CMS exercise caution in proposing and adopting rules intended to "move providers along a progression from adoption to advanced use of certified EHR technology" ("CEHRT"). While TMA supports the use of technology to improve patient care, we take this opportunity to remind CMS that factors outside of physicians' control may affect their ability to meet such future requirements. Rulemaking based on future expectations or assumptions (which may or may not materialize) may lead to unintended consequences and put physicians in the difficult position of trying to meet a seemingly impossible requirement.

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[2] *See* TMA 2015 Survey of Texas Physicians on Meaningful Use, available at: www.texmed.org/WorkArea/DownloadAsset.aspx?id=33772 (last visited May 28, 2015).
[3] *Id.*

For example, much of the EHR value comes through the ability to securely share patient information for continuity of care. Physicians desire the ability to efficiently share information. Across the country, health information exchanges ("HIEs") are failing to operate properly or otherwise meet expectations; however, participation in an HIE remains a core requirement for physicians participating in the meaningful use program. If there is not a functioning HIE in a particular area, physicians are unable to comply. CMS and ONC should continue to analyze market capabilities as well as EHR vendor willingness to cost-effectively connect users to HIEs. The potential unintended consequence is that physicians and health care providers will be required to purchase and use EHRs without ensuring adequate capabilities for the safe and secure exchange of information. This is like mandating the use of cars without adequate roadways.

4. TMA encourages CMS, with stakeholder input, to consider adopting reasonable baseline rules that physicians can meet to avoid penalties under the meaningful use program and additional requirements they may meet to receive incentive payments. We believe this approach would allow many physicians to avoid unnecessary penalties by complying with the baseline rules while allowing CMS to encourage advanced use of EHRs through incentive payments to physicians and providers that go above and beyond the baseline rules. TMA notes that there is precedent for lesser work required for penalty prevention with the CMS e-prescribing and Physician Quality Reporting System ("PQRS") programs.

   In the proposed rule, CMS explains that the applicable statute "requires the Secretary to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use."[4] TMA believes this directive should not serve as an excuse for perpetuating a failing program. As CMS is aware, physicians and providers have expressed ongoing concerns with Stage 1 and 2 objectives and fears that Stage 3 only will exacerbate these concerns.[5] TMA urges ONC and CMS to acknowledge the aspects of the meaningful use program that do not promote innovation or improved patient care and request congressional attention to save the essential core of the program.

5. TMA further recommends CMS introduce flexibility into the current all-or-nothing measures and evaluation structure. The current structure often ignores physicians' efforts to meet meaningful use measures. For example, a physician who records 79 percent of his or her medication orders via computerized provider order entry fails the proposed measure establishing an 80-percent threshold, even if the physician exceeds one or both of the other proposed measures relating to laboratory orders or diagnostic imaging orders.[6] TMA encourages CMS to consider a cumulative approach to certain measures that may allow a

[4] 80 *Fed. Reg.* 16731, 16740 (March 30, 2015).
[5] 80 *Fed. Reg*. 16731, 16738 ("Providers have expressed ongoing concern that the EHR Incentive Programs are complicated, not focused on clinical reality and workflow, and stifling to innovation in health IT development. Specifically, providers have expressed concerns about the number of Stage 1 and 2 objectives and measures becoming obsolete or lacking any link to improving outcomes. In addition, providers have expressed concern that continued focus on Stage 1 measures impedes current and potential future innovation in advanced utilization of health information technology. Providers worry that Stage 3 of meaningful use would exacerbate these existing concerns.").
[6] 80 *Fed. Reg*. 16731, 16751.

physician who may not quite meet one measure to have the opportunity to make up for such a minor shortfall by exceeding other similar measure thresholds.

6. TMA is concerned that many of the proposed rules have the potential to interfere with the patient-physician relationship and the physician's ability to address a patient's specific needs and respond to unique circumstances. TMA strongly urges CMS to allow physicians participating in the meaningful use program to honor patient preferences without unnecessary risk of financial penalty.

**Specific Recommendations**

**II.A.1.a. Uniform Definitions**

**Comment:** TMA agrees with the flexibility provided to choose which stage of meaningful use to use in 2017, and with the industry collectively moving to Stage 3 in 2018 and beyond.

**II.A.1.b. Meaningful EHR User**

**Comment:** TMA recommends that ONC require a standardized format for modularly certified vendors where they must prove disclosure to product purchasers that additional technology is required to meet meaningful use criteria. Vendors that fail to produce proof of disclosure are decertified.

**Rationale:** Modularly certified vendors are omitting this important information from the sales and purchase process, leading their customers to believe they are buying a product that will meet all meaningful use requirements because the vendor is ONC-certified. TMA and the regional extension centers have multiple cases where a physician purchased a modular program and the vendor did not disclose additional software needed to meet meaningful use requirements.

**II.A.1.c.(1)(b)(ii) Eliminate 90-Day EHR Reporting Period**

**Comment:** TMA disagrees with the proposed change that eliminates the 90-day EHR reporting period for year one eligible professionals ("EPs") beginning in 2017.

**Rationale:** TMA believes that physicians participating in the first year should be required to collect only 90 days of patient data as they acclimate to the nuances and complexities of the program.

**Comment:** TMA further believes that physicians transitioning to EHRs should be allowed a 90-day reporting period during the transition year.

**Rationale:** The data migration and transition to another EHR is an enormous undertaking for a practice of any size. It would relieve the reporting burden and stress to allow EPs a 90-day reporting period when they change EHR systems.

**II.A.1.c.(2)(b) Electronic Versus Paper-Based Objectives and Measures**

**Comment:** TMA disagrees with the proposal that paper-based formats not be allowed for the Stage 3 objectives and measures.

**Rationale:** CMS correctly surmises in the explanation that many patients still prefer to receive educational materials and clinical summaries in paper format. The patient-physician relationship is enhanced when physicians are able to provide patients information in the format they desire. Patient preference should be honored, and physicians should not be penalized because they honor their patient's preference. In some practice settings, physicians will not meet the required Stage 3 thresholds because of this limitation.

**II.A.1.c.(2)(d) Flexibility Within Meaningful Use Objectives and Measures**

**Comment:** TMA appreciates the flexibility CMS has created within stated measures that allow physicians to choose the measures most relevant to their unique practice setting. However, we are concerned that this flexibility may create confusion within an already complex program. TMA recommends CMS clearly educate physicians and other providers on the appropriate use of this flexibility — should it remain in the final rule.

CMS has an opportunity to promote true flexibility by allowing specialty societies to determine exclusions and what is — or is not — flexible for said specialty. For example, pediatrics has many issues and nuances that make meeting measures intended for adults a potential patient safety risk.

**II.A.1.c.(2)(h) Discussion of the Relationship of Meaningful Use to CEHRT**

**Comment:** TMA understands the CMS statements regarding steps taken to use CEHRT to engage in e-prescribing or public health reporting, and that it is the user's responsibility to establish and maintain those connections. What CMS may not fully realize is the extra cost to EPs. One EP reported to TMA that her vendor charges $3,500 to interface with ImmTrac, the Texas Immunization Registry. Physicians typically provide immunizations as a service to their patients, and only make a thin margin, if any at all. Thus, a practice cannot support these types of costs. The unintended consequence is that low-volume immunizers stop providing immunizations to patients. As a matter of public health, it is important that all barriers are removed when it comes to administering immunizations.

**II.A.1.c.(2)(i) Discussion of the Relationship Between a Stage 3 Meaningful Use Objective and Its Associated Measure**

**Objective 2: Electronic Prescribing**

**Comment:** TMA recommends that CMS continue to not include over-the-counter ("OTC") medications in this objective for Stage 3.

**Comment:** TMA recommends that CMS eliminate the requirement that EPs query prescriptions for a drug formulary. If the requirement is maintained, TMA recommends that the threshold be set at 60 percent rather than the proposed 80 percent.

**Rationale:** Regardless of whether the technological format of the EHR is local server-based or cloud-based, requiring that most prescriptions be queried against a formulary requires significant bandwidth. Such a requirement results in workflow disruptions, contributes to alert fatigue, and becomes irrelevant, as many of the formulary searches are actually inaccurate, outdated, or engineered by the pharmacy benefit manager to result in a prior authorization scheme whether the drug is covered or not. CMS may consider allowing exclusions for generic prescriptions.

If in 2018 all physicians are required to adhere to Stage 3, regardless of previous participation, CMS's proposal sets the bar too high — particularly for new practices. Lowering the proposed percentage threshold allows practices to continue to help the neediest of patients, many of whom still prefer paper prescriptions as they shop for the lowest price, while maintaining compliance with Stage 3 requirements. Market forces should drive these numbers, not government mandates. E-prescribing still is not mature enough to meet the needs of all patients. One option may be to allow a checkbox for patients preferring paper prescription that could be part of an exclusion. Physicians who are pushed by CMS to not honor patient preferences damage the patient-physician relationship. Physicians should not be penalized for honoring patient preference.

**Objective 3: Clinical Decision Support**

**Comment:** Measure 1, requiring the implementation of five clinical decision support ("CDS") interventions, should be removed.

**Rationale:** TMA is not disputing the value of CDS, but does take issue with how it must be presented to the EP through the CEHRT. This requires extra programming of the CEHRT and comes at significant cost to the end user. The concept that CDS must be tied to clinical quality measures ("CQMs") further complicates the process. It is difficult for EHR vendors to calibrate their software for CDS considering the ranges of opportunities by specialty. This is an example of information technology becoming so general that it is ineffective. Some EHRs require multiple clicks to document an obvious course of action. These multiple clicks contribute nothing to patient care and actually detract from the time the physician has with the patient. Instead, TMA encourages CMS to delegate CDS to specialty societies and not tie it to the meaningful use program.

**Comment:** TMA agrees with Measure 2 of Objective 3, which requires enabled functionality for drug-drug and drug-allergy interaction checks. TMA recommends that CMS allow exclusions from the drug-drug and drug-allergy interaction checks if the EP is a low-volume prescriber.

**Objective 4: Computerized Physician Order Entry**

**Comment:** Sunset the medication order requirement for EPs.

**Rationale:** EPs already are required to e-prescribe for meaningful use, making this measure redundant.

**Comment:** Reduce the proposed lab order measure threshold to 50 percent.

**Rationale:** This still shows significant increase without creating a hardship for practices participating with labs requiring forms that do not allow creation of a lab order through the CEHRT.

**Comment:** Reduce the proposed diagnostic imaging order threshold to 50 percent.

**Rationale:** This still shows significant increase without creating a hardship for practices participating with imaging centers requiring forms that do not allow creation of an imaging order through the CEHRT.

**Objective 5: Patient Electronic Access to Health Information**

**Comment:** While it appears to be a good step to leverage application program interfaces ("APIs"), it is important that this functionality does not create additional burden and cost to the physicians using it. EPs should choose whether or not to enable this functionality for their patients. Some physicians have the patient populations that do not desire and will not use this technology. API technology and workflow in this manner is new and untested. If EPs can meet the patient engagement requirements without use of APIs, they should be able to do so. Some vendors may figure out much more elegant ways to accomplish access points rather than APIs. TMA encourages CMS to allow for such innovation.

**Rationale:** There are considerable HIPAA concerns when APIs are enabled. Physicians take their role as custodians of patient information very seriously, and may feel that APIs threaten protected health information.

**Comment:** Personal health record ("PHR") vendors should not be required to be certified by an ONC-approved testing body.

**Rationale:** Some PHRs are made available free or at low cost to patients. If these vendors must certify, it would increase their cost and reduce the capability of free and low-cost services to patients. This would hinder, not help, patient access to health information. Patient preference must be honored.

**Comment:** Consistent with respecting patient preference, TMA recommends that CMS revise the numerator wording for Measure 2 to read: "The number of patients in the denominator who were provided ~~electronic~~ access, per patient preference, to patient-specific educational resources using clinically relevant information identified from CEHRT."[7]

**Rationale:** By limiting this measure to electronic access, it further limits the dissemination of patient education materials, regardless of the format, when CMS should be encouraging broad distribution by honoring patient preference rather than a single medium.

[7] 80 Fed. Reg. 16731, 16755.

**Comment:** CMS should not reduce the required patient access time limit from four days to 24 hours. This is especially true if the measure now requires online access for more than 80 percent of patients.

**Rationale:** TMA is unaware of any data demonstrating the need to reduce the current timeframe and has concerns that such a changes may impose unnecessary burdens on physician practices. In a busy practice, the primary focus of the team should always be on the clinical needs of the patient. It places an extraordinary burden on some practices to meet a 24-hour time limit. Without data to support this change, CMS will further alienate physicians from the program. This is another area where market forces will drive the speed. Some patient populations will push for faster access, others will not. Physician practices should have the flexibility to make information available in a reasonable timeframe while honoring patient preferences and needs.

**Objective 6: Coordination of Care Through Patient Engagement**

**Comment:** TMA strongly opposes physicians being penalized based on the actions of patients that are beyond the physicians' control and, therefore, recommends the complete elimination of Objective 6. TMA believes that Objective 6 may inappropriately interfere in the patient-physician relationship by requiring the insertion of electronic communication when verbal communication may be superior.

**Rationale:** TMA is concerned that this proposal attempts to change patient behaviors when patients do not necessarily want to change. TMA agrees that patient engagement functionality should be enabled and encouraged, but physicians should not have to coerce patients to use that functionality. For example, one physician reported that his college patients, who are adept in using online technology, refuse to sign up for the patient portal. Physicians cannot, and should not, feel forced to badger patients to use online access to their health information. Patients have complained that they do not like pressure from the practice staff to access their health information and communicate with the staff online. There is no objective evidence to show that improved outcomes will be the result of physicians' actions to change patients' behavior in the proposed manner. Without such evidence, it is not reasonable for CMS to leverage penalties on a physician's inability to socially engineer this particular patient behavior. Moreover, many physicians treat elderly patient populations, and it is not reasonable to expect these patients to have access to a computer and the Internet to download or transmit information, much less the desire to do so. If CMS desires patients to behave a certain way, TMA believes a more appropriate approach would be to incentivize patients, not penalize physicians for patient behavior.

Through TMA's meaningful use survey, 67 percent of respondents indicated the patient portal measures did not help improve the health of patients. Some general comments that reflect the sentiments of many include:

- "Stage 2 MU requires 5 percent of patients to log into our portal to access their records. Most of our patients will not do this. A good majority do not know how to use a computer.

Our EMR does not communicate with other different EMRs and this is now a stage 2 requirement. The technology is just not there, yet CMS thinks it is."

- "The patient portal communication has to be the worst of all the meaningful use measures. Patients complain about it constantly and many refuse to use it. The portal has even failed to deliver messages with important patient information."
- "We do not want to communicate electronically with our patients. There is too much risk of hacking."
- "Our patients are elderly and English is their second language. They do not have computer access nor computer literacy."[8]

When asked about experience with patient portals, some comments mention:

- Compatibility issues,
- Unreliability,
- Inordinate staff time dealing with logins and passwords, and
- EHR vendor issues with the portal.

**Comment:** TMA believes CMS should withdraw proposed Measure 1 requiring 25 percent of patients to view, download or transmit their information.

**Rationale:** TMA understands the importance of patient engagement. However, physicians cannot follow their patients out of the office and force them to access their information electronically. As stated above, **if CMS desires that patients take action, TMA believes the patient should be incentivized to do so.**

**Comment:** CMS should withdraw proposed Measure 2, which requires physicians to initiate or respond to a secure message for 35 percent of all patients.

**Rationale:** Consistent with previous comments, TMA believes CMS must allow physicians to honor patient preference. In some practice settings, secure messaging is a desirable mechanism for communication. Asynchronous communication preference is primarily generational. For many elderly patients with chronic or comorbid conditions, verbal communications are preferred.

This heightens the ability of the physician to be sure the patient fully understands the information presented. TMA is deeply concerned that this measure, as drafted, will inhibit compliance and discourage participation in the meaningful use program. The intent of communication is often lost when secure messaging rather than the spoken voice is used. In many ways, messaging is an inferior communication method. CMS should encourage effective patient communication, not the method of communication.

[8] *See* TMA 2015 Survey of Texas Physicians on Meaningful Use, available at: www.texmed.org/WorkArea/DownloadAsset.aspx?id=33772.

**Comment:** CMS should withdraw Measure 3 requiring that nonclinical, patient-generated data be captured through the CEHRT and into the record for 15 percent of all patients. This should be a capability demonstration until at least 2020. TMA finds it objectionable that CMS labels information from nutritionists, physical therapists, occupational therapists, psychologists, and home health care providers as "nonclinical."

**Rationale:** Physicians are increasingly encouraged to take a holistic view of patients, and that includes other clinical disciplines such as nutrition, physical therapy, psychology and other disciplines. Physicians clearly want to get data from patients, but again, this proposed measure interferes with the patient-physician relationship. TMA is concerned that driving physicians to change patient behavior will negatively impact patient-physician communication.

**Objective 7: Health Information Exchange**

**Comment:** TMA believes that one of the most disappointing aspects of the HITECH Act has been HIEs. Millions of taxpayer dollars have been spent, and still, most HIEs are not able to deliver the much-needed value of health information technology. Until EHRs and HIEs can efficiently and cost effectively connect, physicians should not be put in the terrible position of requiring participation in a broken system. At the very least, there should be an exclusion for physicians that do not have an active HIE in their community. TMA recommends that CMS adopt an exclusion for EPs whose combined cost for HIE participation exceeds $1,000 per year.

**Rationale:** HIEs in general continue to struggle and have yet to achieve the tipping point, much less critical mass with practicing physicians. This is in large part due to EHR vendor data block. It is imperative that ONC and CMS seek solutions for these entities to connect efficiently so that physicians can participate in a way that brings value to their practice and patients.

**Comment:** CMS should eliminate Measure 2, which requires the summary of care record be incorporated into the EHR for 40 percent of encounters where the EP was the recipient of a referral or transition. This should be a demonstration of capability.

**Rationale:** The recipient physician is dependent upon the sending physician to have the updated technology in place to send a summary that can be incorporated into the EHR. Physicians have no control as to which patients are referred with a summary of care. TMA agrees with CMS's desire for physicians to communicate about patients, but how that communication is incorporated into the EHR should be up to the physician. CMS should not define the specifics of how the summary of care is managed and stored.

**Comment on Measure 3:** Performance of a clinical information reconciliation should be a demonstration of capability until 2020.

**Rationale:** There are no proven standards or workflows for completing this activity. There is a lack of standardized vocabulary. CMS should incentivize specialty societies to create a standardized dictionary for EHR vendors to incorporate.

**Objective 8: Public Health and Clinical Data Registry Reporting**

**Comment:** TMA strongly encourages CMS to analyze industry readiness before requiring submission from the CEHRT to various public health registries. TMA also believes CMS should give credit to physicians that report to public health registries when submitting through an HIE.

**Rationale:** While TMA believes it is a good step forward for ONC and CMS to maintain a repository of public health and specialized registries, it does not change the associated expense of submitting information from the CEHRT to these registries. Physicians have been required for years to submit data for public health through the appropriate public health agency website. It makes much more sense to send this information from the CEHRT, but again, vendor data block and high interface fees have reduced the value proposition significantly. In Texas, the Department of State Health Services has plans to build a statewide syndromic surveillance data repository, but it is currently not available and may not be for several years. The county health departments did not receive HITECH funds or grants to expand their technology infrastructure to receive data from ambulatory practices for syndromic surveillance. TMA is very much in favor of public health reporting but does not believe it is an appropriate role for CMS to mandate how state-level reporting is executed.

**II.B.1. Clinical Quality Measure Reporting Requirements for Meaningful Use**

**Comment:** TMA appreciates CMS's work to integrate the reporting of PQRS and CQMs so that EPs may report once and get credit for both programs. However, TMA believes it is time to sunset the CQM reporting option. Another option is to allow physicians participating in PQRS to attest to their participation and not have to report on CQMs.

**Rationale:** The physician reporting burden just for CMS programs has become increasingly onerous. Anything that CMS can do to reduce duplicative work is appreciated. Many EHR vendors still are only certified to electronically submit a handful of CQMs, thus adding to the EP burden.

**III.A. Collection of Information Requirement.**

**Comment:** TMA believes the burden estimates in Table 6 grossly underestimate the time a physician spends collecting data for the numerous objectives and measures associated with meaningful use, and respectfully requests a revisit of these burden estimates to accurately reflect the industry burden nationwide.

**V.C.2.c. Costs of EHR Adoption for EPs**

**Comment:** CMS indicates cost of adoption and average maintenance costs for EHRs. TMA believes there are many other costs associated with maintenance of EHRs in the meaningful use environment. Others costs that CMS should consider in the calculation are:

- Patient portals;
- HIE interface and maintenance fees;
- HIE subscription fees;
- Immunization, syndromic surveillance, cancer, and other registry integration fees; and

- Security risk analysis consultant fees.

TMA continues to work with Texas physicians to help them understand the complexities of the meaningful use program, and continues to field numerous calls from physicians attempting to comply with the requirements. We appreciate the opportunity to share the experiences of our members.

Thank you for the opportunity to comment on the EHR incentive program Stage 3 proposed rule. Should you have additional questions or need any further information, please do not hesitate to contact Shannon Vogel at (512) 370-1411 or shannon.vogel@texmed.org.

Sincerely,

Matthew M. Murray, MD
Chair, Ad hoc Committee on Health Information Technology
Texas Medical Association