TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

February 6, 2015

Karen B. DeSalvo, MD, MPH, MSc
National Coordinator for HIT
Hubert H. Humphrey Building; Suite 729D
200 Independence Avenue SW.
Washington, DC 20201

Re: Federal Health IT Strategic Plan: 2015-2020

Dear Dr. DeSalvo,

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 member physicians and medical students, TMA appreciates this opportunity to review and offer comments on the above referenced Health IT Strategic Plan.

In the current environment, physicians are feeling crushed by increasing regulatory demands, especially with the meaningful use requirements. Physicians are in a precarious position: We are required to comply with overly burdensome requirements that are simply not supported by current health technology. ONC should carefully consider marketplace readiness during rulemaking.

The big picture for HIT is that usability, interoperability, and standardization produce safety and there is no safety in EMRs without these critical elements.

TMA asks you to carefully consider the suggestions to the strategies of the Federal Health IT Strategic plan as detailed in the table below. Thank you for the opportunity to provide comment. Should you have additional questions or need further information, do not hesitate to contact Shannon Vogel in TMA's Health IT department by calling (512) 370-1411.

Sincerely,

Matthew Murray, MD
Chair, *ad hoc* Committee on Health Information Technology

Goal 1: Expand Adoption of Health IT

Objective 1A: Increase the adoption and effective use of health IT products, systems, and services

Strategy 1	To achieve goal 1A, TMA believes an important strategy is to leverage the trust and expertise of successful regional extension centers (RECs). In Texas, the four RECs need continued support as they have provided invaluable assistance with increasing adoption and use of HIT in Texas. TMA suggests extending financial assistance to successful RECs. There is still a need to maintain a strategic focus on supporting physicians who are in the process of selecting an EHR. TMA suggests that this strategy include the promotion of 3rd-party User-Centered Design (UCD) evaluations of EHR to assist physicians with the EHR selection process, and the promotion of improved EHR price transparency. **Perhaps the greatest impediment to the effective use of health IT is the poor usability of EHRs.** EHRs must be modeled to support physician workflow, while increasing patient safety and office efficiency. The strategies to achieve Objective 1A should more clearly articulate an intent to promote improvements in EHR usability. The American Medical Association (AMA) recently published eight EHR usability priorities (https://download.ama-assn.org/resources/doc/ps2/x-pub/ehr-priorities.pdf) that should be incorporated into this strategy: 1) enhance physician's ability to provide quality care, 2) support team-based care, 3) promote care coordination, 4) offer product modularity and configurability, 5) reduce cognitive workload, 6) promote data portability and liquidity, 7) facilitate digital and mobile patient engagement and 8) expedite user input into product design and post-implementation feedback. TMA further agrees with the American College of Physicians position paper on Clinical Documentation and their policy recommendations for EHR systems (http://annals.org/article.aspx?articleid=2089368): 1. EHR developers need to optimize EHR systems to facilitate longitudinal care delivery as well as care that involves teams of clinicians and patients that are managed over time. 2. Clinical documentation in EHR systems must support clinicians' cognitive processes during the documentation process. 3. EHRs must support "write once, reuse many times" and embed tags to identify the original source of information when used subsequent to its first creation. 4. Wherever possible, EHR systems should not require users to check a box or otherwise indicate that an observation has been made or an action has been taken if the data documented in the patient record already substantiate the action(s). 5. EHR systems must facilitate the integration of patient-generated data and must maintain the identity of the source.

	Examples of tactics to consider to achieve these priorites are: • Require certified EHRs (CERHTs) to have APIs and open architecture that enhance EHR modularity and unlock the data silos • Require CEHRTs to enhance their ability to automatically track referrals and consultations • Require CEHRTs to incorporate error recording mechanisms within the EHR to enhance physicians' ability to report problems that impact patient safety, impede workflow or ability to provide quality care **Physicians need well defined standards for storage and transfer of patient information.** Poor usability of HIT products is largely due to the lack of common data standards. Once there are well-established data storage and transfer standards, then usability and interoperability will ensue via market forces. However, along with the recent statement from HIMSS, we believe concrete steps must be taken at the federal level to ensure that widespread interoperability is realized within the very near future. The season of merely 'fostering' standards has ended; it is time to lead and select those standards that will be used nationwide for HIT storage and transfer. The ONC is uniquely positioned to realize this goal.
Strategy 3	TMA appreciates the strategic focus on promoting adherence to best practices and guidelines for the safe development of HIT products. TMA strongly encourages ONC to promote the embedding of User-Centered Design processes into EHR product development life cycles as part of this strategy.
Strategy 5	TMA believes that the strategy to expand the HIT Certification Program should be considered only after a the current program is assessed and improved. TMA is concerned about the delay issues where EHR vendors are unable to meet set deadlines. There is risk of unintended consequences that occur when vendors rush to meet a certification deadline by developing functionality that passes criteria, but is a poor fit within the physicians' workflow. Therefore, CMS should develop a mechanism to track the vendor community's progress on new requirements. It is further recommended that certification requires analysis of the usability of new functionalities developed by vendors to meet the requirements. This should include analysis of the impact on physician practice resources and workflow. In the emerging marketplace of mobile and telehealth product development, TMA is concerned about the potential adverse effect to innovation that HIT product certification may impose. TMA believes that market forces will create the balance needed to foster development of products that allow physicians and other providers to meaningfully use HIT without impairing innovation. In addition, innovation obviously has the potential to actually raise "meaningful use" to a higher level than what could be reasonably anticipated based on today's technology trends. In general, TMA wants CMS to base requirements on the use of these emerging technologies on evidence-based studies that demonstrate improved outcomes.

	Based on these comments, TMA recommends changing strategy 5 to state: "Improve the ONC HIT Certification Program to enhance the usability of health IT products that enhance quality across the care continuum."

Objective 1B: Increase user and market confidence in the safety and safe use of health IT products, systems, and services

Strategy 1	TMA believes that a key element to this strategy is to establish a centralized, national repository of HIT patient safety hazards and to create a federal entity to manage those hazards. TMA remains concerned that the lack of a specific focus in the federal plan to establish a national entity focused on patient safety will result in an environment where we continue to struggle with HIT patient safety through the fragmented system of Patient Safety Organizations. TMA believes strongly that reporting by physicians needs to be done in workflow-friendly ways. For example, reporting tools need to be developed such as a "green button" within EMRs/other HIT products that captures standardized background system-level information with a single click and sends it to the appropriate reporting body. Federal oversight is needed to monitor and manage EHR patient safety, similar to how the National Transportation Safety Board manages transportation safety. ONC should partner with other entities to determine how to accomplish this. We specifically advocate that ONC work with Congress to establish an independent agency, similar to the National Transportation Safety Board, to manage EHR patient safety.
Strategy 2	Sometimes safe use of EHRs results in untenable work flows for the physician which creates patient safety hazards. This IT certification strategy should integrate UCD analyses as part of the certification process. TMA further recommends that ONC work with medical and other professional societies to encourage widespread dissemination and education of the [SAFER Guides](#).
Strategy 6	TMA strongly encourages the promotion of data portability to be a high priority to enable patient data to be transferred from one EHR to another. This will improve data access for patients that change to different physicians or when physicians change EHRs. When physicians are forced to transition to another EHR, the data migration is very expensive and is cost-prohibitive for small practices.

TMA strongly encourages increasing the availability of and access to health data within EHRs. TMA strongly supports efforts that encourage EHR vendors to provide open APIs and to tag data entered in EHRs in a way that allows it to be easily exported, imported and shared.   A single common data standard format for HIT and HIE would enable entities such as post-acute, long-term care, and behavioral health to invest definitively in data systems to support their operations. As it now stands, the lack of HIE is the main determinant in the lack of real-life utility of such systems in the daily business and operations of such facilities. For behavioral health providers in particular, the legal constraints surrounding the exchange of sensitive behavioral health data impede HIE from a practical standpoint. However, once a common data format and transfer protocol emerges, it will be possible to classify certain data subsets in |

	accordance with levels of security and privacy; finally allowing such facilities and providers of behavioral health to place themselves on the common grid without material fear of inadvertent breaches. Without such a standard, however, meaningful HIE may never occur in such facilities. TMA feels strongly that physicians should be able to send *any* piece of a patient's health data from one EHR to any other electronic database. To accomplish this level of data exchange, as quickly as possible CMS and ONC should require EHR vendors to tag *all* EHR data elements with standardized XML. Vendors also would need to be able to receive and process data feeds using this standardized XML, storing it in their native tables. This process is already used for the CCD/CCR, but on a limited scale.

Goal 2: Advance Secure and Interoperable Health Information

Objective 2A: Enable individuals, providers, and public health entities to securely send, receive, find, and use electronic health information

Strategy 1	TMA has adopted the following policies for HIE development and asks that ONC carefully consider them as guiding principles:
	Health Information Exchange
	1. Patient safety, privacy, and quality of care are the guiding principles of all health information exchange (HIE) efforts; cost reduction and efficiency are expected byproducts.
	2. The Texas Medical Association is a professional organization for physicians and as such recognizes that some parts of patients' medical records should be considered the intellectual property of the physician. HIE efforts should recognize that the physician's work product has value for which he or she, along with the patient, has intrinsic ownership, and therefore, both should control its use. Patient records are the documentation of interactions between physicians and patients. Patient privacy protections that traditionally exist in the patient-physician relationship continue to apply where HIT is used. Physicians must uphold their responsibility to protect and secure all information related to the sacred patient-physician relationship.
	3. Patients have the right to withhold information. Physicians may provide a notice to users that the record is incomplete when a patient withholds information.
	4. Patient privacy and confidentiality shall be maintained in all HIE efforts by using secure systems and transmission methods.
	5. Patients must have complete control over all uses of individually identified medical data. Except for emergencies, or otherwise as required by law, their medical data must not be disclosed or disseminated to third parties without patient consent.
	6. Open standards for the interoperable electronic transmission of clinical data should be mutually acceptable to the medical community and compatible with national and regional standards.

Foundational Principles for HIE Participation

7.   Participation in HIE should be the default. Participants should be able to withdraw upon reasonable notice.

8.   HIE will strive to provide complete, timely, and relevant patient-focused information as part of the physician's workflow, at the point of care, in a fully enabled electronic information environment designed to engage patients, transform care delivery, and improve population health. Patients and physicians will have confidence that personal health information is reliable, private, secure, and used with patient consent in appropriate, beneficial ways for patient and public good.

9.   Any costs of supporting systems providing HIT incentives to physicians should be borne by all stakeholders, clearly defined, fair, simple to understand, and accountable, and should support the financial viability of the considered practice.

10.   To ensure HIE activity remains focused on the patient interest, HIE governance must be representative of and responsive to the needs and concerns of stakeholders, with particular attention to the concerns of physicians and patients.

11.   To protect the interest of patients, an HIE must define whether and how it will share information for public health research, and surveillance and evaluation of health care quality. When participants choose to allow these uses, patient information must be de-identified unless informed consent has been obtained and can be documented.

12.   The HIE must be designed and function to enable and enhance coordinated collaboration for improving health and patient safety. Participants should give consideration to special populations who are otherwise incapable of representing themselves (children, disabled, uninsured, homeless, aged, etc.).

13.   The patient's Social Security number will not be used as the de facto unique patient identifier.

14.   Patient data must be transmitted over a secure network, with provisions for authentication and encryption in accordance with eRisk, HIPAA, and other appropriate guidelines. Standard e-mail services do not meet these guidelines. HIE participants need to be aware of potential security risks, including unauthorized physical access and security of computer hardware, and guard against them with technologies such as automatic logout and password protection.

15.   HIE operations will not modify original patient data in any way.

16.   The HIE must have a means to audit, track, and use reasonable efforts to ensure the integrity of all entities or individuals engaged in receiving and converting transaction data.

17.   Dissemination of information identifiable with a specific patient is permissible only when the patient provides express permission to do so.

18. The HIE should maintain and enforce strict conflict of interest policies that require members to disclose all possible conflicts of interest, to recuse themselves from deliberations on matters in which they have a conflict of interest, and to abstain from voting on such matters. The HIE must further maintain financial transparency in its operations, acknowledging all material sources and uses of funds.

19. State support for HIE is important. However, state government's primary role should be to foster coordination of HIE efforts, including providing access to funding or other financial incentives that promote the adoption of health information technologies.

20. TMA physicians should support partnerships with nongovernmental entities developing HIE solutions with minimal mandates, but only where it leads to physicians' stewardship of the data they produce, and patients' control over data that may identify them (CPMS Rep. 3-A-07).

21. TMA supports national health information standards such as Nationwide Health Information Network (NHIN), HL7, Continuity of Care Record (CCR)/Continuity of Care Document (CCD), and other standards adopted by Centers for Medicare & Medicaid Services (CMS). In addition to 4 the CCR/CCD contents, HIE participants' data should also include: labs, radiology results (text), history and physical, discharge summaries, progress, and other notes.

22. TMA supports HIE participation of the United States Department of Veterans Affairs, United States Department of Defense, the uninsured, and other populations that may have medical records inadequately integrated in the health care system.

23. TMA supports a physician safe harbor that mitigates risk if patient data is breached by an HIE or any participant. Each participating entity should be responsible for their own actions or inactions as it relates to a possible HIPAA breach in the release of protected health information.

TMA strongly supports propagation of privacy policies that are based on what is best for the patient. TMA is concerned about policies that allow patients to restrict access to parts of their data (data segmentation). Data segmentation is a significant patient safety risk because the restricted data set could include information that is essential for safe, quality care of the patient. On the extreme, a patient could potentially try to hide their prescription drug abuse. It is recommend development of policies that avoid or carefully manage the risks associated with data segmentation. At the very least, physicians need to be flagged with information about what data is restricted and when it was restricted.

TMA supports policies that encourage HIE patient consent to be used as a tool to educate patients on the circumstances under which their health data can be accessed and used in an HIE for their care, and that other uses will require their consent based on state and federal privacy laws.

TMA believes that requiring each physician to maintain a portal with access for

	each patient further fragments the information that patients need. If a patient with chronic conditions sees numerous physicians, then that patient must remember log-ons and passwords for each practice. This quickly becomes overly burdensome to the patient and is neither safe nor effective for the patient. TMA believes standardized data portability will further enhance the capabilities of the patient to maintain one record across their care continuum.
Strategy 4	Consider focusing efforts on promoting the use of health information exchange at a national level to include exchange in fundamental areas such as laboratory results, radiology reports, and immunization registry information. Having a few key data elements working well is a great start as the country moves toward complete interoperability.
Strategy 5	TMA supports expanded use of the Blue Button in EHRs. There should be increased focus on reducing unintended burden placed on physicians for information sharing programs and other initiatives that require physicians to extract reports from their EHR that at times require additional resources that are costly. To relieve this burden, TMA supports efforts to accelerate development of e-measures with reporting tools built into EHRs to simplify data abstraction. This capability should be considered for all quality reporting programs.

Objective 2B: Identify, prioritize, and advance technical standards to support secure and interoperable health information

Strategy 1	TMA recommends that the federal health IT plan includes the development of a roadmap for implementation of ICD-11. TMA recognizes the industry forces pushing for implementation of ICD-10 in October 2015, despite significant push-back from physicians. It will take a minimum of 7 years to develop and implement ICD-11 based on current development and implementation timelines. Informatics experts are in agreement that ICD-11 provides many benefits not available in ICD-10 including the integration of SNOMED and more robust ability to function within EHRs and other health IT tools. ICD-11 will become increasingly recognized as needed to improve quality of care. If a national roadmap does not include ICD-11 strategies, then a similar situation as faced today is likely in 2025. An ICD conversion is one of the most complex health IT implementation our nation experiences, if not the most complex. The ICD-10 implementation has clearly put an enormous strain on the health IT industry. A health IT implementation with this degree of complexity should be included in our federal health IT plans. TMA, therefore, recommends developing a strategic roadmap to ICD-11 to be included in this strategic plan to better prepare the nation for its inevitable implementation in the 2020s.

Objective 2C: Protect the privacy and security of health information

Strategy 1	ONC should partner with states that are developing privacy and security certifications so that the state and national certification criteria remain aligned. TMA believes that a safe harbor should be established for physicians participating in the HIE, so that as the source of the information, they are

	released from liability should there be a data breach by another entity, such as an HIE that is in possession of that information. TMA believes that a key element to this strategy is to establish a centralized, national repository of HIT patient safety hazards and to create a federal entity to manage those hazards. TMA is concerned that the lack of a specific focus in the federal plan to establish a national entity will result in an environment where we continue to struggle with HIT patient safety through the fragmented system of Patient Safety Organizations. Federal oversight is needed to monitor and manage EHR patient safety, similar to how the National Transportation Safety Board manages transportation safety. ONC should partner with other entities to determine how to accomplish this. TMA specifically advocates that ONC work with Congress to establish an independent agency, similar to the National Transportation Safety Board, to manage EHR patient safety. TMA believes that automation of error-reporting in the EHR at the point-of-care is a critical aspect of improving the collection of issues. Reporting by physicians needs to be done in workflow-friendly ways. For example, reporting tools need to be developed such as a "green button" within EMRs/other HIT products that captures standardized background system-level information with a single click and sends it to the appropriate reporting body.

Goal 3: Strengthen Health Care Delivery

Objective 3A: Improve health care quality, access, and experience through safe, timely, effective, efficient, equitable, and person-centered care

Strategy 2	TMA has numerous comments on the Meaningful Use (MU) strategy and are submitting them here on the assumption that this is the general strategy under which more specific Meaningful Use strategies for 2015-2020 will be developed. First, we recommend that the federal plan for the use of quality data and measures follow the guidelines of both TMA policy and AMA policy. Some specific suggestions regarding MU strategy are: • Decrease the complexity of MU, such as eliminating the core and menu concepts and decreasing the number of requirements • Eliminate the all-or-none approach and add flexibility to the threshold • Eliminate the penalties; alternatively, we suggest creating a tier-based approach, similar to what was done with e-prescribing penalties in the past. Analyze the current MU program to identify criteria that have demonstrated a positive impact on quality of care. Select 3-5 of those criteria as the baseline to avoid penalties, and continue to provide incentives for those who go beyond the baseline. • Do not add more goals, but instead, increase the targets for existing

	criteria
	• Increase alignment of MU with other federal programs
	• Improve alignment of MU goals with market ability
	• Improve sensitivity to the differences in workflow between physicians who work in hospital environments to those who work in an office environment
	• New requirements should have evidence-based studies that demonstrate how the requirement improves the quality of care
	• Avoid mandates that depend on the behavior of patients; physicians want to engage patients and they want patients to engage with them; if technologies are developed that increase patient engagement and can fit within the physician workflow, it will be readily adopted by physicians
	• Consider a partnership between the government and private payers on activities that require provider data or require other efforts on the part of providers. The burden on providers could be significantly reduced with increased uniformity of the requests for data reports, for example.

Objective 3B: Support the delivery of high-value health care

| Strategy 1 | Please see previous comments regarding recommendation to develop a national roadmap for ICD-11 implementation and expanded use of SNOMED in EHRs. This is a critical part of a strategy to improve documentation and coding.

Improve clinical documentation by incorporating principles of improvement such as those outlined in the American College of Physicians position paper.

Engage medical and allied health education programs with curricula that specifically covers HIT and documentation in EHRs. |
|---|---|
| Strategy 4 | Develop a funding mechanism allowing HIE participation and EHR use for long-term care facilities, post-acute care facilities, and home health agencies. |

Objective 3C: Improve clinical and community services and population health

| Strategy 1 | TMA supports efforts to improve EHRs ability to allow clinicians to query their database for data that will help them improve care for their particular population of patients. ONC and CMS should use existing, nationally recognized clinical groups and classifications. They could be incorporated using collapse veiw functionality for better usability. Physicians should be able to sort, prioritize, and collapse problem lists to aid in decision support at the point of care, especially in emergent situations.

Engage CDC and state and local public health agencies in developing actionable goals and timelines for surveillance.

Devise a consent process by which physicians may provide their patients with the opportunity to opt-in to allow health data access for population studies by |
|---|---|

	approved entities in safe and HIPAA-compliant ways.

Goal 4: Advnce the Health and Well-Being of Individuals and Communities

Objective 4A: Empower individual, family, and caregiver health management and engagement

| Strategies 2-5 | TMA agrees with the general concept of increasing patient engagement, but remains concerned about creating specific requirements when the impact that patient engagement tools or activities will have on patient outcomes is unknown. One of the potential unintended consequences of patient engagement activities is to cause a decrease in patient access to physicians, because physicians who are burdened with the cost and management of these tools or activities are forced to see fewer patients. Evidence-based studies should be performed to identify patient engagement tools and activities that improve quality of care and to analyze the resource costs of implementing those tools. An analysis of the cost-benefit for each tool/activity should be conducted when prioritizing initiatives. Physicians are used to this type of due diligence, as that is what they expect to see from clinical trials on new treatments that require them to make changes to their practice.

Although physicians have a role in engaging patients to take a more active role in their health care, the burden of that role varies widely from physician-to-physician and practice-to-practice. It is dependent on many factors, including the socioeconomic and severity-of-illness profiles of each physician's patient population. This disparity makes it difficult to fairly incentivize physicians for the variable amount of work they would have to do to increase patient engagement. Penalizing physicians for failing to meet the criteria would be even more precarious. Instead, TMA suggests including under Objective A the strategy to provide physicians with support to incorporate within their practice the patient engagement tools and activities that are shown to improve quality of care based on evidence-based studies and cost-benefit analyses.

TMA further believes that requiring each physician to maintain a portal with access for each patient further fragments the information that patients need. If a patient with chronic conditions sees numerous physicians, then that patient must remember log-ons and passwords for each practice. This quickly becomes overly burdensome to the patient and is neither safe nor effective for the patient.

TMA has adopted the following policy on personal health records that ONC should consider:

Personal Health Records

1.   TMA supports the use of personal health records (PHRs) by individuals and families.

2.   TMA supports the concept that patients should be able to use their PHR as a source of information regarding their medical status. |
|---|---|

	3. PHRs need standardized formats that contain at minimum core medical information necessary to treat the patient.
	4. TMA supports legislative efforts directed at providing incentives to facilitate PHR use and maintenance.
	5. Physicians should be able to access PHR-released information free of charge.
	6. TMA supports interoperability of PHRs allowing access to patient health information in patient care settings.
	7. TMA supports ensuring that the source of information in PHRs is clearly identifiable.
	Primary care physicians could be incentivized to take a unique docent role as they encourage and help patients with PHR use.

Goal 5: Advance Research, Scientific Knowledge, and innovation

Objective 5B: Accelerate the development and commercialization of innovative technologies and solutions

| Strategy 5 | In order to foster widespread participation in the process of meta-analysis of population data, one innovative strategy should be to develop a task force to study how patients might be allowed to voluntarily donate their electronic personal health information, or parts of it, to research, and to receive monetary compensation – much like plasma donation centers and medication trial studies do in the present day. |

Objective 5C: Invest, disseminate, and translate research on how health IT can improve health and care delivery

| Strategy 1 | Consider exploring ways to partner with private insurers on these activities. Physicians obviously interact with both private and government payers. With a mature, standardized, widespread, and interoperable HIT substrate finally achieved in U.S. health care, CMS, HHS, ONC, NIH, and other entities should develop a specific initiative designed to study the U.S. aviation industry's proven successes in process standardization and safety, and begin to apply these types of processes to specific health care use cases. |