August 16, 2010

Edward W. Marx, Chair
Texas Health Services Authority
PO Box 1564
Austin, Texas 78767-1564

RE: Draft Strategic and Operational Plans for Statewide Health Information Exchange

Dear Mr. Marx:

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 over 44,000 member physicians and medical students, TMA appreciates the work of THSA in providing a plan for health information exchange in Texas and the opportunity to review and offer comments on the Texas Health Services Authority’s Draft Strategic and Operational Plans for Statewide Health Information Exchange. TMA has a keen interest in health information technology and the development and promotion of health information exchanges (HIEs) that support patient safety, privacy, physician workflow and quality of care.

To that end, the Association offers the following comments to the above-referenced draft plan. Should you have any questions about this document, please do not hesitate to contact me through Shannon Moore, TMA Director of Health Information Technology, at (512) 370-1411.

Sincerely,

Joseph Schneider, MD, MBA
Chair, ad hoc Committee on Health Information Technology
I. **Section 1.3 Vision (Page 5)**

In Section 1.3 of the Strategic Plan, THSA recites its vision statement as follows:

To enhance health care quality and effectiveness for all patients, the health care sector should be supported by an infrastructure made up of interoperable, electronic health records composed of standardized, structured data elements that are exchanged among authorized health care organizations and providers across secure regional and statewide networks.

As noted in previous comments submitted by TMA, TMA policy supports efforts to promote interoperability of EMRs and standardized structured data elements as necessary for secure health information exchange. TMA, however, has the following suggestions regarding the role of the THSA and the method for best achieving this shared vision.

TMA House of Delegates Policy acknowledges that state support for HIE is important. It states that “… 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.”

With that role in mind, TMA urges THSA to focus its initial activities on the following:

- Requiring use of national health information technology (HIT) standards, such as the Continuity of Care Record/Document to allow for workflow-friendly interoperability and data sharing, regardless of which software is used;

- Streamlining business processes in the medical office to include 1) access to clinical information pertinent to patient care that fits with physician and patient workflows, including minimization of the need for physicians to integrate and reconcile conflicting data from multiple sources; 2) real time notification of eligibility and coverage; and 3) real time claims adjudication allowing for immediate payment at the end of a patient encounter; and

- Playing the role of a convener, coordinator, communicator, and educator. THSA should serve local health information exchanges (HIEs) as a repository of best practices and should facilitate resource sharing to allow for economies of scale and purchasing power. This could lead to building consensus among stakeholders for a statewide model.

- Support the development and use of an HIE safety reporting system to capture and address issues encountered by physicians and patients that local HIEs or HIE vendors are not willing to address in a safe and timely manner or those that have multi-vendor or multi-HIE implications.
THSA has opportunity to drive Texas HIE performance to a national leadership role in patient safety, usability, and timeliness. In addition, the development of personal health records is an emerging item of importance for the near and long term.

II. Section 1.4 Guiding Principles (Page 7)

In Section 1.4, THSA references guiding principles that have emerged during the planning process regarding state-level planning for health IT and HIE in Texas. Among those principles listed is the following statement:

“HIE design must be flexible to allow for changes in how EHRs are constructed, while adhering to national standards that will facilitate information sharing. Future EHRs will likely separate data (allowing input from registries and personal health records), applications (allowing calculations to be done by web services), and presentation (allowing physicians to customize their user interface much like customizing a home page).”

Acknowledging that registries and PHRs (as noted in THSA’s statement above) likely will be an important part of a future model for information storage and exchange, TMA strongly recommends that THSA allocate funds in a way that identifies best practices in the development and use of PHRs and encourage further research and refinement. As a part of this, TMA stresses the importance of properly identifying and designating patient-entered information and of separating patient-entered information from physician-entered information.

III. Section 1.4 Guiding Principles (Page 8)

In Section 1.4, THSA includes a table “demonstrating how recommended services in the operational plans will ultimately strive to move provider and patient-centered services closest to the point of actual delivery.” This table includes a breakdown of state-level, regional-level, and local services. Notably, the table detailing state-level services includes a reference to aggregated reporting. TMA seeks clarification as to the nature of activities contemplated by this reference.

Additionally, TMA notes that THSA is bound by the limitations on its statutory authority as provided under Chapter 182 of the Health and Safety Code. More specifically, Section 182.102 of the Health and Safety Code contains a list of acts that the corporation is prohibited from performing. Included among those prohibited acts are two references to providing access to aggregated data. THSA is statutorily prohibited from:
providing of access to aggregated, de-identified protected health information to local health information exchanges and other users of quality care studies, disease management and population health assessments; and

providing to public health programs trended, aggregated, de-identified protected health information to help assess the health status of populations and the providing of regular reports of trends and important incidence of events to public health avenues for intervention, education, and prevention programs.

TMA believes that THSA should focus its energies on supporting health information exchange functionality and efficiency.

THSA should not collect, nor have access to aggregated patient data.

IV. Section 3.1.6 Governance Approach (Pages 33-34) and Section 8.2 (Pages 83-84)

In Sections 3.1.6 and 8.2, THSA sets forth the governance structure for the Collaboration Council. The Collaboration Council is charged with the important tasks of reviewing ground-level input, providing oversight of HIE implementation, and providing strategy/policy recommendations to the THSA Board for approval. Given the authority of the Collaboration Council, it is important to have a balanced membership on the Council.

As currently contemplated in the draft plan, the Council is composed of the THSA CEO, one representative per sanctioned regional/local HIE, the HIT coordinator, one DSHS public health representative, one TMA representative, one Texas Hospital Association representative, one Health Plan Association representative, one consumer representative, one individual per approved REC, and one employer representative. If the Collaboration Council comprises 25 HIE reps, four REC reps, and one representative from each listed stakeholder, TMA notes that the Council would be disproportionately weighted with HIE representatives and may be unwieldy with such a large membership (e.g., totaling 35 members.

TMA, therefore, recommends that the THSA significantly reduce the number of HIE representatives on the Collaboration Council to a maximum of four HIE representatives. Additionally, consistent with TMA House of Delegates’ policy, TMA recommends that another physician representative be added to the Council. TMA House of Delegates’ policy stresses the importance of stakeholder input, especially with regard to physician and patient concerns. Specifically, TMA policy states the following:

“To assure 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.”
V. 3.4.5 Strategic Framework for Supporting EHR Adoption (Pages 49-50)

In Section 3.4.5, THSA establishes a framework from EHR adoption, including elements related to incentives, quality, governance, technology and infrastructure, and communication strategy. With regard to communication strategy, TMA agrees that a “robust communication strategy” will need to be implemented in order to educate providers and promote EHR adoption and HIE participation. However, TMA notes that funds were not specifically allocated for physician and patient education. While Regional Extension Centers will do some of this for primary care physicians, specialist physicians and patients are not covered by their funding. TMA, therefore, seeks clarification as to who will bear the costs for the contemplated outreach efforts.

VI. Section 5.1 Risk Mitigation Strategies (Pages 76-78)

In Section 5.1, THSA sets forth risk mitigation strategies, including both a list of potential risks associated with HIEs and plans to address identified risks. TMA recommends that THSA consider three additional risks associated with HIE implementation, namely, those associated with failed HIEs, HIE downtime, and HIE data linkage downtime.

First, TMA notes that THSA has identified service disruption as a potential risk associated with HIE implementation. TMA questions what happens to failed HIEs or HIEs that lose their certification? Given the “network of networks” approach, it is important to address this as the answers are critical to achieving physician and patient trust of these new organizations. Specifically, if an HIE becomes unsustainable or loses certification, who is authorized to take over the flow of patient data for uninterrupted service, who is authorized to provide short term business continuity for physicians who utilize the HIE for services (e.g., e-prescribing) and what is the long-term plan for transition of services? All HIEs should have an acceptable plan for business continuity and legal agreements with another HIE or with THSA to allow for no loss of services or no risk to patient safety in the event of business failure or loss of verification. TMA further recommends that THSA should retain funding for managing this situation, which is almost certain to occur.

TMA has additional concerns related to HIE downtime and downtime recovery (i.e., data restoration). While these may appear to be operational issues that each HIE should address, lack of standard processes across HIEs for these issues will generate significant mistrust of data integrity among patients and physicians. Physicians will need to remember different downtime and data recovery rules for each HIE, which will be impractical. To address this, TMA strongly recommends that THSA require HIEs to develop and follow state standards for providing backup data visibility during downtimes.
and to adopt standardized approaches data restoration, preferably with 100% data recovery.

TMA recommends that THSA provide additional consideration to and more information regarding who will be responsible for analyzing requirements for data recovery if a data link (such as hospital) is down.

Finally, TMA has concerns regarding the availability of retrospective HIE information for inclusion in future legal proceedings. Physicians must be able to show what they saw in the HIE in their defense without having to store “screen captures” in their EHRs. To address this, THSA should require HIEs to have the ability to provide unmodifiable retrospective views of patient data upon request in order to support physicians and other clinicians in a court of law.

VII. 10.2 Standards and Certifications (Pages 91-94)

TMA policy states that “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.”

In Section 10.2, THSA discusses the need to define a set of standards based upon national standards in order to facilitate statewide interoperability. TMA notes that the Continuity of Care Record (CCR) and Continuity of Care Document (CCD) are not mentioned in this section. The CCR and CCD, however, are recognizable national standards for exchange of patient summaries and should, therefore, be integrated into THSA’s draft plan.

THSA should investigate selecting the VistA syntax and data standards used by the Veterans Affairs systems as a logical default standard for the statewide HIE interoperability protocol.

VIII. 10.3 Architecture (Pages 96-97)

In Section 10.3, THSA’s draft plan references four models for technology architecture. In considering the various models and different storage options associated with the models, TMA offers the following recommendations: First, if HIEs are permitted to store data centrally, then THSA must ensure that there are an adequate number of secure data centers across the state to ensure data integrity. Second, if data is not centralized, then there must be requirements that data sources (e.g., labs, physician offices, and hospitals) are always connected to the network.

When viewing exchanged information, physicians should know what types of patient information are retrievable and how to identify the sources, dates, and times of that
information. The source of data is particularly valuable when contradictory information is encountered. Physicians who access and use electronically exchanged patient information through an HIE, PHR, or other telemedicine tool should have easy access to understanding what types of data are available to view, how to determine the sources/dates/times of displayed data, what the consent policy is, and whether data can be excluded and, if so, whether the physician is alerted about the exclusions. All of the above should be standardized across the state.

Finally, TMA queries how duplicate or conflicting data in HIEs will be consolidated or resolved, respectively? Physician and patient usability will be negatively impacted if patient problems are duplicated or are conflicting, for example. Many other data elements, such as allergies and demographics, share the same problem. This is a national issue that threatens the acceptance of HIEs in Texas by patients and physicians.

IX. 11.1 Current HIE Capacities (Page 98)

In Section 11.1.1, THSA establishes goals for areas with existing HIE capacity and areas without HIEs (i.e., the “white space”). THSA states that its plan to address the so-called white space is to leverage its existing HIE pool and to use an open market bidding process (i.e., through a request for proposal process). TMA recommends that THSA provide additional information to address how THSA’s plan will be realized if existing HIEs, nonetheless, fail to cover the white space.

Further, TMA poses the following questions:

- Will THSA allow physicians and hospitals to connect to “out of area” HIEs?
- Do physicians and hospitals have to connect to all local HIEs if there are more than one that serve their service area?
- Can hospitals and physicians connect to any HIE?

X. Section 11.2.6 Special Needs Populations (Page 101)

In Section 11.2.6, THSA’s draft plan discusses the various state systems maintained by DSHS that provide support for special needs populations. TMA strongly recommends that, in addition to those programs discussed in Section 11.2.6, the THSA Strategic Plan make a focused determination to include HIE functions with Texas Veterans Affairs patients, foster care and residential care facility patients of the state. Without such a determination, these additional special needs populations will risk being left behind.

XI. Section 12.2 Consent (Page 105)
In Section 12.2, THSA discusses the important subject of patient privacy and consent to participate in the HIE. THSA notes that five consent options have been considered by THSA’ Privacy and Security workgroups, which have been narrowed to three options, namely opt-out, opt-out with exceptions, and opt-in.

As noted in TMA House of Delegate’s policy, TMA’s position is that participation in the HIE should be the default. However, participants should be able to withdraw upon reasonable notice. Additionally, patients should have the right to withhold information. If information is withheld from transmissions, a notice to users that the record is incomplete should be provided.

Additionally with regard to consent, TMA stress the importance of developing a standard consent form that is simple to both administer and execute. To that end, TMA recommends the development and administration of a value-added “online consent tool” that eases the administration burden on consumers, providers, and HIEs. Such a standard consent tool should interface with EHRs to avoid the necessity of maintaining duplicate systems.

Further, TMA recommends the Texas Medical Disclosure Panel be the administrative body entrusted with the task of developing a model consent form for HIE participation. Under current law, the Texas Medical Disclosure Panel is responsible for determining the risks (if any) that must be disclosed for medical procedures by health care providers or physicians to patients for consent to medical treatment. Tex. Civ. Prac. & Rem. Code §74.103. Additionally, this body is charged with establishing the form and substance of the disclosures.

The Texas Medical Disclosure Panel would be a logical fit for development of HIE consent forms, given the Panel’s expertise with regard to medico-legal issues. Notably, the Texas Medical Disclosure Panel is composed of three Texas-licensed attorneys and six Texas-licensed physicians. Additionally, given that the Texas Medical Disclosure Panel convenes on a regular basis (at least annually), it would be a body that could be responsive to any changes in Texas or federal law affecting patient privacy. Thus, the model consent form could be updated regularly as necessary by the Panel. Notably, the Texas Medical Disclosure’s Panel’s charge (as currently provided under the law) is not broad enough to encompass preparation of HIE consent forms. However, TMA advocates for a change in Texas law to permit the Texas Medical Disclosure Panel to serve such a function.

XII. Additional Comments: Financial Model/Sustainability

Finally, TMA requests that TSHA provide additional information regarding the financial model to be established for participation in an HIE. TMA House of Delegates’ policy provides the following:
“Any costs of supporting systems providing health information technology incentives to physicians should be borne by all stakeholders, clearly defined, fair, simple to understand, accountable, and should support the financial viability of the considered practice.”

Regarding this, TMA poses the following:

- Physicians should not be required to pay to participate in the system since physicians are the ones populating the data for the HIEs.
- If physicians and hospitals are required to pay into the system, what happens if they don’t willingly pay a transaction or subscription fee? Does that patient data not get included?

TMA recommends funds are available at the THSA level to cover the yet unknown issues that will arise when implementing an NHIN compatible model across Texas.