TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

June 1, 2010

Drug Enforcement Administration
ATTN: DEA Federal Register Representative/ODL
8701 Morrissette Dr
Springfield, VA 22152

RE: Docket No. DEA-218

To Whom It May Concern:

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 the almost 45,000 physicians and medical students of the Texas Medical Association, we welcome the opportunity to comment on the Interim Final Rule (IFR) for Electronic Prescriptions for Controlled Substances. Although the TMA strongly supports e-prescribing, we are concerned that the proposed regulation will have a negative effect on patient safety by unintentionally erecting barriers that will keep physicians, particularly those in smaller practices, from utilizing e-prescribing.

Properly designed and implemented e-prescribing has the potential to reduce medical errors and improve the quality of health care. The TMA believes that e-prescribing must NOT:

- create additional inefficiencies;
- impose undue costs on physicians;
- increase the administrative burden on physicians and thus reduce patient care; or
- impose a disproportionate share of legal liability on physician prescribers.

The TMA appreciates the DEA's efforts to allow e-prescribing of controlled substances but we believe that further adjustments are needed.

TMA's specific comments on the Interim Final Rule are offered below.

Sincerely,

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

Section 1311.102 Practitioner responsibilities

Subsection (b) requires that the practitioner must notify the individuals designated under § 1311.125 or § 1311.130 within one business day of discovery that the hard token has been lost, stolen, or compromised or the authentication protocol has been otherwise compromised. A practitioner who fails to comply with this provision may be held responsible for any controlled substance prescriptions written using his two-factor authentication credential. The Texas Medical Association recommends that three business days should be the standard. Staffing and administrative issues may make the one day standard extremely difficult to meet in certain cases. A standard set by regulation should not set a standard that cannot be met.

Subsection (c) states that "If the practitioner is notified by an intermediary or pharmacy that an electronic prescription was not successfully delivered, as provided in § 1311.170, he must ensure that any paper or oral prescription (where permitted) issued as a replacement of the original electronic prescription indicates that the prescription was originally transmitted electronically to a particular pharmacy and that the transmission failed."

The requirement established by subsection (c) will raise difficult compliance problems in real-life workflow. Problems will arise not only in the execution of such notations but also will be ripe with chances to miss making such required notations. Vendors must be required to program their software so that if a prescription is printed a choice would be given to put a phrase such as "Replacement prescription for failed transmission/receipt of electronic prescription to XX pharmacy"***. This technology does not exist at the current time.

Section 1311.120 (21)

This section provides that if a prescription is printed for records for the patient, it must clearly be labeled as a copy and not a valid prescription. This is to prevent reprinting of an already transmitted prescription. Many EMR and e-prescribing systems currently do not typically support this application. The regulations must be flexible to accommodate current and future technology.

Section 1311.105 Identity Proofing

Compliance costs to use e-prescribing can prove to be a powerful disincentive for physicians to use e-prescribing. Undoubtedly, entities performing identity proofing will seek to charge for this service. This cost, plus software costs that physicians will have to pay as vendors upgrade their systems, will create a disincentive for physicians to e-prescribe. Careful examination and monitoring of identity proofing companies should be high on the agenda for the DEA. The ability for the government to address such fees should also be part of the regulations. Costs charged for identity proofing should be public information.

Section 1311.115. Additional Requirements for Two-Factor Authentication

If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140-2 Security Level 1 as incorporated by reference in Section 1311.08, for cryptographic modules or one –time-password devices. The regulations should

look forward to setting a standard for hard token so that a proliferation of hard tokens does not result. Doctors may have six or more different tokens that they need to carry.

1311.140 Physician Workflows

For each e-prescription, there needs to be an electronic confirmation notice from the clearinghouse used that the prescription was received, processed, and forwarded. A second electronic notice should be received from the pharmacy system confirming that the prescription was received. Finally, a third notice should be received when the prescription has been filled. The regulation must include timely notice to the physician of delivery problems as soon as possible so that if a replacement prescription is needed, the physician's workflow is disrupted as little as possible. This dovetails with Sections 1311.200 and 1311.205 relating to pharmacy responsibilities.

The IFR requires that a controlled substance prescription be authenticated before transmission. It is not clear whether other "normal" prescriptions can be signed simultaneously with a controlled substance prescription. TMA recommends that the DEA state that it is permissible to sign multiple prescriptions simultaneously, even if one or more is for a controlled substance.

TMA appreciates that the DEA has allowed the use of biometrics for authentication; however, the use of biometrics is not likely to be cost-effective for small practices in the near-term.

Section 1311.305 Recordkeeping

Subsection (f) provides that "Records required by this subpart must be maintained electronically for two years from the date of their creation or receipt." *"If a registrant changes application providers, the registrant must ensure that any records subject to this part are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format."*
The vendor should be held to as high a standard as the physician and should be required to assist with the migration if the physician changes vendors. The rule should also take into account the situation where the vendor becomes insolvent or otherwise unable to comply with its contractual obligations. To provide otherwise will place an undue hardship on small physician practices preventing them from adopting e-prescribing.

Thank you for the opportunity to comment on the Interim Final Rule. Should you have any questions or need any additional information please do not hesitate to contact me or Shannon Moore at the Texas Medical Association.