

ACP

AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

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To Whom It May Concern:

The American College of Physicians (ACP), representing over 120,000 doctors of internal medicine and medical students, appreciates the opportunity to submit comments on how electronic prescribing (e-prescribing) systems can meet the Drug Enforcement Administration's (DEA's) prescription requirements under the Controlled Substances Act without unduly burdening physicians who wish to electronically prescribe controlled substances.

GENERAL COMMENT

E-prescribing has the potential to mitigate the risks of diversion and abuse of controlled prescriptions by preventing forgeries, and automatically tracking and maintaining records of prescriptions from the time the physician "writes" them to the time the pharmacist dispenses the medications.

SPECIFIC COMMENTS

In response to the publicly posted questions related to the e-prescribing of controlled substances, the ACP wishes to make a few specific comments.

- I. General Issue of Risks with E-prescribing:
 - a. Compared to paper-based prescribing, e-prescribing (with clinical decision support technology) significantly reduces risk through its capacity to:
 - i. Reduce errors resulting from illegible handwriting.
 - ii. Improve the accuracy of writing a prescription by:
 1. checking that the drug and dosage are consistent with the patient's diagnosis and related factors; and
 2. checking that the drug does not conflict with patient allergies, other prescribed medications, listed diagnoses, or other contraindications.
 - iii. Prevent errors of omission by actively suggesting consideration of certain drug usage in specific diagnostic situations (e.g. remind physicians of guidelines for patients with heart disease to use aspirin and beta-blockers.)
 - iv. Reduce transcription errors.
 - v. Reduce delays through the electronic transmission of the prescription to the pharmacy.

II. Specific Issue of Risk with E-prescribing of Controlled Substances:

- a. E-prescribing has the potential to reduce the risk of diversion and abuse of controlled substances compared to the present paper-based system:
 - i. E-prescribing can provide a more secure, closed prescribing system compared to the current system where prescription pads for controlled substances can be stolen or misplaced, and where paper prescriptions can be modified or used by someone other than the patient for whom the script was written.
 - ii. E-prescribing will allow for more granular tracking of prescribed controlled substances to:
 - 1. determine whether a patient is receiving a specific controlled substance from more than one provider, and
 - 2. determine whether the prescription and quantity of controlled substance prescribed by the physician is consistent with diagnosis and current clinical guidelines.

III. Issues related to the Security of E-prescribing of Controlled Substances:

- a. There are certain characteristics that should be in place when using an e-prescribing system to write scripts for controlled substances:
 - i. The system should verify the authority of the physician to prescribe controlled substances e.g. the physician's DEA number and the specific Schedule II -V of controlled substances.
 - ii. The system should generate a "prescription fill status notification" and a "cancellation notification" to advise the physician of whether a prescription has or has not been filled.
 - iii. In addition, there should be established procedures and mechanisms that ensure that electronic prescriptions are not diverted, altered (e.g. forgeries, breeches), or abused.
- b. Current e-prescribing systems use a number of mechanisms to authenticate users (e.g. password defined) and these procedures appear to be adequately secure for most purposes. However, it may be necessary to use an additional "challenge" when prescribing controlled substances to authenticate the physician and the prescription. Possible examples include:
 - i. Use of an encrypted electronic signature, or
 - ii. Use of an authentication procedure at the level of the pharmacy, before the medication is dispensed.
- c. Procedures to limit diversion and abuse must be in place to address those circumstances in which the patient requests or is required to have a paper copy of the prescription – e.g. the hard copy should contain the physician's DEA number, be printed in a defined format, placed on special paper that discourages copying or altering, and be signed in pen.

- IV. Issues related to the Integrity of the Electronic Prescriptions for Controlled Substances:
- a. The integrity of the prescription is greater under e-prescribing than with paper-based prescribing – the prescription is electronically entered into the medical record “as written” with no opportunities to change the script subsequently.
 - b. Electronic backup (and mirror copies) of all prescriptions should be mandatory at the local and remote level.
- V. Issues related to the Privacy of Electronic Prescriptions for Controlled Substances:
- a. Privacy of these prescriptions already falls under HIPAA regulations based upon the recent e-prescribing final rule.
 - b. Authorization to access these data should be role-based given the sensitivity associated with certain medications.
 - c. All treating health care providers should have access to these data, to reduce the incidences of drug-drug interactions, drug-condition contraindications etc.
- VI. Issues related to the Access and Use of the E-prescribing System using “Open Networks:”
- a. In situations where providers have to access an e-prescribing system over an open network i.e. the Internet, technology exists to ensure the transmission of data remains secure i.e. secure virtual private networks (SVPNs).
- VII. Issues Related to State Preemption of Federal Controlled Substance Regulations:
- a. The interpretation of language in the Medicare Modernization Act (MMA), and the e-prescribing final rule released on November 7, 2005, must extend state preemption to the e-prescribing of controlled substances. This is essential, as there is significant variability on this issue amongst the states. The federal e-prescribing rule for controlled substances must supersede related state rules to the extent the state rules are in conflict with the federal rule.

CONCLUSION

The College applauds all attempts to encourage healthcare providers to adopt health technology and ultimately build a functional healthcare information technology infrastructure. Providing an effective framework for e-prescribing of both controlled and uncontrolled substances will help our members to implement this technology in their clinical practices.

Again, the ACP greatly appreciates this opportunity to comment on the proposed standards. Please do not hesitate to contact Dr. Mureen Allen., Senior Associate, at (202) 261-4539 or mallen@acponline.org if you have any questions regarding these submitted comments.

Sincerely,



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Chair, Medical Service Committee