



**American Pharmacists Association**<sup>®</sup>  
Improving medication use. Advancing patient care.

September 25, 2008

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

[Submitted electronically to: [dea.diversion.policy@usdoj.gov](mailto:dea.diversion.policy@usdoj.gov)]

**RE: DEA Proposed Rule: Docket No. DEA—218P: Electronic Prescriptions for Controlled Substances**

Dear Sir/Madam

Thank you for the opportunity to provide comments to the Drug Enforcement Agency (DEA) on its proposed rule that would revise current regulations to allow electronic prescribing (e-prescribing) of controlled substances, published in the Federal Register on June 27, 2008 (73 FR 36722). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 63,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the military.

APhA supports adoption of e-prescribing, e-prescribing standards, and other e-health initiatives that have the potential to enhance patient safety, advance patient care, facilitate optimal outcomes, and improve workflow efficiencies. However, changes and advancements in e-prescribing capabilities must be done with appropriate analysis of practice site utilization, workflow reality and the full impact that changes could have on all stakeholders and on the delivery of patient care. While there is ongoing improvement, successful implementation of e-prescribing requires addressing the challenges that may negatively affect prescribers' and pharmacists' ability to continue to deliver quality healthcare.

One of the remaining e-prescribing challenges is addressed in the Agency's proposal to allow e-prescribing of controlled substances when certain standards are met. APhA appreciates the Agency's support of e-prescribing and recognition of how this provision would benefit the health care system. However, we are concerned with several provisions in the proposed rule that would create undue burdens on prescribers and pharmacists that if left unaddressed, may have the unintended consequence of limiting prescriber and pharmacist uptake of e-prescribing of controlled substances. We offer the following comments on the proposed rule:

## **Pharmacy Issues**

### **§ 1306.05 Manner of issuance of prescriptions**

#### *Agent of the Prescriber - Long Term Care Pharmacy §1306.05(f)*

The proposal states that in long-term care (LTC) settings, prescriptions could be prepared by the secretary or agent of the prescriber but the prescriber must still digitally sign and send the e-prescription for a controlled substance.

- APhA is concerned that this provision does not recognize the current workflow unique to LTC, hospice, home health and other non-hospital, non-ambulatory care settings where the prescriber may write a prescription or make an adjustment to an existing prescription without being in proximity to the specific patient. In such cases, a prescriber depends on a LTC nurse to serve as an agent of the prescriber to communicate information about the patient within the facility and send prescription orders to a pharmacy, thus requiring a three-party communication system between the prescriber or the agent of the prescriber, the facility, and the pharmacy. Prescription orders may be sent from the prescriber, to the LTC facility, then to the pharmacy. Alternatively, prescription orders may be sent directly from the prescriber to the pharmacy with a second communication to the facility so the patient's medical record can be updated as required. We recommend that the Agency specifically recognize the unique prescribing three-party workflow needs for LTC and similar settings to allow these settings to fully participate and benefit from the adoption of e-prescribing.

#### *Other Agents of the Prescriber*

While not specifically described in the proposal, pharmacists play an important role in the medication prescribing process. Pharmacists assist prescribers by providing drug information, feedback on potential or known drug-drug interactions, medication therapy management services, assistance with formulary management issues, and by processing prescription orders from prescribers. In addition, some pharmacists serve as an agent of a prescriber when that pharmacist is working under a collaborative drug therapy management (CDTM) agreement with a prescriber and may have the authority to initiate, modify and/or adjust prescription orders pursuant to a protocol. Currently, 45 states include CDTM in some form in their state pharmacy practice acts. In some states, such California, Montana, Nebraska, New Mexico, Nevada, and North Carolina, the pharmacist may also register with the DEA and initiate, modify and/or adjust prescription orders for controlled substances pursuant to a CDTM protocol.

- APhA recommends that the Agency recognize the opportunity for pharmacists to serve as an agent of the prescriber pursuant to CDTM agreements authorized in state pharmacy practice acts and regulations. Without such recognition, pharmacists practicing in these environments would not be permitted to utilize e-prescribing systems for controlled substances which would have a negative impact on their practice environment, the prescribers they work with, and the patients they serve.

### **§ 1311.130 Electronic prescription system requirements: Transmission of an electronic prescription**

#### *Transmitting or printing an e-prescription §1311.130(b)(c)*

The proposal would not allow an e-prescribing system to print a prescription that was transmitted electronically and would not allow a prescription that was printed to be transmitted electronically.

- APhA appreciates the potential security issue of duplicate prescriptions for controlled substances (one printed and one sent electronically), however, we are concerned that the proposal does not allow flexibility for printing or faxing prescriptions due to transmission failures or glitches, printing copies for prescriber and pharmacy records, or for printing reference copies for patients.
- APhA recommends that the Agency allow for an exemption due to transmission failures or glitches that is similar to the e-prescribing exemption allowed by the Centers for Medicare and Medicaid Services for computer-generated faxes<sup>1</sup>. If an e-prescription transmission failure or glitch occurs, an e-prescription should be allowed to be printed at the point of prescribing so that the patient could take a printed prescription to their pharmacy, or so that a pharmacy's transmission system could convert the prescription to a fax to be printed in the pharmacy.
- APhA also recommends that prescribing systems have the flexibility to print an e-prescription with a clear message stating "this is not a valid prescription – informational only" or similar text so that it is apparent the prescription is for record or reference purposes only. Such a provision is critically important for LTC facilities and similar entities that require a printed prescription be maintained in a patient's chart.
- APhA recommends that the Agency consider requiring a void or recall function with e-prescribing systems for instances related to transmission failures so that the e-prescription could be voided and then allowed to be printed, or, if the print fails, allow the prescription to be sent electronically.

*Prescription Alteration § 1311.130 (f)(g)*

The proposal would not allow alteration of a prescription during the transmission process except for the purposes of interoperability of different software systems communicating with each other to transmit the data. In addition, the proposal would not allow pharmacists to alter an e-prescription for purposes of generic substitution or dosage clarification that may occur at the pharmacy and thus need to be documented on the prescription. As discussed in the proposed rule, the Agency described its understanding that generic substitution of a brand name medication with a generic alternative would occur at the point of prescribing using formulary management systems built into the e-prescribing program, thus being complete prior to the e-prescription being sent.

- APhA is concerned with the lack of flexibility that this proposal would create regarding generic substitution or dosage/direction clarifications requested and documented by pharmacists. While it would be ideal for all formulary management decisions to be made by the prescriber, there is still a need for such action at the pharmacy level. Based on the current practice of processing prescriptions, even paper prescriptions for controlled substances, pharmacists, not prescribers, may be in the position to identify and document generic substitution options. In addition, some state programs require generic substitution at the pharmacy unless the prescriber specifically makes a notation of "dispense as written". In addition, pharmacists document on a prescription any dosage and direction clarifications that they have requested from the prescriber, even for prescriptions that are received

---

<sup>1</sup> 42 CFR § 423.160(a)(3)(ii). After January 1, 2009, electronic transmission of prescriptions or prescription-related information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure and communication problems that would preclude the use of the NCPDP SCRIPT Standard adopted by this section.

electronically due to transmission errors and glitches unique to e-prescribing. We strongly recommend that the Agency recognize the need for pharmacists to document generic substitution and/or clarifications on the prescription record for a controlled substance e-prescription rather than requiring a new prescription for such an event.

### **§ 1311.160 Pharmacy System Requirements: Archiving the internal record**

#### *Digital Signatures for Records and Archiving*

The proposal would require that a copy of each controlled substance e-prescription received be digitally signed by the last intermediary that received/transmitted the prescription or the first pharmacy that received the prescription.

- APhA is concerned that the current proposal lacks the detail needed to determine, based on varying practice models, who is responsible for the digital signature. We recommend that the Agency provide further clarification on who is responsible for digitally signing an e-prescription and in which cases it is the last intermediary or the first pharmacy.
- APhA also recommend that the Agency provide clarification on digital signature requirements for those practice settings that use a single or closed system to transmit e-prescriptions between the prescriber and the pharmacy (e.g. managed care environments, clinics, safety-net providers), or those who use an electronic health record system (or other future technology) that does not require an outside entity to transmit an e-prescription.
- APhA is concerned that all pharmacy systems may not be capable of digitally signing e-prescriptions as such functionality may need to be purchased from the software vendor, and some software vendors may still need to develop such functionality. We recommend that the Agency take into consideration projected expenses for such functionality. In addition, we recommend that the Agency recognize the financial impact digital signatures may have on closed prescriber-pharmacy systems that, as currently proposed, would be required to ensure digital signature capabilities for both prescribers and pharmacies.

### **§ 1311.165 Pharmacy System Requirements: Prescription Processing**

The proposal would require pharmacists to verify that the prescriber's DEA registration is valid each time an e-prescription for a controlled substance is received by checking against the DEA Controlled Substances Act (CSA) Registration Database which is maintained and updated by DEA on a weekly basis.

#### *Validation using DEA CSA Database § 1311.165(a)*

The proposal's requirement for pharmacist to verify a prescriber's DEA number against the DEA CSA database prior to dispensing each e-prescription is more stringent than what is currently required for paper prescription where the numbers are generally stored electronically but not validated for each prescription prior to dispensing. For paper prescriptions, the DEA number is typically checked if the prescriber or the prescriber's DEA number is not in the pharmacy's system (the number is then added to the prescriber's profile), or the pharmacist suspects an invalid or fraudulent controlled substance prescription. Alternatively, the proposal would allow a service provider or intermediary to offer a service to perform the check and would require indication on the prescription record sent to the pharmacy that such a check had occurred.

- APhA is concerned that the proposed requirement for pharmacists, or services providers, to verify the DEA number on each e-prescription against an external DEA CSA registration database may cause delays in prescription processing, significantly impacting pharmacy workflow due to limited access to real-time internet connections, and may cause

interoperability issues between a pharmacy dispensing system set-up to automatically check the DEA CSA database while processing a prescription order. In addition, we are concerned with the potential confusion between different DEA registration verification requirements for electronic versus paper prescriptions. We recommend that the same standards for checking DEA registration validity for paper prescriptions apply to e-prescriptions for controlled substances.

- APhA does not support the proposal's suggestion that pharmacies could purchase the DEA registration database per store/company to facilitate the validation process. Access to such a database should be readily available through a secure system for pharmacies in any practice setting with out adding undue financial burdens.
- APhA is also concerned with the timeliness of DEA registration database updates. If a prescriber receives a new DEA registration number and sends an e-prescription to a pharmacy before the DEA's weekly update of the database, the e-prescription would be rejected, thus impacting patient access to medications.

*DEA Number Extensions § 1311.165(d)*

- APhA recommends that the Agency clarify pharmacy requirements for validating hospital facility extensions. These extensions are added to facility DEA numbers for the purpose of identifying which provider uses the number for prescribing, for example, a medical resident who does not have a DEA number but is authorized to prescribe under the facility's DEA number. While pharmacy software systems generally have the capability of storing extension codes, the codes are facility specific and are not standardized. Pharmacy systems are not equipped to verify all facility specific extensions. We recommend that pharmacy systems only be held accountable for validating those DEA registration numbers, facility codes or identification numbers that are available through the DEA CSA registration database and that the Agency consider ways to improve this system by standardizing the facility extension process.

**§ 1311.170 Pharmacy system requirements: Security**

*Record Retention and Geographically Separate Location § 1311.170(a)*

The proposal would require pharmacies to store backup records of controlled substance e-prescription data and audit records in a alternate storage site that is geographically separated from the primary storage site or pharmacy so as not be susceptible to the same hazards. It would also require that pharmacy systems be capable of generating electronic copies of records in readable and printable spreadsheets that must be readily available and reproducible upon request by authorized personnel.

- We are concerned that this requirement could have a significant financial impact on pharmacies to secure off-site storage locations, ensure security, and maintain access for prescription data backup systems. In particular, independent pharmacies and small or local chains may have difficulty meeting this requirement as they typically do not have facilities or corporate sites other than the pharmacy location itself. We also question the value of this proposal as no similar off-site storage is required for paper prescriptions for controlled substances. We believe that storage of controlled substance electronic prescription data would be adequately maintained through an on-site backup system at the pharmacy. Therefore, we recommend removing the "geographically separated" provision from the storage requirement.

- If the Agency keeps the “geographically separated” provision, APhA recommends that the Agency clarify the meaning of the term so that pharmacies have a better understanding on what type of facility, location, security and distance from the pharmacy is intended.
- APhA recommends that the Agency reduce the five year storage recommendation to two years to match the Agency’s storage requirements for paper prescriptions.
- APhA is concerned that the proposal may suggest that a separate software system be in place to store electronic prescription data and generate prescription and audit reports. We recommend that the Agency clarify which prescription data elements need to be stored so that the information for controlled substances will work with existing pharmacy software systems that are currently used to generate prescription reports. We would not support a provision that required the pharmacy to have a separate software system to generate reports for only controlled substance electronic prescriptions.

*Internal Audit Trail § 1311.170(b)(c)(d)(e)*

The proposal would require pharmacy systems to create and maintain an internal audit trail that indicates each time a controlled substance e-prescription is annotated, altered or viewed by any pharmacy staff. Specifically, the proposal would require: an audit of the pharmacy system every 24 hours to look for potential security incidents (such as attempted or successful unauthorized access, use disclosure, modification or destruction of prescription information); the system to generate an incident report of any auditable events; and the pharmacist to report any auditable events to the service provider within one business day.

- APhA is concerned with the administrative and financial burden that would be created by requiring the collecting and storing of such access data beyond what is currently required to meet state and federal privacy and security regulatory requirements, including requirements set by the Health Insurance Portability and Accountability Act of 1996 (HIPAA); no such system is required for paper prescriptions for controlled substances. While current e-prescribing systems capture access data for prescriptions that have been altered, they may not be to the level of detail proposed. For example, pharmacy systems typically do not capture when a prescription is simply viewed and not altered. There are many legitimate reasons for pharmacists and pharmacy staff to view a prescription through their normal course of daily practice, such as checking for drug-drug interactions, assisting with or performing medication therapy management services that are separate from the dispensing of a prescription, checking remaining refills, checking patient demographic information, or reconciling prescription claims. Pharmacy systems would need to significantly upgrade their information technology (IT) infrastructure and storage capacity to handle the collection and storage of this much data. We recommend that the Agency clarify that the logging of access data does not include viewing of a prescription record but is limited to those events when a prescription record is altered.
- APhA recommends that the Agency clarify that the proposed daily internal pharmacy audit could be set to run automatically rather manually. A manual check would be challenging, time consuming and costly for pharmacy staff.
- APhA is concerned that due to variations in day-to-day pharmacy workloads and staffing levels, pharmacy staff may have difficulties in meeting the one business day requirement for reviewing the internal audit and reporting any discoverable events. APhA recommends that the time frame in which pharmacies are required to report identifiable security events to service providers be extended from one business day to 72 hours upon discovery. In addition, we are concerned that pharmacy systems may not be capable of capturing all

potential auditable security events. We recommend that the Agency clarify its expectations of pharmacy system software capabilities.

*Third-party Audits § 1311.170(f)(g)*

The proposal would require pharmacy dispensing systems to undergo an annual third-party audit to verify that the security and e-prescribing system meet regulatory requirements.

- APhA is concerned that an annual audit requirement may be expensive, overly burdensome, unnecessary on an annual basis, and may serve as a barrier for pharmacies (especially small, rural, independent, and safety-net pharmacies) from accepting e-prescriptions of controlled substances. Pharmacies already have policies and procedures in place to meet state and federal privacy and security regulatory requirements, including HIPAA. In addition, an annual systems audit is not currently required for paper prescriptions for controlled substances. To avoid unnecessary administrative burdens and costs, we recommend limiting the requirement to an initial set-up and validation of the e-prescribing system for controlled substances in a pharmacy; verification of ongoing audit status could remain on file with DEA.
- We are also concerned that the costs for evaluating the impact of the annual audit requirement for vendors (with costs passed down to customers) may have been underestimated in the proposal's economic impact. While we appreciate that the proposal discussed the costs of electronic transaction fees, the additional cost passed down to the pharmacy by the pharmacy system vendor for processing an e-prescription does not appear to be included. We believe that pharmacies could experience significant cost increases due to e-prescribing transaction fees. We recommend that the Agency provide a more accurate estimate by evaluating the potential economic impact of this requirement against a pharmacy's average net revenue, not a pharmacy's percentage of total sales which would likely lead to an underestimate of the economic impact.

*Safety-Net Providers*

We are concerned that the Agency did not adequately address the financial impact this provision would have on safety-net providers that offer medical and pharmacy services to the uninsured. Examples of safety-net providers include Federally-Qualified Health Centers (FQHC), Disproportionate Share Hospitals (DSH), state AIDS Drug Assistance Programs (ADAP), and certain family planning and STD clinics. These clinics generally operate by using a closed prescriber-pharmacy structure that utilize electronic communication system or networks that do not include an external third-party or intermediary. Because safety-net providers operate as a single closed system, the clinic would be responsible for paying for prescriber and pharmacy requirements, the service provider requirements (pharmacy information system vendor), and be responsible for verifying registration, auditing daily logs, and storing prescription records. APhA is concerned that these financial, logistical and administrative challenges may limit adoption of e-prescribing of controlled substances at safety-net facilities.

**§ 1311.180 Record Keeping**

*E-record Retention and Storage*

- APhA is concerned that the proposed five year record retention requirement for e-prescriptions for controlled substances is inconsistent with the current two year requirement for paper prescriptions for controlled substances. Given that many states and other programs

have varying requirements for record keeping, we recommend limiting confusion by ensuring the electronic record keeping requirements match those for paper prescriptions.

- APhA is concerned that the proposal does not adequately recognize the likely financial burdens on pharmacies, including long-term care and safety-net pharmacies, to meet the proposed storage requirements. We expect the requirements would have a significant impact on cost, staff time and storage space. We recommend that the Agency broaden its impact analysis to more accurately reflect costs associated with technology, hardware and software upgrades, staff resources, and quality improvement/oversight.

## **Prescriber Issues**

### **§ 1311.105 Electronic prescription system requirements: Identity proofing.**

#### *Risk Assessment and Assurance levels*

The proposal would require in-person identity proofing to ensure that only licensed and registered practitioners are granted the authority to sign e-prescriptions for controlled substances. Service providers would be required to receive and maintain a record for each prescriber that includes documentation from an entity permitted to do in-person identity proofing. Entities would include sites approved by DEA such as DEA-registered hospitals, state pharmacy licensing boards or controlled substances authorities, or state or local law enforcement agencies. The service provider's record would need to also include verification that the service provider checked with state licensing boards and the DEA to determine that the prescriber's license is current and in good standing, a list of states in which the prescriber intends to practice and prescribe controlled substances electronically, along with the specific state licensing information.

- APhA is concerned that not all service providers are equipped to meet this requirement and that the proposal does not adequately evaluate the impact that such a record retention requirement would have on an entity. We expect the requirements would have a significant impact on cost, staff time and storage space. We recommend that the Agency broaden its impact analysis to more accurately reflect costs associated with technology, hardware and software upgrades, staff resources, and quality improvement/oversight.
- We are concerned with the varying references to service provider versus intermediary in this section and throughout the proposal. We recommend that the Agency clarify the definitions and reference to these terms as this would help in identifying which entity is responsible for which requirements.
- We are also concerned that the proposal assumes that that entities listed as authorized to provide identity proofing would be interested or willing to perform such services as suggested by the Agency. The Agency does not appear to have authority to require DEA-registered hospitals, state pharmacy licensing boards or controlled substances authorities, or state or local law enforcement agencies to perform such duties, and has no assurance that they would be willing and interested. Additionally, there are significant variations in provider access to such entities as they are not equally distributed across individual cities or states, nor are they easily accessible or available in rural locations. We are also concerned that the Agency did address costs to providers that may be associated with this provision.
- To improve health care provider access to DEA-approved identity proofing entities, we recommend that service providers be included since they are often the entity that has more direct contact with the health care provider.

### **§ 1311.110 Electronic prescribing system requirements: Authentication**

#### *Protocol and Process – Electronic Signature Tokens §1311.110(b)*

The proposal would require that e-prescribing systems for controlled substances only be accessible via two authentication factors, including uniquely coded hard tokens for each authorized prescriber. The prescriber would be required to use a hard token (such as a PDA, cell phone, smart card, thumb drive, or multi-factor onetime password token, etc.) that would only be activated by entering a password or biometric before the token could be used to electronically sign the prescription.

- APhA is concerned that this provision may serve as a barrier for prescriber uptake of e-prescribing of controlled substances, especially for those prescribers practicing at multiple sites or in multiple states who would face the challenge of managing different tokens for different prescribing systems and for different states, even if several authentication factors are stored on one token. The logistical challenges for prescribers would also include securing different tokens or devices when not in use and ensuring the appropriate token authentication factors match the appropriate system and/or state. We are concerned that these challenges may serve as a disincentive for prescribers and practice settings and limit adoption of e-prescribing of controlled substances.
- We are also concerned that the proposal depends on token authentication devices that may be limited to today's technology and may not be flexible to allow adoption of future IT advances that would facilitate e-prescribing. In addition, we are concerned that some systems may actually block the use of token devices due to security concerns.

#### *Timing-out and Signing Prescription § 1311.110 (c)*

The proposal suggests that there should be a limit on the amount of time that a prescriber has to pause while completing the prescription order, specifically, if the system is not used for more than two minutes the prescriber would be automatically locked out of the system.

- APhA is concerned that the “timing-out” provision would create administrative and workflow challenges if a prescriber were to pause during the e-prescribing process to review patient information or look-up/request drug information. We recommend that the timing-out provision be removed.

### **§ 1311.135(a) Electronic prescribing system requirements: Revocation of access authorization**

#### *Lost or Stolen Tokens*

- APhA recommends that the timeframe that prescribers have to report a lost, stolen, or compromised token be extended from 12 hours to 24 hours after discovery or the next business day to allow prescribers more time to file a report. In addition, we recommend that the Agency clarify the meaning of the term “compromised”.

### **§ 1311.140 Electronic prescribing system requirements: Providing log of prescriptions to practitioner**

#### *Prescriber Monthly Log Review*


The Agency proposes to require prescribers to review a monthly log of all their controlled substance electronic prescriptions as provided by the service provider (not a log generated by the pharmacy). The service provider would be required to maintain records of the prescriber's review of the monthly logs.

- APhA questions the value of this requirement as it is not part of existing practice for paper prescriptions for controlled substances. In addition, it would be very time consuming, and establishes unreasonable expectations of prescribers. We recommend that this provision be removed from the proposal.

In conclusion, adoption of e-prescribing technology has the potential to significantly increase efficiency, enhance patient safety, improve prescribing practices and formulary management, provide access to a patient's medication history and drug utilization, alert prescribers of possible drug interactions, reduce phone calls between prescribers and pharmacists, pharmacists and plans, and protect our drug supply and patient privacy. Pharmacy systems and prescribing processes have had substantial growth in electronic information exchange and we support the Agency's commitment to further advance the exchange of e-prescriptions for controlled substances. However, as provided in our comments, successful implementation and uptake of e-prescribing of controlled substances will require addressing the challenges that may negatively impact prescriber and pharmacy uptake. Success also requires that all stakeholders, including frontline prescribers and pharmacists responsible for interfacing with these systems, work together with the Agency to find the best solutions for advancing e-prescribing.

Thank you for the opportunity to provide comments on the proposed rule. We look forward to continuing to work with the Agency on this important issue. If you have any questions or require additional information, please contact Marcie Bough, Director of Federal Regulatory Affairs at (202) 429-7538 or at MBough@APhAnet.org.

Sincerely,



John A. Gans, PharmD  
Executive Vice President and CEO

JAG/mb

cc: Harry P. Hagel, RPh, MS, Senior Vice President, Government and Professional Affairs  
Kristina E. Lunner, Vice President, Government Affairs  
Marcie A. Bough, PharmD, Director, Federal Regulatory Affairs