

VIA Electronic Submission to <http://www.regulations.gov>

June 1, 2010

Mark W. Caverly
Chief, Liaison and Policy Section
Office of Diversion Control
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Re: Docket No. DEA-218; 21 CFR Parts 1300, 1304, 1306, and 1311 Electronic Prescriptions for Controlled Substances; Interim Final Rule with Request for Comment (RIN 1117-AA61)

Dear Mr. Caverly:

Thank you for the opportunity to submit our comments on the above-referenced interim final rule (IFR). The National Community Pharmacists Association (NCPA) supports the Drug Enforcement Administration's (DEA) efforts to allow for electronic prescribing of controlled substances (EPCS). NCPA believes that adoption of this rule will support the goals of implementing a comprehensive health information technology (HIT) nationwide infrastructure to improve efficiency and quality in the health care system by encouraging uptake of electronic prescribing for all medications.

NCPA appreciates the revisions DEA, working in conjunction with the Centers for Medicare and Medicaid Services (CMS); the Office of the National Coordinator for Health Information Technology (ONC); and others, updated from the 2008 proposed rule for EPCS. Our comments provide several recommendations to improve safety and efficiencies in EPCS and to increase the likelihood for adoption by pharmacies. NCPA represents America's community pharmacists, including the owners of more than 22,700 community pharmacies, pharmacy franchises, and chains. Together they represent an \$88 billion health-care marketplace, employ over 65,000 pharmacists, and dispense over 40% of all retail prescriptions.

Transmission of Digital Signatures

NCPA encourages DEA to work with NCPDP to require the adoption of a field to accommodate digital signatures within the SCRIPT standard and to provide guidance regarding specifications for such signatures. To date, a business reason has not existed for the adoption of a digital signature within the SCRIPT standard and, therefore, a specific field is not included.

NCPA believes that an interim solution exists within the SCRIPT standard that allows for transmission of a digital signature indicator in controlled substance electronic prescriptions. NCPA encourages DEA to work with NCPDP and intermediaries to implement this interim solution and then adopt a workable final standard that allows for transmission of digital signatures within the standard.

NCPA strongly recommends that DEA recognize the last intermediary, rather than the pharmacy, as the entity that will digitally sign and archive electronic prescriptions for controlled substances. NCPA is concerned that pharmacy applications currently used by its members do not have the capability to digitally sign prescriptions they receive.

Communications involving electronic prescriptions do not normally stream directly from prescriber to pharmacy. DEA recognizes these issues in the IFR by noting that several intermediaries, as many as three to five, may be involved in the transmission process. A pharmacist must verify the validity of an EPCS in the same manner that it verifies any other prescriptions according to DEA's "corresponding responsibility" doctrine¹ and noted throughout the IFR. This verification process includes confirmation of the prescriber's digital signature (if sent), required prescription content, and the prescriber's DEA number.

If a pharmacy receives an unsigned prescription from an intermediary, the pharmacist may have to take extra steps to confirm the validity of the prescription. This may require the pharmacy to track the transmission through several steps, a process that is unnecessarily time consuming and increases the possibility of a fraudulent prescription sent through the system. Intermediaries manage the stream of communication among prescribers, payers, and pharmacies and therefore are in a better position than pharmacies to ensure digital signature of the prescription because of the ability to more thoroughly track the transmission. For this reason, NCPA encourages DEA to require that intermediaries be responsible for ensuring valid digital signatures on all electronic prescriptions for controlled substances.

Quality and Efficiency in Medication Administration and Dispensing in Long-Term Care Facilities (LTCFs) and Other Alternative Sites

NCPA contends that the IFR does not clearly recognize workflow issues related to EPCS in LTCFs where nursing personnel administer medications and an off-site pharmacy provides medications. More than half of NCPA members provide pharmacy services to LTCFs and therefore have distinct concerns related to how EPCS will occur in these settings. Prescribing and dispensing in these settings involve three-way communications among the pharmacy, prescriber, and the nurse serving as the primary point of contact. Most LTCFs do not employ a full-time physician. Therefore, nursing staff is responsible for communicating directly with physicians for purposes of patient care and documentation.

Following communication with prescribers, nursing staff provide the appropriate follow-up care, including communication of prescription information, and documentation in the medical record. Electronic health record (EHR) systems for LTCFs recognize the nursing based model, but DEA does not recognize nursing staff as the appropriate agent of the prescriber for purposes of communicating controlled substance prescription information in any form.

NCPA urges DEA to support the nurse as the agent of the prescriber to ensure efficiency and quality in the medication management and administration process for LTCFs. Without changes to DEA's existing policy, the adoption of EHRs and EPCS may be potentially delayed even further. Furthermore, NCPA seeks clarification regarding whether a LTCF itself must be a DEA registrant if their system is transmitting electronic prescriptions for controlled substances. NCPA urges DEA to allow prescribers to transmit prescriptions electronically through computers housed at non-registered LTCFs.

Prescriber-Pharmacy Communications and Transmission Issues

DEA clarified certain areas of pharmacy's concern from the proposed rule regarding changes that a pharmacist may make to a prescription, but certain communication issues still remain unclear in the IFR. The rule recognizes existing DEA and state laws allowing a pharmacist to make dosage changes to a prescription pursuant to communication with the prescriber. However, the IFR does not specify whether a pharmacy may transmit a communication to the prescriber within the SCRIPT standard to implement these changes or if a new prescription will be required when changes are necessary.

Would pharmacists be required to communicate with the prescriber by telephone or other electronic means outside of the SCRIPT standard, such as an email? DEA must allow pharmacists to make any changes to the prescription electronically without the need to manually make changes or generate a new prescription.

Related to transmission errors, DEA should work with the pharmacy industry to develop a mechanism to allow for an electronic process to correct transmission errors that currently requires prescription orders to be in paper form in these instances. The goal of a nationwide HIT infrastructure and EHR system is to virtually eliminate all paper-based transactions and records and the current DEA proposal falls short of this goal. NCPA recommends that DEA make this a priority area in developing further guidance and improvements related to EPCS.

Adoption of Updated Transaction Standards

Updates for the SCRIPT standard require a time-consuming process that includes HHS formal rulemaking. DEA should be mindful of the time required to update standards when making changes to the EPCS rule or requirements in the future.

Institutional Practitioner Suffixes

DEA is requiring that e-prescribing applications have the capability to accept and document institutional codes provided to residents, interns, and foreign-trained physicians within a hospital or institutional practice. Currently, these institutional codes cannot be verified by a commercially available source, making prescription verification by pharmacists difficult for controlled substance prescriptions regardless of the manner of transmission.

Last year, DEA sought public input on standardization and public availability of institutional DEA suffixesⁱⁱ. NCPA and others in pharmacy provided suggestions and input in this area. NCPA reiterates its comments here. Pharmacies have reported difficulty in obtaining institutional codes for practitioners and prescription blanks oftentimes do not provide much clarity to contact prescribers for this information. Some NCPA members have even reported that institutions will not provide these codes to pharmacies.

NCPA recommends that individual DEA numbers be assigned earlier in physician training to allow for direct tracking of prescribers throughout their career. Institution-specific suffixes make tracking residents difficult, especially if they train in multiple facilities, and prescribing history cannot be linked. If DEA seeks to identify individual prescribers, then a permanent, unique identifier must be assigned to the person and not tied to the practice location, as is the current standard.

If this recommendation is not a feasible option to the DEA, then NCPA recommends that the internal suffix code follow a standard that pharmacy management systems can accommodate. NCPA recommends that DEA work with the pharmacy industry to ensure that data fields in the SCRIPT standards can accommodate these suffixes.

Lack of Certification Entities for Pharmacy Applications May Delay Uptake and Implementation

Another issue of concern to NCPA is the lack of certification entities that understand pharmacy applications. DEA acknowledges in the IFR that it could not identify a certification standards process or organization for certifying pharmacy application systems for security or record retention and, therefore, uptake and implementation of EPCS may be delayed beyond the 7-year estimate.ⁱⁱⁱ

NCPA recommends that DEA recognize Surescripts as a certifier of pharmacy applications for EPCS purposes. Surescripts has been certifying pharmacy applications for e-prescribing for over seven years, and the organization thoroughly understands pharmacy applications operations. This familiarity with pharmacy applications will allow Surescripts to give specific, practical guidance to vendors of such systems to comply with the IFR requirements. Surescript's understanding of pharmacy systems will also reduce programming time and attendant costs, which in turn will allow EPCS to move forward in a more timely fashion.

DEA, CMS and ONC should ensure that certification standards for pharmacy applications meet DEA requirements while ensuring that all pharmacies, particularly small pharmacies, may access the appropriate technology in an affordable manner. NCPA recommends that as appropriate pharmacy certifying entities become available, DEA publish a current list on its website.

Cost Considerations for Community Pharmacy

DEA's cost analysis associated with adoption of EPCS for pharmacies may be underestimated for some community pharmacies. While the cost of programming and audits will be primarily the

responsibility of the application provider, some pharmacies may have to invest in substantial upgrades to systems to meet DEA's functionalities, security, and recordkeeping requirements.

Furthermore, pharmacies would have to provide extensive employee training and possibly adjust workflow functions as the result of the access control requirements and other security issues required in the IFR. These labor costs may seem minor for some pharmacies, but for independent community pharmacies that often employ a limited number of personnel, the costs could be significant because of the need to pay overtime for training employees, hire additional employees, or to contract with consultants to prepare pharmacies to participate in EPCS.

Additional costs could delay adoption which could also eventually delay the adoption of EHRs. DEA should work with CMS and ONC as it refines the IFR to provide grant opportunities for the adoption of certified pharmacy applications that allows the systems to be studied and also would facilitate further adoption of EPCS.

NCPA appreciates the opportunity to comment on the IFR for EPCS and believes that implementation is a positive step toward improving the uptake of e-prescribing and the development of an HIT infrastructure. If you have any questions, please contact me at (703) 683-8200 or john.coster@ncpanet.org.

Sincerely,



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National Community Pharmacists Association

ⁱ 21 CFR 1306.04.

ⁱⁱ 74 Fed. Reg. 46396-46399. *Identification of Institution-based Practitioners*. (September 9, 2009).

ⁱⁱⁱ 75 Fed. Reg. 16296 (March 31, 2010).