



June 1, 2010

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

[Submitted electronically at: www.regulations.gov]

Re: Docket No. DEA-218I, Electronic Prescriptions for Controlled Substances, Interim Final Rule with Request for Comment

Dear Sir/Madam:

The American Pharmacists Association, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, and the National Community Pharmacists Association appreciate the opportunity to comment to the Drug Enforcement Administration (DEA) on its interim final rule (IFR) with request for comment on the electronic prescribing of controlled substances, published in the Federal Register on March 31, 2010 (75 FR 16236). Our collective professional pharmacy organizations represent pharmacists working in all patient care settings within the health care system. We offer the following comments regarding the IFR.

Our organizations appreciate DEA publishing this IFR as it moves us one step closer to providing practitioners with the option of creating and transmitting controlled substance prescription orders electronically and allowing pharmacies the ability to receive, dispense and archive these electronic prescriptions. We also appreciate efforts by DEA to work with the Department of Health and Human Services on issues related to e-prescribing and implementation; explain improvements and changes that address many of the challenges highlighted in comments on the proposed rule; and provide detailed information, FAQs, and other resources on DEA's Web site regarding the IFR.

As the health care system continues to move to a complete electronic infrastructure for health information technology (HIT), it is essential that a structure and function to transmit and receive all prescription orders, controlled substances and non-controlled substances, be developed and adopted in a way that facilitates operational efficiencies, ensures security and patient privacy, restricts diversion, and ensures patient safety.

The IFR outline for the prescribing of controlled substances via electronic means creates a system which facilitates the e-prescribing of controlled substances. However, our organizations request that DEA consider the following recommendations as it finalizes the IFR to better ensure that pharmacists have the needed information to implement and comply with the final regulations:

- Provide additional clarification on changes to electronic prescription orders and communications of these changes between a pharmacist and a registrant practitioner;
- Provide additional clarification on the use of digital signatures and the responsibilities associated with verification of a digital signature;
- Provide additional guidance and work in conjunction with the pharmacy industry to standardize internal code number systems added to the standard 9 digit DEA registration format;
- Ensure that an appropriate number of certification or audit entities exist to meet the needs of pharmacy systems in all types of patient care practice setting (e.g. acute care, long term care, community/retail);
- Provide additional clarification on re-routing/transferring of prescriptions;
- Provide additional clarification on workflow procedures for long-term care settings; and
- Consider additional options for emergency fill procedures.

Changes to electronic orders and communication of these changes

As stated in the IFR, if the content of any of the information required for a controlled substance prescription is altered during its transmission, the prescription is deemed invalid and the pharmacy may not dispense the controlled substance. We appreciate the outline of this procedure but recommend that DEA also provide additional clarification on the process of verifying electronic prescription orders and the communication of changes between the registrant practitioner and the pharmacist. In practice, pursuant to the applicable individual state laws and regulations, pharmacists routinely obtain clarification of prescription orders after secure receipt of the electronic prescription from the transmitting practitioner. As outlined in the IFR and the DEA FAQ document, circumstances that invalidate an electronic controlled substance prescription order during transmission do not apply to changes that occur after receipt at the pharmacy and that changes/clarifications made by the pharmacist are governed by the same laws that apply to paper prescriptions.

Additionally, the current National Council for Prescription Drug Programs (NCPDP) SCRIPT standard supports bi-directional electronic communication between a registrant practitioner and a pharmacy. This bi-directional electronic communication mechanism provides a means by which clarification of prescription orders can be facilitated without implementation of manual procedures such as phoning the registrant practitioner for verbal explanation. We request clarification from DEA that if changes are communicated between the registrant practitioner and a pharmacy via a secure bi-directional format, that the changes reflected in the final transmission from the practitioner to the pharmacy are legally permissible and valid, thus subject to the same laws and regulations that apply to paper prescriptions. Additionally, we recommend that DEA provide guidance clarifying how a standard, such as the NCPDP SCRIPT standard, would apply to provisions authorized in the IFR. Furthermore, we recommend that DEA provide guidance that a final transmission between a registrant practitioner and a pharmacy that reflects all changes

requested verbally or electronically represents a full and complete electronic prescription order that replaces and invalidates the previous transmission prior to changes.

Use of digital signatures and responsibilities associated with verification

We appreciate that the IFR states that DEA will allow the use of digital signatures for non-federal agencies to facilitate the transmission of controlled substance electronic prescriptions between a registrant practitioner and a pharmacy, specifically in those transmissions not using intermediaries. We support this requirement, however, we request that DEA address current marketplace gaps that may inhibit the implementation of such technology into practice. Currently, a specific digital signature field does not exist in the NCPDP SCRIPT standard. We urge DEA to continue to work with industry and NCPDP to address this need.

Additionally, we are concerned about instances stated in the IFR where an electronic prescription order for a controlled substance may not be translated/modified (especially the DEA “data”). We interpret this provision to mean that the translation/modification by an intermediary (an entity that facilitates the transmission of electronic prescription orders) would render the digital signature invalid. Considering that the vast majority of electronic prescriptions are processed by an intermediary, we request DEA clarify the meaning and intent of the application of digital signatures on the security of the DEA “data.” If it is DEA’s intent that individual fields of an electronic controlled substance prescription be digitally signed rather than the entire prescription, the implementation would be significantly more complex and require significant changes to standards and system capabilities.

Regarding digital signature verification, we request additional clarification regarding the verification processes by a pharmacy to ensure the validity of digital signatures received. As stated in the IFR, digital signatures will not be supplied by or linked to the DEA registration; rather, they will be supplied and furnished by a certification authority cross certified with the Federal PKI Policy Authority. Since an individual practitioner will have in some cases multiple digital signature keys for multiple practice settings and electronic record keeping systems, we request clarification on the verification process for the receiving pharmacy versus the last intermediary on not only the validity of the digital signature but also the association of the digital signature to a specific location.

Internal code number systems

We appreciate that DEA had requested comments (Docket No. DEA-321, November 2009) on institution-based internal code numbers systems and considered submitted comments in the development of the IFR. In the IFR, DEA states that it should be possible for NCPDP to add a code for an institution-based DEA number that allows up to 35 characters (with the first nine characters in the standard DEA format and the remaining characters providing sufficient space to accommodate most institutional coding systems) until DEA and the industry can standardize the format. We encourage DEA to continue to work with NCPDP and other stakeholders to revise the standard’s provider identifier structure field to ensure institutional coding systems can be accommodated as quickly as possible. It is our understanding that not all systems are capable of capturing additional data fields beyond the initial DEA number. To accommodate a standardized

format for internal code numbers in pharmacy management systems, changes will need to be made to pharmacy dispensing systems in some circumstances, including the reformatting of data fields to ensure the extension number is properly utilized.

In addition, we recommend that DEA facilitate the development and maintenance of a central database that includes every institution and extension number associated with the individual practitioner or explore alternative options to manage institutional coding systems.

Certification/audit entities

We appreciate and support DEA expanding the categories of third-party auditors to become certified for the e-prescribing of controlled substances beyond those who perform SysTrust, WebTrust, or SAS 70 audits to also include certified information system auditors (CISA) who perform compliance audits as a regular ongoing business activity. The CISA certification is sponsored by the Information Systems Audit and Control Association (ISACA) and is recognized by the American National Standards Institute under ISO/IEC 17024. The certification is required by the Federal Bridge Certification Authority for third-party auditors and by the Federal Reserve Bank for its examiners, and is approved by the Department of Defense. We agree with DEA that allowing other certified IT auditors will provide application providers with more options and potentially reduce the cost of a certification audit.

However, while we support DEA expanding the auditor choices for the industry, we are concerned that the expanded list may not be an appropriate number of certification or audit entities to meet the needs of pharmacy systems in all types of patient care setting (e.g. acute care, long term care, community, and managed care). Our organizations are also concerned with the capabilities of these entities to begin certification in the capacity outlined by DEA in June 2010. We request that DEA provide additional information to pharmacy dispensing system vendors, pharmacies, and registrant practitioners about the specific entities available for certification, and details regarding their capabilities and readiness to serve in this capacity.

Re-routing/transfers of prescriptions

We request further clarification on the applicability of re-routing and transfer procedures for C-II prescriptions. We anticipate that instances will arise where a C-II prescription is received, opened and processed at a pharmacy but dispensing may not occur at that pharmacy. This change in pharmacy may be due to patient preference of where to pick-up their prescription, the medication being out of stock, formulary/insurance coverage determinations, or other issues. Because there is no paper-prescription and no means to transfer an opened C-II prescription to another pharmacy, we recommend DEA develop additional guidance to address this specific issue. (For example, is a new prescription required to be sent to the new pharmacy rather than transferring the prescription?)

We also question the capabilities of all pharmacy dispensing systems to be able to transmit CIII-V electronic prescriptions to other pharmacy systems via an intermediary. We recommend DEA work with stakeholders to establish standards needed to ensure such transfers may occur electronically, rather than relying on the pharmacist to phone another pharmacy to facilitate the transfer.

Long-term care settings

We ask for additional clarification on processes and procedures related to long-term and post-acute care settings, and utilization of agents of the prescriber in the prescribing process and workflow. Such facilities include skilled nursing, nursing and assisted living facilities; home health, independent and adult care environments; rehabilitation facilities; long-term acute care hospitals; and hospice. We are concerned that implementation in these practice settings may not be adequately addressed to account for the unique three-way communication workflow between a registrant practitioner (or nurse serving as an agent of the prescriber), the facility, and the pharmacy. Specifically, we recommend that DEA clarify definitions for the terms “installed electronic prescription application” and “registered location”, and how these definitions apply to such care settings and the transmission of the prescription order.

Emergency fills

We appreciate that DEA outlines in the IFR procedures for processing an emergency oral prescription that is reduced to a written prescription dispensed with the understanding that the pharmacy will receive a written or electronic prescription within 7 days of the emergency oral prescription. We recommend DEA also consider also allowing faxed prescriptions in emergency situations in cases of electronic prescribing network failures or communication problems that may preclude the use of electronic prescribing systems.

Additional recommendations

We request that DEA also consider the following recommendations:

- Revise reporting requirements of identifiable security problems generated from internal audits to allow more time for pharmacy staff to comply and report security incidents to DEA;
- Revise and clarify frequency of pharmacy dispensing system audits by third-party auditors to be less frequent and limited to changes to functionality outlined in the IFR rather than any change to a pharmacy’s dispensing system functionality.

Additional support for IFR revisions

Finally, we thank DEA for addressing several provisions that were of concern in the proposed rule related to pharmacy implementation and requirements. Specifically, we appreciate the following revisions:

- Auditable functions include electronic controlled substance prescription orders that are received, annotated, modified, or deleted and do not include generic substitution or each time a prescription file is opened;
- Record retention for electronic controlled substance prescription orders is two years rather than five;
- Record storage location is not specified rather than requiring specific off-site storage.

Conclusion

Again, thank you for the opportunity to provide comments on this important issue. We look forward to continuing to work with DEA and other public and private stakeholders to facilitate implementation of the electronic prescribing of controlled substances.

Sincerely,

American Pharmacists Association
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
National Community Pharmacists Association

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