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September 22, 2008

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

Re: Docket No. DEA-218, Electronic Prescriptions for Controlled Substances

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Notice of Proposed Rulemaking relating to electronic prescriptions for controlled substances (proposed rule). ASHP represents pharmacists who practice in hospitals and health systems. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings (including inpatient, outpatient, home care, and long-term-care settings), and pharmacy students.

ASHP supports the use of computerized entry of medication orders or prescriptions by the prescriber when (1) it is planned, implemented, and managed with pharmacists' involvement, (2) such orders are part of a single, shared data-base that is fully integrated with the pharmacy information system and other key information system components, especially the patient's medication administration record, (3) such computerized order entry improves the safety, efficiency, and accuracy of the medication use process, and (4) it includes provisions for the pharmacist to review and verify the order's appropriateness before medication administration, except in those instances when review would cause a medically unacceptable delay.

As medication experts, pharmacists play several roles in the prescribing process. Providers consult with pharmacists prior to prescribing medications to their patients, and pharmacists dispense the prescriptions. Pharmacists also meet the primary care needs of patients by providing medication management and, in states where it is authorized, collaborative drug therapy management (CDTM). CDTM is a multidisciplinary process for selecting appropriate drug therapies, educating patients, monitoring patients, and

continually assessing outcomes of therapy. Under CDTM, the patient's physician and pharmacist establish an agreement under which the pharmacist is delegated authority to manage specific aspects of the patient's medication therapy. As the DEA develops its final rule, ASHP encourages the agency to recognize that it will have a significant impact on both the drug therapy management and dispensing roles of the pharmacist.

Additionally, ASHP believes that this proposed rule should only apply to electronic prescribing for ambulatory patients, and should not be confused with the use of computerized prescriber order entry (CPOE) for the inpatient communication of medication orders.

ASHP has organized its comments to address Sections II, and IV through IX. of the proposed rule.

II. Framework of the Pertinent Provisions of the CSA and DEA Regulations

DEA states that, as a rule, pharmacists themselves do not have the authority to independently prescribe controlled substances. However, pharmacists who are considered mid-level practitioners are recognized by DEA as controlled substance registrants. The agency further notes that pharmacists rely on the prescription, as written by the individual practitioner, for authority to conduct dispensing. As noted previously, some pharmacists meet the primary care needs of patients by providing collaborative drug therapy management. These pharmacists may be unable to provide needed patient care if they are not recognized as providers with prescribing authority.

- **ASHP recommends that DEA not exclude pharmacists as providers under the proposed rule.**

IV. Existing Electronic Prescription Systems

In the proposed rule, DEA recognizes that many pharmacy systems have been reprogrammed to capture data from electronic prescriptions directly, but few electronic prescriptions are currently sent.

- **ASHP recommends that there be a centralized database of pharmacies that support e-prescribing so that vendors can notify prescribers which pharmacies can receive e-prescriptions.**

Additionally, NCPDP SCRIPT standard and Surescripts do not always support discrete data elements for dosing, route, and frequency. Nor do these entities mandate a standard drug nomenclature. Without explicit standards for medication names, dosing, route, and frequency, semantic interoperability is not assured between the physician and pharmacy systems. It is a well known principle that semantic interoperability is a prerequisite to increasing patient safety and value in transferring data between systems.

- **DEA should identify a way to support and encourage NCPDP SCRIPT and Surescripts to support discrete data elements for dosing, route, and frequency, to help prevent fraud and increase patient safety.**
- **DEA should support and encourage the adoption of a standard drug nomenclature.**

ASHP notes that current e-prescribing systems protect against noncontrolled substance prescription forgery, fraud, etc., by revalidating the prescriber at the moment of signing/transmitting a prescription. However, the use of timeouts is easily circumvented and not typically useable as a protection.

DEA acknowledges that complexity in the electronic prescription network arises from practitioners who serve on the staff of hospitals. Hospital electronic record systems are written in computer languages other than NCPDP SCRIPT, often HL7. If a hospital staff practitioner writes an electronic prescription for a patient to fill at a pharmacy outside of the hospital, the intermediaries or pharmacies have to be able to translate the electronic prescriptions from HL7 to their own computer system language. Furthermore, hospital staff practitioners are not required to register with DEA. They are allowed to issue prescriptions under the hospital DEA registration number with a hospital-assigned extension that identifies the specific person issuing the prescription. DEA does not dictate the format of the extension. In at least some cases, pharmacy computer and computerized electronic order entry systems have not been able to handle these extensions. Furthermore, some states also require the Department of Public Safety (DPS) or equivalent department number, presenting a second challenge to storage and transmission.

ASHP notes that neither NCPDP SCRIPT nor HL7 is a programming language, but an output format that is usually easily produced. Hospital systems generally use HL7 for intersystem communications because it can describe the panoply of transactions that must be handled. The same tools that can generate HL7 can easily generate NCPDP SCRIPT, presuming that the required data are available. Any system that purports to generate an e-prescription should do so using the NCPDP SCRIPT standard, if that is the standard DEA supports.

- **ASHP recommends that DEA establish NCPDP SCRIPT as the standard for e-prescribing inter-system communication, and mandate that controlled substance prescriptions be communicated in that format, augmented as necessary to support DEA requirements.**

ASHP notes that the manner in which the DEA number extension may be applied will determine whether or not the DEA number itself may be validated. Whichever method is used to support such extensions must permit the original DEA number to be validated, and must permit the e-prescribing system and receiving pharmacy systems to validate

whether or not the DEA number in question represents a facility for which extensions are permissible.

- **ASHP recommends that DEA examine the validation of the DEA number with the extension, and find an industry solution, since the use of an institutional DEA number is not a person identifier under these circumstances.**

This discussion of prescription transmission presumes that an e-prescription is necessarily being transmitted between different systems. DEA must consider and implement appropriate language to be used when the prescribing system and the fulfilling pharmacy system are part of the same computer system, as may often be the case in a hospital. In this instance, data are transmitted within the same technical infrastructure. There is no need to use external transmission intermediaries, such as SureScripts.

V. Potential Vulnerabilities That Need To Be Addressed To Prevent Electronic Prescribing From Contributing to the Diversion of Controlled Substances

ASHP notes that there are several potential abuse scenarios possible when systems can both electronically transmit and print prescriptions. For example, when a prescription is both printed for the patient and transmitted by fax to a pharmacy, the prescription could be taken to another pharmacy and filled in duplicate. As noted subsequently, it is important that prescriptions in general, and controlled substance prescriptions in particular, are either transmitted or printed, but not both.

VI. Alternatives Considered

DEA is proposing that both the electronic prescription service provider and the pharmacy system provider would need to obtain annual third-party audits for security and processing integrity. The service provider would have to generate a monthly log, which practitioners would be required to check for obvious anomalies. ASHP believes that all system vulnerabilities should be limited through technology where possible. Alternatives should not create additional paperwork or a need for mandatory third party audits, which add to overhead costs and reduce productivity, particularly for independent retail stores or small chain pharmacies.

VII. Risk Assessment of Electronic Prescriptions for Controlled Substances

DEA states that, with electronic prescribing, once an identity is established, all electronic prescriptions appear the same. The agency should be aware that, while it is true that strange handwriting or formatting will no longer be 'triggers' for a pharmacist to question a prescription, unusual quantities, doses, refills, free text instructions or prescriptions for drugs by a prescriber who should not handle them (e.g., a prescription for dextroamphetamine from a dentist) can prompt further review of electronic prescriptions.

DEA is proposing in-person identity proofing requirements; however, the agency does not state whether this requirement would be a one-time requirement, or whether it would be applied to each system that a physician may utilize. For example, physicians that need to write discharge prescriptions from different hospitals might encounter several e-prescribing systems. Does DEA propose that a separate 'hard token' or proofing document be obtained for each system? If so, this could be a significant burden. If this is a 'one-time' process, it is not clear how that process would be maintained or integrated across different organizations.

VIII. Proposed Standards for Electronic Prescription Systems for Controlled Substances

Under the proposed rule, DEA is requiring that, prior to dispensing, the pharmacy must verify that the practitioner is authorized by DEA to issue the prescription. To support such a rule, the DEA must provide an authoritative and current clearinghouse of DEA numbers that an e-prescribing or pharmacy system can query in order to validate a DEA number, since performing and documenting this lookup manually would place unacceptable burdens on the pharmacy.

- **ASHP recommends that DEA provide an accurate and current electronically addressable list of DEA numbers for e-prescribing systems and pharmacy systems to validate DEA numbers automatically, if the agency is going to require that such validation occur on all prescriptions. Further, if the DEA number has an extension, this DEA list must indicate whether or not the registrant with the number queried can support practitioners by extension.**

DEA would also require that the prescription be transmitted immediately on signing, to ensure that a prescription cannot be altered once it is signed. Additionally, the system must not allow a prescription to be printed once it has been transmitted, or to be transmitted if it was printed. The agency states that these conditions are necessary to prevent a single prescription from being used to generate multiple copies to be filled. Furthermore, a prescription created electronically for a controlled substance must remain in its electronic form throughout the transmission process to the pharmacy; electronic prescriptions may not be converted to other transmission methods (e.g., facsimile) at any time during the transmission.

ASHP is concerned that if a computer system is down, or a transmission error occurs, a prescription may not be received by the pharmacy. Since there is no additional opportunity to resend the prescription information, the patient will not receive the needed medication.

- **ASHP recommends that DEA allow the prescription to be resent in the event of a technical malfunction, downed computer system, or transmission error, with appropriate documentation explaining the reason the prescription was resent.**

ASHP is also concerned about DEA's requirement that, if the system is inactive for 2 minutes after the practitioner authenticates to the system, the system must require the practitioner to reauthenticate. What ultimately needs to be secured is the act of signature which, at the time it occurs, must bind the contents of the prescription at that moment to the properly authenticated prescriber. A two-factor authentication, generally recognized as the state of the art, applied at the point of signature, will provide more effective authentication.

- **ASHP recommends that DEA pursue two-factor authentication at the time of signature by the prescriber as the method of ensuring that the prescription was generated intentionally by a properly licensed prescriber.**
- **ASHP encourages DEA to perform an analysis of the projected costs for pharmacies to implement this digital signature requirement before finalizing the proposed rule.**

DEA is also proposing that any system that will be used to create controlled substance prescriptions must have a third-party audit prior to accepting controlled substances prescriptions for processing, and annually thereafter, that meets the criteria for a SysTrust or WebTrust audit for security and processing integrity. For pharmacies, an SAS 70 audit would also be acceptable. The requirement of a SysTrust SAS 70 audit is financially burdensome to service providers that are hospitals or clinics, especially small clinics.

- **ASHP recommends that DEA ensure that required audits can be performed at a reasonable cost, or to determine some other reasonable business solution that makes such audits practical for small physician practices, clinics, and hospitals.**

DEA is requiring that the pharmacy system create and maintain a backup copy of all controlled substance prescriptions at an alternate storage site that is geographically separate from the primary storage site.

- **ASHP recommends that DEA not require that this information be kept geographically separate, since electronic prescribing information is already maintained in multiple systems, and the requirement of maintaining a remote data storage site would add significant costs to independent pharmacies in particular.**

XI. Digitally Signed Prescriptions for Federal Health Care Agencies

DEA would require that the system check the DEA CSA database at least once a week and revoke access to signing controlled substance prescriptions for any practitioner using the system whose registration or federal agency authorization has been terminated, revoked, or suspended.

- **ASHP recommends the database should be checked every day, to prevent a person whose access has been revoked to continue to send invalid prescriptions. In order to facilitate this process, ASHP recommends that DEA provide a Web-accessed portal to which a software system can provide a query for a list of DEA numbers and receive a structured message in return indicating the status of each submitted number. This portal must be constructed in such a way that the multiplicity e-prescribing systems and pharmacy systems across the country can place such inquiries and receive responses within 2 seconds.**

ASHP appreciates this opportunity to present its written comments on the proposed rule. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs