

September 25, 2008

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

RE: Docket No. DEA—218
Federal Register, Vol 73, No. 125; Notice of Proposed Rulemaking
Electronic Prescriptions for Controlled Substances

Dear Acting Administrator Leonhart:

The eHealth Initiative, representing nearly 200 leading stakeholders across the U.S. health care community, is pleased to submit its comments on the DEA's proposed rule to allow the electronic prescribing of controlled substances. With controlled substances representing about 10% of all prescriptions, the promulgation of this proposed rule represents a vital step in expanding the usage of electronic prescribing by ambulatory care clinicians. It also addresses one of the major recommendations in the June 2008 report *Electronic Prescribing: Becoming Mainstream Practice*, which calls for the removal of the DEA prohibition of electronic prescribing of controlled substances. This report was authored jointly by the eHealth Initiative and the Center for Improving Medication Management, under the stewardship of a multi-stakeholder steering group.

The eHealth Initiative (eHI) is an independent, non-profit multi-stakeholder organization whose mission is to improve the quality, safety and efficiency of health care through information and information technology. eHI engages multiple stakeholders across every sector of health care to reach agreement on and drive the adoption of common principles, policies and best practices for mobilizing information electronically to improve health and health care in a way that is responsible, sustainable, responsive to each stakeholder's needs—particularly patients, and which builds and maintains the public's trust.

As a leading advocate for electronic prescribing and the many benefits it can bestow, including enhanced patient safety and convenience, lower medication costs, and greater efficiency and productivity for prescribers and pharmacies, the eHealth Initiative is pleased that the DEA recognizes the same benefits are achievable for controlled substances. However, we are concerned that the proposed rule would create additional software, hardware, cost, and workflow burdens of a magnitude which might undermine market receptivity to electronic prescribing of controlled substances—and thus slow adoption of electronic prescribing overall.

Clearly, this is not the DEA's intention, nor is it the desire of our members. In submitting these comments, our goal is to help the DEA better understand just how exacting the proposed rule's requirements are, and to offer suggestions that will

allow our industry to move forward on electronic prescribing of controlled substances; balanced with the DEA's need to regulate these substances in a responsible manner.

Many of our members will also submit their individual organization's comments to the DEA on the proposed rule, complementing and expanding on those which follow.

General Comments/Recommendations on the Proposed Rule

- *Flexibility on Meeting Technical Security Requirements*

It is important for the DEA to recognize that its technical security requirements must co-exist with those imposed by other federal agencies and state governments upon prescribers and pharmacies. We would thus recommend that, rather than specifying a single approach, the DEA should be open to recognizing all existing and potential future approaches that effectively meet DEA statutory enforcement responsibilities. For example, biometric authentication using fingerprint pattern or iris recognition is already well established and commonly used in the industry with commercially available computing devices.

- *Cost and Workflow Impact on Practices and Pharmacies Adopting Electronic Prescribing of Controlled Substances*

Implementing e-prescribing for controlled substances will increase prescriber costs, necessitate changes in practice workflow, and initially impact productivity. There will be added costs for registration, hard token hardware and software, software upgrades, annual system audits, and, especially, for the separate prescribing workflow for controlled drugs. Relative to the latter, the DEA's analysis (Sec. XIII of the proposed rule) does not include the added cost incurred by prescribers each time a controlled substance prescription is written (compared to the current paper-based system).

The key to making electronic prescribing of controlled substances feasible and appealing to prescribers is ensuring it is a smoothly integrated component of a single, uniform workflow for all prescriptions, with as few additional elements as possible. If it is not, and significant additional cost and workflow changes are asked of prescribers, there is really no incentive to move from paper-based to electronic prescribing of controlled substances. Absent such incentive, we are concerned the potential for tremendous societal benefits from electronic prescribing may be lost if a balance point between the DEA's enforcement responsibilities and the feasibility of industry adoption cannot be reached. The appendices offer a set of simplified alternatives for electronic prescribing of controlled substances that, we believe, both accommodate the DEA's diversion prevention charge and the industry's ability to absorb the cost and technical and workflow changes required.

- *Need for Real World Pilot Testing of DEA Requirements for Electronic Prescribing of Controlled Substances Prior to National Rollout*

Considering the complex untested technologies and new business processes that e-prescribing of controlled substances would require, we would urge the DEA to

conduct real world pilot testing of its specifications in advance of any national rollout. A good model for this is provided in the 2007 Department of Health and Human Services report entitled, "Pilot Testing of Initial Electronic Prescribing Standards." The time and resources spent on careful pilot testing will pay dividends in achieving wider industry acceptance and a smoother rollout process for all.

Appendix I of this document provides comments on the proposed rule from the prescriber perspective. Appendix II offers comments from the pharmacy perspective. Appendix III lists the organizations that contributed to this comment.

Summary

The eHealth Initiative believes that allowing electronic prescribing of controlled substances will help advance the usage of this crucial technology, representing a major leap forward in terms of quality, patient safety, enhanced prescriber and pharmacy efficiency, and lower health care costs that will benefit every health care system stakeholder. Given this great potential, we hope the DEA will work constructively with health care stakeholders to make electronic prescribing of controlled substances as easy and cost- and burden-free as possible, to ensure its optimal adoption and impact. Our foregoing comments and those provided in the appendices are offered to help clear the path for such widespread adoption. We look forward to working collaboratively with the DEA in pursuit of this worthy common goal, and hope the guidance provided in this letter is helpful in establishing a final rule that is workable for all.

Please don't hesitate to contact me or our Manager of Government Relations and Public Policy, Brian Wagner, at (202) 624-3282 or email at Brian.Wagner@ehealthinitiative.org if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Janet M. Marchibroda". The signature is written in a cursive, flowing style.

Janet M. Marchibroda
Chief Executive Officer
eHealth Initiative

Appendix I—Specific Comments on Proposed Rule from the Prescriber Perspective

(Note: All DEA proposals are *italicized* followed by page citations from the June 27, 2008 Federal Register Notice of Proposed Rulemaking)

A. In-Person Identity Proofing Requirements

Proposal to permit the conducting of in-person identity proofing of prescribing practitioners within: (36739)

- o *A DEA-registered hospital that has previously granted the practitioner privileges at the hospital (e.g., a hospital credentialing office);*
- o *The State professional or licensing board, or State controlled substances authority, that has authorized the practitioner to prescribe controlled substances;*
- o *A State or local law enforcement agency.*

Comments:

Identity-proofing should be streamlined and simplified. As described by the DEA, it will be difficult for many prescribers to find the time to undergo this, and will be very time consuming for system vendors and state licensing boards to accomplish the necessary credential checking. Also, the proposed fees associated with identity proofing, estimated by the DEA at \$62 per prescriber, added to the already costly DEA registration process that includes a \$551 license fee for renewals, represent additional barriers to the adoption of electronic prescribing of controlled substances.

Many public key infrastructure (PKI) certifying authorities (CA) offer both in-person and on-line antecedent data-based identity verification procedures. Current digital identity vetting technology offers prescribers a completely on-line process, based on antecedent data including verification of medical license and DEA registry status that can be completed in less than 10 minutes. This process is used by the pharmaceutical industry to provide digital identity credentials to clinical investigators and by healthcare information exchanges to provide credentials to medical professionals and first responders.

We therefore recommend that the DEA permit identity-proofing without an in-person requirement.

If the DEA does choose to go forward with the in-person requirement, it should consider whether the above agencies are equipped or willing to perform identity-proofing. We would recommend that the list of performing agencies be expanded to include those approved by an authorized PKI CA. Suggested agencies would include the Secretary of State's office, passport application processing agencies, and the American Association of Medical Colleges.

B. Authentication Protocol Requirements

Whether authentication protocol requirements, use of a hard token and two-factor authentication, meeting the requirements of Level 4 are sufficient to address DEA's concerns, or whether (a) more stringent requirements, such as those imposed in a

public key infrastructure system, are necessary, or (b) DEA's concerns could be addressed with Level 3 requirements combined with risk-mitigating controls.
(36738)

Access to the electronic prescribing system for the purposes of signing prescriptions must meet the standards for Level 4 authentication in NIST SP 800-63. That is, the system must require at least two-factor authentication to access the system; one factor must be a cryptographic key stored on a hard token that meets the requirements for Level 4 authentication in NIST SP 800-63 or a multi-factor one time password token. The hard token must be a hardware device that meets the following criteria: (36739)

- *The token must require entry of a password or biometric to activate the authentication key.*
- *The token is not able to export the authentication key.*
- *The token must be validated under Federal Information Processing Standard (FIPS) 140-2 as follows:*
 - *_ Overall validation at Level 2 or higher.*
 - *_ Physical security at Level 3 or higher.*

Comments:

- We are concerned about the DEA's authentication proposal and believe that the requirement to use a hard token is unworkable in most practice settings. Given the sheer volume of prescription activity, requiring a physician, especially a high volume prescriber, to comply with two-factor authentication using a hard token combined with a separate authentication process is onerous and will significantly affect practice workflows. This proposed requirement is even more challenging for physicians who prescribe controlled substances for patients in multiple states, as they would need multiple tokens. Adding just a few minutes a day for each controlled substance prescription would substantially affect physician practice workflows and take time away from patient care. The efficiencies intended under an electronic system would be lost if the hard token approach is adopted. In order for hard tokens to work, the computer to which it is authenticating must be properly configured. The technological complexities and costs associated with these adjustments, especially for smaller practices, have not been thoroughly assessed by the DEA.

Moreover, hospitals and other settings outside the physicians' practice must also be configured to accept hard tokens and most of these settings prohibit the connection of foreign devices to their systems due to security concerns. We believe the DEA's proposed authentication requirement will detract significantly from the workability of an e-prescribing system for controlled substances and would deter physicians from using the system. The Certification Commission for Healthcare Information Technology (CCHIT), an electronic health records (EHRs) certification body funded by the Department of Health and Human Services (HHS), does not recommend the requirement of a hard token. A two-factor authentication is not unreasonable, however, the requirement that one factor be a hard token is not adequately flexible, given the alternative technologies, such as biometric identification. Should

the DEA adopt a two-factor authentication standard, we strongly urge the DEA to remove the requirement that one factor must be a hard token.

- The DEA should permit biometric authentication as a preferred alternative to a hard token. Biometrics are more secure than hard tokens. They can not be stolen, borrowed, or left behind. Biometric authorization has been implemented successfully at many healthcare institutions. It would not be reasonable for the DEA to insist that facilities invest in new, less secure technology for this one purpose.

C. Proposed Standards for Electronic Prescription Systems

The security of the system must be audited annually using a third-party audit that meets the requirements of a SysTrust or WebTrust audit for security and processing integrity. (36739)

Comments:

- These audits will be costly, and the bills will ultimately be paid by the prescribers in the form of higher software and subscription fees. The DEA has not explained why it believes a yearly audit is necessary. By comparison, the Certification Commission for Health Information Technology (CCHIT) certifies EHR systems for three years. The DEA has not indicated how often it would expect to modify system requirements.
- Prescribers are not likely to be technically competent to review these audits. Rather than make prescribers responsible for reviewing audits, the DEA should simply publish a list of qualifying systems.
- How will prescribers be informed about the qualification status of systems available for use? It appears that a prescriber will have to ask each system vendor for a copy of the most recent audit. Will the DEA maintain an authoritative list? If so, why would prescribers be required to do anything more than pick a system from the list?

The system must have an automatic lock out if the system is unused for more than 2 minutes. (36739)

Comments:

- It is important to define and explain this further. What does "lock out" mean? Out of the specific prescription being prescribed? Out of the second authentication workflow? Out of the prescribing module, requiring authentication to re-enter? Out of the EMR being used at the time? Also, what does "unused" mean? Failure to transmit the prescription? No interaction with the computer at all? Does this mean if a prescriber starts but does not transmit the prescription because he or she pauses to examine the patient, and then comes back to the screen 3 minutes later, he or she is locked out of the e-prescribing module? The EMR? The whole computer? Does the prescription vanish and does the prescriber have to start over?
- If the end point is to avoid prescribing by unauthorized users, the end point of this is the second factor authentication, and a clear indication of each of the

controlled substance medications that will be prescribed at that time. It is not clear that anything is gained by a lock out after 2 minutes. The most important point is the easy ability to inspect the impending e-prescription and to strongly authenticate (e.g., fingerprint) the prescriber's identity and his approval of transmission.

- The 2 minute lock out rule does not take into account the realities of a fast-paced prescribing environment where physicians are constantly multi-tasking. For example, if a physician began to enter a prescription into the system and had to take an urgent call, the physician would be logged out of the system within 2 minutes. We, therefore, recommend that the physician be provided with the flexibility to set an automatic timeout according to his/her practice workflow.

The prescription must contain all of the required data (date of issuance of the prescription; patient name and address; registrant full name, address, DEA registration number; drug name, dosage form, quantity prescribed, and directions for use; and any other information specific to certain controlled substances prescriptions mandated by law or DEA regulations). Prior to signing the controlled substance prescription, the system must show the prescribing practitioner at least the patient name and address, drug name, dosage unit and strength, quantity, directions for use, and the DEA number of the prescriber whose identity is being used to sign the prescription. (36739)

Comments:

- To support this, EMR vendors may have to move quickly to structured, codified SIG, but this is an area where the e-prescribing standard has not yet been approved/accepted.

Where more than one prescription has been prepared for signing, prior to authenticating to the system the practitioner must positively indicate which prescription(s) are to be signed. (36739)

Comments:

- What does this mean in practice? For example, prior to performing the separate e-prescribing authentication, the prescriber could be presented with a list of the controlled prescriptions, which have been drafted by the prescriber or others, and which are ready to be signed. Must the prescriber check a box next to each waiting prescription, or is it satisfactory to click an "all" button? If the latter is not acceptable, please explain why this is so.
- This may be a good thing if it means a prescriber can prepare a future prescription, but not yet sign/transmit it. We hope that the DEA does not intend to control the "how" of this but rather leave it to prescribers and e-prescribing / EHR vendors to work out the strategy.

The practitioner must authenticate himself to the system immediately before signing a prescription; (36739) and,

After authenticating to the system but prior to transmitting the prescription, the system must present the practitioner with a statement indicating that the

practitioner understands that he is signing the prescription being transmitted. If the practitioner does not so indicate, by performing the signature function, the prescription cannot be transmitted. (36739)

Comments:

- Although the DEA indicates that the purpose of agreeing to this statement would be to “help positively bind the practitioner to the prescription,” we believe that this attestation is unwarranted and therefore should not be required. Furthermore, prescribers must currently adhere to CSA and DEA requirements and e-prescribing controlled substances does not alter this responsibility. The sheer volume of information proposed by the DEA, which the prescriber needs to review prior to the transmission of the prescription, is not workable in existing practice settings. We thus urge the DEA to remove the attestation requirement.
- A better approach would be to present a simple dialog box with a clear and short warning that a prescription for a controlled substance is about to be signed. This dialog could have three buttons: Agree, Cancel, and Check Record. When prescribers get prescription renewal requests in their EMRs now they have to minimize or temporarily ‘cancel’ the request - check the chart for appropriateness - and then click yes or no. The DEA proposed rule does not appear to include this necessary capability.

The system must transmit the electronic prescription immediately upon signature. The system must not transmit a controlled substance prescription unless it is signed by a practitioner authorized to sign such prescriptions. (36739)

Comments:

- “Immediately” makes sense, but prescribers will worry if they have done something wrong or be in trouble if/when the inevitable glitch arises that delays transmission. The DEA should word this so the intent is clear that that the e-prescribing application is to be configured to electronically transmit the prescription as soon as it has been signed by the prescriber, and describe how transmission errors are to be handled.

The electronic data file must include an indication that the prescription was signed; and, (36739)

The system must not allow printing of prescriptions that have been transmitted; if a prescription is printed, it must not be transmitted. (36739)

Comments:

- The key to this rule is the definition of “transmitted.” The DEA must make it clear that an e-prescription is not considered to be “transmitted” unless it has been successfully received by the pharmacist who will fill the prescription, and an acknowledgment has been returned to the prescriber’s system.
- This is not workable as written, given that many prescribers prepare prescriptions in advance. Under the current system prescribers are permitted to write scripts with future fill dates and this should not be jeopardized.

Patients should not be required to make otherwise unnecessary trips to their prescribers' offices just because the date coincides with the expiration of a prescription. Prescribers should not be required to revert to paper as the only solution to common prescribing events.

- We suggest the following alternative language: "If electronic transmission is prevented by weather, power loss, or equipment failure, or other similar system failure, prescriptions may be faxed to the pharmacy or printed."
- Prescribers may want to print a copy of the prescription and place it in the patient's record. The DEA should allow the printing of copies that clearly indicate that they are printed copies of e-prescriptions.
- Another version of that prescription may need to be faxed / printed – as depending on the market – the certainty of e-prescriptions going thru to the pharmacist can vary, with a great degree of uncertainty in some circumstances.

D. Proposed Post-Transmission Requirements

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 transmission. (36740)

Comments:

- Given that there are circumstances, such as transmission failure, where printing or faxing are appropriate, could an electronically submitted prescription, upon printing or faxing, show a "Submitted electronically" imprint so that any viewers of a printed/faxed version would have an indication that it was previously e-prescribed? Also, for internal record keeping purposes, we think the DEA should permit a prescriber to generate a print-out of an electronic controlled substance prescription, as long as the print out clearly delineates that it is a "duplicate" or "copy".

The registrant must retain sole possession of the hard token. If a token is lost or compromised and the registrant fails to notify the service provider within 12 hours of discovery, the registrant will be held responsible for any prescriptions written using the token. (36740)

Comments:

- What does "held responsible" for prescriptions mean? Could this include criminal charges? Could it include liability for abuse of fraudulently obtained prescriptions? What is the parallel in the current paper-based world? This introduces new liability concerns. We recommend that prescribers not be held responsible for actions resulting from a lost or stolen hard token.
- The timeframe is too short. It is unclear whether service providers would be open on weekends to accept these reports. The time limit should be extended to at least 48 hours.

- How would this be accomplished – electronically, call to e-prescribing service provider? Does the DEA also need to be notified?
- What does “compromised” mean, and how would someone know if a key was “compromised?”
- This may be unreasonable. We believe that an interpretation that the individual must guarantee physical possession at all times would be unreasonable. For example, if a prescriber goes on vacation or out for a walk, must the device travel with him/her. Clarity is needed on what this means and the implications for not keeping physical possession of this key.
- This is one of the most compelling reasons to make the biometric option available.

The practitioner and pharmacist must notify DEA and the service provider if they identify problems in the logs they review that indicate that prescriptions have been created without their knowledge or altered. (36740)

Comments:

- While it is not unreasonable to ask for notification of irregularities, being held responsible for failure to notify may deter most prescribers from electronic prescribing of controlled substances.

E. Proposals for Audits

Specifically, DEA is 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; (36747) and,

The practitioner must determine initially and at least annually thereafter that the third-party audit report of the service provider indicates that the system and service provider meet DEA’s regulatory requirements regarding the electronic prescribing of controlled substances. (36748)

Comments:

- Prescribers are not law enforcement experts, nor are they computer technicians. Yet, these requirements to review and accept third-party audits of independent vendors place an undue burden on prescribers to take on these roles.
- This proposed rule places a disproportionate share of legal responsibility on prescribers and pharmacies. There should be more responsibility accepted by the DEA to certify “service providers” (vendors) and “intermediaries.”
- EHR systems certified by CCHIT are only certified every three years therefore it’s unclear why an annual audit is needed.
- It is unclear whether DEA requirements are expected to change yearly.

- Costs of audits could easily be shifted to prescribers.
- It is unclear how a prescriber would know they are purchasing a DEA compliant system if the system is an e-prescribing stand-alone, since CCHIT only certifies EHRs.
- It is unclear how the names of these compliant systems would be made widely available to prescribers.

F. Proposals for Prescribing Logs

DEA is proposing that electronic prescription service providers generate and send practitioners a log of all controlled substance prescriptions the practitioner has written in the previous month. The practitioner would be required to review the log and indicate to the service provider that the practitioner has reviewed it. A record of the indication that the review has occurred must be retained for five years. (36748)

Comments:

- We share a desire to engage prescribers to help the DEA identify suspicious patterns, but need the DEA's reassurance that the intent is not to catch well-meaning prescribers who on a rare occasion unintentionally miss a suspicious prescription.
- We are concerned that while the DEA phrases this almost as a casual review, ("they do not expect that prescribers will check each entry in this log against the medical record, but rather just scan it for names they don't recognize, or drugs they typically don't prescribe"), the implications for this review will dictate otherwise. We believe the effort required to review these logs will be much more rigorous and time-consuming, and one more reason prescribers may opt not to adopt electronic prescribing of controlled substances.
- Electronic prescription service providers should be required to provide these logs in a standard, electronic format that will enable practitioners to perform this audit (or have it performed on their behalf) automatically.
- In cases of failed transmissions, the DEA must specify exactly how prescribing activities will be logged. Assume that, for whatever reason, an e-prescription is not presented to a pharmacist for filling. The prescriber may then choose to write a new, paper prescription for the patient. The patient's medical record will now show that two prescriptions have been written for the same drug and for the same time period. How will the prescriber demonstrate that the e-prescription was never filled? It is likely that the log of the e-prescribing software will show that the prescription was sent. Likewise, the log from the intermediary may show that the prescription was transferred. The DEA must mandate that prescription logs are fail-safe from the point of view of the prescriber. Unless every system in the chain receives a clear acknowledgment that the prescription was both filled and picked up by the patient, the log must show that the attempted e-prescription failed.

G. Other Comments/Issues

1. *The standards for electronic health records system security developed by the Certification Commission for Healthcare Information Technology (CCHIT) require systems to support two-factor identification (36741)*

Comments:

This is an erroneous statement. CCHIT does not as yet certify systems to support two-factor identification. CCHIT's has established this as a goal (excerpted below) for its 2010 Roadmap, in response to issuance of the DEA's proposed rule:

SC 03.13 The system shall support two-factor authentication in alignment with NIST 800-63 Level 3 Authentication. Note: This is to support the 21 CFR Parts 1300, 1304, et al. Electronic Prescriptions for Controlled Substances; Proposed Rule published on Friday, June 27, 2008, Federal Register / Vol. 73, No. 125.F11"

As such, the DEA's assumption that CCHIT certified systems already implemented have this two-factor identification capability is incorrect; adding this capability to existing systems would represent an added cost to their users, and another barrier to adoption of electronic prescribing of controlled substances.

2. *Interaction with Medicare's New Electronic Prescribing Incentive/Disincentive Program*

Comments:

Shortly after the DEA published the proposed regulation for electronic prescriptions of controlled substances, the President signed the "Medicare Improvements for Patients and Providers Act of 2008" (MIPPA) (P.L. 110-275) into law on July 15, 2008. In order to encourage the adoption and use of e-prescribing, this new law includes both incentives and the imposition of penalties to encourage e-prescribing, and among many other things, creates incentives for physicians to electronically prescribe prescriptions written for Medicare patients under Part D of the Medicare program. Based upon allowed Medicare charges, physicians who e-prescribe in 2009 and 2010 will be eligible for a 2 percent Medicare payment bonus, which will be phased down to 1 percent in 2011 and 2012 and 0.5 percent in 2013. Physicians, who do not e-prescribe, will be penalized by 1 percent in 2012, by 1.5 percent in 2013, and by 2 percent in 2014 and beyond.

At this time, the Secretary has not published conforming regulations stipulating how the e-prescribing program in MIPPA will operate. For example, it is unclear whether controlled substances will be excluded from determining whether a physician will be exempt from receiving incentives and/or facing penalties. Given the complexity, costs, and liability concerns associated with the DEA's proposed rule, physicians may be reluctant to adopt e-prescribing for controlled substances. We, therefore, urge the DEA to recommend that CMS use discretionary authority as provided under MIPPA to exempt the e-prescribing of controlled substances from any assessment of penalties against physicians who choose not to e-prescribe controlled substances. In order to enhance e-

prescribing adoption and usage rates, the DEA should also recommend to CMS that physicians be entitled to receive incentive payments, regardless of whether they choose to e-prescribe controlled substances in accordance with the DEA's final rule and requirements.

Appendix II—Comments on the Proposed Rule from the Pharmacy Perspective

(Comments below refer to specific sections of the DEA's regulations for the Controlled Substances Act which are being revised or added, as provided beginning on page 36751 of the June 27, 2008 Federal Register Notice of Proposed Rulemaking)

A. Proposals for Audits

1. Third-party Audits

Section 1311.170 (f) of the proposed rule would require the pharmacy dispensing system to undergo a third party audit prior to accepting any electronic controlled substance prescriptions and to redo the audit annually thereafter.

Comments:

Undergoing these types of audits is not a common practice in the industry. Such an audit process is not currently required for paper prescriptions, including written prescriptions for controlled substances. We question the need for requiring such an annual audit merely because the pharmacy receives and maintains electronic prescriptions for controlled substances.

We believe this requirement is unnecessary as current polices and procedures are in place to comply with state statutory requirements, state board of pharmacy regulations, and the HIPAA privacy and security rules to adequately address privacy and security issues. Additionally, pharmacies are currently required to certify new releases of their systems with SureScripts-RxHub. We ask that the DEA recognize the efforts that are currently in place to protect privacy and security. In addition, we ask that DEA require that the pharmacy system be auditable by the DEA or a DEA-named entity, rather than required to go through the costly and potentially unnecessary process of annual third-party audits.

In the case that the DEA moves forward with the third party audit requirement, we question the need for annual pharmacy audits, as systems typically will not change from year to year. We believe it would be more reasonable to require that the system vendors have their system audited, and be required to maintain their audited status with the DEA.

2. Internal Audit Trail

Section 1311.170(b) of the proposed rule would require the pharmacy system to create and maintain an internal audit trail that indicates each time a controlled substance prescription file is opened, annotated, altered, or deleted. The pharmacy system would have to identify each person who views, annotates, or alters the prescription record.

Comments:

We have a number of concerns about this requirement. First, we question the need to require the audit trail to include every time a prescription is viewed. For example, if a patient calls to verify their last co-payment made on a prescription, the prescription would be viewed. We question how this type of information would be useful or relevant to the DEA. Second, there is no similar audit requirement for paper or for non-controlled electronic prescriptions. We question the need just because a prescription is received electronically. Third, the DEA would require the audit trail to be saved for five years. Having to save an audit trail of every time every prescription for five years would be very costly and burdensome.

3. *Analyze Audit Trail and Report to DEA*

Section 1311.170(d) of the proposed rule would require the system to analyze the audit logs at least once every 24 hours and generate an incident report of events that could have compromised the integrity of the prescription records.

Comments:

We request that the DEA clarify that this system will be an automated process. A manual process would be tedious, unworkable within the 24 hour time frame, and may require additional personnel thus increasing cost to pharmacy. Even with an automated process, 24 hours may prove to be difficult to complete an audit.

Section 1311.170(c) of the proposed rule would require that auditable events must, at a minimum, include attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in the prescription system.

Comments:

We request clarification of the term "modification," as it is not clear what is meant by an "unauthorized modification."

Section 1311.170 (e) of the proposed rule would require that any incidents of auditable events must be reported to the service provider and the DEA within one business day. Such a requirement may not be feasible considering increased workloads on busy days or after long weekends or holidays. We suggest a time period of forty-eight to seventy-two hours upon discovery would be reasonable and sufficient.

B. Proposals for Record Retention

1. *Backup System*

Section 1131.170(a) of the proposed rule would require that the pharmacy system create and maintain a backup copy of all controlled substance prescriptions at an alternate storage site that is geographically separated and distinct from the primary storage site so as not to be susceptible to the same hazards such as a flood, hurricane, or other natural or man-made disaster.

Comments:

We question the need for this proposed requirement, as it is currently not required for paper prescriptions, including written prescriptions for controlled substances, and would be extremely costly for pharmacies to implement. Technology such as an automated backup system would be sufficient to ensure that records are retained without having to store them in a separate geographical location.

2. *Downloading Electronic Copies*

Section 1311.165 (g) of the proposed rule would require that the pharmacy system be capable of downloading an electronic copy of controlled substance prescription records into a database or spreadsheet format that is readily readable and can be easily sorted by the data elements listed in paragraph (f) of this section (prescriber name, patient name, drug dispensed, and date dispensed). The DEA would require that these databases or spreadsheets be available to be printed or provided electronically without the need for additional specialized software.

Comments:

In the chain pharmacy environment, database and spreadsheet formats with this information are available at the corporate level; however, typically this is not an available process at the store level. We request that the DEA not to require this functionality at the store level, and that access through a request to corporate headquarters be acceptable.

In addition, page 36749 of the preamble to this proposed rule states that the DEA is proposing that records maintained electronically must be *immediately* retrievable from all other records by prescriber's name, patient's name, drug dispensed, and date filled. We would recommend that this information be available to the DEA on a "readily retrievable" basis as that is the current standard and process for paper and non-controlled electronic prescriptions. Requiring records to be immediately printed upon request may not be possible at the individual pharmacy level.

C. **Proposals for Validation of DEA Registration**

1. *Validation of the DEA number*

Section 1311.165(a) of the proposed rule would require the pharmacy system to verify that the DEA registration of the prescriber is still valid at the time the prescription was signed.

Comments:

Currently, pharmacists do not validate a prescriber's DEA number unless the pharmacist has reason to believe that the DEA number is invalid. The DEA proposed rule offers the pharmacy an option to purchase a costly CSA registration database or have the prescriber's system or the intermediary's system check the database for validity during the transaction, which most likely would impose a cost to be paid by the pharmacy. Page 36745 of the proposed rule's preamble also notes that regardless of which party checks the validity of

the DEA registration, the pharmacy is *solely* responsible and liable for the dispensing of the controlled substance.

While we understand this section's intent, the CSA database is not available in real-time thus making it impossible to validate DEA numbers that have not yet been integrated into the system. It could take up to a month for a new prescriber's DEA number to enter the CSA database. This would force pharmacies to reject electronic prescriptions for prescribers not yet entered into the database.

2. Reading and Retaining the Full DEA Registration Number

Section 1311.165(d) of the proposed rule would require the pharmacy system to be capable of reading and retaining the full DEA registration number, including any extensions, or other identification numbers.

Comments:

Pharmacies have the capability to receive the DEA extension in the pharmacy system; however, given that the DEA does not assign the extension and there is not a standard assignment protocol among health care institutions, validation of this extension may not possible at the pharmacy level. We ask the DEA to clarify that pharmacies will not be held responsible for the validation of any extensions or other institutionally provided identification number that is not recognized by the DEA and is not able to be identified by the CSA database.

D. Proposals for Archiving and Digitally Signing the Initial Record

Section 1311.160 of the proposed rule would require that a copy of each electronic controlled substance prescription record received by the pharmacy is digitally signed by the last intermediary that transmitted the record or the first pharmacy system that received the electronic prescription.

Comments:

We request DEA clarification on how same system exchanges between a physician and a pharmacy will operate, as the rule assumes that an outside provider will be responsible for transmitting an electronic prescription. In the future, this scenario may change given the increase in physician use of EHR databases.

Additionally, the copy of each electronic controlled substance prescription must be retained by the pharmacy for five years which is inconsistent with the current requirements that written controlled substance prescriptions be kept for two years. We disagree with the DEA's proposal to keep electronic records for five years and its assumption that this would not impose a burden on pharmacies. To comply, pharmacies would have to acquire additional hardware, software, and personnel, especially if the DEA decides to require the additional proposed audit information. Finally, pharmacies would incur increased liability exposure for the responsibility of maintaining the additional information.

E. Other Pharmacy Concerns

1. Transmission of electronic prescriptions

Section 1311.130(b) of the proposed rule would require that the electronic prescription system not allow the printing of an electronic prescription that has been transmitted or vice versa.

Comments:

We understand the DEA's concern regarding the issuance of multiple prescriptions; however, there may be situations where the transmission has failed due to technical disruptions, or the receiving pharmacy is closed thus warranting printing or another communication to transmit the prescription. This proposal is not consistent with the current procedure for non-controlled electronic prescriptions where patients can obtain their prescription, and a copy of their prescription, in the circumstances noted above where there is an issue with transmitting the electronic prescription. We ask that the DEA address situations in which prescriptions cannot be delivered to the pharmacy because of temporary or transient network transmission failures and to permit prescriptions to be faxed to the pharmacy or printed under those circumstances.

Additionally, we request that the DEA clarify why it does not consider an electronic prescription for a controlled substance "transmitted" until it has successfully reached the pharmacy that will fill the prescription. If there is a technical problem that prevents this at the pharmacy end, we would urge the DEA to allow for such prescriptions to be faxed in such circumstances, to avoid delays for the patients.

2. Electronic Prescription Requirements: Prescription Contents

Section 1311.115(c) of the proposed rule would require an electronic prescription for a controlled substance to have the practitioner name, address, and DEA registration number for the prescribing practitioner only. The DEA will not allow multiple DEA registration numbers to be transmitted on the e-prescription.

Comments:

We have two concerns with this proposed restriction. First, this would not allow information such as the designated agent or supervisor to be transmitted to the pharmacy, which may be necessary or useful information for the pharmacist. Second, we ask the DEA to clarify how prescriptions for detoxification should be handled, as prescribers for such prescriptions must maintain two DEA registration numbers: a standard number and one for detoxification treatment purposed. We would add that the NCPDP SCRIPT standard does allow for more than one DEA registration number to be transmitted. The SCRIPT standard allows this to meet a need for this information to be transmitted to the pharmacy.

3. Prescription Alterations

Section 1311.230(d) of the proposed rule states a controlled substance prescription may not be altered during transmission. Any changes to the content during transmission would render the prescription invalid. Page 36744 of the proposed rule's preamble gives the example of generic substitution as a situation where an element of the prescription is altered.

Comments:

Pharmacists commonly dispense generic equivalents of brand name medications that have been prescribed. We would thus ask the DEA to permit this practice to continue for electronic prescriptions, to remove an important disincentive to adopt electronic prescribing, while allowing both payers and patients to benefit from lower medication costs.

4. Prescription Transfers

Page 36750 of the proposed rule's preamble states that a pharmacy would be allowed to transfer an electronic prescription with remaining refills to another pharmacy for filling provided the transfer is communicated between two licensed pharmacists.

Comments:

In practice, if a prescription transfer occurs within the same pharmacy chain, only one licensed pharmacist is necessary to complete the transfer if that pharmacy chain uses a common database among its pharmacies. We would thus ask the DEA to recognize and permit this practice in the final rule.

5. Long Term Care Pharmacy

Section 1306.05(f) of the proposed rule states that a prescription may be prepared by the secretary or agent of a practitioner.

Comments:

In a long term care setting, the DEA currently does not recognize the nurse as the agent of the prescriber. We would ask the DEA to permit nurses to act as an agent of the prescriber, to remove a significant barrier to the adoption of e-prescribing in the long term care setting.

Appendix III—eHI DEA Work Group Participants

The following organizations contributed to the development of this joint comment letter:

- American Academy of Pediatrics
- American College of Cardiology
- American College of Emergency Physicians
- American College of Physicians
- American Hospital Association
- American Medical Association
- BearingPoint
- CVS/Caremark
- DrFirst
- Florida Agency for Health Care Administration, Office of HIT
- Gold Standard
- ICW
- Kaiser Permanente
- Medical Group Management Association
- MediVoice
- MedStar
- National Association of Chain Drug Stores
- PhRMA
- SureScripts-RxHub
- VisionTree
- Walgreens