

May 27, 2010

Michelle M. Leonhart
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
Reference: Docket No. DEA-218

Dear Ms. Leonhart:

Emdeon Inc. (NYSE: EM), a leading provider of healthcare revenue and payment cycle management solutions, reiterates its support for the approval of security standards for the electronic prescribing (ePrescribing) of controlled substances and its commitment to assist the U.S. Drug Enforcement Administration (DEA) and the healthcare industry in implementation of the Interim Final Rule (IFR) for ePrescribing controlled substances. Emdeon appreciates the opportunity to provide input on the IFR and to highlight what we have learned through our work with the DEA on the nation's first pilot program for ePrescribing of controlled substances in Massachusetts.

To help put our comments in context, we would like to begin by providing some background on Emdeon and our role in connecting every facet of the U.S. healthcare system today. Emdeon is a health information intermediary that connects consumers, providers, pharmacies and payers to facilitate financial, administrative and clinical health information exchange. We are the largest financial and administrative healthcare information exchange in the nation, and our clinical exchange volumes are growing dramatically with an annual run rate of 100 million e-prescriptions and 30 million clinical messages (test orders and results) per year. In total, we facilitate over 5 billion healthcare information exchanges each year. The Emdeon network connects 500,000 physicians, 81,000 dentists, 55,000 pharmacies, 5,000 hospitals and 1,200 payers. This secure and interoperable network is vital to the daily function of the U.S. healthcare system.

As the only ePrescribing network with market-based experience in this area, Emdeon is already demonstrating the achievability of ePrescribing of controlled substances and its potential impact on healthcare through its eRx Network®. Emdeon anticipates that full implementation of the Interim Final Rule would be a major leap forward for healthcare safety, efficiency and cost savings in the United States.

Electronic Prescribing Experience

Emdeon has been at the forefront of electronic prescribing since 2001, working closely with our pharmacy and physician customers and the industry at large to drive electronic adoption. We

are committed to expanding the utilization of ePrescribing by promoting and preserving the interoperability of all participants through our ePrescribing network, eRx Network. eRx Network is an open and interoperable network with direct connectivity to tens of thousands of retail pharmacies and more than 140,000 physicians.

In 2008, eRx Network joined the pilot program headed by the Massachusetts Department of Public Health (MDPH). This research project was funded by the Agency for Health Research and Quality (AHRQ) as part of a long-term effort to demonstrate that electronic prescribing for controlled substances is technologically feasible, enhances the secure management of these medications and potentially can increase patient safety. The project began in 2007 led by MDPH with participation from DrFirst, a leading ePrescribing software vendor; Berkshire Health Systems, Inc.; the Schneider Institute for Health Policy at Brandeis University; physicians and pharmacists of Berkshire County, Mass.; and other leading healthcare organizations in Massachusetts. eRx Network joined the effort in 2008 as an implementation solution to electronically connect prescribers to pharmacies.

The comments that follow reflect Emdeon's experience and the lessons learned to date from this important pilot project. Emdeon is committed to supporting our customers and the industry as a whole in attaining compliance with the new regulation.

Digital Signature Indicator

Page 16283: The interim final rule retains the proposed requirement that the electronic prescription application include an indication that the prescription was signed in the information transmitted to the pharmacy; and 3. Indication That the Prescription was Signed (page 16256) *DEA Response*. DEA is not specifying by regulation how the field indicating that a prescription has been signed could be formatted, only that such a field must exist and that electronic prescription applications must indicate that the prescription has been signed using that particular field. As DEA noted in the NPRM, the field indicating that the prescription was signed could be a single character field that populates automatically when the practitioner "signs" the prescription. DEA is not requiring that a signature be transmitted. The field is needed to provide the pharmacy assurance that the practitioner in fact authorized the prescription. Although most existing applications may not transmit the prescription unless the prescription is approved or signed, and DEA is making that an application requirement, the pharmacy has no way to determine whether the electronic prescription application the practitioner used to write the prescription meets the requirement absent an indication that the prescription was signed. The prescription application's internal audit trail is not available to the pharmacist who has to determine whether he can legally dispense the medication. If a pharmacy receives an electronic prescription for a controlled substance in which the field indicates that the prescription has not been signed, the pharmacy must treat this as it would any written prescription that does not contain a manual signature as required by DEA regulations.

1311.120 Electronic prescription application requirements

(a) A practitioner may only use an electronic prescription application that meets the requirements in paragraph (b) of this section to issue electronic controlled substance prescriptions.

(b) The electronic prescription application must meet the requirements of this subpart including the following:

(17) Unless the digital signature created by an individual practitioner's private key is being transmitted to the pharmacy with the prescription, the electronic prescription application must include in the data file transmitted an indication that the prescription was signed by the prescribing practitioner.

Emdeon supports the interim final rule requirement to add a dedicated field accommodating the prescription digital signature indicator. An interim solution is being built for the current regulated National Council for Prescription Drug Programs (NCPDP) SCRIPT version 8.1 to denote the prescription was signed. An interim solution is also being built (which may be the same) for SCRIPT version 10.6 which is going through the HHS regulatory process. A longer term solution is also being analyzed for a future version of SCRIPT. Anytime significant modifications are required to a standard that has been named in regulation (e.g. NCPDP SCRIPT) the regulatory process must be invoked which adds delays to the implementation timeframe for the industry.

As an alternative interim solution, Emdeon today supports the signature indicator in controlled substance claims. The indicator is sent in an XML “envelope” or “wrapper” in the header of the prescription. This wrapper also includes other information to identify new prescriptions as controlled substances for the participating pharmacies. This wrapper meets the rule by including a field indicating that a prescription has been signed. On page 16256 of the DEA Response, DEA is not specifying by regulation how the field indicating that a prescription has been signed could be formatted, only that such a field must exist and that electronic prescription applications must indicate that the prescription has been signed using that particular field.

Emdeon believes both the XML wrapper solution and the solution being built by NCPDP can be effective interim solutions for processing controlled substances, as the longer term process for creating a dedicated field within the SCRIPT standard is implemented. Additionally, Emdeon assumes that the physician application will validate all prescriptions and support the industry standards for identifying controlled substances and communicating this to the aggregator and pharmacy.

6. PKI and Digital Signatures

The interim final rule states that if the digital signature is not transmitted in the controlled script, the pharmacy or last intermediary will have to digitally sign the prescription.

Page 16260, 16261: Under the interim final rule, using a private key to sign controlled substance prescriptions will be an option provided that the associated digital certificate is obtained from a certification authority that is cross-certified with the Federal PKI Policy Authority at a basic assurance level or above. The electronic prescription application will have to support the use of digital signatures, applying the same criteria as proposed for Federal systems. The private key associated with the digital certificate will have to be stored on a hard token (separate from the computer being accessed) that meets the requirements for FIPS 140-2 Security Level 1 or higher. If a practitioner digitally signs a prescription with his own private key and transmits the prescription with the digital signature attached, the pharmacy will have to validate the prescription but no other digital signatures will need to be applied. (If the practitioner uses his own private key to sign a prescription, the electronic prescribing application will not have to apply an application digital signature). If the digital signature is not transmitted, the pharmacy or last intermediary will have to digitally sign the prescription. DEA emphasizes that Federal systems will be free to impose more stringent requirements on their users, as they have indicated that they do.

1311.210 Archiving the initial record

- (a) Except as provided in paragraph (c) of this section, a copy of each electronic controlled substance prescription record that a pharmacy receives must be digitally signed by one of the following:
- (1) The last intermediary transmitting the record to the pharmacy must digitally sign the prescription immediately prior to transmission to the pharmacy.
 - (2) The first pharmacy application that receives the electronic prescription must digitally sign the prescription immediately on receipt.
- (b) If the last intermediary digitally signs the record, it must forward the digitally signed copy to the pharmacy.
- (c) If a pharmacy receives a digitally signed prescription that includes the individual practitioner's digital signature, the pharmacy application must do the following:
- (1) Verify the digital signature as provided in FIPS 186-3, as incorporated by reference in 1311.08.
 - (2) Check the validity of the certificate holder's digital certificate by checking the certificate revocation list. The pharmacy may cache the CRL until it expires.
 - (3) Archive the digitally signed record. The pharmacy record must retain an indication that the prescription was verified upon receipt. No additional digital signature is required.

Emdeon supports the use of a field indicating the prescription has been signed; however, we believe it is important for the DEA to separately consider the participants and pathways associated with an electronic prescribing transaction to clearly delineate each participant's area of responsibility. Intermediaries, or clearinghouses, are entities that accept an electronic transaction from another organization and electronically routes the transaction to a receiving entity. When requested by the submitter, intermediaries also perform value-added services to the electronic transaction, including version control, data validation, digital signatures, and routing. Emdeon strongly believes intermediaries are an important partner in the electronic prescribing process; connecting multiple partners and routing claims that goes above and beyond the ability to convert from one software version to another.

In cases when a digital signature indicator is transmitted in a controlled substance prescription from the physician, and thus, it is assumed the prescription has been signed as a result, Emdeon, or other intermediaries that happen to be the last intermediary, can provide a service to its pharmacy customers by digitally signing the prescription as stated above. However, our interpretation is that by signing the prescription in this manner, the last intermediary is certifying for the pharmacy that the electronic prescription was transmitted with a digital signature indicator and is digitally signed by the intermediary, as received.

Transmission of Digital Signature

The digital signature option appears to assume there is a direct connection between the prescriber system and the pharmacy system. In interpreting further, it appears if an intermediary is involved, the prescription may not be translated/modified (especially the DEA "data") – this translation/modification would render the digital signature invalid. If the transmission is digitally signed (a wrapper), any change to the packet of information—including reformatting—makes the digital signature invalid. If an intermediary performs functions of translation, mapping, etc, we do not understand how the intermediary could perform the same functions in the digital signature scenario.

Signing and Transmitting the Prescription

Page 16283: As some commenters recommended, the interim final rule requires two-factor authentication to be synonymous with signing. In fact, the interim final rule expressly states that the completion of the two-factor authentication protocol by the practitioner legally constitutes that practitioner's signature of the prescription. When the practitioner completes the two-factor authentication protocol, the application must apply its (or the practitioner's) private key to digitally sign at least the information required under part 1306. That digitally signed record must be electronically archived. As commenters suggested, this revision allows other staff members to add information not required by DEA regulations after signature, such as pharmacy URLs, and at LTCFs, allows staff to review and annotate records before transmission, so that current workflows can be maintained.

As an intermediary, Emdeon wishes to clarify that such entities have similar latitude in adding information to a prescription that does not alter the restricted content as required by the rule, similarly to the latitude allowed by staff members within prescriber offices, such as with the inclusion of pharmacy URLs, during the transmission process as stated above.

Content Alteration

G. Transmission Issues (page 16263)

DEA Response: DEA has revised the rule to clarify that the content of the required information must not be altered during transmission between the practitioner and pharmacy. The requirement not to alter prescription information during transmission applies to actions by intermediaries. It does not apply to changes that occur after receipt at the pharmacy. Changes made by the pharmacy are governed by the same laws and regulations that apply to paper prescriptions. Again, any applicable State laws must also be complied with. As for changes by intermediaries during transmission, DEA is limiting only changes to the DEA-required elements (those set forth in 21 CFR part 1306). An intermediary could add information about the practitioner other than his name, address, and DEA registration number or about the patient, other than name and address. Alteration during transmission would be identified by comparing the digitally signed prescription retained by the electronic prescription application and the digitally signed prescription retained by the pharmacy.

1311.170 (e) and (f) Transmission requirements

(e) The contents of the prescription required by part 1306 of this chapter must not be altered during transmission between the practitioner and pharmacy. Any change to the content during transmission, including truncation or removal of data, will render the electronic prescription invalid. The electronic prescription data may be converted from one software version to another between the electronic prescription application and the pharmacy application; conversion including altering the structure of fields or machine language so that the receiving pharmacy application can read the prescription and import the data.

(f) An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (e.g., facsimile) for transmission.

1306.05 Manner of issuance of prescriptions

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

1311.120 Electronic prescription application requirements

(b) The electronic prescription application must meet the requirements of this subpart including the following:

- (9) The electronic prescription application must present for the practitioner's review and approval all of the following data for each controlled substance prescription:
- (i) The date of issuance.
 - (ii) The full name of the patient.
 - (iii) The drug name.
 - (iv) The dosage strength and form, quantity prescribed, and directions for use.
 - (v) The number of refills authorized, if applicable, for prescriptions for Schedule III, IV, and V controlled substances.
 - (vi) For prescriptions written in accordance with the requirements of 1306.12(b) of this chapter, the earliest date on which a pharmacy may fill each prescription.
 - (vii) The name, address, and DEA registration number of the prescribing practitioner.
 - (viii) The statement required under 1311.140(a)(3).

Emdeon supports the transmission requirements as stated in section 1311.170 (e) and the requirement for transmitting the necessary unaltered content as outlined in part 1306.05 (a), and 1311.120 (b) (9). It is our interpretation that an alteration to a script is allowed for intermediaries, if the alteration does not include changes to the content as stated in part 1306.05 (a) and 1311.120 (b) (9). For example, allowable alterations by intermediaries may include modification for version control and routing information.

Aggregators/Intermediaries

6. PKI and Digital Signatures (page 16260)

DEA Response. DEA agrees with the practitioner organizations and other commenters that the digital signature option should be available to any practitioner or group that wants to adopt it and has revised the interim final rule to provide this option to any group. DEA believes it is important to provide as much flexibility as possible in the regulation and accommodate alternative approaches even if they are unlikely to be widely used in the short-term. DEA notes that a number of commenters, including a major pharmacy chain, anticipate that once the SCRIPT standard is mature, the intermediaries will no longer be needed and prescriptions will then move directly from practitioner to pharmacy as they do in closed systems.

Emdeon maintains support for an environment of interoperability that allows physicians and pharmacists the flexibility and choices they need to operate their businesses effectively. However, there are many real-time benefits intermediaries provide to the industry in processing controlled substances, including confirming prescriber eligibility, confirming the rules in the SCRIPT standard are met between physician and pharmacy participants, supporting multiple machine languages for various software formats and versions, and performing patient eligibility checks. These benefits go above and beyond the important networking role of intermediaries in connecting multiple parties and handling network routing.

1311.115 Additional requirements for two-factor authentication.

- (a) To sign a controlled substance prescription, the electronic prescription application must require the practitioner to authenticate to the application using an authentication protocol that uses two of the following three factors:
- (1) Something only the practitioner knows, such as a password or response to a challenge question.
 - (2) Something the practitioner is, biometric data such as a fingerprint or iris scan.
 - (3) Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.

(b) If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140-2 Security Level 1, as incorporated by reference in 1311.08, for cryptographic modules or one-time-password devices.

(c) If one factor is a biometric, the biometric subsystem must comply with the requirements of 1311.116.

Emdeon currently processes controlled substance prescriptions in support of this two-factor authentication requirement with the crypto key technology being utilized by physicians within the MDPH research project.

Implementation

Promoting industry adoption of the interim final rule as soon as possible is a goal we all share, recognizing it will take time to become fully compliant with the rule in its current form. For example, it will take time for certification organizations to be put in place for the CAs (Certifying Authorities), CSPs (Credentialing Service Providers), and for third party certification or audit requirements to be met by pharmacies and pharmacy application providers (defined in Section 1311.200). Additionally, we all understand time will be needed to develop and approve a permanent field within the SCRIPT standard to accommodate the digital signature indicator. We recommend that the DEA work with the industry representative groups to establish interim implementation guidelines which may allow for adoption variances while long term infrastructure is developed and implemented to meet the minimum requirements of the interim final rule.

Closing

Emdeon supports efforts to move the industry forward in complying with the new DEA regulations and welcomes the opportunity to work with the DEA, Centers for Medicare & Medicaid Services (CMS), the National Council for Prescription Drug Programs (NCPDP), American Medication Association (AMA), Medical Group Management Association (MGMA), American Academy of Family Physicians (AAFP) and others, to ensure a smooth transition and successful implementation as the rules are finalized.

Sincerely,



George Lazenby
CEO



Mark Lyle
Senior Vice President, Pharmacy Services