

May 28, 2010

Department of Justice
Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Docket No. DEA-218

21 CFR Parts 1300, 1304, 1306, and 1311

RIN: 1117-AA61
Electronic Prescriptions for Controlled Substances
Interim Final Rule with Request for Comment

Dear Ms. Leonhart:

On behalf of the American Medical Informatics Association (AMIA), I am pleased to submit these comments in response to the above-referenced interim final rule. AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of information and communications technology.

AMIA's 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public and population health, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations. As a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure and public health considerations, we appreciate the opportunity to submit comments on the interim final rule.

AMIA thanks the Drug Enforcement Agency (DEA, or the Agency) for issuing this interim final rule, which revises the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Controlled Substances Act, or CSA) and related regulations to allow healthcare providers to write prescriptions for controlled substances electronically. We appreciate that, in writing the interim final rule, the Agency has considered input from many commenters, and we offer our viewpoints on some of their criticisms. We recognize that electronic prescribing (also known as *e-prescribing*) activities fall under the jurisdiction of the Department of Justice and the DEA. At the same time, e-prescribing takes place

within the range of activities regulated by the U.S. Department of Health and Human Services (HHS), and we have referenced a number of recent proposed and interim final rules and guidances issued by HHS or its agencies.

As DEA notes in the interim final rule, the CSA is set up so that no action related to a controlled substance is legally permissible unless it is specifically permitted by CSA. (16237) Accordingly, this rule is being promulgated to establish the parameters by which practitioners may prescribe, pharmacies may dispense, and any number of intermediaries may process, electronic prescriptions of controlled substances lawfully. Currently, only a small percentage of prescriptions are issued electronically, but the practice is growing rapidly as the technology supporting, and rules governing, health information technology (HIT) continue to mature.

AMIA is mindful of the additional work that the rule will impose upon healthcare professionals who wish to issue or accept electronic prescriptions. (As noted on pg 16239, generally, pharmacies today maintain prescription records electronically, even for prescriptions which they receive on paper. In contrast, most doctors currently issue their prescriptions on paper, so of the two groups, doctors are further from full adoption of e-prescribing.) As DEA emphasizes, “the electronic prescribing of controlled substances is in addition to, not a replacement of, existing requirements for written and oral prescriptions for controlled substances,” (16244) so compliance with laws such as HIPAA does not mean the practitioner’s actions will be in compliance with the interim final rule. (16280) Similarly, consistent with existing law, “[t]he practitioner issuing an electronic controlled substance prescription is responsible if a prescription does not conform in all essential respects to the law and regulations.” (16281) AMIA agrees that existing laws should not be displaced by the new rule, but we wish to ensure that the burdens of compliance are duly considered and mitigated to the extent possible.

Likewise, although the Agency states several times that e-prescribing is completely voluntary for both practitioners and pharmacists (e.g. 16262, 16278), it is a required element of Meaningful Use (MU) per the proposed rule from the Centers for Medicare and Medicaid Services (CMS) [Electronic Health Record Incentive Program, 42 CFR Parts 412, 413, 422, and 495], so in practice, a practitioner who issues prescriptions could avoid e-prescribing temporarily, at most. Not only would the practitioner be ineligible for incentive funding being made available for MU over the next few years, but he/she would actually be penalized for failing to implement the new technologies. Practitioners may also have other reasons to issue prescriptions electronically. As the interim final rule notes, “DEA expects that over time, as electronic prescribing becomes the norm, practitioners issuing paper prescriptions for controlled substances may find that their prescriptions are examined more closely.” (16300) While increased oversight from law enforcement might not necessarily require the practitioner to do more non-medical work (in responding to audits and other inquiries), the possibility of such inconvenience is likely to be another factor that contributes to the practical necessity of switching from paper to electronic prescriptions. The interim final rule also states that an EHR that does not comply with the e-prescribing standards could still be used to keep an electronic record of the prescription, and for printing out a paper prescription for the doctor to sign. (16279) Again, as the result would be a paper prescription, this option would be inadequate as it would necessitate maintaining a separate infrastructure for printing

controlled substance prescriptions and these printed prescriptions would be inconsistent with the e-prescribing criterion of the MU rule.

Issues Raised by Electronic Prescribing

While e-prescribing has the potential to be beneficial in many ways, its relatively novel methods of getting prescriptions from practitioner to pharmacy also carry new challenges that require attention. For instance, AMIA appreciates that the Agency has endeavored to minimize the number of steps required for a practitioner to issue an e-prescription. (A practitioner can review a list of controlled substance prescriptions without using two-factor authentication, then use two-factor authentication to sign them. (16256) While it would be impossible to predict every type of issue that could arise as e-prescribing is implemented widely, examples like this, and the ones described below, will help conformity with the new rule to be more manageable.

In the world of paper prescriptions, the prescription itself “serves both as a record of the practitioner’s determination of the legitimate medical need for the drug to be dispensed, and as a record of the dispensing, providing the pharmacy with the legal justification and authority to dispense the medication prescribed by the practitioner.” (16238) In contrast, an electronic prescription provides no inherent forensic evidence, which is unfortunate as such evidence could be used to exonerate a practitioner if his/her name or DEA registration number were to be used to create a fraudulent prescription. AMIA agrees that the threat of fraudulent electronic prescriptions is troublesome, but if e-prescribing is to be implemented, we believe that two-factor authentication reduces the risk to an acceptable level, as discussed below.

DEA recognizes that “[a]lthough practitioners may write most of their prescriptions while at their offices, they will probably want the ability to access their office applications when they are away from the office so they can issue prescriptions remotely when needed; such access will frequently be through the Internet and may use wireless connections.” AMIA believes that if e-prescribing is to replace a significant proportion of traditional paper prescribing, the ability for a practitioner to issue a prescription electronically while away from his/her office is essential. Of course, the practitioner must be assured by the application provider that all such electronic transmissions will be encrypted in transit. (See the Guidance regarding rendering health information “not unsecured” contained in the interim final rule from the Department of Health and Human Services concerning Breach Notification for Unsecured Protected Health Information, 45 CFR PARTS 160 and 164.)

It is useful that the Agency has also considered the likely benefits of switching to electronic prescriptions: “although illegible handwritten prescriptions are unquestionably a problem, in most cases the pharmacists resolve the problem by calling the practitioner to clarify the prescription rather than risk dispensing the wrong drug.” (16292) Such a statement is useful in valuing the effect of the new rule, because in some situations its new costs and burdens should be weighed against a small savings of time and administrative resources, rather than saved lives or reduced injuries from incompatible drug combinations.

Of course, the Agency also recognized the fallibility of electronic systems, and the frustration that can result in humans who interface with them. “The formulary and contraindication checks are functions that practitioners sometimes disable because they do not work as they should or take too much time.... [E]lectronic prescriptions may provide benefits in avoided medication errors, reduced processing time, and reduced callbacks. These benefits of electronic prescriptions are not directly attributable to this rule because they accrue to electronic prescribing, not the incremental changes being required in this rule.... Whether formulary and contraindication callbacks are eliminated will depend on the functions of the electronic prescription applications and the accuracy of the drug databases that they use.” (16299)

A final advantage of e-prescribing discussed in the interim final rule is a “reduction in forgeries [which] will also benefit practitioners who will be less likely to be at risk of being accused of diverting controlled substances and of then having to prove that they were not responsible.” (16300) Because we do not know the current number of forgeries, AMIA strongly supports the collection of data to monitor the impact of e-prescribing on this problem.

New Involvement of Third Parties

Whereas the paper prescribing standard normally involved only the practitioner issuing the prescription, and the pharmacist filling it, e-prescribing almost always involves other parties. Perhaps most important among these new third parties are the vendors who will provide the software that gets the prescription from the prescriber to the pharmacy. Practitioners will rely on these application providers to comply with the specific terms of the interim final rule, such as the retention of several pieces of information about the electronic prescriptions as required by §1311.120. (16306) At the outset, an “electronic prescription application must allow the setting of logical access controls to ensure that only DEA registrants or persons exempted from the requirement of registration are allowed to indicate that prescriptions are ready to be signed and sign controlled substance prescriptions.” (16242) While much of the responsibility for compliance with the rule will be shifted to the application provider after that point, it makes sense that the application provider must be able to allow only authorized practitioners to access its application.

A big reason these application providers are so crucial is that e-prescribing ceases to work if their product fails: if an application is not working properly, a “practitioner must not use the application to issue controlled substance prescriptions until it is notified that the application is again compliant and all relevant updates to the application have been installed.” (16286) Consequently, AMIA agrees with the requirement that application providers notify practitioners and pharmacies about any problems with the application as soon as possible. (16289) However, we are concerned that five business days after the problem has been identified is entirely too long for the application provider to notify the prescriber. Prescribing, as the Agency knows, is a seven-day-a-week, 24-hour-a-day enterprise. Thus, we believe that prescribers should be notified of any malfunctions or other problems with e-prescribing applications not later than 24 hours after the problem has been discovered.

Further, the interim final rule requires application providers to take steps to help detect fraud. Under the scheme described on pg 16263, the application will be required to automatically provide the practitioner with a monthly log of all the controlled substance prescriptions he/she has issued. Assuming, as the rule

does, that the log is provided to the practitioner without him/her having to ask for it, will result in more practitioners actually reviewing the logs (although the rule does not require the practitioner to indicate his/her review of the log (16283)), and detecting, “without excessive delay, any instances of fraud or misappropriation of their two-factor authentication credentials.”

In fact, DEA appears to be relying on industry innovation, as its approach in the rule is one of setting general guidelines rather than specific standards, in order to allow for flexibility (pg 16278-79) in ways affected individuals (such as doctors and pharmacists) may conform to them. Although this policy approach might foster competition among application providers, it may still fail to limit the costs of e-prescribing systems. “Adoption of these applications has been relatively slow, primarily because of their cost, the disruption caused during implementation, and lack of mature standards that allow for interoperability among applications.” (16238) “The barriers to adoption continue to be the high cost of the applications, which may be greater than the subsidies; the disruption that implementation creates in a practice; and uncertainty about the applications themselves.” (16301)

Helping practitioners to ensure application providers are giving them a good product “DEA proposed third-party audits as a way to provide registrants with an objective appraisal of the applications they purchase and use.... except for registrants associated with very large practices, large healthcare systems, or chain pharmacies...the majority of registrants cannot be expected to determine, on their own, whether an application meets DEA’s requirements. If they are to have assurance that the application they are using is in compliance with DEA regulatory requirements, that assurance must come from another source.” (16269) We appreciate the Agency’s recognition that a third party audit or independent certification can provide assurance that e-prescribing applications will be compliant with the requirements of this interim final rule. In regard to certification, we support the certification and accreditation programs for EHRs and EHR Modules (such as an e-prescribing application) outlined in the proposed rule from the Office of the National Coordinator for Health Information Technology, Proposed Establishment of Certification Programs for Health Information Technology, 45 CFR Part 170.

Another third party will conduct identity proofing. “The interim final rule requires that practitioners wishing to prescribe controlled substances undergo identity proofing by an independent third-party credential service provider (CSP) or certification authority (CA) that is recognized by a Federal agency as conducting identity proofing at the basic assurance level (Assurance Level 3 for CAs) or greater. The CSP or CA will then issue the credential. This approach removes the electronic prescription application provider from the process of issuing the credential, which limits the ability of individuals at the application provider to steal identities and ensures, to as great an extent as possible, that a person will not be issued a credential using someone else’s identity.” (16290, 16303, 16245) §1311.110(e) “DEA has expanded upon the proposed rule to allow institutional practitioners, which are themselves DEA registrants, to conduct the identity proofing for any individual practitioner whom the institutional practitioner is granting access to issue prescriptions using the institution’s electronic prescribing application.” “An institutional practitioner that elects to conduct identity proofing must retain a record of the identity-proofing.” (16312) AMIA appreciates that the rule allows institutional practitioners to conduct their own identity proofing, but we remain concerned about the expense and time that will be

required of individual practitioners or small practices that will have to find and contract with a third party CSP or CA.

Finally, there are third parties who handle and process electronic prescriptions while they are in transit between the practitioner and the pharmacy. DEA believes the involvement of intermediaries will not compromise the integrity of electronic prescribing of controlled substances, provided the requirements of the interim final rule are satisfied (16272); AMIA has no reason to question this assumption.

Additional Security Considerations

Diversion, by which controlled substances make their way into the wrong hands, was a problem before e-prescribing was contemplated, and it will continue to be a problem into the future. Holding a DEA registration creates “an expectation of due diligence on the part of the practitioner to ensure that information regarding potential diversion is provided to law enforcement authorities, where circumstances so warrant.” (16261) The interim final rule says that determining whether or not an electronic prescription was actually issued by the practitioner who digitally signed it “would be very difficult with the existing processes,” (16240) so the Agency has declared that e-prescribing will require two-factor authentication, meaning that the practitioner will need both a password and a “hard token” to digitally sign a prescription.

AMIA agrees that the two-factor authentication requirement will be helpful in limiting the possibility of someone other than the registrant issuing an electronic prescription. While the use of the hard token, especially for a practitioner who issues dozens of prescriptions per day, might be burdensome at first, the concomitant increase in security may justify the additional time spent, which should be minimal after the practitioner gets acclimated to the routine. As the interim final rule provides no exception to the two-factor authentication requirement for small practices, we are concerned that solo and small group practitioners are often significantly constrained not only in terms of financial resources, but in terms of the time available for all manner of administrative tasks. AMIA has no objection to the provision allowing practitioners to replace the hard token authentication factor with a biometric authentication factor, but we do not believe many practitioners will choose the more expensive biometric option. For the ones who do, we agree that requiring a biometric reader device to have a false match rate of .001 or lower is an appropriate standard.

The interim final rule dictates that “...information required under part 1306 must not be altered after the prescription is digitally signed. If any of the required information is altered, the prescription must be canceled.” (16287) We agree with this requirement because, as the DEA notes, “[u]nless the record is digitally signed before it moves through the transmission system, practitioners would be able to repudiate prescriptions by claiming that they had been altered during transmission (inadvertently or purposefully).” (16259)

The Agency has chosen to require that electronic records be maintained for two years from the date the prescription was created or received. AMIA supports this requirement, and we appreciate that the Agency has made it easier on practitioners and pharmacies by removing “the requirement for storage of back-up records at another location.” (16267) Similarly, we have no objection to the rule’s other terms

regarding electronic record-keeping: §1311.305(a) “If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.” (16319) “Practitioners who issue electronic prescriptions for controlled substances must use electronic prescription applications that retain the record of the digitally signed prescription information and the internal audit trail and any auditable event identified by the internal audit trail....Registrants and application service providers must retain a copy of any security incident report filed with the Administration.” (16284)

The interim final rule recounts that “[s]ome commenters believed that allowing practitioners to sign prescriptions for multiple patients at one time posed health and safety risks for the patients. Others stated that the prescriber might not notice fraudulent prescriptions in a long list.... DEA has revised the rule to allow signing of multiple prescriptions for only a single patient at one time.” AMIA notes that a practitioner must always be vigilant in looking for mistakes before signing, or digitally signing, his/her name to any prescription; as the interim final rule says, “[t]he individual practitioner is responsible for ensuring that the prescription conforms to all legal requirements,” (16238) and the same responsibilities exist when “issuing prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription.”(16311) We therefore believe that allowing practitioners to sign prescriptions for multiple patients at the same time would not cause those practitioners to inadvertently sign prescriptions containing errors.

For the practitioner’s review of the prescription, “DEA has revised the rule to limit the required data displayed for the practitioner on the screen where the practitioner signs the controlled substance prescription to the patient’s name, drug information, refill/fill information, and the practitioner information.” (16254) AMIA believes this information is adequate for the purpose of detecting fraud.

In regard to the issue of costs --- Table 6 (attached) presents the projected implementation rate for practitioners (16296); Table 7 (attached) shows projected annualized costs. (16297) We hope that DEA is correct in its estimate that it will only take five minutes to enter the data to grant access for the first time at a practice or pharmacy. (16295

AMIA again wishes to thank the Agency for issuing this interim final rule and appreciates the opportunity to submit comments. Please feel free to contact me at any time for further discussion of the issues raised here.

Sincerely,

A handwritten signature in black ink that reads "Edward H. Shortliffe". The signature is written in a cursive, flowing style.

Edward H. Shortliffe, MD, PhD
President and CEO

**TABLE 6—IMPLEMENTATION RATES
FOR PRACTITIONERS**

	Implementation rate (percentage)	Cumulative percentage
YEAR 1	6.0	6.0
YEAR 2	10.0	16.0
YEAR 3	20.0	36.0
YEAR 4	20.0	56.0
YEAR 5	20.0	76.0
YEAR 6	10.0	86.0
YEAR 7	5.0	91.0

**TABLE 6—IMPLEMENTATION RATES
FOR PRACTITIONERS—Continued**

	Implementation rate (percentage)	Cumulative percentage
YEAR 8	2.0	93.0
YEAR 9	1.0	94.0
YEAR 10 ...	1.0	95.0
YEAR 11 ...	1.0	96.0
YEAR 12 ...	1.0	97.0
YEAR 13 ...	1.0	98.0
YEAR 14 ...	1.0	99.0
YEAR 15 ...	1.0	100.0

TABLE 7—OPTION 1 ANNUALIZED COSTS BY ITEM AND BY SECTOR—7.0 PERCENT

	Practitioners' offices	Hospitals	Pharmacies	Application providers	Totals
Credential	\$14,669,488	\$14,669,488
Credential application	3,844,882	3,844,882
Registration check	30,405	30,405
Granting access	303,086	\$16,752	319,838
Training for granting	7,147,886	50,255	7,198,142
Review security logs	4,248,868	\$1,524,079	1,959,040	7,731,986
ID verification	4,717,580	4,717,580
Reprogram applications	\$3,842,530	3,842,530
Obtain certification	391,021	391,021
Audit of applications	583,957	583,957
Totals	30,244,615	6,241,658	2,026,046	4,817,509	43,329,829