



Published by Point-Of-Care Partners www.pocp.com

Knocking Down Another Barrier: ePrescribing of Controlled Substances is Now Allowed

By Tony Schueth, Editor and Chief

As if things weren't busy enough in Washington, the Drug Enforcement Administration (DEA) finally issued a long-awaited regulation that permits ePrescribing of controlled substances. The DEA has taken more than two years to promulgate this rule, which addresses issues and hundreds of comments received on the draft rule that came out in 2008. Officially published in the *Federal Register* on March 31, the rule's provisions will go into effect in 60 days. It can be downloaded at <http://frwebgate.access.gpo.gov/cgi-bin/multidb.cgi>

Here's the *Cliff Notes* version of the rule:

- **Authentication.** To prescribe controlled substances electronically, a clinician must access the ePrescribing component of an electronic health record (EHR) or ePrescribing system via two of the following: 1) hard token, 2) knowledge factor (e.g., PIN or password) or 3) biometric.
- **Upfront identify proofing.** ePrescribers for controlled substances must be credentialed by a certified third party. This involves checking the person's government-issued photo ID against the person presenting it, and determining that the person is legally able to prescribe controlled substances. That entity would provide a certificate which would, then, be given to the vendor. Without that certification, the prescriber would be restricted from prescribing controlled substances.
- **ePrescriptions.** All ePrescriptions for controlled substances must be dated as of, and signed on, the date issued. They must include the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed and directions for use; and the name, address and registration number of the practitioner.
- **Paper prescriptions.** The Prescriber could use the clinical software system to originate the prescription, and then print it for manual signature on paper. Such prescriptions are subject to existing requirements. In addition, the ePrescribing application or EHR may print copies of an electronically transmitted Schedule 3-5 prescription, if they are clearly labeled as such, not valid for dispensing.
- **PKI.** Use of public key infrastructure (a big issue in the 2008 proposed rule) is optional.
- **Extra review and digital "signoff" needed.** Someone other than the prescriber may "queue" the prescription; however, the DEA is requiring that the application display a list of controlled substance prescriptions for the practitioner's review before authorization. A separate list must be displayed for each patient. The application must prompt the prescriber to begin the two-factor authentication protocol, the completion of which

legally signs the prescription(s). The application must, then, digitally sign and archive at least the DEA-required information.

- **Monthly logs.** The application must generate a monthly log of controlled substance prescriptions issued by a registrant, archive a record of those logs, and provide the logs to the practitioner. The practitioner is not required to review the monthly log, but can use it as a tool in case abuse is suspected.
- **Prescription content and formats.** Content may not be altered during transmission, although intermediaries may alter formats and certain legally allowed changes may be made at a pharmacy after receipt. Pharmacy changes for ePrescriptions are governed by the same statutory and regulatory limitations that apply to paper prescriptions. Intermediaries may not convert an electronic controlled substance prescription into a fax.
- **Audit trails.** Both the ePrescription and pharmacy application must maintain an internal audit trail that records any modifications, annotations, or deletions of an electronic controlled substance prescription, or when a functionality required by the rule is interfered with; the time and date of the action; and the person taking the action. The application provider and the registrants must develop a list of “auditable events,” which should be occurrences that indicate a potential security problem.
- **Record retention.** Once a prescription is created electronically, all records of the prescription must be retained electronically for two years from the date on which they were created or received. Pharmacy records must be backed up daily, although the rule does not specify where back-up files must be stored.

We applaud the DEA for finally issuing this regulation. Its absence has been a significant barrier to ePrescribing and electronic health record (EHR) adoption because an electronic prescriber must have two processes for prescribing: one for controlled and one for non-controlled substances.

We think this rule is an improvement over the 2008 Notice of Proposed Rulemaking. However, it still places far more requirements on the electronic transmission of controlled substance prescriptions than on the antiquated paper process. Moreover, we find some of its requirements to be overly burdensome on providers. Nonetheless, we hope this signals a new willingness by the DEA to work with the ePrescribing industry and use technology to prevent and detect prescription drug diversion.

POCP has been intimately involved in working on this issue with the federal government and other relevant stakeholders (e.g., National Committee on Vital and Health Statistics) since 2002. We are well-positioned to interpret the DEA’s new requirements and apply them to your situation, whether you are a vendor, health care provider, payer, state government or other stakeholder. Give us a call or drop us a line. Let us put our value-driven products and services to work for you.

Gazing into the Crystal Ball: What Will the DEA Rule Mean for ePrescribing?

By Tony Schueth, Editor in Chief

Now that the DEA rule is finally published, everyone is scrambling to figure out what it means. We have been working this issue for the better part of a decade. As a result, we have more than a few ideas about how this rule will impact the industry, based on our experience with the DEA and other federal agencies, our hands-on work in the ePrescribing space, and our ability to pull pieces together to make informed market analysis. Even though things are obviously in a state of flux, there are some things we DO know at this time and can make some educated guesses about.

Regulatory Requirements. This rule is technically called an Interim Final rule with Comment (IFC). That means its provisions will go into effect almost immediately, although some may – and we emphasize may – change in response to the comments received. Things may change if there is a huge public backlash; however, we believe this is unlikely. In addition, the core details in the IFC and rationales for them are fairly close what was in the draft rule issued in 2008. If you feel strongly about elements of this rule, it is a good idea to send in comments to the DEA in the next 60 days; however, we are not expecting many changes as a result of this latest round of industry input. Our only advice is to provide sound justification for your objections and alternatives.

Vendors. Most EHRs and ePrescribing system vendors are not ready to meet the DEA’s requirements, and will be challenged to deal with them at the same time they are scrambling to adjust to the meaningful use requirements of the American Recovery and Reinvestment Act of 2009 (ARRA). Frankly, many vendors have waited to see what the DEA would require before beginning any detailed development work. To be sure, there are some vendor solutions available for authentication; however, it is unclear how these might be integrated with various ePrescribing offerings or how much they will add to the price tag.

Institutional providers. The DEA’s IFC benefits institutional prescribers the most, as they are well positioned to hit the ground running, especially around the most onerous – authentication and identity proofing. Most large institutions already have credentialing services for their providers, who will not have to spend extra time and money in getting vetted for ePrescribing. Many large institutions are able to meet the access controls and workflow changes required by the DEA’s requirements, or can easily retrofit what they have.

Small group and solo- providers. Small group- and solo- physician practices will be burdened the most by the DEA’s new rules. That is because of the extra time, additional expense and hassle it will take to get credentialed, buy an appropriate system and integrate the new requirements into their work flow. As a result, they may delay purchasing an application, totally drop back to paper for controlled substance prescriptions; or they will print and wet-sign controlled substance prescriptions. This is likely to diminish the DEA’s goals of prescription drug diversion, because it keeps paper prescriptions in the hands of patients.

Regional Extension Centers (RECs). The DEA’s IFC comes at a good time for the new RECs. These are just getting off the ground, so they can bake the DEA’s requirements into their planning and implementations. They might consider what it would take to become a credentialing organization. This would be helpful in many areas, particularly in rural parts of the country that lack such infrastructure, and possibly provide an additional income stream. Facilitating ePrescribing, in general, furthers the RECs’ missions and helps them to earn grant

monies, as the electronic transmission of controlled substances can contribute to the Meaningful Use metrics.

Pharmacies. The DEA’s requirements will affect pharmacy vendors more than pharmacies themselves. Pharmacy vendors will need to make multiple changes to meet the new requirements to process electronic controlled substance prescriptions. But, since electronic prescriptions for controlled substances **cannot be converted to fax** during transmission, pharmacies that currently do not accept electronic prescriptions, will not be able to receive these prescriptions in the same manner as other legend drugs. These pharmacies that do not accept electronic prescriptions will need to verify that Schedule III-V prescriptions are manually signed by the prescriber if they are received via fax and Schedule II prescriptions will continue to be received as a paper prescription. However, the new IFC changes very little for those pharmacies that accept electronic prescription in terms of the pharmacies’ day-to-day activities. Obviously, community pharmacies will need to feed the DEA’s requirements into selecting their ePrescription solutions and into their workflow.

States. The DEA’s IFC is a “floor,” which means that States may place additional requirements upon this federal base. Many States have additional requirements on place for ePrescribing of controlled substances, and these are still operative. Some States defer to the DEA. Others have been waiting for the DEA rule to come out so they can update their laws and regulations during coming Board of Pharmac meetings and legislative sessions. POCP maintains an up-to-date compendium of State pharmacy laws related to ePrescribing. Let us send you the latest or develop a customized profile for your market area.

Ultimately, we view this rule as being very good for ePrescribing, as the restriction of ePrescribing of controlled substances stood as one of the last barriers to adoption and utilization of ePrescribing functionality. The risk is that since it hits amid several other game-changing events – mostly emanating from ARRA – it won’t be studied, reviewed and understood in the same way as, say, “meaningful use,” which it has been observed, is “sucking the wind out of” anything else HIT-related. We advise that you don’t fall into that trap. And, if you need an extra set of hands or experienced brains, don’t hesitate to contact us.

<p>This message was sent from David Green to david.green@pocp.com. It was sent from: Point-of-Care Partners, LLC, 11236 NW 49th Street, Coral Springs, Florida 33076-2771. You can modify/update your subscription via the link below.</p>	<p>Email Marketing by</p> <div data-bbox="1177 1501 1421 1585" style="border: 1px solid black; height: 40px; width: 150px;"></div>
--	--

[Manage your subscription](#)