Topical Review
Electronic Prescribing of Controlled Substances (EPCS)
June 20, 2011

Controlled substances can now be legally prescribed electronically, once specific criteria [1] are met. States across the country are working to adapt regulations to accommodate this rule, vendors are changing their products, and new groups are stepping forward to help create the needed infrastructure. Electronic prescribing of controlled substances is coming, but is not ready for clinician use just yet. This tool offers advice for getting the medical office or pharmacy ready, current best practices for managing controlled substances, and the projected changes in best practices based on the present legislation.

Getting Ready for Electronic Prescribing of Controlled Substances: Medical Office

1. Evaluate the relative impact of EPCS for your office by surveying the number of controlled substance prescriptions currently handled in a day, week, or month.
   a. If more than 30% of prescriptions are controlled substances, consider implementing most, if not all, of the following suggestions.
   b. If 10% to 30% of prescriptions are controlled substances, consider implementing the top 3 of the following suggestions most appropriate to your practice.
   c. If less than 10% of prescriptions are controlled substances, consider implementing one or 2 of the following suggestions most appropriate to your practice.
2. Choose an e-prescribing application that is certified for EPCS by a DEA[2]-approved authority. Each prescriber of controlled substances will need 2-factor authentication credentials.
   a. With your software vendors, identify the timeline on which this certification or audit is expected to be completed. This determines the date you can begin using EPCS.
3. Reshape workflows that leverage time freed up for office staff to balance the additional prescriber time needed for EPCS. Work with your vendor to answer:
   i. How should refills be handled?
   ii. Who has the ability to approve CS[3] prescriptions and send them to the pharmacy?
   iii. How does the system prevent or limit fraud or misuse by staff?
   iv. How should prescribers and staff educate patients on changes that e-prescribing brings?
4. Acclimate patients to calling the pharmacy for renewal requests of non-controlled substances. When EPCS is available, the transition to calling the pharmacy for controlled substances will be seamless.
5. Create a document defining the conditions for a patient requesting a renewal for a controlled substance that should prompt a referral and discussion to the prescriber. After EPCS is ready, share this document with the top twenty pharmacies to which these prescriptions are sent.

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[1] As defined in 21 CFR Parts 1300, 1304, 1306, and 1311
[2] DEA = Drug Enforcement Administration
[3] CS = Controlled Substances

6. Script a patient education process for the staff to review with patients. This script should include the best way to request a renewal after patients receive a prescription for controlled substances.
7. Add e-prescribing training to the orientation of new employees that have prescription responsibilities.

Note: If a transmission of EPCS fails, current regulations for a paper prescription of CS should be followed.

Getting Ready for Electronic Prescribing of Controlled Substances: Pharmacy

1. Use electronic communication tools to provide more detailed communications to medical offices when resolving or anticipating questions regarding non-controlled substances.
2. Create a document defining the conditions that warrant a referral of a patient to their provider for further evaluation. After EPCS is ready, share this with your top twenty medical offices. Keep a copy on hand for ad hoc requests.
3. Script a patient education process for pharmacy staff to review with patients on the best way to request a renewal.
4. Instruct patients to call for refills and renewals for all prescriptions.
    a. Choose or upgrade the pharmacy software to include an e-prescribing module that is certified for EPCS by a DEA-approved authority. Each pharmacist may need 2-factor authentication credentials, but this has not yet been finalized.
5. Work with your vendor to educate staff regarding processes that change as a result of e-Prescribing controlled substances.
6. Work with prescribers to establish an understanding of usual time frames needed to process renewal requests, any additional information prescribers may need along with the request, and conditions that would prompt a patient to make an appointment with their provider for a renewal.
7. Incorporate controlled substance legal requirements into the standard medication counseling. Provide patients with reasonable expectations regarding the process for requesting renewals and define the scenarios where the patient must see their primary care provider.

References and Further Information

Full legal text of the interim final rule for electronic prescribing of controlled substances:
http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf

Q&A for EPCS: http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm

Rationale for pharmacists in the medical home model:
http://www.cshp.org/uploads/file/Newsroom/2010/why_pharmacists_belong_in_med_home_5_2010.pdf

Episode #14: Complexities of e-Prescribing: Physician and Pharmacist Viewpoints:

http://www.himss.org/ASP/physicianCommunityPodcast.asp

Renewal Requests

Bottom Line: Work shifts from office staff to the prescriber

Current Best Practice:	Expected change after EPCS:
• Patients call the prescriber's office to request renewals; *OR* • Pharmacies fax a renewal request to the prescriber's office; *THEN* • Secretary/Nurse prepares the prescription for prescriber review and authorization. In electronic systems, the prescription is printed instead of sent electronically.	• Patient calls the pharmacy to request renewal. • Pharmacy sends electronic renewal request to the prescriber's office. • Secretary/Nurse prepares the prescription for prescriber review and authorization. The response is sent electronically. o If the electronic transaction fails, the prescription is printed, signed, and managed as a paper prescription.

Rationale: The record of previous dispensing allows pharmacists to submit an accurate electronic request for a renewal, decreasing the burden of phone calls on medical office staff. The pharmacist is often in a better position to determine the medication the patient is requesting since the record of previous dispensing limits the possible medications the patient could be requesting. Communication fields in pharmacy software allow for robust notes to accompany the request and facilitate a reply by the prescriber, including whether the patient needs to be seen by their primary care provider before a prescription can be issued.

New Prescriptions

Bottom Line: No big changes in workflow

Current Best Practice	Expected change after EPCS
• The prescriber generates the prescription using an e-prescribing application or writes a paper prescription • The prescription is printed for a wet signature o State legislations vary with respect to fax and phone processes	• The prescriber generates the prescription using an e-prescribing application • Then "Signs" the prescription electronically using 2-factor authentication • Then transmits the prescription electronically to the patient's pharmacy of choice.

Rationale: No expected workflow changes as the prescriber is the primary actor in the current best practice and is expected to remain so after EPCS.

EPCS Documentation

Bottom Line: Automatic documentation is balanced against more documentation

Current Best Practice	Expected change after EPCS
- Prescriptions for controlled substances are documented in the chart as to: - Drug - Quantity - Directions - Start and stop dates - Some documentation of prescriptions for the chronic patient may be delegated - Ideally, documentation is in the chart that the patient is aware that deviations from the normal pattern of use will result in appropriate penalties.	- If the prescriber already has an EMR[4], the documentation of controlled substances does not change much. - There will likely be a new step in the clinic's workflow: a check to see if the patient already has a prescription (from another pharmacy and/or from another physician) for a given CS prescription. - These kinds of databases are already available in some states (e.g., Ohio); their existence and the form they take will vary from state to state.
Electronic documentation in both pharmacy and prescriber's office makes information surrounding the CS prescription more available. Though not easily done in today's paper based systems, workflows for checking adherence, timeliness of past fills, pharmacies used, and past prescribers may quickly develop, as much to mitigate the prescriber's and pharmacy's liability as to improve safety and accuracy of care. The advent of EPCS makes these functions much more realistic and accessible.	

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[4] EMR = Electronic Medical Record

EPCS Patient and Staff Education	
Bottom Line: Work shifts from the prescriber's office to pharmacies	
Current Best Practice	**Expected change after EPCS**

• Patients usually learn about controlled substance requirements in two ways:
 	
  a. From the pharmacist, when a prescription cannot be filled.
 	
  b. From practitioners and their staff, when a controlled substance prescription is needed, often prompted by a patient's request for renewal.
 	
• Staff may or may not have formal training on the legal requirements of controlled substance prescriptions. The same is true for learning workflows and procedures within the office or pharmacy to educate and instruct patients on the expectations and requirements surrounding controlled substances.
	• Counseling and education regarding controlled substance requirements will likely take on a much larger role in the pharmacy while simultaneously decreasing at the provider's office.
	
	• Additional formal staff education is needed in places where office staff participates in the electronic prescriptive process.
	
	• Accommodations in workflows may be necessary to allow for additional patient instruction time.
	
	• Offices may need to restructure workflows to leverage staff freed up from some demands (many renewal requests and CS education tasks will be shunted to the pharmacy) to provide support for prescribers that now have additional demands placed on them (2-factor authentication is required for both new prescriptions and renewal requests)

Rationale: Patients are increasingly being instructed by the practitioner's office to request renewals through the pharmacy. The increased complexity of sending controlled substances electronically requires that prescribers have a prominent role in the final disposition of all controlled substance prescriptions sent electronically, increasing demands for their time while that of their office staff decreases. Pharmacists are in a key position as both requestors of renewal prescriptions and dispensers of the final product to educate the patient regarding the regulations, expectations, and best practices surrounding controlled substances.

Annotations and Comments

Until the Rules' publication, there was no legal authority for an electronically transmitted controlled substance prescription. This resulted in:

- A complete separation of activities in which controlled substance prescriptions are written on paper while non-controlled substance prescriptions are transmitted electronically.

<div align="center">OR</div>

- A process by which the prescriptions are entered electronically in order to gain the safety checks associated with CPOE[5], but a corresponding paper copy is printed and signed for delivery to the pharmacy in order to handle the regulatory aspect of a legal prescription.
- EPCS aligns the medication order check process more consistently, improves patient satisfaction by reducing different methods by which their medications are dispensed, and affords high traceability of prescriptions through the security requirements defined by DEA.

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[5] CPOE = Computerized Physician Order Entry