

Forging a Pathway for Electronic Prescribing of Controlled Substances



Electronic prescribing (e-prescribing) helps clinical providers and pharmacies prescribe and dispense medications efficiently and safely. Although adoption and use of e-prescribing has increased significantly in recent years, from 7 percent of physicians e-prescribing through an electronic health record in 2008 to 48 percent in 2012¹, e-prescribing of controlled substances (EPCS) has lagged.

One barrier contributing to this lag was the lack of security standards for EPCS. Without appropriate standards to prevent and detect the diversion of federally controlled substances, such as narcotics, stimulants, and sedatives, from the legitimate medical market to the illicit market, the U.S. Drug Enforcement Administration (DEA) did not allow EPCS. As a result, prescribing has become a fractured system, comprising a combination of electronic prescriptions for non-controlled substances and paper-based prescriptions for controlled substances.

To facilitate the adoption and use of EPCS, Dr. Grant Carrow and his team at the Massachusetts Department of Public Health conducted a research and demonstration project to develop a system that electronically created and securely transmitted prescriptions for controlled substances. Dr. Carrow started the project in 2007 and received a waiver of regulations from the DEA to allow EPCS. The team navigated DEA and technology requirements, security measures, and workflow processes to demonstrate a safe and secure system for EPCS. This effort helped inform the DEA's devel-

opment of the Interim Final Rule (IFR) published in 2010 allowing controlled substances to be prescribed electronically nationwide for the first time.²

The IFR requires rigorous security measures for providers, pharmacies, e-prescribing system vendors, and e-prescribing networks (i.e., the technology system that receives and transmits an electronic prescription between a provider and pharmacy) to prevent drug diversion and abuse and to ensure controlled substances are prescribed and dispensed safely. Dr. Carrow and his partners demonstrated that safe and secure EPCS is feasible. In a survey of providers who participated in the project, conducted by Brandeis University, respondents indicated that EPCS:

- Was easy to use (73 percent).
- Improved monitoring of medications in their practice (59 percent).
- Improved workflow and efficiency (66 percent).
- Improved coordination with pharmacists (56 percent).
- Made it easier to identify diversion or misuse of medications (43 percent).²

“In our survey of prescribers engaged in EPCS, a majority reported a positive experience and that security measures were less burdensome than expected.”

Dr. Grant Carrow
Massachusetts Department of Public Health



A video highlighting the project is available at <http://healthit.ahrq.gov/AHRQHealthITSuccessStories-CarrowVideo>.

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Integrating Systems

A system to support EPCS must be integrated with a seamless and secure flow of information from the provider to an e-prescribing network and then to the pharmacy. To establish a system for EPCS, Dr. Carrow and his team partnered with: 185 providers from a range of specialties affiliated with Berkshire Health Systems in Berkshire County, Massachusetts; nine independent, grocery, hospital employee, and national chain pharmacies; DrFirst, an e-prescribing system application vendor; and Emdeon/eRx Network.

Findings and Lessons Learned

Dr. Carrow and his team were successful in implementing EPCS systems into medical practices and pharmacies that complied with DEA parameters in the test environment, although the process was challenging. Findings and lessons learned from the project can inform other community and State initiatives implementing EPCS.

- **Providers were satisfied with the EPCS system and found it to have value.** Half of the providers in the study used the EPCS system at least once; of those, the majority indicated a positive experience.²
- **Providers need sustained training and technical assistance to support their buy-in and use of EPCS.** Providers' initial expectations of EPCS security measures were that they would be burdensome.⁴ However, after having had experience with EPCS, providers found the security measures to be less burdensome than expected.² Some providers who did not use EPCS during the project felt the learning curve was difficult.³
- **Provider adoption of EPCS is dependent on a critical mass of community pharmacies capable of participating in EPCS.** Unless a critical number of pharmacies within a community are able to participate in EPCS, it is inefficient for providers to adopt because not all patients use a pharmacy that partici-

pates in EPCS. This results in the need for a provider to implement two workflows—one for using EPCS when a patient's preferred pharmacy participates in EPCS and one for hand-written prescriptions when a patient's preferred pharmacy does not participate in EPCS.

- **Development of an EPCS system that complies with DEA requirements is feasible but challenging.** The project did not encounter any significant security breaches or reported instances of diversion but did find that the use of a hard token (cryptographic key) for two-factor authentication required continued maintenance of device drivers. For scalability, the use of a hard token as part of two-factor authentication should be reconsidered. A driverless system, such as a one-time password, would likely be more scalable.
- **Reconciliation of prescriptions sent via EPCS is feasible via a State prescription monitoring program.** To enable reconciliation of prescriptions sent via EPCS, a common unique identifier, such as the transaction control reference number, is needed to link dispensing and prescribing records.

Implications

This effort helped inform the DEA's development of the IFR published in 2010 allowing controlled substances to be prescribed electronically nationwide for the first time. However, considering the extensive level of cooperation needed among the many parties involved in EPCS (e.g., providers, pharmacists, DEA, vendors and patients), it is likely that adoption of EPCS will occur on a community-by-community basis, as provider-prescribing systems, intermediaries, and pharmacy systems that comply with the IFR become available. The findings and lessons learned from this research and demonstration project will inform other community and State initiatives working to develop and implement EPCS systems that are compliant with DEA regulations.

1 Hufstader M, Swain M, Furukawa M. State Variation in E-Prescribing Trends in the United States. ONC Data Brief. No. 4. Washington, D.C: Office of the National Coordinator for Health Information Technology, November 2012.

2 Department of Justice. Electronic Prescriptions for Controlled Substances; Final Rule 21 CFR Parts 1300, 1304, 1306, and 1311. Fed Regist. 2010 Mar 31; 75(61):16236-16319.

3 Thomas CP, Kim M, Kelleher SJ, et al. Early experience with electronic prescribing of controlled substances in a community setting. J Am Med Inform Assoc 2013 Jun; 20(e1):e44-51.

4 Thomas CP, Kim M, McDonald A, et al. Prescribers' expectations and barriers to electronic prescribing of controlled substances. J Am Med Inform Assoc 2012; 19(3):375-81.

