

Enabling Electronic Prescribing and Enhanced Management of Controlled Medications

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Summary: The expansion of electronic prescribing (e-prescribing) to cover federally controlled substances (e.g., narcotics, stimulants, sedatives) was intended to: 1) demonstrate a mechanism for increasing access to these medications, particularly for patients with chronic medical conditions who are frequently prescribed such medications; and 2) reduce the diversion of dangerous pharmaceuticals to non-medical use and abuse. The goal of this project was to foster the safe and productive adoption of e-prescribing of federally controlled substances through the design, implementation, and evaluation of a safe, secure, and efficient system for electronic transmission of controlled substance prescriptions by ambulatory care clinicians at the point-of-care. This work informs the U.S. Drug Enforcement Administration (DEA) as it implements the Interim Final Rule (75 FR 16236) (IFR) governing the e-prescribing of controlled substances (EPCS).

The project team, led by Dr. Grant Carrow and the Massachusetts Department of Public Health (MDPH) Drug Control Program, partnered with health information technology (IT) solution providers DrFirst, Inc. and Emdeon to design, implement, and field-test a system for EPCS in a contained ambulatory care environment within the Berkshire Health System (Berkshire County, MA). Concurrently, the project developed and tested a data interface between the e-prescribing system and the Massachusetts Prescription Monitoring Program (MA PMP) to monitor nonmedical use and abuse of federally controlled medications while supporting enhanced patient-clinician communication, medication access, and safety of patients with chronic medical conditions.

Specific Aims:

- Develop, implement, and verify a system of safe and secure electronic transmission of prescriptions for federally controlled substances in an ambulatory care setting. **(Achieved)**
- Develop and test the interfacing of this e-prescribing system with the Massachusetts PMP to monitor prescription fraud and nonmedical use of controlled medications. **(Achieved)**
- Conduct systems process and outcomes evaluations of the improvements to patient care, risk reduction, patient and clinician benefits, patient safety, and information privacy and confidentiality that are expected as a result of this system. **(Achieved)**
- Develop and implement a plan for dissemination of findings. **(Achieved)**

2012 Activities: The focus of activity in 2012 was on identifying and summarizing the findings from implementing and using the EPCS system, as well as developing the final report. Various challenges—

including rigorous requirements of the IFR, which was promulgated 2.5 years after the start of this project; the complexity of having to modify the EPCS system well into the project; and interdependency of the various software applications— contributed to achieving full IFR compliance. Due to the additional time allowed by the DEA to meet the IFR mandate, the project team was able to use an 8-month no-cost extension to identify areas in which compliance could be achieved and to complete the project, including preparation of a second published article. The project ended in May 2012.

Impact and Findings: The project recruited, trained, and supported 187 providers, 151 of whom were issued hard tokens over the course of the project. The hard tokens, to be inserted into the computer at the time of EPCS transmission, were part of a two-factor user-authentication process to identify the user and maintain security of the system. Of the 151 providers, 81 (53.6 percent) created and transmitted at least one controlled substance e-prescription. The prescribing providers created and transmitted 9,874 controlled substance e-prescriptions, and those who were active each sent an average of 15.5 such e-prescriptions per day to the participating pharmacies during the last 8 months of the study.

Creating and processing controlled substance e-prescriptions was determined to be more complicated than for e-prescribing of non-controlled drugs due to security requirements associated with the IFR and interdependent IT systems. In particular, there was greater than expected difficulty encountered in deploying the hard token due to compatibility issues with some prescribers' PC-based operating systems. After an initial transition period, EPCS had a net positive impact on the workflow of the pharmacists. As with electronic prescriptions for non-controlled drugs, delivery of the EPCS script to the pharmacy improved and in many cases the prescription was ready when the patient arrived at the pharmacy.

In a survey conducted by collaborators at Brandeis University, users of EPCS reported a significant decrease in some of the problems associated with written prescriptions for controlled substances (e.g., incorrect drug or dose was prescribed, prescription altered, or reported lost and required replacing), but not others (counterfeit prescription was discovered). Perceived improvements are consistent with those identified with e-prescribing of non-controlled medications, and with expectations for the potential impact of EPCS. Additionally, although physicians initially expected security measures to be a large burden, especially carrying a security token, these requirements were not a big barrier. These results were published in two papers in the Journal of the American Medical Informatics Association: [Early experience with electronic prescribing of controlled substances in a community setting](#), and [Prescribers' expectations and barriers to electronic prescribing of controlled substances](#). With the development of new approaches to two-factor authentication such as biometrics and one-time password technology, alternatives to security tokens may be available as EPCS is adopted elsewhere.

Ultimately, the study demonstrated that a safe, secure, and reliable system of EPCS can be adopted with minimal difficulty by a targeted medical community. It was also shown that existing systems can support this process using the recognized standards (NCPDP SCRIPT) with minor modification. There were certain barriers to successful implementation for all prescribers, which serve as lessons as other communities begin to implement EPCS. Most importantly, if a critical number of community pharmacies do not have systems in place to accept EPCS, physicians will not see the value in changing systems and office workflow to accommodate this practice.

Based on a limited sample of controlled substance e-prescriptions and using the NCPDP SCRIPT Transaction Control Reference Number (UIB-030-010), the study showed that it is feasible for a state PMP to reconcile prescriptions transmitted by a prescribing system with prescriptions dispensed by a

receiving pharmacy. There are areas that require additional study. With new Federal rules governing EPCS, additional research should build upon the findings of this project to assess workflow and security measures required by the IFR for prescribers and pharmacies. Further refinement and analysis of EPCS data use will also produce assessment models that can be adopted by other PMPs.

Target Population: Adults

Strategic Goal: Develop and disseminate health IT evidence and evidence-based tools to support patient-centered care, the coordination of care across transitions in care settings, and the use of electronic exchange of health information to improve quality of care.

Business Goal: Implementation and Use
