

Enabling Electronic Prescribing and Enhanced Management of Controlled Medications

Principal Investigator:	Carrow, Grant, Ph.D.
Organization:	Massachusetts Department of Public Health
Mechanism:	RFA: HS07-006: Ambulatory Safety and Quality Program: Improving Quality Through Clinician Use of Health Information Technology (IQHIT)
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Project Period:	September 2007 – September 2011, Including No-Cost Extension
AHRQ Funding Amount:	\$1,199,794
Summary Status as of:	December 2010

Target Population: Adults

Summary: Expansion of electronic prescribing (e-prescribing) to cover federally-controlled substances (e.g., narcotics, stimulants, sedatives) is expected to increase access to needed medications and reduce risks of prescription fraud. The goal of this project is to foster the safe and productive adoption of e-prescribing of federally-controlled substances. The project examines the adoption and diffusion of e-prescribing by ambulatory care clinicians at the point-of-care. The aims of the project are being achieved through the design, implementation, and evaluation of a safe, secure, and efficient system for electronic transmission of controlled substance prescriptions. As a result, these efforts are helping to inform the U.S. Drug Enforcement Administration (DEA) as it implements the recently-promulgated Interim Final Rule (75 FR 16236) governing the electronic prescribing of controlled substances (EPCS).

The project team, led by the Massachusetts Department of Public Health (MDPH), Drug Control Program, is partnering with health information technology solutions providers DrFirst, Inc. and Emdeon to design, implement, and field-test a system for e-prescribing controlled substances in a contained ambulatory care environment. Concurrently, the project is developing and testing 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. **(Ongoing)**
- 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. **(Ongoing)**
- Develop and implement a plan for dissemination of findings. **(Ongoing)**

2010 Activities: Throughout the year the project team activated and expanded EPCS access to the initial pilot group of 33 providers, completed the recruitment and activation of the remaining participating

providers, and resolved systems errors as they arose. The evaluation team also continued its analysis of baseline provider survey data and conducted a post-implementation survey of the Group I prescribers to assess their perspectives on the EPCS technology after being exposed to it for 6 months. At the end of 2010, there were 157 participating prescribers, of which 142 were in possession of cryptokeys, which are the key pieces of information that control the transmission of EPCSs. In 2010, prescribing providers with cryptokeys created and transmitted 3,246 EPCSs to the nine participating pharmacies.

The project leadership reviewed all implementation issues including one that resulted in a temporary deactivation of the system on July 26, 2010 after it was discovered that, under certain circumstances, an EPCS could be transmitted to a pharmacy without the presence of a cryptokey. After analysis, the cause of the issue was identified and technical modifications were made. The system was reactivated in early October 2010.

On March 31, 2010, the DEA published its Interim Final Rule (IFR) on Electronic Prescribing of Controlled Substances in the Federal Register. The Final Rule went into effect on June 1, 2010, resulting in the allocation of significant project resources to analyze the changes and assess its impact on the project. As the project team gained a better understanding of the IFR and the requirements of each section, efforts to come into compliance were initiated on several fronts. The team has been in discussions with the DEA on compliance with the IFR for prescribing and pharmacy applications and the framework for revisions to the memorandum of agreement with the MDPH Drug Control Program. Since the promulgation of the IFR, the project partners, in conjunction with the DEA, conducted a gap analysis of the DEA requirements to determine the extent of the prescribing and pharmacy application compliance. This analysis provided the foundation for waivers to be included in new memoranda of agreement between the DEA and MDPH for prescribing and pharmacy applications. Project leadership and DrFirst explored the options for securing an identity-proofing process and establishing a relationship with certification authorities for the participating providers. The project team also reached out to the American Institute of Certified Public Accountants (AICPA) and the Information Systems Audit and Control Association, referenced in the IFR, to determine the readiness of their membership to conduct third-party audits for prescribing and pharmacy applications, as required in the IFR. As a result of these discussions, the Trust Services Task Force of the AICPA has begun developing audit guidelines for the accounting industry, which will initially be conducting the required third party audits.

To help inform the industry about EPCS and the DEA's IFR, the project team collaborated with Emdeon on the development and airing of a town hall Webinar in September 2010. The Webinar was aired twice and was attended by more than 300 providers, pharmacists, vendor representatives, and State regulators. Because of the successful attendance, planning has begun for several additional Webinars focusing on industry segment-specific issues. The project team also conducted an orientation on the requirements of the IFR for the Berkshire County pharmacy managers who are participating in the project.

During 2010, the project also collaborated with DrFirst to create an interface file of Schedules II through V prescriptions to be securely accessed by the MA PMP on a periodic basis. The availability of this data, along with dispensed prescription information currently received by MA PMP from the pharmacies, will allow the reconciliation of prescribed to dispensed federally controlled medications. In order for this to occur, however, the MA PMP recognized there needed to be a key field, preferably a sequencing number, in each database. To achieve this, the MA PMP staff worked closely with the American Society for Automation in Pharmacy in the development of its PMP Standard version 4.1 to ensure a specific field

for this purpose was included when the Standard was released at the beginning of January 2011. As a result of these efforts, the MA PMP will be using a new field to validate the process of reconciling prescribed and dispensed controlled substances prescriptions created within the scope of the project.

Additional presentations included the project team's first public demonstration of EPCS at the Agency for Healthcare Research and Quality Grantee and Contractor Health IT Conference in June. The evaluation team also presented project-related posters at the Academy Health Annual Research Meeting in June and the American Public Health Association Annual Meeting in November.

Grantee's Most Recent Self-Reported Quarterly Status (as of December 2010): The project team is mostly on track for meeting all its aims and milestones and the project budget is moderately underspent. Throughout the project year, the activities remained slightly behind schedule due to circumstances beyond the control of the project team, such as the significant delay in receiving a waiver from the DEA at the beginning of the project, followed by a 6-month period during which the project could not proceed with plans to activate EPCS until certain issues were resolved between the DEA and the Department of Health and Human Services. The project did not fully regain lost time and requested a no-cost extension, which was approved through September 29, 2011.

Preliminary Impact and Findings: In terms of system participation among the active providers, operational satisfaction appears to be high. However, anecdotal reports suggest that some providers may not be using the EPCS system for several reasons, including the lack of a participating pharmacy in the immediate service area, patients' pharmacy preferences, low controlled-substances prescribing patterns in some participating specialties, and slow provider adoption of EPCS technology. A followup provider survey is planned for 2011 to evaluate these issues.

Based on the project team's gap analysis of the IFR, consensus among the participants is that compliance with the IFR requirements will be achieved gradually by the end of the project. Compliance with certain IFR sections may be achieved sooner if pharmacies can operationalize policies and procedures. The DEA and MDPH acknowledged, however, that because of technological and industry standard processing limitations, it may not be possible to come into compliance with all sections of the IFR before the conclusion of the project in September 2011. More specifically, completion of third party certification audits of prescribing and pharmacy applications, the revisions of the National Council for Prescription Drug Programs transmission standards, and the ability of pharmacy applications to use, read, and store digital signatures may not be finalized until the last quarter of 2011.

Strategic Goal: Develop and disseminate health IT evidence and evidence-based tools to improve the quality and safety of medication management via the integration and utilization of medication management systems and technologies.

Business Goal: Implementation and Use