

**Project Title:** Enabling Electronic Prescribing and Enhanced Management of Controlled Medications

**Principal Investigator:** Carrow, Grant, Ph.D.

**Organization:** Massachusetts State Department of Public Health

**Mechanism:** RFA: HS07-006: Ambulatory Safety and Quality Program: Improving Quality through Clinician Use of Health IT (IQHIT)

**Grant Number:** R18 HS 017157

**Project Period:** 09/07 – 09/10

**AHRQ Funding Amount:** \$1,199,794

**Summary Status as of:** December 2008

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**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

**Summary:** This project was initiated in September 2007 and has completed the first third of the grant period. The immediate goal of this project is to foster the safe and productive adoption of electronic prescribing (e-prescribing) nationwide through the design, implementation, evaluation, and dissemination of model security standards for consideration by the U.S. Drug Enforcement Administration (DEA) as the agency develops regulations and policy governing e-prescribing of federally controlled substances. The project team is partnering with health information technology (health IT) solutions providers, such as DrFirst, Inc., and eRX Network, LLC, to design, implement, and field test a system for e-prescribing controlled substances in a contained ambulatory care environment. Concurrently, the project will develop and test the interfacing of the e-prescribing system data with Massachusetts Prescription Monitoring Program data to monitor for nonmedical use and abuse of federally controlled medications, while supporting enhanced patient-clinician communication, medication access, and safety of patients with chronic medical conditions.

This research and demonstration project will examine the adoption and diffusion of e-prescribing, a key component of health IT, and electronic health records (EHRs) to improve medication management by ambulatory care clinicians at the point-of-care. The project will also contribute to the discussions about considered expansion of e-prescribing to cover federally controlled substances (e.g., narcotics, stimulants, sedatives), particularly for patients with chronic medical conditions who are frequently treated with federally controlled substances, and the potential for e-prescribing of federally controlled substances to be associated with reduced risks of prescription fraud and other drug diversion.

### 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. **(Ongoing)**
- Develop and test the interfacing of the e-prescribing system described in the first aim with the Massachusetts Prescription Monitoring Program to monitor for prescription fraud and nonmedical use and abuse of controlled medications, while supporting enhanced patient-clinician communication, medication access, and safety of patients with chronic medical conditions. **(Ongoing)**
- Conduct systems process and outcomes evaluations of improvements to patient care, risk reductions, patient and clinician benefits, patient safety, and information privacy and confidentiality expected to ensue from the implementation of the first two aims. **(Ongoing)**

- Develop and implement a plan for dissemination of findings for all aims listed above. **(Ongoing)**

**2008 Activities:** A memorandum of agreement (MOA) between the U.S. Drug Enforcement Administration and the Massachusetts Department of Public Health (MDPH) was finalized and signed by the agencies on September 18, 2008. The MOA provides the regulatory framework and security requirements for electronic prescribing of controlled substances (EPCS) for the purposes of the project.

The leadership team for the project, including key persons and service providers, was fully assembled by early 2008. However, MDPH was informed in June 2008 that Surescripts, the e-prescribing network service provider for the project, would no longer be able to participate in the project. MDPH subsequently identified eRx Network, LLC, a Texas-based information technology company, as an alternative network service provider. In the last quarter of 2008, eRx Network formally joined the project. eRx Network identified three pharmacy IT system vendors, in addition to those in their own network, representing 10 pharmacies, that are capable of receiving e-prescriptions from eRx Network, and initiated discussions to identify the technical considerations required to achieve successful transmission for EPCS.

In June 2008, Berkshire Health Systems, the project test site, hosted an information dissemination meeting in Pittsfield, MA, for more than 90 invited providers and pharmacies from Berkshire County. The leadership team presented the project and fielded questions from the group. Feedback from participant evaluations suggested that the project was well received and that both providers and pharmacists are looking forward to participating.

The evaluation team finalized the scope and specific items of the prescriber survey and in December 2008, the survey was administered to a wide range of prescribers representing medical specialties, surgery, pediatrics, and obstetrics-gynecology at organized meetings. By December 31, 2008, 100 surveys were completed and returned to the liaison, representing approximately an 80 percent return rate for those distributed. In addition, the evaluation team made a number of visits to Berkshire County to conduct interviews with several pharmacies to discuss participation in the project, gather “process” information from the operational managers, identify any implementation issues, and address any lingering concerns that might impede participation.

The project has experienced delays in regards to the Department of Health and Human Services (DHHS) and DEA reaching a final agreement over the conditions of participation spelled out in the September 18, 2008, MOA between MDPH and DEA.

The leadership team discussed the composition of the project advisory group and developed a list of 32 individuals/organizations that may be approached concerning participation. A meeting would be planned to coincide with full implementation of EPCS. MDPH has been exploring the feasibility of conducting a symposium on e-prescribing in the Boston area after the implementation phase begins. The intent would be to bring together representatives from e-prescribing projects in the state and region to discuss their projects and findings.

**Preliminary Impact and Findings:** The project team has confirmed a number of potential regulatory barriers to EPCS that may be of interest to policymakers. Preliminary analyses of some States' laws indicate that there are prohibitions to EPCS, particularly for prescriptions for Schedule II pharmaceuticals, in at least some States. These States may need to change statutes and/or regulations to fully permit EPCS. Since changing statutes and regulations takes considerable time, there may be delays in full implementation of EPCS even after a final rule is promulgated by DEA. In presentations, the PI and colleagues have suggested some strategies States may employ to expedite implementation of new EPCS regulations.

An additional finding is that many States place responsibility for security and validity of prescriptions on prescribers and pharmacies, both of which are regulated/licensed at State and Federal levels. Transaction

system providers (e.g., e-prescribing software, transmission networks and switches, and pharmacy software) are not separately regulated/licensed. These additional responsibilities may be barriers to adoption of EPCS by prescribers and/or pharmacies. Another finding is that electronic prescriptions for controlled substances are currently rejected automatically by Massachusetts Medicaid (MassHealth). There will need to be changes to reimbursement mechanisms to allow for acceptance of controlled substance e-prescriptions by Medicaid and possibly other third-party payers.

The above preliminary findings were presented at several conferences, including the AHRQ Annual Conference in September 2008 and the Annual Conference of the National Association of State Controlled Substances Authorities (NASCSA) in October 2008. As a result of the NASCSA presentation, the NASCSA Executive Committee published the presentation on the organization's Web site and a notice in the organization's newsletter to disseminate the findings.

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### **Selected Outputs**

MDPH contributed to conferences and meetings at which the project was a subject of presentations and discussion. The conferences, meetings, and presenters were as follows:

Massachusetts Health Council, Pharmacy Committee, Boston, MA, March 26, 2008, Grant Carrow, Ph.D. (PI).

Massachusetts Health Data Consortium: eRx Forum, Burlington, MA, April 10, 2008, Grant Carrow, Ph.D. (PI).

Joint Meeting of the Executive Directors of the Massachusetts Boards of Medicine, Pharmacy, Dentistry, Nursing, and Physician Assistants, Boston, MA, May 20, 2008, Grant Carrow, Ph.D. (PI) and Stephen J. Kelleher, Jr., F.A.C.H.E. (PM).

Massachusetts College of Pharmacy and Health Sciences, E-Prescribing Conference, Framingham, MA, October 7, 2008, Grant Carrow, Ph.D. (PI).

National Association of State Controlled Substances Authorities (NASCSA) Annual Conference, Jacksonville, FL, October 23, 2008, Grant Carrow, Ph.D. (PI) and Peter Kaufman, M.D.

2008 AHRQ Annual Conference Session – e-Prescribing: Enabling Change and Measuring Impact. Presentation: Enabling Electronic Prescribing and Enhanced Management of Controlled Substances ([PowerPoint@ File](#), 510 KB; [Web Version](#)).

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**Grantee's Most Recent Self-Reported Quarterly Status:** The project is meeting about 30 to 65 percent of its milestones; there is a plan for achieving some milestones, but not others. A revised protocol will enable achievement of all aims of the project and nearly all milestones except for the originally planned numbers of participating practitioners and e-prescriptions. Progress on the first aim, and to a lesser degree on other aims, was limited in the reporting period by the restriction from expenditure of all Year 2 funds pending an agreement between DHHS and the DEA. Nevertheless, groundwork in several areas continued using Year 1 funds. The project is significantly under spent, by more than 20 percent of its budget. Under spending is a function of delays in meeting the originally planned timetable as a result of unanticipated complexities in executing the project, including negotiating the DEA MOA as well as the withdrawal from the project of the original e-prescribing network provider. Moreover, AHRQ has restricted all Year 2 funds pending a final agreement between DHHS and DEA regarding the conditions of participation defined in the MOA between MDPH and DEA of September 18, 2008. Once Year 2 funds are released, the project will follow the original timetable, albeit with a shifted timeframe, as well as resume planned spending.

**Milestones:** Progress in meeting many milestones is stalled.

**Budget:** Significantly under spent, more than 20 percent.