
HHS Road Tests eRX Standards

Experts predict that a shift to electronic prescribing (eRX) systems could avoid more than 2 million adverse drug events annually, of which 130,000 are life-threatening.¹ eRX also has enormous potential to create savings in healthcare costs, through reduction of adverse drug events and improved work flow. One recent study estimated the potential savings at \$27 billion per year in the United States.² In a 2007 report on the eRX initiative, Secretary of Health and Human Services (HHS) Michael Leavitt provided the results of pilot testing of the system in 5 sites nationwide. That report is summarized here.

Adoption of eRX technology remains limited because of the inability of multiple systems to share information effectively, and the lack of a standard format and vocabulary. To help stimulate the use of eRX, Congress mandated the following under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003:

- If a prescriber writes prescriptions electronically, that prescriber must use eRX standards for certain Part D-covered drugs.
- Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans, and other Part D sponsors must support and comply with eRX standards when communicating with prescribers who want to use eRX technology.
- Dispensing and nondispensing pharmacists who electronically

transmit prescription and certain other information for Medicare Part D-eligible individuals receiving covered drugs must use the adopted final eRX standards.

The standards selected must achieve several goals:

- To the extent practicable, the standards would not impose undue administrative burdens on prescribing healthcare professionals and dispensing pharmacies and pharmacists.
- The selected standards would be compatible with the standards established under Part C of Title XI and section 1860D-4(b)(2)(B)(i) of the Social Security Act, and with general health information technology standards.
- The standards would permit the electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration (FDA) and

National Library of Medicine (NLM).

Medicare Part D eRX standards became effective January 1, 2006. HHS also recognized 6 “initial” standards that might, pending confirmation from pilot testing, be suitable for adoption as additional final eRX standards.

Five sites tested these initial standards in a pilot project. The goals were to test clarity of communicated information, integration of these new standards with foundation standards, and outcomes associated with using them to eRX in the Part D context. The Agency for Healthcare Research and Quality’s (AHRQ’s) National Resource Center for Health Information Technology (NRC) then evaluated the pilot sites’ efforts, and summarized and synthesized findings across the pilot project.

Specifically, pilot sites were asked to address the following questions:

- Are the right data being sent? Are the data usable and accurate?
- Are the data well understood at all points of the transaction?
- Are all the initial eRX data communications standards included in the pilot project working? Can they effectively and unequivocally communicate the necessary information from sender to receiver to support eRX functions?
- Are the data for the patient and

Exhibit 1: Initial Standards and Testing Summary/Results

Name	Standard Description	Summary/Results
Formulary and benefit information National Council for Prescription Drug Programs (NCPDP) (Formulary and Benefit Standard V1.0)	Displays the formulary status and alternative drugs, copays, and other status information. NCPDP developed a standard using RxHub protocol.	Determine if the standard developed by NCPDP using RxHub protocol should be adopted as a standard. Technically able to support Part D use.
Exchange of medication history (NCPDP SCRIPT V8.1)	Includes the status, provider, patient, coordination of benefit, request, and response segments of SCRIPT.	Determine readiness of the NCPDP's standard medication history message. Technically able to support Part D use.
Fill status notification (NCPDP SCRIPT V8.1)	Informs when Rx is filled, not filled, or partially filled. Includes provider, patient, and drug segments of SCRIPT message. Not yet generally used.	Assess its business value and clinical utility. Technically able to support Part D use.
Structured and Codified Signatura (SIG) (NCPDP SCRIPT V8.1)	Indication, dose, dose calculation, dose restriction, route, frequency, interval, site, administration time, duration, and stop-order instructions.	Test a standard structured code set for expressing patient instructions developed through standards development organization efforts. In current state, technically unable to support Part D use.
Clinical drug terminology (RxNorm)	A clinical drug nomenclature that provides standard names for clinical drugs and for dose forms as administered. It also provides links from clinical drugs to their active ingredients, drug components, and most related brand names.	Determine whether RxNorm terminology translates to National Drug Codes (NDCs) for new prescriptions, renewals, and changes. In current state, technically unable to support Part D use.
Prior authorization messages (ASC X12N 278, V. 4010A1 and ASC X12N 275, V. 4010 w/HL7)	Requires header information, requester, subscriber, utilization management, and other relevant information for prior authorization requests.	Determine functionality of new versions of the ASC X12N 278 standards. In current state, technically unable to support Part D use.

the prescription transmitted accurately among all participants in the transaction, such as the pharmacy, pharmacy benefits manager (PBM), router, plan, and prescriber?

- Did the initial standards work well together, and with the foundation standards? If not, why not and what work-arounds were used?
- How can the initial standards be improved to address work-arounds?
- How long did it take to conduct each transaction using the initial standards?

- Can all appropriate drugs and other therapies be ordered via eRX?

Pilot Site Characteristics

Each site selected for the pilot project held the potential to produce special information for the government based on the standards tested, methodologies used, and context in which eRX was implemented or assessed.

- RAND Corporation focused on New Jersey physicians in an e-prescribing program sponsored by Horizon Blue Cross/Blue Shield of New Jersey.

- Brigham and Women's Hospital (BWH) worked in an academic medical systems setting with physicians from the CareGroup Health System in Boston.

- Achieve, the largest information technology vendor for the long-term care (LTC) industry, conducted a pilot-site study implementing eRX in facilities that had never before used this technology.
- University Hospitals Health System and Ohio KePRO, the Quality Improvement Organization (QIO) in Ohio, teamed up to study the implementation of the standards in 300 primary and

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specialty-care physician offices.

- SureScripts, the nation's largest provider of eRX networking and certification services, worked with physician offices in 5 states.

Findings from Standards Testing

The evaluation of the pilot sites' results is listed in Exhibit 1. The exchange of information within 3 of the eRX technology standards was found to be viable, including (1) formulary and benefit information, (2) exchange of medication history, and (3) fill-status notification. Pilot sites found that the remaining 3 technology standards are not yet capable of supporting eRX for Medicare Part D in their current state: (1) structured and codified SIG, (2) clinical drug terminology, and (3) prior authorization messages.

SIG

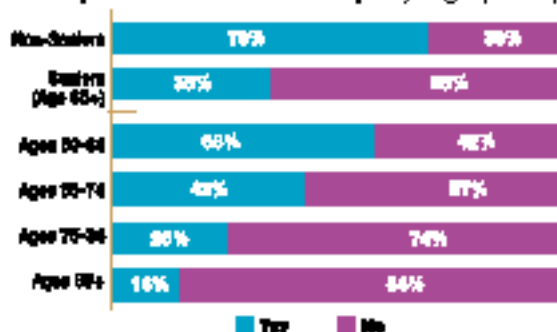
Currently, there is no standardized format for vocabulary for signatura (SIGs), leaving room for misinterpretation and error. A standard structure and code set for expressing SIGs would enhance patient safety, although free text capability must be preserved for special circumstances. NCPDP convened a group of industry experts to develop a standard that would structure SIG components. At the time of the pilot sites' initial start date, the likelihood that the proposed standard would be balloted and adopted by the National Council for Prescription Drug Programs (NCPDP) was not a near-term prospect. As a result, the pilot sites agreed to test NCPDP's proposed Structured and Codified SIG Standard 1.0 in a laboratory setting.

The results of the testing (using various approaches across the sites) showed that the SIG standard needs additional work with reference to field definitions and examples, field naming conventions, and clarifications of field use where new codes are recommended, such

ADVERTORIAL

Only about one third of all seniors own or use a computer, and this decreases notably with increasing age. This number has very real implications for health plans and other healthcare marketers who need to design non-electronic communications for this audience.

Computer Use/Ownership By Age (2006)



Source: WilsonRxSM Survey, ©2006 Wilson Health Information, LLC, New Hope, PA. For information, visit www.wilsonrx.com

Given that over 50% of seniors ages 60-74 do use computers, could this present an opportunity to use the computer as a means to communicate with this segment of seniors on improving their health? Additional data in the *Eisai Senior Health Digest* reports that seniors use their computers 74 % of the time seeking information about diseases. Additionally, 64 % use computers seeking information about medications.

The *Eisai Senior Health Digest* provides useful and actionable information, specific for seniors. This information is not available elsewhere, and is designed to help you better manage your senior members' care.

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as the SIG Free Text Indicator field. Contradictions with other structured fields exist, and there are limitations on directions for topical drugs (such as the area of application). The PRN designation could be interpreted as either “as needed” or “as required,” and the standard does not allow for quick revisions for new drug administration. Mistranslations and contradictions in dosage/timing directions leave room for misinterpretation and error. With additional development, the standard may provide a controlled vocabulary that reflects prescriber thinking, offers structure and simplicity, and improves communications between prescribers and pharmacies.

RxNorm

RxNorm is a standardized nomenclature for clinical drugs developed by NLM that provides standard names for clinical drugs (active ingredient + strength + dose form) and for dose forms as administered to a patient. RxNorm links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. These concepts are relevant to how a physician would order a drug. RxNorm links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. National Drug Codes (NDCs) for specific drug products, which identify not only the drug but also its manufacturer and the size of the package from which it is dispensed, are linked to that product in RxNorm. NDC codes are relevant to how a pharmacy would



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dispense the drug.

In August 2006, the FDA published a Notice of Proposed Rule Making which would, among other things, result in changes to the electronic drug registration and listing system pursuant to which FDA would issue all NDCs, and registrants would be required to submit certain information. This would result in a more up-to date and accurate centralized electronic repository for these NDCs. RxNorm includes the NDCs that are available from the FDA and other sources willing to provide them to NLM.

RxNorm was included in the pilot project to determine how well its clinical drug, strength, and dosage information can be translated from the prescriber’s system into a NDC at the dispenser’s system that represents the prescriber’s intent. To date, this translation has typically required the use of intermediary knowledge-based vendor products. RxNorm has considerable potential to simplify eRX, create efficiencies, and reduce dependence on other sources of NDCs at the dispensing end. It was able to represent both new prescriptions and renewal requests on which it was tested.

However, RxNorm requires further evaluation and refinement before it can be required for eRX. In at least some of the versions tested, RxNorm erroneously linked some NDCs to lists of ingredients rather than to the drugs themselves. Testing also revealed some cases in which the NDC codes in RxNorm did not match to an SCD—the semantic clinical drug, which always contains the ingredient(s), strength, and dose form, in that order. This indicates there was either an error in matching to the correct RxNorm concept, or an error with RxNorm itself, with more than 1 term being available for the same clinical drug concept. As with other vocabulary standards, RxNorm will never cover 100% of what is needed in every circumstance, so some provision for exceptions will be needed. One example encountered in the pilot testing was the lack of standard names and identifiers for pharmacy-compounded drugs. Analysis shows that as of December 2006, RxNorm was technically not able to support this function for required use in Medicare Part D eRX.

Prior Authorization

The current system of prior authorization (PA) requires multiple phone and written contacts between the prescriber, the pharmacist, and the health plan. The PA standard incorporates real-time PA functionality in the ASC X12N 278 Health Care Services Review transaction. There were two models considered—solicited and unsolicited. Under the solicited model, the prescriber questions the health plan or PBM. Under the unsolicited

PROVIDER ACTION

Impact to You

It is predicted that the use of eRX systems will avoid more than 2 million adverse drug events annually, of which 130,000 are life-threatening.¹ As a result e-prescribing has enormous potential to create savings in health-care costs, through reduction of adverse drug events and improved work flow.

What You Need to Know

Although adoption of eRX technology remains limited because of the inability of multiple systems to share information effectively and the lack of a standard format and vocabulary, Federal regulators are moving to pilot-test standards and mandate its use.

What You Need to Do

Continue to stay abreast of Federal regulations and guidance with regard to eRX. Those practices that want to be ahead of the curve will begin planning for implementation of eRX systems within their practice setting.

ed model, the questions and criteria reside on the point-of-care software systems and the clinician knows all the questions needed for a particular drug before sending the PA request.

All pilot sites selected the unsolicited model for testing. The specific process for the unsolicited model of electronic PA (ePA) is as follows:

- Payers and PBMs publish drug-specific ePA requirements using the NCPDP Formulary & Benefits file specification.
- Prescribing systems use ePA flags to alert prescribers of authorization requirements.
- Prescribers provide needed information in the format of an electronic ePA request.
- Prescribing systems submit electronic ePA requests to Payer/PBMs using the XI2 278 transaction, including appropriate patient information (diagnosis/conditions).
- Payer/PBMs respond using the 278 response, and potentially note the authorization result in the claim adjudication system.

The pilot sites examined various approaches to assessing the impact of a standardized on the prescriber's workflow, changes in prescribing behaviors, and perceptions of access to appropriate medications both in lab environments and live implementations. Because health plans typically require PA only for a small subset of drugs, the pilot sites had limited live experience with this standard.

The proposed ePA standard could facilitate tracking of authorizations, automatically populate relevant patient information in applications, and simplify the overall system. However, the standard is not currently technically able to support the complex nature of the PA process, nor is adoption widespread enough for the standard to be adopted as a final standard for the Medicare Part D eRX program.

Long-term Care

The Achieve long-term care (LTC) pilot site focused on whether eRX in general could be successfully im-

plemented in a LTC setting, given its unique needs and work flow. Analysis shows that eRX can be supported, with some technical accommodations to the standards for Part D implementation.

In testing the functionality of eRX standards, the grantees/contractor also tracked various outcomes of eRX in the pilot project. These included:

- *Workflow:* Direct computer-to-computer transmission and improved connectivity to eRX networks and communication with outside entities improves workflow for both prescribers and pharmacists.
- *Prescriber Utilization of eRX:* Office staff play a significant role in eRX, particularly in the LTC setting.
- *Physician Uptake:* Adoption rates/retention were reasonable and, barring technical problems related to electronic devices and incomplete patient data, retention was generally good.
- *Patient Satisfaction:* There was limited pilot-site experience in this area, but of the small sample surveyed, adults under 65 years of age preferred eRX over paper.
- *Formulary Versus Generic Prescribing:* The role of eRX in the use of formulary medication and generics is still very preliminary, with prescribers uncertain about the accuracy and completeness of formulary information.
- *Medication History Utilization:* Providers may have been unaware of the availability of this function, and comments ranged from a perception of medication history as inaccurate, to those who viewed it as a good sup-

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- plement to patient self-reporting.
- *Inappropriate Prescribing/Adverse Drug Events:* Data may demonstrate a potential decrease in medication errors, with many respondents indicating they overrode drug–drug interactions at least sometimes.
 - *Callbacks:* Anecdotes indicate that especially in LTC, callbacks were dramatically reduced but in another pilot site’s survey, no significant differences were noted.

Ultimately, the impact of eRX will depend on adoption by prescribers themselves. A copy of the full pilot project evaluation report can be accessed at: <http://healthit.ahrq.gov/erxpilots>. MPM

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