Pilot Testing of Initial Electronic Prescribing Standards – Cooperative Agreements Required Under Section 1860D-(4) (e) of the Social Security Act as Amended by the Medicare Prescription Drug, Improvement, and Modernization Action (MMA) of 2003

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EXECUTIVE SUMMARY

The current system of prescribing and dispensing medications in the United States has widespread problems with safety and efficiency. Experts predict that a shift to electronic prescribing (e-prescribing) systems could avoid more than 2 million adverse drug events annually, of which 130,000 are life-threatening[1]. E-prescribing also has enormous potential to create savings in health care costs, through reduction of adverse drug events and in improved workflows. One recent study estimated the potential savings at $27 billion per year in the United States[2].

However, adoption of e-prescribing technology remains limited. The inability of multiple systems to share information effectively, and the lack of a standard format and vocabulary, reduces the effectiveness and attractiveness of using an electronic system.

Because of e-prescribing's potential to reduce errors and costs, Congress mandated the establishment of standards for the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Although prescribers are not required to write prescriptions electronically, if they do, they must utilize the adopted e-prescribing standards. 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 electronic prescribing standards when communicating with prescribers who want to use e-prescribing technology. Furthermore, dispensing and non-dispensing pharmacists who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible individuals are also required to use the adopted final e-prescribing standards.

The standards are to be selected to 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; and
- 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).

With input from the National Committee on Vital and Health Statistics (NCVHS), the Department of Health and Human Services (HHS) identified and adopted three e-prescribing standards that met the criteria for "adequate industry experience" ("foundation" standards) for use as Medicare Part D e-prescribing standards effective January 1, 2006. In addition, HHS has recognized six "initial" standards that might, pending confirmation from pilot testing, be suitable for adoption as additional final e-prescribing standards.

HHS selected five pilot sites to test these initial standards in its pilot project. The pilot sites were set up to test the initial standards themselves (to ensure that they communicated the intended information in a clear and unambiguous manner) as well as how the initial standards would interact with each other and the foundation standards (how the initial standards would adapt to specific business practices and whether they would operate efficiently in different work

environments, i.e., the clinical and economic outcomes associated with using them to e-prescribe in the Part D context). The Agency for Healthcare Research and Quality's (AHRQ) National Resource Center for Health Information Technology (NRC) then evaluated the pilot sites' efforts, and summarized and synthesized findings across the pilot project.

Pilot Site Characteristics

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

- RAND 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 e-prescribing in facilities that had never before used this technology.

- University Hospitals Health System and Ohio KePRO, the Quality Improvement Organization in Ohio, teamed up to study the implementation of the standards in 300 primary and specialty care physician offices.

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

Findings from Standards Testing

Even in the case of standards that are technically mature, implementation issues will always exist. The testing of the initial standards conducted by the pilot project reflects this assumption.

The evaluation of the pilot sites' results in the context of their characteristics and testing methods yielded the following findings:

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Exhibit 1: Summary of Initial Standards and Testing Summary/Results

Name	Standard Description	Standards Testing Summary/Results
Initial Standards		
Formulary and benefit information National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard Version 1.0	Displays the formulary status and alternative drugs as well as co-pays and other status information. NCPDP has developed a standard using RxHub protocol.	Determine if the standard developed by NCPDP using RxHub protocol should be adopted as a standard. *Analysis shows that this standard is technically able to convey the information needed to support this function for use in Part D.*
Exchange of medication history NCPDP SCRIPT Version 8.1	Includes the status, provider, patient, coordination of benefit, request, and response segments of SCRIPT.	Determine readiness of the NCPDP's standard medication history message. *Analysis shows that this standard is technically able to convey the information needed to support this function for use in Part D.*
Fill status notification NCPDP SCRIPT Version 8.1	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. *Analysis shows that this standard is technically able to convey the information needed to support this function for use in Part D.*
Structured and Codified SIG NCPDP SCRIPT Version 8.1	Indication, dose, dose calculation, dose restriction, route, frequency, interval, site, administration time and duration, and stop order instructions.	Test a standard structured code set for expressing patient instructions developed through standards development organization efforts. *Analysis shows that, in its current state, this standard is technically unable to convey the information needed to support this function for use in Part D*
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. *Analysis shows that, in its current state, this standard is technically unable to convey the information needed to support this function for use in Part D.*
Prior authorization messages ASC X12N 278, Version 4010A1 and ASC X12N 275, Version 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. *Analysis shows that, in its current state, this standard is technically unable to convey the information needed to support this function for use in Part D.*

Long-Term Care. In addition, the Achieve long-term care pilot site focused on whether e-prescribing in general could be successfully implemented in a long-term care setting, given its unique needs and workflows. ***Analysis shows that e-prescribing can be supported, with some technical accommodations to the standards, in long-term care facilities for Part D implementation.***

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

- *Workflow* – direct computer to computer transmission and improved connectivity to e-prescribing networks and communication with outside entities improves workflow for both prescribers and pharmacists
- *Prescriber Utilization of E-Prescribing* – office staff plays a significant role in e-prescribing, particularly in the long-term care 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 e-prescribing over paper.
- *Formulary Versus Generic Prescribing* – the role of e-prescribing in the use of on-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 supplement 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 long-term care, callbacks were dramatically reduced but in another pilot site's survey, no significant differences were noted.

Ultimately, the impact of e-prescribing 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**

SECTION I
INTRODUCTION

1. Background

Efforts to modernize the American health care system have accelerated over the last five years due to several landmark studies revealing the toll of medication errors. In 1999, the Institute of Medicine (IOM) estimated that as many as 7,000 people died each year from medication errors alone, accounting for 1 out of 131 ambulatory deaths.[3] Another study by the Center for Information Technology Leadership showed that 8.8 million adverse drug events (ADEs) occur each year in ambulatory care. In hospitals, the average patient is subject to at least one medication error per day.[4] This study also revealed that fully one quarter, or 3 million, of these errors were "preventable."[5]

According to CMS in its proposed rule (Federal Register 2005; 42 CFR Part 423: 6260), preventable ADEs occurring in hospitals cost the American health care system $3.5 billion per year. Testimony before the National Committee on Vital and Health Statistics (NCVHS) indicates that ADEs in ambulatory settings amount to upwards of $887 million. Aside from the significant problem of illegible handwriting, the current paper-based system for recording and communicating drug prescriptions in the United States is a poor medium of communication and is associated with inefficient workflows.[6] Industry testimony before the NCVHS also indicates that almost 30 percent of prescriptions require pharmacy callbacks, resulting in 900 million prescription-related telephone calls annually.

To address these concerns, scholars, health experts, and industry leaders have supported the switch from paper to an electronic system of prescribing. Electronic prescribing, also known as e-prescribing, eliminates incorrect handwriting interpretation, ensures that vital fields include meaningful and relevant data,[7] and is available to the physician at the point of care. Electronic prescribing also enables the delivery of clinical decision support (CDS)[8] including formulary checks, checks for allergies, drug-drug interactions, unusually high doses, and clinical conditions, as well as suggestions for appropriate dosages given the patient's level of renal function and age. In addition, in its final e-prescribing rule (70 FR 67568) CMS noted that experts predict a reduction in errors when physicians send medication orders to pharmacies electronically. All told, e-prescribing can help avoid more than 2 million ADEs annually, of which 130,000 are life-threatening.[9]

In terms of monetary savings, e-prescribing has the potential to make a profound impact. In addition to reducing the aforementioned nearly $3.5 billion spent annually on ADEs, e-prescribing could also generate savings by improving providers' ability to make more informed decisions about appropriate and cost-effective medications. According to the AHRQ reporting on the Center for Information Technology Leadership, an additional cost savings of $2.7 billion would result from e-prescribing's ability to reduce clinicians' phone time. CMS also reports that the e-Health Initiative recently estimated that widespread adoption of e-prescribing could save the United States healthcare system $27 billion per year.

However, e-prescribing is much more than the simple electronic transmission of a prescription between prescriber and pharmacy. E-prescribing can also enable significant improvements in patient safety, quality of care and cost effectiveness. On a practical level, e-prescribing represents just one part of a complete clinical strategy and at its highest functioning level, e-prescribing solutions form part of a complete medication record, both leveraging and adding to data captured during other clinical processes.

Today, prescribers (physicians and others who have authority to write prescriptions) make their prescribing decisions using whatever medical, medication, and eligibility information is known or available to them. Typically, they give a handwritten prescription to the patient or phone or fax it to the dispenser (the patient's pharmacy of choice). Prescribers also may use their computers to send faxes to dispensers either directly or through an e-prescribing network. At the dispensing site, tasks are somewhat more automated. Through internal and external electronic claims, eligibility, and benefits verification processes, the dispensing pharmacist may identify contraindications, lower-cost alternatives, or the need for prior authorization. At any step in the process, the dispenser may need to contact the prescriber by phone for clarification or approval of change. Dispensers also must frequently call the prescriber to obtain approval for refills or renewals where they are not specified on the prescription or when they have run out.

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Prescribers may not have access to the latest drug information, or lack a complete or accurate medication list or medical history for their patient and, as a result, they can miss potential contraindications or duplicate therapies. Dispensers often have difficulty reading handwritten prescriptions, and frequently have little or no information about the patient's condition for which the prescription is written. Contacting the prescriber by phone to clarify what is ordered and to make changes often results in delays for the patient, and it is time-consuming for both the prescriber and the dispenser. There are disconnects between the prescriber and patient in the medication process, with little or no feedback to the prescriber on whether a prescription was filled, or what generic substitutions were made.

Conversely, electronic prescribing is conducted in one of two ways, either via a hand-held device, such as a personal digital assistant (PDA), "smart phones" or though a web browser on a desktop application. Depending on the e-prescribing application that is chosen by the physician's practice, the patient's demographics might have been downloaded in the physician's database as part of the installation. When the prescriber starts his/her day, information on patients who are scheduled might be loaded in a queue for the prescriber to access. At this time, eligibility checks and medication history could be performed. When the prescriber is ready to prescribe, he/she could have at his/her disposal the patient's formulary information and past medication history. When the prescriber writes a prescription for a patient he/she could bring up the patient file on the e-prescribing application. From there the prescriber could search for the medication to be prescribed or could pick from a list of his/her most commonly prescribed medications. When a medication is selected, formulary and benefits (FB) and drug utilization review (DUR) could be performed. The e-prescribing system could warn the prescriber of any contraindications or alerts with the option to override it or choose another medication. Next, the prescriber could populate the quantity and directions fields, and the number of refills to complete the process. The prescriber could then send the electronic prescription to the patient's pharmacy of choice. This entire process could take less than one minute to perform.

Despite growing industry consensus, efforts towards e-prescribing adoption have yielded limited results. According to NCVHS testimony, in any given year physicians write over three billion prescriptions, and 65 percent of Americans take prescription drugs; however, according to industry surveys results provided to the NCVHS, only 5 percent to 18 percent of physicians use e-prescribing. A primary reason cited as to why fewer than 3 percent of all prescriptions are written with integrated e-prescribing systems is the lack of e-prescribing standards. Moreover, NCVHS contends that the few standards that are available often are not published with sufficient precision to be implemented in a way that is truly "standard."

To realize the most significant benefits of e-prescribing, systems must be able to function across key steps in the drug delivery chain – from writing prescriptions, to dispensing drugs, to payment. Currently, stakeholders in this chain have diverse interests and varying technological infrastructures. Physician prescribers, pharmacy dispensers and the various Part D sponsors – Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans – must work together if integrated e-prescribing is to become a reality.

Developing the standards that will facilitate e-prescribing is one of the key action items in the federal government's plan to build a nationwide electronic health information infrastructure in the United States. E-prescribing has the potential to drive change in the healthcare industry.

Because of e-prescribing's likelihood of reducing medication errors and costs, and enhancing patient safety, Congress legislatively mandated that Medicare Part D plans support an "electronic prescription (e-prescribing) program."

2. Statutory Requirements

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended Title XVIII of the Social Security Act (the Act) to establish the Voluntary Prescription Drug Benefit Program. Included in the provisions of section 1860D-4(e) of the Act is the requirement that the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals comply with standards adopted by the Secretary. Medicare Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA-PD) and other Part D sponsors are required to support and comply with electronic prescribing standards once they are in effect, including any standards that were in effect when the drug benefit began in 2006.

There is no requirement that providers or pharmacies implement e-prescribing. However, providers and pharmacies that electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries are required to comply with any applicable final standards that are in effect.

The MMA requires the adoption of final standards to support the e-prescribing program described in the MMA. The MMA mandates e-prescribing standards that allow for information exchange, to the extent feasible, on an interactive, real-time basis; and allow for the exchange of information only as it relates to the appropriate prescribing of drugs, including quality assurance measures and systems. The MMA requires that standards for e-prescribing be consistent with the objectives of improving patient safety, quality of care, and efficiencies.

The MMA requires standards for conveying:

1. Eligibility and benefits information, including the drugs included in the applicable formulary, and tiered formulary structure, and any requirements for prior authorization.

2. The following information with respect to the prescribing and dispensing of a covered Part D drug:

a. information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warning or cautions, and when indicated, dosage adjustments; and

b. information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

3. Information that relates to the medical history concerning an individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

In addition, the MMA requires design criteria for these standards so that they are compatible with general health information technology standards, permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration (FDA) and the National Library of Medicine (NLM), and, to the extent practicable, they do not impose an undue administrative burden on the industry.

To provide for efficient implementation of the requirements, section 1860D-4(e) of the Act required the Secretary to conduct a pilot project to test initial standards recognized under section 1860D-4(e)(4)(A) of the Act, prior to issuing the final standards in accordance with section 1860D-4(e)(4)(D) of the Act, and provide a report to the Congress by April 1, 2007, on his evaluation of the pilot project. Section 1860D-4(e)(4)(C)(ii) of the Act allows for an exception to the requirement to pilot test initial standards if, after consultation with standards setting organizations (SSOs) and industry users, the Secretary has determined that there already is adequate industry experience for a standard. Any such "foundation standards" can be proposed and adopted through notice and comment rulemaking as final standards without pilot testing.

Section 1860D-4(e) of the Act also requires that the Secretary promulgate final uniform standards by no later than April 1, 2008.

3. E-prescribing Standards and NCVHS

The MMA charged the National Committee on Vital and Health Statistics (NCVHS) with developing, in consultation with various named parties, recommendations for uniform standards that would enable electronic prescribing in ambulatory care settings, and promote patient safety and quality health care. The NCVHS held hearings to obtain testimony regarding which standards were needed to support e-prescribing; how MMA requirements were supported or not supported by current standards (i.e., standards gaps and limitations); and any related issues that might affect e-prescribing implementation or acceptance.

Standards are the essential building blocks for the widespread adoption of electronic prescribing and other health information technologies (HIT). The standards that have been recognized for e-prescribing under the MMA are published specifications that were developed and/or approved by standard setting organizations (SSOs). These standards establish common vocabulary, content, technical or other specific criteria that serve as a rule, a guideline, or a definition that would promote interoperability amongst users. This concept of "interoperability" entails various systems successfully inter-communicating with one another through standard mechanisms (i.e., "standard transactions") that convey standardized content (i.e., common data elements and vocabularies). Such standards, combined with a real time and secure network, would ensure that providers have instant, secure access to accurate and timely patient information through an electronic health record or similar application. The result would be the ability to coordinate and monitor patient care across different providers. Collecting and transmitting patient data is a complex process. The data elements and transmission specifications must "match" at both the source and destination computer systems, which is only achievable with adherence to the same standards.

From expert testimony, the NCVHS determined that standards needed to be identified for basic prescribing functions between a prescriber and pharmacy; to support eligibility verifications (including individual formularies); and for decision support functionality (e.g., drug utilization review functions), while identifying standards gaps and limitations in all of these

instances. The NCVHS identified three types of e-prescribing standards as necessary to support electronic prescribing. They are: message format standards that provide communication protocols and data content requirements (including those that support medication decision making); terminologies to ensure data comparability and interoperability; and unique identifiers for all relevant entities within the e-prescribing process. The NCVHS held hearings and industry participants debated the criteria for immediate adoption as well as whether specific standards should be recommended as foundation standards. That recommended criteria included that the standard was from a standard setting organization that was accredited by the American National Standards Institute (ANSI); that the standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner; and that the standard is recognized by key industry stakeholders as the industry standard. Three standards met these criteria and were recommended by the NCVHS for adoption as foundation standards for the new Part D requirement.

4. Regulatory Requirements

After reviewing the NCVHS recommendations, the Secretary concurred with NCVHS' conclusion that the three standards recommended as having had adequate industry experience could in fact be adopted as final standards through notice and comment rulemaking without pilot testing. These standards were called "foundation" standards, because while they do not support the full range of e-prescribing functionality, they are a base onto which other standards can be built.

The proposed foundation standards were:
- The NCPDP Telecommunications Standard Version 5, Release 1 and the NCPDP Batch Standard Batch Implementation Guide Version 1.1 for eligibility communications between retail pharmacy dispensers and Part D sponsors.
- The Accredited Standards Committee (ASC) X12N 270/271 Version 4010 and Addenda to Version 4010 for eligibility communications between prescribers and Part D sponsors.
- The NCPDP SCRIPT Standard Version 5, Release 0 for exchanging new prescriptions, changes, renewals, cancellations and certain other transactions between prescribers and dispensers.
- Formulary representation and medication history standards, if certain conditions were met and the identified standards had adequate industry experience.

Public comments supported adoption of the first three standards, and HHS published a final rule on November 7, 2005 (70 FR 67568) adopting them, effective January 1, 2006, when the Part D benefit took effect. This rule also established a streamlined process for updating adopted standards by identifying backward compatible, later versions of the standards that were not also HIPAA standards. Use of such subsequent versions of an adopted standard would be voluntary. Subsequent industry input indicated that the adopted SCRIPT standard, Version 5.0, should be updated with a later version of the standard (Version 8, Release 1). Using the streamlined process, HHS published an Interim Final Rule on June 23, 2006 (71 FR 36020) updating the adopted SCRIPT standard, thereby permitting either version to be used.

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SECTION II
PILOT TESTING OF STANDARDS

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The MMA called for a pilot project to evaluate the interoperability potential of initial e-prescribing standards prior to promulgation of the final uniform standards. To fulfill this

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requirement, the Secretary selected (based on NCVHS input) six "initial" standards (see Exhibit 1) to be tested during calendar year 2006. This was accomplished under four cooperative agreements and one contract entered into by the Agency for Healthcare Research and Quality (AHRQ), on behalf of the Centers for Medicare & Medicaid Services (CMS). Details of the scope of the pilot testing were publicized in a Request for Application for the pilot project announced on September 14, 2005. (Available through www.grants.nih.gov/grants/guide/rfa-files/RFA-HS-06-001.html)

1. Testing Criteria

During 2006, the initial standards were tested in five sites (Exhibit 2), in a variety of settings to determine whether they were ready for broad adoption. The grantees/contractor were asked to determine whether the initial standards allowed participants to effectively and unequivocally communicate the necessary information among all participants in the transactions, such as the pharmacy, pharmacy benefits manager (PBM), router, plan and prescriber. They also were asked to explore how the initial standards worked with the three "foundation" standards. Pilot sites also tracked generally anticipated e-prescribing outcomes, such as a reduction in medical errors. Specifically, they 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 e-prescribing data communications standards included in the pilot project working? Can they effectively and unequivocally communicate the necessary information from sender to receiver to support electronic prescribing functions? Are the data for the patient and 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 workarounds were used?
- How can the initial standards be improved to address workarounds?
- How long did it take to conduct each transaction using the initial standards?
- Can all appropriate drugs and other therapies be ordered via electronic prescribing?

2. Grantee/Contractor Selections

Exhibit 2 details the names of the organizations selected as the four pilot site grantees/one contractor and the titles of their respective parts of the pilot project.

Exhibit 2. Grantee/Contractor Project Titles for Electronic Prescribing Pilot Project

Organization Name	Project Name
Achieve Healthcare Information Technologies, LP (LTC)	LTC E-prescribing Standards Pilot Site Study
Brigham and Women's Hospital	Electronic Prescribing Using a Community Utility: The e-Prescribing Gateway
Ohio KePRO*	A Practice-Based Pilot Site Test of Emerging E-prescribing Standards
RAND Corporation	Test of Medicare's Initial Electronic Prescribing Standards in the New Jersey E-prescribing Action Coalition
SureScripts, LLC	Maximizing the Effectiveness of E-prescribing Between

One of the strengths of the pilot testing was the diversity and uniqueness of the five grantees/contractor. Grantees/contractor represented the spectrum of communities involved with e-prescribing, including most practice settings, and focused on utilization by pharmacists, physicians, nurses, medical assistants, and technology vendors.

Grantee/contractor applications were considered based on specific characteristics/criteria which included but was not limited to:

- the applicants' research designs and methods

- nature of the prescribing pool, specialty, size of practice and percent participation

- geographic diversity of sites and locations

- proposed data collection and analysis

- outcomes reporting, including use of on-formulary medications and generics

- medication errors and adverse drug events

- workflow changes

- prescriber uptake and dropout

- changes in new, renewal and in-fill status rates

- use of Food and Drug Administration/National Library of Medicine (FDA/NLM) structured product labeling for electronic drug information

- applications that included both intervention and control sites; public/private partnerships; and practice-based research networks.

Each pilot site focused on different perspectives on the functionality and impact of initial standards by evaluating them on different sectors of the healthcare system, different geographies, and different practice settings using different technology application vendors, pharmacies and other stakeholders in the e-prescribing industry (Exhibit 3).

Exhibit 3.   Settings and Stakeholders Included in Pilot Site Tests

	Achieve LTC	Brigham & Women's	Ohio KePRO	RAND	SureScripts
Settings					
1-2 physician offices		yes	yes	yes	yes
Small offices		yes	yes	yes	yes
Larger offices		yes	yes	yes	yes
Academic clinics		yes		yes	yes
Long term care	yes				
Stakeholders					
Prescribers	yes	yes	yes	yes	yes
Pharmacists	yes	yes	yes	yes	yes
Patients				yes	yes
RNs	yes				yes
Technology Vendors	yes	yes	yes	yes	yes
Medical Assistants					yes
Others	Licensed Practical Nurses/Nurse Practitioners/Physician Assistants		yes		yes

3. Overview of Grantees'/Contractor Pilot Site Tests

A.   Achieve Healthcare Information Technologies, LLP
"LTC E-prescribing Standards Pilot Site"
Principal Investigator: Michael Bordelon, Vice President of Research and Development, Achieve Healthcare

- Only pilot site focused on e-prescribing standards in a long-term care setting.
- Partnered with Minnesota's Benedictine Health System (BHS), Preferred Choice Pharmacy (LTC pharmacy) and RNA, a planning management system software vendor.
- Additional partners included Prime Therapeutics; Blue Cross Blue Shield of Minnesota; the State of Minnesota's Medicaid Program; and RxHub.
- Provided perspective on unique e-prescribing standards and workflow within LTC facilities.

B.   Brigham and Women's Hospital
"Electronic Prescribing Using a Community Utility: The E-prescribing Gateway"
Principal Investigator: Jeffrey M. Rothschild, M.D., M.P.H., Brigham and Women's Hospital

- Partnered with prescribers, dispensers, and pharmacy plans and payers.
- Physician prescribers were drawn from CareGroup Health System, a physician community with multiple sites in the Boston area.
- Also partnered with RxHub and SureScripts.
- Focused on application of e-prescribing standards in mature practices.
- Assessed standards' impact on medication errors.

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C. **RAND Corporation**
"Test of Medicare's Initial Electronic Prescribing Standards in the New Jersey E-Prescribing Action Coalition"
Principal Investigator: Douglas S. Bell, RAND Research Scientist, and Assistant Professor of Medicine, University of California at Los Angeles School of Medicine

- A collaborative effort of RAND, Horizon Blue Cross/Blue Shield of New Jersey (BCBSNJ) and the pharmaceutical benefits management (PBM) company Caremark Rx.
- Focused on New Jersey physicians in the Horizon E-prescribing Program who used iScribe, either on handheld personal digital assistants (PDAs) or through a web browser.
- Also partnered with Caremark's mail-order pharmacy and Walgreens' retail pharmacy, and data exchanges and hubs, RxHub and SureScripts.

D. **SureScripts, LLC**
"Maximizing the Effectiveness of E-prescribing Between Physicians and Community Pharmacies"

Principal Investigator: Ken Whittemore Jr**.,** R.Ph., M.B.A., Vice President, Professional and Regulatory Affairs, SureScripts; Kate Lapane, Associate Professor, Community Health, Brown University

- SureScripts, the nation's largest provider of electronic prescribing networking and certification services, partnered with several organizations and academic institutions including Brown University and Midwestern University; the Chain Pharmacy Advisory Council; the Independent Pharmacy Advisory Council; AllScripts; MedPlus/Quest Diagnostics; DrFirst; and Zix Corp.
- Implemented e-prescribing systems in multiple geographies and clinical practice settings in Florida, Massachusetts, Nevada, New Jersey, and Tennessee.
- Diversity of stakeholders involved in SureScripts' pilot site was one of its most defining aspects.
- Conducted end-to-end testing of standards within their integrated e-prescribing system, and pharmacy workflow.

E. **University Hospitals Health System**
"A Practice-Based Pilot Site Test of Emerging E-prescribing Standards"
Principal Investigator: Robert Elson, M.D., M.S., Project Manager, UPCP-Ohio KePRO CMS E-Rx Pilot Site

- University Primary and Specialty Care Practices (UPCP)-based pilot site of 300 primary and specialty care physicians in northeast Ohio.
- Collaborated with NDC Health; University Hospitals' owned health plan, QualChoice; Aetna Insurance Company; and Ohio KePro, the state's quality improvement organization (QIO); The University of Minnesota Division of Health Services Research; Medical Group Management Association (MGMA) Center for Research; RxHub and SureScripts.
- Focused on e-prescribing in small practices (2-3 physicians) and impact of standards on workflow and practice cultures.

1. Evaluation Contractor

As AHRQ has significant health IT evaluation expertise among program staff and existing contractors, including AHRQ's National Resource Center for Health Information Technology (NRC), it chose the NRC to perform the evaluation of CMS' e-prescribing pilot project. The NRC has existing resources with excellent evaluation and e-prescribing expertise, including resources from the National Opinion Research Center (NORC), Vanderbilt University, Partners Healthcare, and others.

2. Evaluation Objectives

The AHRQ/NRC evaluation team was charged with making informed recommendations regarding initial standards' functionality, interoperability with foundation standards, and their impact on workflow, clinical, and other outcomes. Specifically, the primary objectives of the evaluation were to: 1) systematically collect and interpret the evidence (e.g., testing methods and findings) reported by e-prescribing grantees/contractor; 2) determine which initial standards were functional (and those which were not); 3) document the benefits, challenges, and technical considerations for mass implementation of the initial standards in different settings; and 4) interpret the impacts that e-prescribing has on various health care settings. This section describes the methods followed by the AHRQ/NRC staff and consultants to carry out these tasks.

3. Research Questions

The AHRQ/NRC evaluation team identified key questions for each of the evaluation components, including both the functionality of the standards as well as their outcomes and likely impacts.

A. Functionality. In evaluating the functionality of the standards, the AHRQ/NRC evaluation team employed the same key question provided initially as guidance to grantees/contractor as they prepared their RFAs: Did the standards allow participants to effectively and unequivocally communicate the necessary information between all participants in the transaction, such as the pharmacy, pharmacy benefits manager (PBM), router, plan and prescriber?

B. Outcomes and Impacts. In addition to testing the basic functionality of the standards, pilot sites were evaluated on a wide variety of outcomes, including:

- Does e-prescribing affect the number of medication errors and adverse drug events?

- Does e-prescribing improve workflow in prescriber offices (fewer interactions with pharmacies, freeing up support staff time for other functions, more time available for patient interaction)?

- What are the uptake and dropout rates among prescribers?

- Does e-prescribing affect patient satisfaction?

4. Data Collection Activities

The AHRQ/NRC evaluation team systematically collected both qualitative and quantitative data from various sources. Qualitative data were collected through: 1) semi-structured interviews with grantee/contractor staff, 2) observational site visits to grantees/contractor using a tailored protocol, and 3) unstructured interviews with key informants. Quantitative data (collected by the grantees/contractor themselves) included technical testing results which measured the functionality and interoperability of foundation and initial standards, and findings from the various evaluations which investigated different impacts and e-prescribing outcomes. These data were collected by reviewing grantee/contractor documents including the proposals, presentations, and progress and final reports.

A. Review of Grantee/Contractor Documents. The AHRQ/NRC evaluation team reviewed various grantee/contractor documents including grant/project proposals, quarterly progress reports, final project reports, and all publications and presentations produced during the grant/contract period. The objective was to collect information on their testing of the initial standards, note any proposal changes, and assess testing and evaluation methods. The document reviews also served as an information source for site-specific questions for the site visit protocol.

B. Structured Telephone Calls with Key Grantee/Contractor Staff. Prior to the site visits, the AHRQ/NRC evaluation team contacted key grantee/contractor staff (e.g., the Principal Investigators, evaluator, project coordinator, etc.) to discuss their pilot sites and help them to prepare for the upcoming site visit by reviewing overall objectives and expectations. Grantees/contractor provided a project status update and any preliminary or final results. These calls finalized the site visit arrangements and agenda, and lasted 45-60 minutes each.

C. Grantee/Contractor Site Visits. The evaluation team conducted one-day visits to all e-prescribing grantees/contractor to: 1) collect test and evaluation data not yet reported; 2) document barriers and challenges to standards' implementation and testing; 3) collect information to assess testing methods and evaluation approaches; and 4) discuss preliminary findings from grantees'/contractor's data analyses. Site visits were conducted by evaluation team members and consultants based upon the site visit protocol (Appendix A).

D. Key Informant Interviews. The AHRQ/NRC evaluation team also conducted telephone interviews with key informants. These calls were made following completion of all site visits and validated the information learned during those visits. Key informants included individuals with industry experience working with various aspects of e-prescribing, including prescribers, dispensers (e.g., pharmacy staff), software vendors, and individuals who have developed and evaluated e-prescribing programs and applications.

5. Data Analysis

The evaluation team used information from each of the three following categories to help inform CMS recommendations regarding the overall functionality of initial standards: 1) grantee/contractor characteristics; 2) standards testing and evaluation results; and 3) assessment of grantee/contractor testing and evaluation methods. By reviewing the findings across all three areas, the evaluation team was able to assess grantee/contractor results within the context of the settings and methods within which the testing occurred. This allowed the evaluation team to reach informed conclusions on how each grantee/contractor result should be used in developing recommendations for CMS.

SECTION IV
EVALUATION FINDINGS

1. Pilot Testing of the Standards

Each grantee/contractor tested different combinations of foundation and initial standards as outlined in Exhibit 4. Each of the initial standards was tested by four or five of the pilot sites. However, the type of testing varied from site to site.

Exhibit 4.   Summary of Standards Tested and Methodology by Pilot Site

	ACHIEVE	BRIGHAM & WOMEN'S	OHIO KePRO	RAND	SURESCRIPTS
Initial Standards					
Medication History	No	Yes-live	Yes-live	Yes-live	Yes-live
Formulary & Benefits	Yes-live	Yes-live	Yes-live	Yes-live	Yes-live
SCRIPT Fill Status	Yes-live	Yes-evaluate only	Yes-live	Yes-live	Yes-live
Prior Authorization	Yes-live	Yes-lab	Yes-live	Yes-live	No
Structured & Codified SIG	No	Yes-lab	Yes-lab	Yes-lab	Yes-lab
RxNorm	No	Yes-lab	Yes-lab	Yes-lab	Yes-lab
Foundation Standards					
NCPDP Telecom	Yes-live	No	No	No	Yes-live
ANSI X12N 270/271	Yes-live	Yes-live	Yes-live	No	Yes-live
NCPDP SCRIPT: New, Refill, Change, Cancel, Renew, etc.	Yes-live	Yes-evaluate only	No∗	Yes-live	Yes-live

In instances where enough transaction volume was expected, pilot sites tested some standards in a "live" environment, with prescribers generating an electronic prescription and transmitting that prescription electronically to a pharmacy. For example, the medication history, formulary and benefits, and prior authorization standards were tested predominantly in this way. In other instances where live experience volumes were expected to be insufficient to generate statistically meaningful results, some pilot sites evaluated standards in a "lab" environment using presentations to expert panels, workgroups, interview and survey techniques, as well as other tools for analyzing the adequacy of the standard's content and usability. For example, the structured and codified SIG standard and the RxNorm standard were tested exclusively in this way.

Another factor in determining if an initial standard is ready for mass implementation is whether it is interoperable with foundation standards. One pilot project objective was to determine in which settings the initial standards interoperate (or do not interoperate) with foundation standards. Evaluation staff collected information from grantees on whether any modifications (either to the initial or foundation standards) were required in order to make them interoperable. A distinction was made between an initial standard's limitations which were attributed to the standard itself, and those which could be attributed to implementation issues. In the latter case, specific implementation challenges were documented and described.

∗ Ohio KePro did not specifically test and report on Formulary & Benefits, Eligibility, New Rx or Renewals, but these were transactions that took place with their participants. E-prescribing had been in place with their practices long before the pilot project began. The variable of interest was the influence of e-prescribing of drugs on costs and quality of care.

The foundation standards were included in the majority of pilot sites, even though they are not initial standards that required testing under the MMA. The purpose of including these standards was to ensure initial standards could interoperate with the foundation standards. As shown in Exhibit 4, pilot sites reported on which standards they tested (yes) and those standards they did not test (no). The testing method used by one of the pilot sites, "evaluate only" represents mapping of the structure and content of the initial standards to the foundation standards to identify potential interoperability issues.

In almost all cases, the three foundation standards, NCPDP Telecommunication 1.0, the NCPDP SCRIPT standard Version 5.0, as updated by Version 8.1, and the ANSI X12N 270/271 demonstrated their interoperability with each of the respective initial standards. The only exception was in the long-term care setting as detailed below.

2. Results and Analysis of Standards Testing

A. Formulary & Benefits

The Formulary & Benefits standard, NCPDP Formulary & Benefits Standard Version 1.0, is intended to provide prescribers with information about a patient's drug coverage at the point of care. The data standard must provide a uniform way for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. The standard covers a range of data, including 1) general formulary data (for example, therapeutic classes and subclasses); 2) formulary status of individual drugs (i.e., which drugs are covered); 3) preferred alternatives (including, but not limited to restrictions that may impact if a drug will be covered, such as quantity limits and prior authorization); and 4) co-payment (not just the single co-payment for the drug being considered, but the co-payments for one drug versus another).

The standard's goal is to provide this information to the prescriber during the prescribing process so that he/she can make the most appropriate drug choice for the patient without extensive back-and-forth administrative activities with the pharmacy or the health plan. This NCPDP Formulary and Benefits Standard Version 1.0 was implemented live in all pilot sites where technology vendors were certified prior to production. This standard works in tandem with the eligibility request and response (ASC X12N 270/271). Once the individual is identified, the appropriate drug benefit coverage is located and transmitted to the requestor.

Analysis

Overall, the pilot project demonstrated that the commonly used parts of the NCPDP Formulary and Benefits standard have been successfully implemented among a variety of e-prescribing partners, and that it may deliver value in approximating patients' drug coverage. While complex, it has been clearly demonstrated that the standard can technically support the transaction, and that it is ready for implementation under Part D. However, as with all standards, the pilot project identified implementation issues that must be addressed in order to achieve the potential benefits, the most important of which is that systems must be able to match patients to health plans, or the formulary and benefits data will not be available. The industry may need to further specify how the standard should be used and how it should evolve based on additional research and development.

B.   Medication History

The medication history standard NCPDP SCRIPT 8.1 provides a uniform means for prescribers, dispensers, and payers to communicate a list of drugs prescribed or claimed for a patient, to prescribers. Other information about medication history may include the dispensing pharmacy and the prescriber. Grantees/contractor tested medication history from only dispensed medication sources (retail pharmacy), only payer/PBM sources, and both prescription sources. The results demonstrated that there is a difference in how the standard is implemented based on the source of the medication history.

Analysis

This standard is relatively mature, widely adopted by the prescribing industry, and is useful in preventing medication errors, and for understanding medication management compliance. The pilot sites found that the proposed standard is technically well structured, supports the exchange of information, and is ready to be used in Part D prescribing. When they do use it, clinicians need to understand that the medication history is only as good as its source. Medication history is available from a number of sources, but not one provides a comprehensive listing. For example, SureScripts data includes dispensed medications from retail and independent pharmacies; RxHub provides medication history from PBM/payer sources. The lack of a universal source for this information has limited clinicians' willingness to access medication history, believing that the information is not complete enough to provide real value. While Medication History was available during the entire study period, it was not viewed very often. This is likely because a majority of users were not aware that it was available and it was not intuitive to physicians where on the application this information was housed. To promote widespread adoption of this standard it will be necessary to resolve any implementation issues, for example, reconcile data from a large number of sources to provide complete and useful information.

C.   Fill Status Notification

The Fill Status Notification, RxFill, is part of the NCPDP SCRIPT 8.1 standard, but it was not named a foundation standard due to lack of industry experience. The standard covers notification from a pharmacy to a prescriber when the prescription has been dispensed (medication picked up by patient), partially dispensed (partial amount of medication picked up by the patient), or not dispensed (medication not picked up by patient) and medication returned to stock.

Several of the pilot sites evaluated the Prescription Fill Status transaction in lab environments. Since RxFill is a "push" message from the pharmacy to the prescriber, pharmacy software systems are critical to this transaction. Pilot testing of this transaction and functionality varied widely among each of the grantees/contractor. Two pilot sites tested the RxFill message type in conjunction with the medication history message type in order to explore the value of patients' adherence to medication regimens based on data from the fill status transaction compared to using the medication history transaction alone. However, the pilot sites hypothesized that the medication history message includes all the information contained in the RxFill message, making it rather redundant.

Analysis

The standard is clearly technically sufficient to support the pharmacy sending prescription status messages to the prescriber. The standard's challenges are not related to structure and format, but to its implementation. Currently there are pharmacy computer systems

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and technologies available to track patient pick-up. But the majority of pharmacy systems either do not have this software capability, or the pharmacy has not yet made the necessary hardware/connectivity investment.

RxFill would encourage adherence and compliance with medication therapy. As promising as that premise is, the observations from the pilot sites indicate there is no pressing marketplace demand for RxFill. Prescribers who participated in focus groups were genuinely interested as to whether their patients were taking and following prescribed treatments regimens and if notification of "no fill" were presented, they would want to take action based on that information. However, there appears to be no industry consensus on what constitutes a filled prescription, and how long a time to wait for a prescription to remain unretrieved to be classified as a "no fill." Other concerns included issues of additional workload and potential liability issues. To fully implement this standard, pharmacy management systems would need to design and develop the capabilities to track, trigger, and send the RxFill Status messages and the supporting data, initiate these changes and modify workflows as needed.

D. Prior Authorization

Often, physicians must certify with an insurer that a patient meets specific, defined criteria for a drug to be covered. The current system requires multiple phone and written contacts between the prescriber, the pharmacist, and the health plan. The prior authorization standard incorporates real-time prior authorization 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* 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 ending the PA request. As RxHub was able to provide key drug-specific prior authorization requirements as requested by the payer/PBM, all pilot sites selected the unsolicited model.

The specific process for the unsolicited model of electronic prior authorization is as follows:

1) Payers and PBMs publish drug-specific prior authorization requirements using the NCPDP Formulary & Benefits file specification;

2) Prescribing systems use prior authorization flags to alert prescribers of authorization requirements;

3) Prescribers provide needed information in the format of an electronic prior authorization request;

4) Prescribing systems submit electronic prior authorization requests to Payer/PBMs using the XI2 278 transaction, including appropriate patient information (diagnosis/conditions);

5) Payer/PBMs respond using the 278 response, and potentially note the authorization result in the claim adjudication system.

The grantees/contractor examined various approaches to assessing the impact of a standardized electronic prior authorization (ePA) on the prescriber's workflow, changes in prescribing behaviors and perceptions of access to appropriate medications both in lab environments and live implementations.

Analysis

Because health plans typically require prior authorization only for a small subset of drugs, the pilot sites had limited live experience with this standard. The grantees/contractor examined various approaches to assessing the potential impact of a standardized electronic prior authorization on workflow, prescribing behaviors and access to appropriate medications both in laboratory and live environments. The electronic prior authorization standard has the potential to improve operational efficiencies for providers by standardizing payer processes. With the current paper process, providers face challenges such as losing forms, manually researching detailed patient information, and staying abreast of the latest payer requirements, as well as timeliness of responses to enable appropriate treatment. The proposed electronic prior authorization process 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 prior authorization process, nor is adoption widespread enough for the standard to be adopted as a final standard for the Medicare Part D e-prescribing program.

E.   Structured and Codified SIG

Patient instructions for taking medications are called the *signatura*, commonly abbreviated SIG. Currently, there is no standardized format for vocabulary for 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 NCPDP was not a near–term prospect. As a result, the grantees/contractor agreed to test NCPDP's proposed Structured and Codified SIG Standard 1.0 in a laboratory setting.

Each grantee/contractor chose a different approach to testing this standard. They included review of the proposed SIG standard; identification of test cases; using live transactions and selecting samples of prescriptions with a wide variety of SIGs; recreating each test case in a laboratory environment; and developing a test harness that would include functions of an electronic information exchange application. Another approach was to analyze an initial sample (significant in number) with an attempt to represent each distinct SIG using the proposed standard's 128 data fields.

Analysis

The Structured and Codified 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 as the SIG Free Text Indicator field. It is imperative that the prescriber's instructions be translated exactly into e-prescribing and pharmacy practice management systems to reduce medication errors, decrease healthcare costs and improve patient safety. For example, contradictions with other structured fields exist, and there are limitations on directions for topical drugs (such as the area of application). The PRN designation (pro re nata or "as needed") could be interpreted as either "as needed" or "as required", and the standard does not allow for quick revisions for new drug administration. Mis-translations 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. Analysis shows that the standard is not technically able to support this function for use in Medicare Part D e-prescribing in its current state.

F.   RxNorm

RxNorm, a standardized nomenclature for clinical drugs developed by the National Library of Medicine (NLM), provides standard names for clinical drugs (active ingredient + strength + dose form) and for dose forms as administered to a patient. It 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 dispense the drug. In August 2006, 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.

Currently, there are multiple systems using different databases to uniquely identify drugs. RxNorm intends to create one standard format for drug names, with links from clinical drugs to their active ingredients, drug components, and most related brand names. It is deployed in live settings for integrating patient medication information from multiple systems, e.g., Department of Defense, the Veterans Administration and Regional Health Information Exchanges. In this pilot testing, RxNorm terminology was evaluated in the context of the NCPDP SCRIPT 8.1 standard for new prescriptions, renewals, and changes. 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 an 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.

The grantees/contractor tested this standard in a laboratory setting to gain understanding of the completeness and accuracy of RxNorm for representing new prescriptions and renewal requests that were actually transmitted between prescriber's offices and pharmacies. Each pilot site used the RxNorm Release Documentation File available at the time of testing. This range included the monthly RxNorm Files released in July through December 2006, excluding October 2006.

Analysis

RxNorm has considerable potential to simplify e-prescribing, 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. RxNorm requires further evaluation and refinement before it can be required for e-prescribing. 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

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RxNorm concept, or an error with RxNorm itself, with more than one term being available for the same clinical drug concept (i.e., unresolved synonymy). As with other vocabulary standards, RX Norm will never cover 100 percent 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 e-prescribing.

G.   Long-Term Care (LTC)

The NCPDP SCRIPT Standard Version 8.1, is an update to the NCPDP SCRIPT Version 5.0 foundation standard used for transmission of basic information about e-prescriptions, including not only new orders but also change, renewal, and cancellation of existing prescriptions. The final rule provided for an exemption from this requirement in LTC settings. In the long-term care pilot site, Achieve tested this standard and found that modifications were required in order to ensure accurate transmission of the data in the LTC setting.

In long-term care, a prescription order typically remains an open order with no end date or with a date far in the future. At times, a prescriber needs to modify this order and notify the pharmacy. The changes would include a significant change of dose, form, strength, or route, or the modifications of frequency, or a minor change related to the order. The prescriber system will always send a CANCEL and a NEWRX, regardless of the type of change. This process differs from the Change Request (RXCHG), because it is initiated from the prescriber, not the pharmacy. With the request coming from the prescriber, there is no need for a response approving the request. The pharmacy, upon reviewing these changes, could determine if the original order needs to be cancelled or if it can be modified.

In the long-term care environment there is a need to send a refill request from a facility to a pharmacy. An example is when a medication supply for a resident is running low (2-3 doses) and a new supply is needed from the pharmacy, the nurse needs a way to notify the pharmacy that a refill for the medication is needed. Typically, the physician is not involved in this process until the end of the month when all of the resident's orders are signed in batch. The proposed solution is to insert the long-term care facility into the refill communications process in between the pharmacy and provider. Therefore, there is a need to maintain three separate identifiers for the refill request and response transactions.

Currently, the Census Update Transaction is originated by the long-term care facility and notifies the pharmacy about census events. The transaction can be used in three cases - to notify the pharmacy of a new resident, a change to demographic information of a resident, or the discharge of a resident. In long-term care these changes to the patient status happen regularly. They are not necessarily tied to a prescription, but they may drive processes at the pharmacy. Because of this, a message type is necessary to convey patient information "decoupled" from any prescription information.

Analysis

Because of the unique nature of this pilot site, CMS granted Achieve an exemption from testing the initial standards' interoperability with the foundation standards. It also did not test Medication History standard.

In the two pilot site treatment facilities, Achieve was able to provide coverage information for 84 out of the 196 residents (43%) using the eligibility information available from RxHub. This 43% coverage percentage was much higher than the investigators had anticipated.
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Additionally, no changes were made to the NCPDP Formulary and Benefits 1.0 standard for the LTC environment.

However, the long-term care pilot site had substantial findings for one of the foundation standards. This pilot site found that, in the LTC setting, NCPDP SCRIPT Version 8.1, an update to the foundation standard NCPDP SCRIPT Version 5.0, needed revision to accommodate the prescribing workflows. The pilot site is working with the National Council for Prescription Drug Programs (NCPDP), the organization that developed the standard, to develop needed modifications. These modifications include the need to update prescriptions without having to create a new order, the ability to send a refill request from the facility to the pharmacy without the physician's intervention, and the ability to update patient information outside the context of a prescription.

The pilot site participants implemented these "workarounds" to facilitate the use of the standard. The grantee/contractor has submitted to NCPDP a formal request to incorporate these changes into the next version of the standard. The NRC evaluation team determined from the Achieve pilot site results that e-prescribing could be implemented in the LTC setting once these changes are adopted.

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SECTION V

ADDITIONAL INFORMATION: BUSINESS PROCESS AND RETURN ON INVESTMENT (ROI)

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1. Overview

In addition to standards testing, each pilot site concentrated on different e-prescribing outcomes and approached these outcomes from a wide variety of care settings and stakeholders.

A.   Workflow

It is anticipated that e-prescribing will improve workflow for both prescribers and dispensers. Widespread adoption of e-prescribing will require that prescribers realize these improvements in workflow, or that other perceived benefits of e-prescribing are large enough to counteract any negative impact on workflow.

Although the use of e-prescribing is growing, few medical prescribing programs communicate to pharmacies through direct digital communication. Most transmit hard copies via fax machines, which is not e-prescribing because the fax does not originate as electronic media. Most pharmacies, however, are connected to e-prescribing networks and capable of communicating with outside entities, particularly payers. Over 95 percent of America's 56,000 retail pharmacies are connected to networks capable of receiving and exchanging prescription medication history. In contrast to most medical practices, automation is a key component of pharmacy operations. Concerns over "lost" prescriptions, not being able to transmit prescriptions electronically for Schedule II drugs, not knowing how to verify if a prescription was electronically transmitted to the correct pharmacy and other issues with e-prescribing exist within the clinical community. Yet, unless prescribers adopt the technologies in a way that simplifies two-way communication, theoretical gains in productivity and associated cost savings will never be realized.

B.   Prescriber Utilization of E-Prescribing

An unanticipated finding was the role of the office staff in e-prescribing. One of the common themes among the five pilot sites was that non-physician office personnel play a large role in the prescribing workflow, with the nurse as a prescribing agent being especially prevalent. While unexpected, their role was clearly part of a successful workflow. An early observation in the Achieve pilot site was that physician adoption would be minimal. The Achieve study saw the majority of e-prescribing order entry performed by nurses (22 RNs and 38 LPNs). In this instance, nurses drafted orders for physicians to sign, accounting for 94 percent of all orders entered into the e-prescribing environment. Due to the prescribing workflow, Achieve felt that the charge nurse was the linchpin to its success. Towards the end of its work, it also had incorporated a few nurse practitioners who were trained to e-prescribe. This type of prescribing behavior was also found in the other pilot sites.

E-prescribing caused a shift in responsibility both to and away from nurses. One drawback was that when the nurse acted as the prescribing agent, patient safety alerts were often ignored. In the SureScripts pilot site, this was attributed to the belief that most drug-drug interactions were already known by the clinician, and that "everything interacts with everything," making for an overwhelming amount of alerts. Another workflow change was that e-prescribing renewals were more often delegated to the office staff. In one study, physicians perceived that e-prescribing reduced the number of phone calls to their office staff, so in return they shifted some of their own workload toward their surrogates.

C.   Physician Uptake

Among the eligible physicians in the intervention clinic at Brigham & Women's Hospital (BWH), 22 or 11 percent of attending physicians agreed to participate in the study, although more may have used the e-prescribing module. It was found in the RAND study that of the 12 office sites that were planning to install an e-prescribing system, two sites cancelled the installation and four sites did not have any prescriber using the product. Of the enrolled offices, 50 percent continued to rely solely on authorized prescribers to interact with e-prescribing systems. Of the remaining 6 sites that used the system over half of all prescribers continued to use paper. Some reasons that were given to explain continued use of paper were technical problems related to the device itself and incomplete patient data loaded into the e-prescribing system. These findings have significant implications for the flow of formulary and other decision-support messaging.

In the Ohio KePro pilot site, a control group of 22 practices (77 physicians) and a study group of 25 practices (130 physicians) showed that adoption increased toward the end of the study period. About 2/3 of the physicians in the study group were e-prescribing at least 150 prescriptions per month. Once adopted, dropout was unusual. Two-thirds of the high volume e-prescribing physicians did not e-prescribe directly but used surrogates. In October 2006, 16,000 of 48,000 prescriptions were entered directly by the prescriber.

For e-prescribing to be successful, prescribers must participate and find value in the e-prescribing systems. All five pilot sites tracked prescriber uptake and/or satisfaction. All of the pilot sites had reasonable adoption of e-prescribing, and the adoption rates and retention were generally good, though there were some drop outs during the study. This may support the need for further study to better understand alignment of roles and e-prescribing functionality.

D. Patient Satisfaction

Patient satisfaction is another important component driving e-prescribing. Even if e-prescribing improves prescriber workflow, if patients report problems when they go to pick up a prescription, prescriber adoption may be limited. Only one site, SureScripts, included this outcome in their study. They found that of the 834 patients surveyed, 56 percent either moderately or strongly preferred e-prescribing over paper prescriptions. Adults under 65 years of age were 2.2 times more likely to strongly prefer e-prescribing. However, due to the limited experience of the pilot sites in this area, further study is warranted.

E. Formulary Versus Generic Prescribing

Health plans and pharmacy benefit managers use a variety of cost incentives to steer utilization to the most cost-effective drugs. However, these incentives are most effective if they are communicated to the prescriber. Because each health plan has different incentives, physicians rarely know what a particular patient will pay for one drug compared to its alternatives. In a paper-based system, the onus is generally on a patient to ask their provider to consider lower-cost alternatives. E-prescribing creates the possibility for providers to see information about a patient's drug coverage, and which drugs are preferred by the patient's insurer, at the time of prescribing. An e-prescribing system may also remind the prescriber when generic alternatives to a brand-name drug are available, prompting discussions with patients regarding cost efficiencies of generic versus brand name drugs, and subsequent allowances for generic substitution versus "dispense as written" directives.

The RAND pilot site found a small but significant temporal increase in the use of generic medications that was loosely correlated with the extent of e-prescribing use categories. Patient income also was significantly inversely associated with a higher likelihood of a generic medication claim. Prescribers in the RAND survey had mixed perceptions about the use of formulary information. There was skepticism/uncertainty about the accuracy and completeness of the formulary information, with 53 percent of respondents believing that "drug coverage information appears to be missing in the system for those with prescription benefits." The role of e-prescribing in the use of on-formulary medications and generics is still very preliminary. Generic prescribing may be most impacted by any prescribing tool that shows generic alternatives for brand name medications.

F. Medication History Utilization

The availability of a patient's medication history can enable prescribers and pharmacists to prevent medical errors by checking for redundant drugs and drug-drug interactions. Three pilot sites specifically tracked how frequently prescribers accessed medication history information via the e-prescribing system, or asked them how useful they found this information.

Prescribers who used the medication history function believed that it provided some benefit. In the SureScripts pilot site, there was variance in the frequency with which medication history information was used, with 53 percent of the 205 respondents at baseline stating they reviewed medication history most of the time (45 percent of 217 upon follow-up). Provider comments ranged from those who perceived the information as inaccurate, to a few providers who believed it was a good supplement to a patient's "faulty" memory. At site visits where

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medication history was discussed, there was poor integration of this functionality into the e-prescribing workflow in some cases, and physician feedback suggests that they received very little education about the presence of this feature.

E-prescribing has the potential to alert prescribers when they are prescribing a medication that would be inappropriate. Tests for appropriateness included total number of medications, the Beers list of medications that are generally inappropriate for the elderly, medications that should be avoided in the presence of certain medical conditions, and duplicative medications. E-prescribing also has the potential to reduce the number of adverse drug events which in turn could reduce hospitalization and emergency department visits. This capability to check for these alerts at the time of prescribing, which normally happens in the pharmacy setting, has been shown to reduce pharmacy callbacks.

G. Inappropriate Prescribing/Adverse Drug Events

In the LTC setting, Achieve analyzed inappropriate prescribing based on three criteria: number of residents with 9 or more medications; rate of physician order changes when prompted to comply with Beers list recommendations; and rate of therapeutic duplications. Preliminary data demonstrated a 1.5 percent decrease in orders per resident per month, as well as a 2.4 percent decrease in the number of residents with 9 or more active orders per month. This suggests a slight improvement in quality and safety that the investigators acknowledge might have been more dramatic had prescribers (rather than their agents) used the system.

Based on prior work in the inpatient environment, BWH constructed an adverse drug event (ADE) monitor that is undergoing testing, and has been found to have acceptable reliability. For the purposes of this project, they are conducting a chart review of any patient whose record triggers one of their ADE monitoring rules. Preliminary data from this group have demonstrated a potential decrease in medication errors that are undergoing further analysis. In the SureScripts pilot site, the great majority of clinician respondents said that they overrode drug-drug interaction alerts at least sometimes. Providers were aware of the potential for an important alert to be missed, but noted that "everything interacts with everything", making for an overwhelming amount of alerting.

H. Callbacks

Anecdotes from the Achieve/LTC pharmacists and nurses indicate the system has dramatically reduced callbacks during new admissions. At BWH, preliminary data reveals that approximately 13 percent of observed pharmacy calls were for prescription clarification or incorrect prescriptions. At RAND, using their online prescriber survey, with a 58 percent overall response rate, there was no significant difference between the number of calls related to prescription drug coverage before and after implementation of e-prescribing. In the SureScript pilot site, staff commented that e-prescribing cut down on pharmacy-generated calls about illegible scripts.

2. Conclusions

Electronic prescribing is still in its infancy. While the pilot sites have demonstrated the potential for effective standards-based implementation of three of the initial standards, there is additional work to be done on the three remaining initial standards in order to make them suitable for adoption for Part D. The testing of the initial standards conducted by the pilot project reflects each respective standard's technical ability to convey the needed information, but

implementation issues remain. It is anticipated that these implementation issues will be addressed through industry and stakeholder input into the established process leading up to the issuance of final e-prescribing standards.

Additionally, the pilot project was impacted by the limited amount of time in which to recruit grantees/contractor and conduct pilot site activities; the small size of the pilot sites themselves which may or may not represent a statistically significant sample; and the ability of the grantees/contractor to recruit the right set of participants to make the outcomes meaningful.

The majority of practices consist in size of one to two physicians. Their adoption of e-prescribing may be slower. Their overall requirements for support will be higher than physicians in larger practices, who will likely deploy e-prescribing on the way toward more comprehensive, patient-focused health information technology systems.

On the surface, e-prescribing involves getting a prescription from point A to point B. In reality, the complexity of e-prescribing necessitates testing of all aspects of the process and determining which standards can support each of the steps in that process. The testing and adoption of this second layer of standards as demonstrated by the pilot sites should be just part of an ongoing effort to continue to work with industry, standards setting organizations and other interested stakeholders to fully adopt and implement electronic prescribing in order to reap its many potential benefits.

Appendix A: Site Visit Protocol

Pre-Site Visit Activities
- Baseline data collection via addendum to progress reports
- Kick-off conference call with pilot site staff
- Review of available data
- Development of a tailored protocol based on knowledge gaps for each grantee/contractor
- Determine who from pilot site should participate (PI, PM, technical lead, evaluation lead)
- Determine location (especially if demonstration is involved)

On Site Activities
1. **Project Overview**
   - What is the status of your project relative to goals?
   - Ultimately what will CMS/AHRQ learn from your project?
   - Any demonstration that the pilot site can provide of how various standards are being used
2. **Standards Testing**
   For each standard a pilot site is testing, prompt to provide additional detail on …
   - Status of implementation
   - Method of testing
   - Status of testing activity
   - Findings from initial testing
     - What criteria are you using for a "successful" use of the standard?
     - What is the data you are using to confirm successful transactions or identify issues (transaction logs, prescriber/pharmacist experience, other means?)
     - How much of this data is analyzed and can be shared?
     - Workflow issues
     - Data transfer issues
     - Extent to which issues are related to core business practice v. implementation
     - Setting specific issues associated with the standard
     - What "workarounds" are necessary, please describe?
   - *Overall what are the implications of your findings for CMS recommendations regarding this standard?*
     - What parts of the standard are problematic, why?
     - What are the key implementation issues associated with using the standard?
     - What aspects of your experience are most/least able to be generalized?
3. **Outcomes Testing**
   For each outcome being tested, provide additional detail on…
   - Status of evaluation
   - Research design
   - Status of data collection/analysis
   - Availability of data and analytic results (what format can these be shared in?)
   - Summary of findings
   - Implications of findings for the CMS evaluation
4. **Wrap-up**
   - Review final impressions and take-aways
   - Review next steps
     - Additional materials to be provided
     - Follow-up calls

GLOSSARY

Electronic Prescribing Terminology Covered in the Report

Adverse Drug Events (ADEs): Any injury due to medication (Bates et al., 1995b) (e.g., drowsiness from diphenhydramine).

Accredited Standards Committee (ASC) X12N 270/271: see X12N 270/271

American National Standards Institute (ANSI): A private nonprofit federation that includes industry, standards development organizations, trade associations, professional and technical societies, government, labor and consumer groups. It serves as a forum for public and private sector cooperative development of voluntary national consensus standards.

Beer's List: A national guideline and reference guide for pharmacists and physicians to improve the use of medication in the elderly, developed with explicit criteria based on the risk-benefit definition of appropriateness, and originally with the frail elderly nursing facility resident in mind.

Dispenser : A person or other legal entity, licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located, to provide drug products for human use by prescription in the course of professional practice.

Fill Status : Informs when Rx is filled, not filled, or partially filled. Includes provider, patient, and drug segments of SCRIPT message. Not yet generally used.

Final Standards: Uniform standards that are adopted through notice and comment rulemaking for use in the e-prescribing program under Title I of the MMA. Medicare prescription drug program sponsors, Medicare Advantage (MA) Organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans and other Part D sponsors will be required to support and comply with these standards when electronically transmitting prescriptions and prescription related information between dispensing pharmacies and pharmacists.

Formulary and Benefit Information: This standard displays the formulary (a list of drugs covered by a plan) status and alternative drugs as well as co-pays and other status information.

Foundation Standards: Standards for which there is adequate industry experience that have been adopted by DHHS Secretary through notice and comment rulemaking without pilot testing.

Initial Standards: Standards that NCVHS reviewed and commented on that were ultimately recognized by the Secretary as initial uniform standards relating to the requirements for e-prescribing. These standards lacked "adequate industry experience" and thus were subject to pilot testing via the AHRQ interagency agreement with CMS.

Medicare Advantage (MA) Organizations: A public or private entity organized and licensed by a State as a risk-bearing entity that is certified by CMS as meeting the MA contract requirements.

Medicare Advantage Plan: **A** type of Medicare plan offered by a private company that contracts with Medicare to provide Medicare Part A and Part B benefits; also called Part C.

Medicare Advantage Prescription Drug Plans (MA-PDs): A Medicare Advantage plan that provides qualified prescription drug coverage under Part D of Title XVIII of the Social Security Act.

Medicare Prescription Drug Plan (PDP): A stand-alone plan that only offers prescription drug coverage under Part D of Title XVIII of the Social Security Act.

Medication Error: Any error occurring in the medication use process (Bates et al., 1995)[11] Includes preventable, inappropriate use of medication including prescribing, dispensing, and administering.

Medication History (Hx) – Standard that includes the status, provider, patient, coordination of benefit, repeatable drug, request, and response segments of SCRIPT.

National Council for Prescription Drug Programs (NCPDP): A not-for-profit ANSI-accredited Standards Development Organization that develops and maintains standards through a consensus building process among more than 1450 members representing all pharmacy sectors.

NCPDP Provider Identifier Number: Widely accepted as the dispenser (pharmacy) identifier (there is currently no single identifier required for prescribers). Its database contains information to support various claims processing functions.

NCPDP SCRIPT Change Request and Response: The primary means by which a pharmacy may request of a provider a clarification, correction, or change in drug as a result of therapeutic substitution or other rationale.

NCPDP SCRIPT Cancellation: Cancels a prescription previously sent to a pharmacy.

NCPDP SCRIPT Fill Status: (see Fill Status)

NCPDP SCRIPT Formulary and Benefit Information: (see Formulary and Benefit Information)

NCPDP SCRIPT Medication History: (see Medication History)

NCPDP SCRIPT Standard: provides for the exchange of new prescriptions, changes, renewals, cancellations, and Fill Status notifications. The NCPDP SCRIPT Standard supports a wide variety of transactions, from new prescriptions to refill requests, prescription change responses to fill status notification.

NCPDP Telecommunication Standard: The HIPAA standard for eligibility communications between retail pharmacy dispensers and payers/PBMs.

Part D Sponsors: private organizations that contract with Medicare to offer prescription drug insurance plans under Part D of Title XVIII of the Social Security Act.

Pharmacy Benefits Managers (PBMs): Private companies that administer pharmacy benefits and manage the purchasing, dispensing and reimbursing of prescription drugs. PBMs provide a wide array of services to health insurers or to large health care purchasers and may negotiate rebates or discounts from pharmaceutical manufacturers and retail pharmacies, and process claims for prescription drugs. PBMs play a key role in managing pharmacy benefit plans in the Medicare drug program.

Practice Management System (PMS): Tools (usually computer software) that organize routine medical and business tasks.

Prior Authorization: The portion of X12N 278 standard that supports prior authorization. It requires header information, requester, subscriber, utilization management, and other relevant information.

Prescriber: A physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

RxNorm: A clinical drug nomenclature produced by the National Library of Medicine that provides standard names for clinical drugs and for dose forms, and links from clinical drugs to their active ingredients, drug components, and most related brand names. It includes the semantic clinical drug (ingredient plus strength and dose form) and the semantic branded drug representation (proprietary, branded ingredient plus strength).

Schedule II Drugs: A drug or chemical substance whose possession and use are regulated under the Controlled Substances Act, including, among others, narcotics, hallucinogens, etc.

SIG Messages: Indication, dose, dose calculation, dose restriction, route, frequency, interval, site, administration time and duration, stop.

X12N 270/271: The HIPAA standard for eligibility and benefits communications between dentists, professionals, institutions, and health plans.

X12N 278 prior authorization: (see Prior Authorization)

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