

## **Pilot Testing of Electronic Prescribing Standards**

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## Abstract

**Purpose:** The purpose of this study was to evaluate six standards being considered as potential initial standards for e-prescribing under Medicare Part D.

**Scope:** The standards being considered are for drug formulary & benefit information, patients' medication histories, the "fill status" of individual prescriptions, electronic prior authorization (ePA) requests, drug identifiers, and the "Sig" portion of prescriptions. The study was conducted among participants in the E-Prescribe program of Horizon Blue Cross Blue Shield of New Jersey.

**Methods:** Each standard was evaluated through one or more of the following methods: workflow modeling, an expert panel process, physician and pharmacy site visits, a survey of e-prescribing participants and non-participants, analyses of prescription claims before and after e-prescribing activation, the creation and deployment of a working prototype system for electronic PA, prescriber focus groups, and tests of the standard's capacity to represent a sample of actual prescriptions.

**Results:** E-prescribers used the system to differing extents; 37% of those surveyed reported use of e-prescribing for nearly all prescriptions whereas 17% reported having quit e-prescribing. The formulary & benefit and medication history standards are hindered by usability challenges including inadequate drug identifiers. RxNorm drug identifiers were available for 99% of 19,956 non-device prescriptions and renewal requests. Electronic PA was well received but the proposed standards needed modification. Prescribers had significant concerns about fill status alerting. Experts showed little agreement in using the Sig standard. We recommend that each standard receive further development or evaluation before being mandated; RxNorm warrants the highest priority for further testing.

**Key Words:** Electronic prescribing, adoption of health information technology, formulary adherence, medication safety.

## Purpose

The purpose of the project described in this report was to pilot test six electronic prescribing (e-prescribing) standards that are under consideration as potential initial standards for e-prescribing under Medicare Part D. The project's aims were to (1) develop quantitative work process models that link information from the standards to their effects on clinical and drug utilization outcomes, (2) elucidate the standards' technical adequacy and implementation through an expert panel process, (3) assess the effects on physician office operations of implementing e-prescribing systems that use the formulary and the medication history standards, (4) compare changes in drug use patterns, possible medication errors, and hospitalizations based on medication claims from before and after the implementation of e-prescribing with these two standards, (5) explore methods for presenting patient adherence information to prescribers, (6) evaluate a working prototype for electronic prior authorization using the proposed standards, (7) assess the completeness and semantic content of RxNorm, and (8) assess the potential completeness and semantic content of the structured and codified Sig standard.

## Scope

**Background & Context.** The Medicare Modernization Act of 2003 requires Medicare Part D health plans to accept electronic prescriptions. In addition, it requires the Secretary of Health and Human Services to issue "Initial Standards" for e-prescribing under Medicare by April 2008, informed by results of pilot testing to be conducted in 2006. However, an exception to pilot testing was made for standards for which there exists adequate industry experience. The Department of Health and Human Services proposed a set of such standards that do not require pilot testing, which they termed Foundation Standards for e-prescribing. Six other Initial Standards (**Table 1**) required pilot testing.

**Table 1. Initial Standards for Pilot Testing**

<u>Abbreviation</u>	<u>Full Name of Standard</u>	<u>Critical Data Elements</u>	<u>Central Purpose</u>
F & B	NCPDP Formulary and Benefit Standard, v. 1.0	Formulary Status, Coverage limits, Alternatives, and Copay by NDC code	Display formulary status & patients' costs at time of prescribing
Med Hx	Medication History transaction of NCPDP SCRIPT, v. 8.1	Repeatable SCRIPT Drug segment for each past dispensed drug claim	Display history of prior filled medications; enable safety alerting.
Fill Status	Fill Status Notification (RxFill) transaction of NCPDP SCRIPT, v. 8.1	SCRIPT Message Reference Number from original prescription	Inform prescribers when patients may be failing to receive medications
ePA	ASC X12N 278 ASC X12N 275 wrapper with HL7 attachment	Drug Requested, Patient data elements requested for review and values returned.	Online completion of drug prior authorization requests.
RxNorm	The NLM's RxNorm drug nomenclature (July, 2006 and Nov., 2006 versions)	Concept unique identifier (CUI) for Semantic Clinical Drugs (SCDs)	Unambiguous reference to a drug, dose, and dose-form concept
Sig	NCPDP Structured and Codified Sig standard, v. 1.0 (June 2006 draft)	Dose, Route, Site, Frequency, Interval, Administration Time, Duration, Indication	Computer-interpretable patient instructions

The *Formulary and Benefit* (F&B) standard provides data about drug insurance benefit plans as opposed to data about individual patients. This data is downloaded by e-prescribing system vendors in a “batch” fashion, an approach necessary to enable the display of coverage information for each medication in the pick-lists that prescribers use to make initial medication choices. Several types of F&B data can be represented, including formulary status lists (FSL), alternatives (ALT), coverage limitations (COV), and copay information (COP). Prescription benefit management companies (PBMs) typically certify individual vendors' presentation of a given F&B data type before the PBM grants them access to it.

The *Medication History* part of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard is intended to give prescribers information about patients' current and past medications by listing the pharmacy claims that the patient's health plan has paid for. This standard is now being implemented by SureScripts to list medication purchases beyond those paid for by insurance.

The *Fill Status Notification* part of NCPDP SCRIPT has been available since 1999 but it has rarely been used in production among e-prescribing systems. Originated by the pharmacy, the transaction is designed to notify the prescriber of events in the pharmacy, including the dispensing, partial dispensing, or non-dispensing (usually a return-to-stock event) for both an initial prescription and its refills. Several problems with this transaction have been recognized, most notably its poor reliability for identifying patient non-adherence and the new burden it could create both for pharmacies and for prescribers.<sup>1</sup>

*Prior authorization* (PA) is the process of requesting approval for a prescription's coverage from the health plan or PBM. PA often requires the completion of PA request forms that are then reviewed against

<sup>1</sup> A February, 2005 NCPDP whitepaper and the SCRIPT 8.1 implementation guide, taken together, highlight the following issues. Each prescription written could result in multiple different kinds of fill status messages and many pharmacies do not have computerized systems to track all of the triggering events. Thus, 100% participation by pharmacies is unlikely in the foreseeable future. In this setting, the absence of a “dispensed” event would not reliably indicate patient non-adherence. “Not dispensed” events could also be insufficient for adherence monitoring because the time before a triggering “return to stock” event is not standardized and could be 2 weeks or more. Finally, handling fill status messages could create substantial new work for providers.

pre-established appropriateness criteria. One proposed means of streamlining PA is to enable the completion of electronic PA requests (ePA) through e-prescribing systems. The prior authorization transaction proposed for pilot testing in the request for applications for this project was the X12N 278. The 4010 version of this standard is a HIPAA-named transaction that was originally designed for service or procedure PA. Even with work-arounds, this transaction is incapable of transmitting the criteria that are often required by health plans or PBMs. Thus, a PA Attachment modeled after Claims Attachments was created. The PA Attachment required a wrapper, the X12N 275. We sought to assess the potential impact of standardized ePA on prescribers' work processes, prescribing patterns, and perceptions of access to appropriate medications. We therefore needed to use this entire set of transactions — the X12N 278, X12N 275, and the HL7 PA Attachment.

*RxNorm* is a drug nomenclature that was created by the National Library of Medicine to standardize the representation of clinical drugs, distinguishing drugs based on their therapeutic or diagnostic intent. Each term in RxNorm is identified by a concept unique identifier (CUI). The core concept in RxNorm is the Semantic Clinical Drug (SCD), which represents a unique combination of active ingredients, the strength for each ingredient, and the dosage form. An example is Verapamil 180 MG Extended Release Tablet, which is represented in RxNorm by the CUI 483374. RxNorm's promise for e-prescribing lies in its use as an interlingua for drug concepts in transactions among trading partners. Most pharmaceutical-related applications today manage drug concepts using one of the commercial drug knowledge compendia, such as Wolters-Kluwer's MediSpan product or First DataBank's National Drug Data File, but trading partners often license different vocabularies. Thus, to transmit drug concepts among different systems, e-prescribing standards rely mostly on the FDA's NDC codes to identify drugs. NDC codes have many shortcomings as drug identifiers, however, including the existence of multiple codes for the same clinical drug, and the use of codes that are outdated, erroneous, or unpublished by the FDA. For example, an instance of the Verapamil SCD concept shown above could be represented by any of more than 80 NDC codes. The use of RxNorm codes could greatly decrease this complexity by providing one unambiguous, permanent identifier for each clinically distinct drug.

The *Structured and Codified Sig* (Sig) standard is intended to provide a machine-interpretable representation for the patient instructions portion of a prescription, thereby enabling more automated safety checking, improved communication between prescribers and pharmacists, and better efficiency of prescribing, renewal, and dispensing activities. The current draft standard was created by an industry-wide task group convened by the NCPDP.

**Settings & Participants.** Our study was set within the E-Prescribe program of Horizon Blue Cross Blue Shield of NJ (BCBSNJ). After an initial pilot phase involving 50 electronic prescribers in 2002–2004, Horizon BCBSNJ prepared a major expansion of the Program in late 2004, intended to recruit up to 1000 prescribers, with 700 seats for Caremark's iScribe e-prescribing product, 200 for Allscripts's Touchscript e-prescribing product, and 100 for InstantDx's OnCallData e-prescribing product. The program enrolled and installed e-prescribing systems for individual physicians rather than practices as a whole. Participants were required to have a computerized practice management system and high-speed Internet access in their office. They also needed to be a Horizon network provider, but they could use the tool to write and transmit prescriptions for any patient, regardless of their insurance. The Program covered the costs of hardware, software, installation, training and ongoing support, at an estimated cost of \$4200–6400 per prescriber. The program was also designed to promote the actual use of e-prescribing through quarterly honoraria of \$150–500 per prescriber based on an estimated proportion of prescription claims that had been written electronically. Horizon estimates their total investment to date at \$6.5M.

## Methods

Each of the six proposed Initial Standards for e-prescribing was evaluated using a set of methodologies that was tailored to the standard's level of use and to the research questions that were most important for determining each standard's readiness for adoption and effectiveness for improving medication management processes and patient outcomes. **Table 2** provides an overview of the methods

used to evaluate each standard. Each part of the study was approved by RAND’s IRB, aspects involving Horizon patient data (all de-identified) were approved by Horizon’s Privacy Board, and aspects involving physician site visits were approved by the UMDNJ IRB.

**Table 2. Methods for each research question in the RFA; methods used to evaluate each standard**

<u>Research Questions</u>	<u>Evaluation Methods</u>	<u>Standard</u>	<u>Evaluation Methods</u>
<p><b>Technical-level</b> (Do the standards work? Do they work well together? How can they be improved? How do the initial standards work with the foundation standards? Are the right data being sent? Are the data usable? What is missing? What should be changed to improve functionality? Other suggestions.)</p>	<ul style="list-style-type: none"> <li>• Expert panel</li> </ul>	F&B	<ul style="list-style-type: none"> <li>• Work process model</li> <li>• Expert panel</li> <li>• Physician, pharmacy site visits</li> <li>• Prescriber survey</li> <li>• Claims data analysis</li> </ul>
<p><b>Workflow-level</b> (Effect on Functionality—integration with practice management, EHR and Decision Support Systems. Standards effect on quality and patient safety. How the use of an electronic prescribing system improved care from prescriber perspective. Does the use of initial standards increase efficiency of prescribing?)</p>	<ul style="list-style-type: none"> <li>• Work process model</li> <li>• Expert panel</li> <li>• Physician, pharmacy site visits</li> <li>• Prescriber survey</li> </ul>	Med Hx	<ul style="list-style-type: none"> <li>• Work process model</li> <li>• Expert panel</li> <li>• Physician, pharmacy site visits</li> <li>• Prescriber survey</li> <li>• Claims data analysis</li> </ul>
<p><b>Adoption and Implementation</b> (Participants by type by month for the duration of the pilot. Reasons for changes (+/-) in participation and retention rates. Barriers to the adoption of initial standards. Critical success factors for adoption of initial standards.)</p>	<ul style="list-style-type: none"> <li>• Program Enrollment</li> <li>• Physician, pharmacy site visits</li> <li>• Prescriber survey</li> </ul>	Electronic Prior Auth	<ul style="list-style-type: none"> <li>• Work process model</li> <li>• Comparison of existing forms with HL7 standard</li> <li>• Usage in live pilot study</li> <li>• Prescriber survey</li> <li>• Physician, pharmacy site visits</li> </ul>
<p><b>Outcomes level</b> (Effect on adverse drug events. Changes to medication error rates. Impact on beneficiaries.)</p>	<ul style="list-style-type: none"> <li>• Prescriber survey</li> <li>• Claims data analysis</li> </ul>	RxNorm	<ul style="list-style-type: none"> <li>• Work process model</li> <li>• Assessment of coverage for a sample of Rx data</li> <li>• Expert panel</li> </ul>
<p><b>Patient experience with health care</b> (e.g. the CAHPS instrument)</p>	<i>Unable to measure</i>	Sig	<ul style="list-style-type: none"> <li>• Assessment of reviewers’ agreement in representing a sample of Rx data</li> </ul>

## Work Process Modeling

To predict the effects of standard transactions on healthcare workflow and clinical outcomes, we created quantitative models by following 3 steps: 1) **process mapping** to graphically represent the relationships among work processes that may be altered by e-prescribing with the standard vs. without; 2) **model parameterization** of the key work processes and quantitative estimation of parameter values; and 3) **model building and simulation** to predict the time and labor costs and medication outcomes, before and after implementation of the relevant package of standards.

Process mapping is a workflow diagramming technique intended to clarify a process or series of parallel processes. Beginning from a macro-level map of the overall medication management process, including the major activities 1) prescribe, 2) transmit, 3) dispense, 4) administer, and 5) monitor (Bell et al., 2004), we developed more detailed micro-level process models consisting of tasks, which are all of the activities performed for medication management, and routing rules, which describe a task’s inputs and/or outputs and the occurrence of conditional task workflows. We revised our initial process maps based on comments from our technical expert panel and based on work process descriptions elicited in site visit interviews (see below).

We parameterized our process models by estimating the resources consumed by each task for an average prescription (especially physician time, staff time, pharmacist time, etc.) and by estimating the event probabilities associated with process branch points for an average prescription.

To simulate the prescription processes, we implemented the process model structure in Excel. The deterministic simulation model considered four variants of basic prescription processes: new prescriptions with traditional prescribing, new prescriptions with electronic prescribing, renewal prescriptions with traditional prescribing, and renewal prescriptions with electronic prescribing. The standards being evaluated were then assumed to be individually implemented as additional electronic prescribing features. The resulting models allow simulation of a group of patients who require either new prescriptions or prescription renewals via either traditional prescribing or electronic prescribing. From these simulations, we estimated the workload and outcomes that would result from prescriptions created with and without each of the standards.

## **Expert Panels**

To evaluate the standards' technical adequacy, we convened a panel of experts representing organizations involved in their implementation. The organizations included 5 point-of-care system vendors, 2 e-prescribing intermediary companies, 4 pharmacies and/or prescription benefit management companies (PBMs), and 2 drug knowledge content providers. Companies were recruited for the panel based on those that the intermediary companies RxHub and SureScripts nominated in January, 2006 as having the most experience in actual use of the initial standards. Of 15 companies approached, 14 agreed to participate. We did not conduct an expert panel evaluation of the PA and Sig standards because none of the panel organizations had direct experience with these standards beyond the evidence generated from our own pilot testing, as reported elsewhere in this report.

The technical expert panel process involved eight steps designed to elicit narrative evidence and ratings regarding each standard's technical adequacy. Each expert panel began with the design of a questionnaire intended to elicit experts' narrative feedback and ratings regarding data quality, usability, completeness of the standard, system architecture, and overall functioning of the standard. The questionnaires included both narrative and rating-scale questions related to each standard's accuracy, usability, completeness, and interoperability. Draft questionnaires were then revised to address panelists' comments. Panelist organizations responded to final surveys by distributing questions to the appropriate technical experts within the company. Study staff collected responses and distributed de-identified findings back to the panel. An audio-recorded conference call was then conducted with the panelists to discuss areas of disagreement and to elicit more detailed information on emergent themes. Finally, a qualitative analysis of narrative responses and transcripts was conducted in ATLAS.ti.

## **Physician Site Visits**

Twelve ambulatory care offices that were scheduled for installation of e-prescribing through the Horizon E-Prescribe Program were selected to participate in site visits. We used purposive sampling to select 6 offices scheduled for Allscripts implementation and 6 offices scheduled for iScribe implementation, and to also include diverse medical specialties and practice settings. Practices were each paid \$1,000 to offset the costs of data collection and practice disruption.

We conducted site visits prior to e-prescribing installation (in March to May, 2006) and approximately 3 months after (June to September, 2006). Audio-recorded interviews were conducted with 3 to 6 key personnel at each site — including at least one interview with a representative of each of the following groups: physicians, office managers, and staff involved in prescription workflow — focusing on prescribing workflow and expectations about the systems (at baseline). Followup interviews included questions about changes in workflow. All interviews from the baseline and follow up site visits were transcribed for analysis. ATLAS.ti was used to code and analyze all text data (field notes and interview transcripts). Reports were generated to determine common themes across sites and to generate site specific summaries, and the lead investigator selected representative segments of text to illustrate the common themes and site specific issues.

## Pharmacy Site Visits

For pharmacy site visits, we recruited participation from a large, national pharmacy chain that was processing SCRIPT-standard prescription transactions in New Jersey stores. We selected two New Jersey stores from this chain based on their proximity to E-Prescribe participants and based on their having pharmacist managers and technicians with sufficient tenure and expertise to evaluate the impact of e-prescribing on their workflow. During May 2006, these two stores processed an average of 54 electronic prescriptions per week. Pharmacy personnel were not compensated for participating in the research.

Site visits were completed in August, 2006. In each, a trained pharmacist–field researcher conducted audio-recorded semi-structured interviews with at least one pharmacist manager and one pharmacy technician. The interview was designed to elicit these individuals’ perceptions about work processes in handling electronic vs. handwritten prescriptions. The field researcher also recorded field notes on pharmacy layout, workflow and organizational culture using an observation template. Both field notes and interview transcripts were coded and analyzed using the comment feature in Microsoft Word.

## Prescriber Survey

We conducted an online survey to compare the perceptions of e-prescribers and non-e-prescribers regarding aspects of the prescribing process. The survey included: 1) questions for all prescribers about practice characteristics, the adequacy of the drug formulary and medication history currently available, and the current adequacy and burden of the prior authorization process; 2) questions for e-prescribers only about their use of and barriers to using the e-prescribing system, including the formulary and benefits information and medication history information provided by the system; 3) questions designed to assess computer attitudes and skills; and 4) demographic and background questions. Items were drawn or adapted from previously fielded instruments or were written by the research team. Draft questionnaires were revised for clarity and uniformity of language and format and appropriateness of response categories by RAND’s Survey Research Group (SRG).

Those invited to participate were sampled from enrollees in Horizon’s E-Prescribe program as of September, 2006. The sample frame was limited to 921 physicians who had known e-mail addresses. For the non-e-prescriber group, Horizon randomly sampled 200 out of 249 physicians in the sample frame who had volunteered for e-prescribing but were on the waiting list and were not scheduled for installation. For the e-prescribing group, Horizon randomly sampled 250 out of 602 physicians in the sample frame who had completed an iScribe installation plus 50 out of 70 physicians in the sample frame who had completed an Allscripts installation.

In October, 2006, Horizon faxed a letter to sampled prescribers introducing the study and explaining its procedures, including a \$100 honorarium for survey completion. Three days after the faxed letter, RAND sent each physician an e-mail invitation containing a randomly-assigned personal identification number they could use to take the survey on the RAND/SRG survey website. Incorrect and invalid email addresses were corrected by followup contact when possible and the email re-sent. Non-responders received a series of email, phone, and mail reminders until the survey was closed in December, 2006.

Because survey results relate to several standards, we report the survey response rates here. Among the 500 sampled providers, we were unable to obtain a deliverable, unique email address for 89 (18%), leaving 411 who were actually invited by email. Of these, 16 were ineligible because they had left the practice. Of the 395 contacted and eligible, 228 (58%) completed the survey. Respondents’ mean age was 47 (range 27 to 82), and there were no statistically significant differences between e-prescribers and non-e-prescribers in age, specialty, practice size, or electronic medical record use.

## Claims Data Analysis

To assess the effect of e-prescribing on drug use and outcomes, we conducted time series comparisons of pharmacy and medical service claims for primary care patients whose primary care provider (PCP) activated an e-prescribing system (EPS) vs. those cared for by targeted physicians who did not have an EPS. To ensure that those in the EPS group would have at least 6 months of prescription

claims available after EPS activation, physicians who activated e-prescribing after 12/31/05 were excluded. Horizon created de-identified data sets for all of patients with health maintenance organization or point of service insurance who were continuously enrolled with an EPS or a non-EPS PCP from 1/1/05 – 6/30/06, and then for all of these patients' pharmacy claims from 1/1/03 – 6/30/06.

To compare generic drug use between groups, we chose to focus on ACE inhibitors (ACEI) because clinically interchangeable generic and branded options existed within this class. We defined "new" ACEI prescription events based on ACEI claims that occurred with no ACEI claim during 12 months of Horizon enrollment previous to the claim. We conducted multivariate logistic regression, with correction for clustering at the physician and patient levels, to test whether the probability of new ACEI prescriptions being generic (vs. brand) was associated with having activated eRx.

The EPS group consisted of 319 PCPs whose 28,634 continuously-enrolled patients had 400,000 prescription claims; the non-participant group consisted of 2092 PCPs whose 175,623 continuously-enrolled patients had 2.4 million prescription claims. Approximately 99% of the physicians in both groups were family physicians, internists, and pediatricians. The distribution of actual eRx use within the eRx group was bimodal, such that most used the eRx extensively or hardly at all. To account for these differences in use, participating physicians were categorized into groups of low (n = 167), medium (n = 91), and high (n = 61) eRx use, based on their having average monthly rates of 0 to <12.5, 12.5 to <50, or 50+ electronically-generated prescriptions for Horizon patients, respectively.

## **Focus Group Evaluation of Fill Status/Adherence Alert Storyboards**

To explore the acceptability and potential value of presenting prescribers with information about patients' adherence to a medication therapy regimen in the context of electronic prescribing, we conducted 3 focus groups among prescribers in New Jersey and Washington, DC in November and December, 2006. Two of the focus groups each included six physicians, and the third included 8 physicians, one nurse practitioner, and one physician assistant, all of whom were current users of the Allscripts system. A flyer describing the focus groups and its \$150 honorarium was distributed to practices in regions where several Allscripts offices were concentrated. During each focus group, participants were asked to view a series of 7 storyboards that showed different ways of presenting information about a patient's medications. Developed in collaboration with Allscripts, several of the storyboards showed the current web-interface for the Allscripts e-prescribing system and others detailed prototypes for non-adherence alerts that could be based data from the Medication History or on additional information that would be available from the Fill Status standard. Discussions were moderated and recorded by a RAND Survey Research Group facilitator, and audio recordings were transcribed. Transcripts were analyzed by 3 investigators using the Microsoft Word comment feature.

## **Implementation and Evaluation of Electronic Prior Authorization**

To assess the potential impact of standardized electronic prior authorization processes (ePA) on prescribers' workflow and perceptions of access to appropriate medications, we designed and implemented systems for conducting end-to-end ePA transactions for Horizon patients. The project's limited timeframe and budget demanded that Caremark, which conducts PA review on behalf of Horizon, would need to feed ePA requests into its existing PA review processes, as opposed to developing parallel review processes and re-evaluating Horizon's review criteria. Thus, the questions that Horizon asks in its current PA forms needed to be asked electronically. RxHub, Caremark, Horizon, and RAND participated in comparing the HL7 PA Attachments to the Horizon PA forms. Based on the results of this comparison, allowance for a "custom" question type was made in the PA Attachment format used in the pilot.

Both Allscripts and iScribe built working modules in their e-prescribing systems for prescribers and their staff to place ePA requests. RxHub extended its electronic prescription routing system to receive and validate ePA transactions from Allscripts and iScribe using the X12N 278 and 275 and PA Attachment standards. RxHub also built a portal that Caremark's PA staff used to approve or deny ePA requests, with these decisions being transmitted back to the originating prescriber via the X12N 278

standard. Following the “unsolicited” model proposed by HL7, RxHub built a file transfer protocol to distribute the ePA question sets to iScribe and Allscripts.

The ePA system was made available to 43 iScribe and 19 Allscripts prescribers who volunteered to participate in its pilot testing. To evaluate the system, we conducted an online survey of all ePA participants and conducted site visits to 2 ePA participants’ offices. Because participants might not have had an opportunity to request ePA for an actual patient at the time of the survey, we asked them to complete a set of test patient cases using the ePA system before completing the survey. Other prescribers’ views of PA processes were elicited through the online survey and site visits described above.

## **Laboratory Evaluation of RxNorm**

To evaluate RxNorm’s readiness for use in e-prescribing transactions we conducted a pilot test to assess (a) the completeness of its Semantic Clinical Drug (SCD) concepts for representing the medications requested in large samples of new prescriptions and renewal requests that had been transmitted between prescribers and retail pharmacies in the course of actual patient care, and (b) the agreement between independent attempts to match each medication in these samples to a unique Semantic Clinical Drug (SCD) concept.

SureScripts created a de-identified dataset containing the drug description and representative NDC codes from 10,000 SCRIPT new prescription messages that had been transmitted from Allscripts prescribers to retail pharmacies in April, 2006. In addition, Allscripts created a de-identified dataset containing the drug description and representative NDC code fields from 10,098 SCRIPT renewal request messages received by Allscripts from SureScripts network pharmacies in August, 2006. We excluded prescriptions for medical devices, based on the assignment of a device flag by Wolters Kluwer.

Three independent attempts were made to match each non-device prescription to an SCD. The drug knowledge base vendors First DataBank and Wolters Kluwer made independent match attempts using the NDC codes they maintain in association with their proprietary drug concept identifiers (for First DataBank, the GCN SEQNO, and for Wolters Kluwer, the MediSpan GPI). Each vendor then retrieved an RxNorm SCD for each drug, where available, based on mappings that they maintain from their concept identifiers to RxNorm. Both vendors had updated these mappings using the July 11, 2006 release of RxNorm. One vendor supplemented their matches by manually searching RxNorm strings to find SCD concepts that had not mapped automatically based on the NDC codes. To provide a third mapping from NDC codes to RxNorm SCDs, we created a dataset associating NDC codes with SCDs based on the codes that were included as concept “attributes” in the November 22, 2006 release of RxNorm. We assessed completeness as the proportion of prescriptions for which any match attempt found an SCD and agreement as the proportion for which all 3 match attempts found the same SCD. Cases of incompleteness and disagreement were further examined and categorized.

## **Laboratory Evaluation of the Structured and Codified Sig Standard**

A pilot test was conducted using actual prescriptions to evaluate the Sig standard. We obtained de-identified Sig strings for the 10,000 SCRIPT new prescription messages that we had used for the RxNorm evaluation. After normalizing these strings to remove minor variations due to spaces, punctuation, and common spelling errors, we then rank-ordered the unique Sig strings based on their frequency of occurrence in the sample. From this list of unique Sig strings, we selected a purposive sample of 45 strings for mapping into the Structured and Codified Sig format. Thirty four of these strings were selected such that, in aggregate, they would make use of as many fields as possible within the Structured and Codified Sig standard. These selections were then supplemented by including the 3 most common Sig strings in the sample and 8 additional Sig strings that were selected at random.

An Excel spreadsheet was created for mapping individual Sig strings into the key fields within the Structured and Codified Sig format. For each of the standard’s 14 segments, the spreadsheet provided cells for representing each field except for the fields that would contain a controlled vocabulary code, code system identifier, or code system version. In total, the spreadsheet provided for using 45 fields.

Since a definitive list of SNOMED codes for each field had not yet been completed by the task group, we asked expert reviewers to map Sig strings using the terms that they would expect SNOMED to contain for each field. Four reviewers were selected based on existing collaboration in our coalition plus one expert on the SNOMED coding system. Three reviewers are pharmacists or PharmDs who are members of the NCPDP Sig Task Group and one reviewer is employed by RxHub.

One of us (SN), a pharmacist who was involved in creating the Sig standard, then used the Excel spreadsheet to create a reference mapping for all 45 Sig strings. The mappings for 3 Sig strings from the sample were selected for use as low-, medium-, and high-complexity examples of the mapping task. The four reviewers noted above were then given 21 of the remaining 42 Sig strings to map, assigned at random such that each Sig was mapped by two reviewers in addition to our own pharmacist expert.

We analyzed the results of this exercise to compare the representations generated for each Sig string both qualitatively and quantitatively to determine whether different reviewers mapped the Sigs identically and if not, to identify areas of discrepancies. To quantitatively analyze the degree of agreement in the representation of each Sig, the spreadsheets were “cleaned” by standardizing capitalization and removing extraneous prepositional phrases (e.g., fields containing “in a thin film” or “as a thin film” both became “thin film”). Excel spreadsheets were manipulated so the data could be imported into Microsoft Access, and queries to identify instances of agreement were executed. Each Sig had a total of 3 mappings for comparison: one by our expert pharmacist, and two by other reviewers. All 3 reviewers’ judgments were given equal weight in the comparison. We examined overall agreement considering all the fields that were used for a given Sig, and we also examined the agreement among reviewers within each segment for comparable Sigs.

## Results

This section presents the study’s principal findings available to date, organized by standard, with one additional section for findings related to overall e-prescribing adoption. It is important to recognize that data collection for many parts of the study was concluded in late December, 2006, due to difficulties in study recruitment and in secondary data preparation. Thus, analyses are ongoing for many parts of the study. Nonetheless, this section presents the conclusions and recommendations that can be made based on the analyses completed to date.

### Implementation of E-prescribing

Recruitment for the Horizon E-prescribe Program differed for each of the participating point of care (POC) e-prescribing vendors. Allscripts sites were recruited through outreach to physician-leaders at larger medical groups that generally had more than 5 physicians per office. InstantDx recruitment was targeted to a few medical groups having a specific practice management system that the InstantDx product was designed to work with.

iScribe participants were recruited from an eligible population of 6200 individual physicians who had been responsible for more than 500 Horizon BCBSNJ prescription claims in the previous year and who were practicing in offices with 5 or fewer physicians. Recruitment was conducted in phases, with each phase including 1 to 5 direct mail pieces (describing the benefits of e-prescribing and its ease of implementation through the Horizon program), with follow-up by field sales staff and/or members of the Horizon provider relations team. The first phase targeted prescribers above the 80th percentile of Horizon prescribing volume. Subsequent phases targeted incrementally lower-volume prescribers as well as following up with non-responders from earlier phases. As the program was nearing its enrollment capacity, the number of outbound direct mail pieces sent was reduced, and the lowest 20% of eligible prescribers received no direct marketing. In all, direct marketing was distributed to 4900 prescribers. Several hundred prescribers who did not receive recruitment also responded, having learned of the program through word-of-mouth or through partnership with a targeted prescriber. Physicians who volunteered for the program without having been recruited were also allowed to enroll.

The iScribe target of 700 enrollees was achieved after recruitment over 9 months and the program was extended to admit a total of 770 prescribers. Additional volunteers were put on a waiting list. Of the 770 enrollees, 630 (82%) had been among the original eligible population and 140 (18%) had not (most originating < 500 claims per year for Horizon BCBSNJ patients); 585 (76%) had been sent marketing materials and 185 (24%) had not. Thus, among those who received recruitment, 12% enrolled (585/4900).

For each system, enrollees were screened for appropriate Internet access and practice management systems, had the necessary wireless and PDA hardware installed, and then received training on the system before being considered active. **Table 3** shows the activated participant count by month for each system. By December, 2006, iScribe was installed and activated for 770 physicians, the Allscripts system was installed and activated for 150 physicians, and the InstantDx system was installed and activated for 37 physicians. A total of 80 iScribe enrollees and 48 Allscripts enrollees withdrew from the program, either before or after activation. Those who withdrew were replaced from the waiting list, making the effective withdrawal rate 12% for these 2 vendors (128/1048). The reasons that enrollees gave Horizon for withdrawal included an inability to make the system work for their practice, switching to a full EHR system, and switching to a different e-prescribing program that was being sponsored by Aetna.

**Table 3. Withdrawals and net participants by month in the Horizon BCBSNJ E-Prescribe Program**

	2005												2006											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	
<b>iScribe</b>																								
Tot. Activated	11	27	73	132	161	219	307	369	450	552	638	663	713	726	737	744	757	757	757	760	764	765	770	
Withdrawal										7	17	1	17	8	4	5	3	3				12	3	
<b>Allscripts</b>																								
Tot. Activated													2	11	22	22	48	65	77	83	122	132	150	
Withdrawal														3	10		20	3		5		7		
<b>InstantDx, Tot. Activated</b>													19	31	34	34	38	38	38	42	40	39	37	

iScribe users in the program have generated a total of 1.28 million electronic prescriptions since January 2005, with prescribing rates increasing to November 2006, when the average volume was 111 prescriptions per month per prescriber. Of these prescriptions, about 44% were transmitted electronically, with the rest having been printed and given to the patient. iScribe’s electronic transmissions are sent via the SCRIPT standard, with transmissions to retail and some mail-order pharmacies being handled by the intermediary MedAvant, which converts some transmissions to fax depending on the pharmacy. Allscripts users in the program have generated 57,987 prescriptions since January, 2006, with 11,197 generated in November. Of these prescriptions, 37% were transmitted electronically, 54% were faxed directly to pharmacies, and 9% were printed for the patient.

RxHub estimated the number of X12N 270/271 Eligibility checks originating from Allscripts and iScribe users in the Horizon program (based on New Jersey Zip codes). In the last half of 2006, the two vendors together averaged 173,074 checks per month, with an average success rate of 44%. Eligibility checks per month ranged from 68,056 to 477,124, apparently because a large number of eligibility checks may be generated when new e-prescribers are brought online.

**Physician Site Visits.** The 12 practices that participated in site visits ranged in size from 1–6 physicians and 2–11 staff. Of these, only five installed and fully implemented e-prescribing. At three sites the system had been installed, one or more prescribers had stopped using it, but their office staff continued to use the program for transmitting new prescriptions and/or prescription renewals. At two sites, the system had been successfully installed but the practice had discontinued its use altogether. Finally, two sites had cancelled or postponed indefinitely their installation of the program. A key difference among the practices was their relationship to outside sources of information technology support. Several successful practices had access to IT support through their affiliation with a community hospital. Additionally, the practices that discontinued use experienced what they perceived to be significant delays in getting IT support from the e-prescribing vendors.

**Physician Survey.** Among e-prescribers who responded to our physician survey, 37% reported using the system to write all prescriptions except DEA Schedule II Medications, 46% reported using the system

for some prescriptions, and 17% reported no longer using the system for any prescriptions. Among those in the latter two categories, the top reasons given (rated “agree” or “strongly agree”) for not using the e-prescribing system included technical problems with the PDA such as network connectivity (88%), and patients being absent from the PDA (83%); somewhat less-frequent barriers included pharmacies not reliably receiving and processing the prescriptions sent electronically (47%), the system taking too much of the prescriber’s time (42%), and insufficient training (23%).

All respondents to our survey had relatively high scores on a computer attitudes scale that we adapted from an existing instrument<sup>2</sup> (6 items, maximum score 30 points, Cronbach’s  $\alpha=0.90$ ), but computer attitudes differed significantly between those who quit using the system, those who use the system for some, and those who use the system for nearly all prescriptions (means 21.8 vs. 23.8 vs. 25.4, respectively, ANOVA  $P=0.003$ ). Computer attitude scores did not differ significantly between the e-prescribing group overall and the survey’s control group (means 24.1 vs. 24.5,  $P=0.4$ ). Of note, physicians in the control group had signed up for e-prescribing but had been put on a waiting list.

## Formulary and Benefit standard (F & B)

**Work process model.** In simulating the potential effects of implementing the F&B standard, we assumed that without the standard e-prescribing systems can prevent 50% of insurance coverage exceptions (that would warrant a pharmacy call-back) by presenting generic alternatives. We assumed that F&B data enables a further improvement to prevent 80% of callbacks, with the number of such phone calls estimated to decrease from 3.3 to 2.2 per 100 new prescriptions and from 1.7 to 1.1 per 100 renewal prescriptions. However, prescribers’ attending to the more complex F&B information was estimated to require an average of 5% more prescriber time compared with generic alternatives alone. This largely neutralized the time savings in telephone calls and downstream rework for prescribers (1% net time savings with the standard), but it resulted in an expected savings in staff time by 7% for new prescriptions and 8% for renewal prescriptions. We did not attempt to estimate the probability of patients’ ultimately not obtaining the medication given an insurance coverage exception.

**Site Visits.** Participants in the post-e-prescribing implementation site visits had varied opinions about the benefits of formulary and benefit information. An office manager at one site related what happened when the information in the system did not match the information that pharmacists had, saying “I was caught in the middle ... It was just [the] pharmacist saying, ‘No, it’s not covered. It’s not going through my system,’ and the doctor saying, ‘Well, it’s going through mine and it’s fine.’” A physician at another site expressed a somewhat different opinion, saying “I think it’s a hundred percent accurate, as far as formulary... we don’t listen to it, but we know.”

**Physician Survey.** E-prescribers responding to our online survey did not differ significantly from non-e-prescribers in their perceptions about the number of calls they get about drug coverage problems or the time they spend dealing with calls about drug coverage problems. In addition, e-prescribers had mixed perceptions about the value of the drug coverage information they received. For example, 29% agreed or strongly agreed, 41% were neutral, and 30% disagreed or strongly disagreed with the statement that e-prescribing drug coverage information reduced the number of calls to their office from pharmacies and patients regarding drug coverage problems. Perceptions were slightly more favorable toward the statement that e-prescribing drug coverage information helps in managing patients’ costs (39% agree or strongly agree, 37% neutral, 24% disagree or strongly disagree).

**Technical Expert Panel.** The expert panel identified several problems that, in aggregate, lead to F&B data being absent for many patients. First, the standard assumes that the patient’s current drug insurance plan is identified through a successful Eligibility check, but these checks often fail for reasons that include plans’ non-participation with RxHub, differences between the provider and the health plan in patient identifying data (e.g. DOB, zip code errors), and some patients being uninsured. One panelist

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<sup>2</sup> van Braak JP, Goeman K. Differences between general computer attitudes and perceived computer attributes: development and validation of a scale. *Psychol Rep.* 2003 2003/04;92(2):655-60.

observed that the usefulness of F&B data “is directly related to the number of successful eligibility transaction matches in terms of identifying a patient. Even though the PBMs [affiliated with RxHub] combined probably cover 50% to 70% of covered lives in the country, our experience has been around 30%. In many cases, the number is lower and can vary from practice to practice even within the same geography.” Another POC system vendor panelist observed “There is a need for expansion of eligibility and formulary to additional payors.” (In the U.S. overall, RxHub estimated that its coverage rates range from 15% to 96% among different Metropolitan Statistical Areas). POC system vendors also criticized the absence of recognizable health plan names being provided in the “Cross-reference List” file, as this prevented its use for looking up patients’ coverage when the eligibility transaction fails.

Panelists also identified problems with the accuracy of F&B data arising from the use of representative NDC codes as drug identifiers. “Because of the potential differences in NDC number, items provided in the formulary & alternatives files may not result in a one-to-one match on the vendor side. The impact of this is that when the physician chooses a drug, he or she may get erroneous formulary error messages or no message at all.” Panelists enthusiastically supported the development of RxNorm as the standard drug identifier for F&B. “RxNorm would be great if fully implemented across the board, including OTCs,” observed one panelist.

Differences in coverage among different employer-level groups within individual health plans is another major source of inaccuracy in the F&B data presented to clinicians. “Current process is at a representative level, so member-specific exceptions and other variances are not accurately reflected in the F&B display,” explained one PBM Panelist. “Representative level means at a client [health plan] level. For example, one client may have several groups which have varying F&B information, however only one representative F&B is displayed,” clarified another.

Another usability problem with the standard is the variance in its use among health plans and PBMs. As one panelist summarized, “One payer/PBM may support all F&B lists while another supports only one. One payer/PBM may provide optional data elements while another doesn’t.” This creates difficulties in presenting clinicians with consistent coverage information. One POC system vendor panelist noted that “different F&B data providers have different requirements on the presentation of some of the elements of the data ... that require great effort to accommodate. Multiple eligibility occurrences lead to [further] difficulties in deciding on appropriate information presentation.” However, one F&B file, the formulary status list (FSL), was used by all panelist companies. To further assess the industry’s use of different F&B files, RxHub counted the number of downloads for each list. Each list is provided by a single PBM but they sometimes contain data for several of the PBM’s health plan clients. Thus the download count depends on the number of distinct lists that PBMs are publishing, the number of POC vendors downloading each, and the frequency of refreshing the lists. In the last half of 2006, RxHub was providing average downloads per month of 728 for FSL, 89 for ALT, 21 for COV, and 2 for COP files.

**Claims data.** Preliminary results of multivariate logistic regression modeling show that the probability of generic use for new ACEI prescriptions has increased over time for all prescribers, but high users of the EPS had a significant additional increase in their likelihood of prescribing a generic ACEI after the date of eRx activation vs. before (OR = 2.5,  $p = 0.02$ ), whereas no significant difference was found for low or medium eRx users or controls. Generic drug use was also significantly associated with patient income (OR = 0.95 for each \$10,000 increase in annual household income) and Hispanic race as estimated by patient zip code data (OR = 0.69). Controlling for these factors, no significant association was found between generic ACEI starts and patient age, gender, or black race. Among ACEI prescription refills we found no significant association between generic use and the level of EPS use or non-use.

Because of unanticipated difficulties in Horizon’s data preparation, we were unable to complete the analyses we had proposed to evaluate patients’ adherence to medications and rates of hospital service use before the project’s terminus.

**Conclusions and Recommendations.** Overall, our study shows that aspects of the NCPDP F&B standard have been successfully implemented among a variety of e-prescribing partners, but that technical and implementation factors with the standard are probably limiting the benefits it can deliver. These limitations translate into the mixed opinions that we observed in our prescriber survey about value of the

drug coverage–related information that they can see. Furthermore, prescribers probably cannot distinguish F&B information *per se* from coverage-related information that was displayed based on other sources, such as generic *vs.* brand status and the custom alternative-drug messages that iScribe had implemented. Thus, although we found a jump in the rate of generic use for new ACEI prescriptions after eRx was activated and fully used, this effect cannot be attributed to the F&B standard, since the standard does not represent the generic *vs.* brand status of individual medications.

Overall, we did not find sufficient evidence to make a strong recommendation either for or against making F&B an Initial Standard for e-prescribing. Levels of experience with the “formulary status list” component of the standard appear to be high, but all participants in our study are currently interfacing with RxHub. Thus, we cannot comment on the readiness of industry participants that do not currently work with RxHub, including some state Medicaid health plans. The benefits of using the formulary status list alone are also unclear. Levels of experience with other parts of the standard are much lower, and the inconsistent use of these parts suggests the need for more research and coordination within the industry before these could be mandated. The copay file appears to be particularly underused, given that the *patient’s* medication costs should be the prescriber’s primary cost consideration.<sup>3</sup>

The greatest near-term potential for improving use of the standard is the further development of RxNorm to serve as the preferred drug identifier. In addition to improving the accurate use of F&B information, RxNorm would likely reduce the work needed to maintain F&B files, making it more feasible for health plans to deliver more complete F&B information. The F&B standard currently has fields to support the use of RxNorm, so no changes would be needed in the standard itself. Additional pilot studies are needed, however, to demonstrate RxNorm’s coverage of current F&B data and which concept identifiers would best fit the needs of different F&B files.

More research and development is also needed to establish a “real time benefit check” transaction that could confirm a specific patient’s coverage for a specific drug and dose that has been selected by a prescriber. RxHub has developed such a transaction but it is currently being used by only one of its PBM clients. Further studies should investigate the degree to which this transaction could increase the cost-effectiveness of prescribing decisions and reduce the rework associated with the coverage exceptions that continue to arise due to the inability of the F&B batch standard to represent individual-level coverage.

## Medication History standard (Med Hx)

**Work process model.** Our work process model for the Med Hx standard focused on its capacity to enable safety alerts based on more complete medication lists (e.g., reducing drug-drug interactions and therapeutic duplication). In addition to preventing adverse drug events, this information could improve work process efficiency by reducing the need for pharmacies to call prescribers back for safety problems they detect. Med Hx data could also be used by prescribers to monitor whether prescriptions they have written are being filled or refilled by their patients, but we did not model this effect given the additional problems that providers see in assuming this role (see focus group results).

In simulating the Med Hx standard’s effects, our base-case estimate of the rate of potential safety problems was 0.3 per 100 new prescriptions and 0.15 per 100 renewal prescriptions. The degree to which Med Hx improved safety alerts was varied in a sensitivity analysis from 50% to 100% (base case 80%). Our results suggest a small (less than 1%) time savings for both providers and pharmacies, based on 0.1 to 0.2 calls reduced per 100 prescriptions. The amount of time saved is linearly related to the level of improvement in safety problem detection enabled by the standard.

**Site Visits.** Although prescribers and office managers who were interviewed in post-implementation site visits appreciated having access to medications that *they* had previously prescribed, they did not seem to be aware that they could access claims-based medication history data. One provider summed up this commonly-held view, saying “It’ll basically have whatever we input for the patient, but patients see other

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<sup>3</sup> Bell DS, Marken RS, Meili RC, Wang CJ, Rosen M, Brook RH. Recommendations for comparing electronic prescribing systems: results of an expert consensus process. Health Aff (Millwood). 2004;Suppl Web Exclusives:W4-305-17.

doctors, and if they aren't using that system, there's no information there as far as what they prescribe, so that's a big limitation. That's huge."

**Physician Survey.** Overall, only 37% of e-prescribers reported being familiar with how to access the downloaded Med Hx information that was available in their system. Among those reporting familiarity with this function, only 16% reported using it either often or very often.

The survey also asked both e-prescribers and non-e-prescribers about the value of the information that they typically have about their patients' medication history. Compared to non-e-prescribers, e-prescribers were more likely to agree or strongly agree with statements that the medication history information they typically have enables them to identify clinically important drug-drug interactions (83% vs. 67%,  $P=0.02$ ) and to prevent callbacks from pharmacies for potential safety problems (68% vs. 54%,  $P=0.01$ ). However, they did not perceive any greater ability to identify medications prescribed by other providers that they didn't realize the patient was taking (65% vs. 61% agree or strongly agree,  $P=0.4$ ).

**Technical Expert Panel.** In assessing the overall data quality and usability of the standard, panelists observed that outright errors in Med Hx data are rare, but POC vendors expressed difficulty in using Med Hx data because many important fields, including the prescriber's identity, the Sig, the quantity dispensed, and the dispensing pharmacy, are optional and are often left empty. The lack of this information hinders reconciliation with prescriptions generated through the e-prescribing system. Reconciliation is necessary to use Med Hx records in automated alerting without generating large numbers of false alerts. Some POC vendors said they had given up on reconciling medication history data and they drive alerts only from prescription data that they originated. Others described having invested more in complex reconciliation algorithms, but with 60% success at best.

Another major usability and interoperability problem that panelists cited was the lack of an adequate drug identifier. Med Hx records generally use the dispensed drug's NDC code, but as documented elsewhere in this report, NDC codes often cannot be accurately mapped to the drug compendia that e-prescribing systems use internally. The panel enthusiastically supported the development of RxNorm to improve drug representation, one saying "If RxNorm becomes a reality and this value is stored on the history, it will make the drug alert checking that much better."

Panelists also pointed out that retrieving Med Hx relies on the patient's being identified through a successful X12N 270/271 Eligibility check, and in many practices half or more of Eligibility checks fail. One point of care (POC) e-prescribing vendor said "In order for this medication history to be used effectively, it should be available in a consistent manner for the majority of the patients being managed by a provider or practice. In areas of scarce PBM coverage, for example, providers do not find this information useful even when available -- a key usability concern."

**Claims Data.** In a preliminary analysis of potential drug-drug interactions (DDIs) in our claims data set, we identified prescription claims that would indicate the patient's simultaneous possession of both medications participating in one of the 25 most-severe DDIs.<sup>4</sup> Among 2.8 million prescription claims for patients of e-prescribing and control physicians, we detected a total of 1780 such potentially-severe DDI events, for an overall rate of 6.4 events per 10,000 prescriptions. The DDI event rate increased overall from the pre- to the post- EPS period (from 5.6 to 7.8 events per 10,000 Rx, chi square  $P<.0001$ ). Attributing each event to the prescriber of the second (incident) prescription, 153 were attributable to EPS prescribers (7.4 per 10,000 Rx), vs. 1021 to control-group prescribers (6.4 per 10,000 Rx), and 606 to prescribers in neither group (6.3 per 10,000 Rx,  $P=.001$ ). The pre- to post- increase did not differ significantly among groups. Among the DDI events that were attributable to an EPS or control prescriber, the same physician had prescribed both drugs in the interacting drug pair for 53% of cases; for the other 47% of cases, the two interacting drugs had been prescribed by different physicians.

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<sup>4</sup> Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts. Arch Intern Med. 2003 Dec 8-22;163(22):2716-24.

A preliminary analysis of claims data also showed little change in the incidence of new prescriptions for potentially inappropriate medications among patients over 65 years of age<sup>5</sup> in either the EPS group (0.63% to 0.65% of prescriptions) or in the control group (0.69 to 0.68% of prescriptions).

**Conclusions and Recommendations.** Overall, the feedback from our expert panel would indicate that the structure of the Med Hx transaction is adequate to deliver valuable information about patients' medications, but this value is being undermined by the data's inconsistent availability and usability problems that make it difficult to reconcile the data it provides. The beneficial effects of e-prescribing that our survey respondents perceived in drug-drug interactions and in preventing safety-related callbacks were probably not attributable to Med Hx data, given that POC vendors are generally unable to use it for safety alerting. This finding is corroborated by our finding that survey respondents did not perceive any greater ability to learn what other providers had prescribed.

Thus, we would recommend pursuing further improvements in the implementation of Med Hx before making it a mandatory e-prescribing standard. These improvements would include testing the addition of RxNorm codes to unambiguously identify the drugs prescribed and testing the use of the National Provider Identifier (NPI) for prescriber identification to enable better reconciliation of medication histories. Panelists also suggested exploring whether the originating SCRIPT prescription identifier could be included in Med Hx records. This would allow even more accurate reconciliation, and a field is available in the NCPDP Telecommunications standard that could be used to transmit this data to the PBM. However, carrying this identifier through to the Med Hx transaction would require more extensive changes in the PBMs' claims databases for prescriptions that today remain a small minority of all claims.

## Fill Status Notification standard

**Technical Expert Panel.** The RxFill transaction of the NCPDP SCRIPT standard continues to be rarely used in the industry and few members of our panel had attempted to implement it in production systems. However, the panel was able to discuss several aspects of the transaction's problems and potential benefits. Our panelists representing smaller, community pharmacists indicated that at least some would need to implement new software systems to capture the dispensing and return-to-stock events needed to trigger RxFill messages. POC prescribing system vendors also indicated that reconciling RxFill messages with the original prescription could also be challenging because the originating SCRIPT reference number is an optional field. Although the transaction might provide information that prescribers could use to improve medication adherence, several panelists observed that there is no marketplace demand for RxFill. As one participant put it, even "if a physician wants it, who is going to pay for it?"

One panelist suggested that using the RxFill (dispensed) message alone could suffice for non-adherence alerting, since the lack of a message within some specified time interval could be used to trigger an alert. However, another panelist observed that the existence of opt-out mechanisms would undermine this mechanism, even if implementation of RxFill message was mandated saying, "If patients are opting-in or opting-out ... then [if] the physician doesn't get a 'filled' response what does the physician know? Maybe I opted out. They can't really determine that it was filled, and they can't determine that it wasn't filled." Panelists were also concerned about mechanisms for letting patients opt-in or opt-out of providing this information. One said, "The process of setting-up and maintaining the [opt-in or opt-out] indicator would be significant. Numerous interfacing systems would need to change to allow for modification of this indicator." However, another said, "that's something that can be designed for and I think that having a patient opt in or out of this is probably something on which we should do more research."

**Fill Status Alerting Focus Groups.** As anticipated in the NCPDP white paper on the Fill Status transaction (described the Scope section), the Allscripts users who participated in our focus groups had significant concerns about the new burdens that Fill Status alerting could place on their time and their

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<sup>5</sup> Malone DC, Hutchins DS, Hauptert H, Hansten P, Duncan B, Van Bergen RC, et al. Assessment of potential drug-drug interactions with a prescription claims database. *Am J Health Syst Pharm.* 2005 Oct 1;62(19):1983-91.

offices. Prescribers were generally interested in whether their patients are taking what is prescribed and they want to take action based on this information. However, most indicated that their adherence monitoring activities were limited to the patient visit and that they would not have time to telephone patients about failures to fill or refill prescriptions. Time was also cited as a barrier to discussing adherence during the patient visit. A minority of providers had some familiarity with the existing feature in the Allscripts web interface for browsing the patient's Med Hx records.

There was significant concern among prescribers about new medico-legal liability that could result from the existence of non-adherence alerting. Although some debated whether the ignorance that generally exists today would be any protection, one participant summed up the concern by saying "I can imagine lawyers using it in instances to say 'You were aware Mrs. S wasn't taking her medications. Why didn't you take greater steps to encourage her compliance before she had this stroke?'"

**Conclusions and Recommendations.** The Rx Fill function of the NCPDP SCRIPT standard does not appear ready to be included among Medicare's Initial Standards for e-prescribing.

We recommend that further research be undertaken to identify specific circumstances in which medication adherence could provide a sufficient return, in terms of health or cost savings in reduced service use, to make the financial incentive for physicians and pharmacies sufficient to develop and support RxFill. Such adherence programs might be part of pay-for-performance programs for physicians or medication therapy management programs for pharmacies.

Confidentiality and privacy issues around RxFill should also be better addressed by the industry. Additional research on both patient- and physician-level opt-in or opt-out needs to be conducted. While standards and systems would need to be modified to support this, members of the industry believe that implementing opt-in or opt-out programs would be feasible if the financial incentives are adequate.

## Electronic Prior Authorization standards

**Physician and pharmacy site visits.** Both physicians and their staff viewed the traditional PA process as burdensome and time-consuming. A nurse at one site visit summed up this feeling when she said, "I hate prior authorization(s). I hate them with a passion because of the time they take." A physician at another pilot site observed that the traditional PA process "takes time away from true patient care." Its purpose is viewed as cost savings for the health plan, and the perception is that the plan is questioning the prescribers' clinical judgment. "PAs are about the bottom line. Hopefully we can still give an equally effective medicine," said one ePA pilot physician. "The doctor should have the final say rather than the insurance agent," said another. Some conceded that the PA process occasionally has educational value. "Occasionally (the criteria sets) are useful," said one site visit participant. However, other prescribers admitted to answering the PA questions in whatever way they think will result in approval. "Basically, you have to say what the insurance people want to hear," said one pilot physician. "I frequently lie, yell or scream," said another physician. "It's a guessing game. What does it take to get the job done?" observed yet another. Physicians also admitted to avoiding medications that require PA. However, without e-prescribing, there is no consistent way of identifying which drugs require PA. Instead, the need for PA is generally discovered when the pharmacy submits the claim to the PBM. According to our pharmacy site visit, all but one PBM with beneficiaries in New Jersey require that pharmacists return the prescription to the prescriber to complete the PA request.

**Prescriber Survey.** In our online survey, nearly all physicians agreed or strongly agreed with the statement that the PA is frustrating for them (91%) and for their patients (91%). We also asked prescribers to estimate the average time that each step in the PA process takes and we asked the percent of the time that each step is completed by staff rather than by them personally. Adding the steps together, prescribers average estimate for the total time needed to complete a PA request was 36 minutes, which broke down to 23 staff minutes and 13 physician minutes.

**Working prototype development.** In designing its Attachment standard for electronic drug PA (ePA), HL7 assumed that the industry would be willing to use a single set of standardized questions for pre-defined drug categories. However, we found that very few of the questions developed for the HL7

standard were useful for the PA review processes that Horizon conducts. Furthermore our Coalition partners questioned the concept of being able to standardize drug PA questions, at least in the near term. Their primary concerns were that (1) the wording of PA questions is sometimes carefully tailored to meet the needs of specific health plans or even specific employer groups within health plans and (2) that PA criteria often need to be changed quickly in response to changes in knowledge about pharmaceutical effectiveness, risks, and costs. This kind of tailoring and rapid evolution of PA criteria could not be supported by the process proposed for the HL7 PA attachment, in which each change in a data element to be collected in PA requests for each drug class would be balloted by the SDO.

In implementing systems for conducting ePA in actual patient care, we found the combination of the X12N 278, X12N 275 and HL7 PA Attachment to be cumbersome, with a difficult learning curve. Nonetheless, we were able to construct a working system using these standards after modifying the PA Attachment standard to allow for custom questions that the health plan could specify and for a free text question that prescribers could use for open-ended comments on the patient's particular clinical situation.

**Survey of ePA pilot users.** Of the 62 prescribers who pilot tested these ePA systems, 3 had undeliverable email addresses and thus never received an invitation to the online survey. Of the remaining 59, 27 (46%) completed the survey before the end of the project. Of these, 10 were Allscripts users and 17 were iScribe users. Overall, users expressed favorable opinions about the ePA process. After completing a set of test PA cases, ePA participants in our online survey overwhelmingly rated the ePA process as potentially less frustrating for patients and prescribers alike. During the 2–3 months that the ePA system was available for our users, only one ePA transaction was conducted for an actual patient. However, preliminary analysis of prescription claims has shown virtually no missed opportunities. Overall, prescribers seemed to avoid prescribing PA drugs more than we had anticipated, and we also found that PA requests were unnecessary for many Horizon patients based on a group-level coverage check. Analysis of these findings is ongoing.

**Work process model.** The Electronic PA standard is modeled as facilitating more efficient and more complete PA requests, which in turn can reduce chart pulls, phone calls from patients, PBMs, and pharmacies. Our data suggests PA is required for on the order of 1.5% new prescription and 0.75% of renewals, and that a significant amount of time is needed to file a request. The workflow simulation model assumed the total time spent on completing an average PA application would reduce by half for both prescribers (from 13.8 to 7.5 minutes) and their staff (from 22.7 to 12.4 minutes), and the number of phone calls would drop from 3 to 1 when an e-prescribing system is enabled with the standard. The simulation result shows, in comparison with the time spent with basic e-prescribing, that the PA standard could result in 4% time savings overall for prescribers and 35% time saving for staff per 100 new prescription, and 2% and 38% respective time saving per 100 renewal prescription. The time saving is robust, although the amount is depending on the prevalence of PA requirements and the time spent on filing an application.

**Conclusions and Recommendations.** Though electronic prior authorization (ePA) appears promising for improving workflow and the efficiency and acceptance of PA, we would recommend against adopting the proposed ePA standards as Initial Standards, given that they needed significant modification to support actual PA processes in our pilot study. Additional research is needed to make the ePA standards more usable, to integrate them with more accurate indications of the need to obtain PA for individual patients, and to estimate the potential costs and benefits of transitioning to an electronic PA infrastructure.

## RxNorm

**Completeness of SCD concepts.** In the sample of 10,000 de-identified *new prescriptions*, 79 were excluded for having all-zero NDC codes, leaving 9921 prescriptions with 1964 distinct NDC codes. An additional 132 prescriptions were flagged as representing devices, leaving 9789 non-device prescriptions using 1912 distinct NDC codes. For 148 prescriptions (1.5%), no matching SCD was found by any of the 3 independent efforts (using First DataBank, MediSpan, or the RxNorm distribution). Among the

prescriptions with no matching SCDs, 93% were multi-vitamins, bowel preparations, drugs packaged in a drug delivery device, or other packages containing more than one distinct clinical drug, such as multi-phasic oral contraceptives. Among the prescriptions that did match to an SCD, all 3 matching efforts were successful for 8956 prescriptions (91.5%), another 554 prescriptions (5.7%) had an SCD match by 2 of the 3, and 131 (1.3%) were matched to an SCD by only one of the 3 efforts. One effort had a modestly higher matching rate, having found SCDs for 9601 prescriptions (98.1%), compared with the other two, which found matches for 9236 prescriptions (94.4%) and 9270 prescriptions (94.7%).

All 10,098 *renewal requests* in our sample contained valid NDC codes; 63 were flagged as devices and excluded, leaving 10,035 non-device requests using 1660 distinct NDC codes. Of these, 47 (0.5%), did not match to an SCD. These missing concepts mostly fell in the same categories as the concepts missing for new prescriptions, listed above (96%). Another 48 prescriptions (0.4%) were matched to an SCD by one of the 3 efforts, 163 (1.6%) by two of the 3, and 9777 (97.4%) by all 3. The 3 individual efforts were similar in their success rates, finding SCD matches for 97.8, 98.9, and 99.3%, respectively.

Of all the NDC codes that did not match to an SCD (including both new prescriptions and renewal requests), only 10, representing 25 prescriptions, were actually missing from the RxNorm distribution files. The remaining NDC codes were mapped to “Clinical Drug” or “Branded Drug” concepts that we were not able to link to specific SCDs.

**Agreement between independent SCD matches** RxNorm is intended to provide a single SCD identifier for each clinically distinct drug that is currently available by prescription. Thus, when the SCDs returned by independent matching efforts on the same prescription do not agree, there has either been an error in matching to the correct RxNorm concept or an unresolved synonymy in RxNorm itself, with more than one term being available for the same clinical drug concept (essentially, an RxNorm editing error).

Among the 9510 new prescriptions in our sample that had at least 2 independent SCD matches, there was a disagreement among the SCDs for 592 of the prescriptions (6.2%). There were 411 such disagreements among renewal requests (4.1%). Most of these disagreements fell into one of a few categories, the most common being matches to the Acid vs. the Salt form of the same drug, and to a general vs. a more specific XR form of the same drug (e.g. 12-hour XR). Other mismatch categories included matches to an erroneous strength, ingredient, or dose form. We worked with the National Library of Medicine (NLM) to further characterize the root causes of these mismatch errors. They identified 234 distinct SCD pairs that had been matched to the same prescription or renewal request. For 46 of these (20%), one of the SCDs that was used by a vendors had been changed to “obsolete” status as of the current RxNorm release (i.e. synonymy had already been identified). Another 70 of these (30%), upon review, appeared to represent unrecognized synonymy that RxNorm editors now intend to resolve. Analysis of the remaining 118 SCD disagreements is ongoing, but preliminarily they appear to be due to errors in one of the NDC-to-SCD mappings that were used by one of the matching efforts.

**Conclusions and Recommendations.** Overall, RxNorm contained SCDs matching 99% of 19956 new prescriptions and renewal requests; many of those missing fell in the category of drug delivery devices or packages, which is a new term type currently being added to RxNorm by NLM. The disagreement rate in using RxNorm was higher, but of disagreements due to unresolved synonymy, almost half had already been resolved by NLM editors in the last year and NLM’s experience in using our feedback suggests that they may be able to accelerate their resolution of remaining synonymy based on reports such as ours. Other mismatch problems are likely due to inconsistencies in NDC codes, which could not be easily resolved by NLM. However, NDC errors probably cause at least as many mismatches when representative NDC codes are used as drug identifiers.

These results indicate that RxNorm may be ready for use as an interlingua for unique drug identification in e-prescribing transactions. However, since industry experience with RxNorm remains limited, we recommend that it undergo further testing and demonstration in production before its use is mandated in e-prescribing transactions. Of note, all of the NCPDP standards we evaluated include fields for RxNorm codes, so no modifications in the structure of these standards would be necessary to begin incorporating SCD identifiers. Given the strong needs that we identified for better drug identifiers to improve the usability of both the F&B and Med Hx transactions, this testing should be a high priority.

## Structured and Codified Sig standard

The sample of 10,000 new prescription messages included 2217 distinct Sig strings, the most common being “take 1 tablet daily” (n=1809) and “take 1 tablet twice daily” (n=474). Of all Sig strings in the sample, 677 were used more than once and 1540 were unique.

Of the 42 unique Sigs we selected for mapping sample, there were no instances in which two reviewers agreed on the representation across all segments and fields. Among the 43 key fields that we asked reviewers to use in representing these Sigs, 10 (23%) were not used by any reviewer for any Sig. These unused fields were the “rate of administration” and “rate unit of text” fields from the dose segment, all 6 fields in the dose calculation segment, and “multiple route modifier” and “indication value units.”

Fifteen (35.7 %) of the 42 Sigs could be represented by a single set of the Sig fields, without making use of the “repeating Sig” feature in the standard. For the remaining 27 Sigs (64%), at least one reviewer used more than one “repeat” of the Sig fields (which were represented by inserting additional lines for the same Sig in the spreadsheet). The numbers of iterations that the reviewers believed were necessary ranged from one to six and varied widely.

We performed more detailed comparisons of agreement among the 15 Sigs that were represented by all reviewers using a single iteration or line in the database. In analyzing agreement by segment, there were many instances in which *two* reviewers had populated all fields within a segment using the same values for a given Sig, but there were far fewer instances in which all three reviewers had this level of agreement. Levels of agreement were highest for the “Dose” and “Interval” segments. Four segments had no instances of agreement: repeating Sig, duration, dose restriction, and the stop segment. In analyzing agreement at the level of individual fields, there were 14 fields in which at least 2 reviewers had used the same values to represent the same Sig, and there were 19 for which there no instances of agreement between any 2 reviewers among the non-repeating Sigs (the remaining 10 being unused by any reviewer).

In examining the causes of reviewer disagreement qualitatively, it appeared that reviewers were sometimes confused by field names, leading to their consistently interchanging the placement of similar data into alternative fields. Some field names seemed to be especially confusing to the reviewers, with more frequent incorrect use of those fields, primarily those field names that contained both the words “units” and “text” in the same field name. (Note that “units” generally suggests numerical values, and “text” would tend to imply words or alpha characters, but these were combined in the same field name.)

When Sigs contained multiple dosing and/or multiple frequencies, such as “1 to 2 tablets” or “every 4 to 6 hours,” none of the reviewers correctly identified the proper use of the modifier fields for variable dosing or variable frequency; also in these cases, the Sig Sequence Position was not utilized as described in the Structured and Codified Sig Format Implementation Guide. Finally, three of the recommended values suggested for the Free Text String Indicator are sufficiently similar that reviewers were not able to determine proper use. The values causing misuse of this field are “1”—Capture what the prescriber ordered; “2”—Completely from structured Sig; and “3”—Pure free text. None of the reviewers correctly utilized the values for the Free Text String Indicator field.

**Conclusions and Recommendations.** We recommend against adopting the Structured and Codified Sig standard as an Initial Standard, given that in our pilot test, reviewers using it did not map Sigs accurately or consistently. We would suggest further development focused on simplifying the standard and on the development of documentation or educational exercises that could guide more consistent use. Our detailed results will be provided to the NCPDP task force to assist in developing changes in the standard or educational materials that could increase reviewers’ consistency.

## List of Publications and Products

Several manuscripts are in preparation for publication as peer-reviewed journal articles or as RAND Working Papers, but none of these are complete as of the deadline for this report. As they become available, these will be posted or referenced on RAND’s web page for this project, at <http://www.rand.org/health/projects/erx/standards.html>. We will also ensure that AHRQ’s HIT Resource Center has an opportunity to post or reference our articles on their Web site.