UC1: E-Prescribing

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## Revision History

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<tr>
<td>0.1</td>
<td>Initial Draft Use Case</td>
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<td>09/16/2005</td>
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Overview of the E-Prescribing Use Case

*Description:*
Electronic prescribing is a critical component in the overall strategy to enhance healthcare quality. By delivering clear and accurate information throughout the prescribing process, E-Prescribing can make great headway toward addressing the estimated 3 million preventable adverse drug events (CITL, 2004) and reducing the estimated 7,000 deaths from medication error (Institute of Medicine, 1999) that occur each year.

In 2001, $154.5 billion was spent on outpatient retail prescription drugs in the US (NIHCM, 2002), with prescription drug costs constituting the fastest-growing component of the US healthcare spend. E-Prescribing can play a significant role containing these costs and improving process efficiency by helping to eliminate preventable adverse drug events resulting in potential savings of up to $4.5 billion a year (RAND, 2005), by providing relevant formulary information at the point of care, and by reducing the rework currently required for the estimated 5% of prescriptions that are incomplete, unclear, or illegible.

With our growing dependence on medications for both extending and enhancing the quality of our lives, the need for our healthcare providers to have ready access to our medication information at the point of care has never been greater. The plight of the tens of thousands of people whose lives have been disrupted by Hurricane Katrina’s aftermath has served as stark reminder of the fragile nature of our current healthcare information system.

Before the potential benefits of E-Prescribing can be taken out of the theoretical and into the real, it must first be defined. The definition of what constitutes E-Prescribing varies widely. This variation contributes to the wide range of reported utilization levels of E-Prescribing in the United States. For the purpose of this use case, we define “true” E-Prescribing as a state wherein all aspects of the prescribing process are conducted via electronic means and at no time is there a reversion to a paper-based process. Simply put, E-Prescribing uses “all electrons, all the time” (see Figure 1 below).
While one can point to many localized instances where adoption of particular aspects of E-Prescribing is high, E-Prescribing is in limited use in the United States as a whole and there are few locales, if any, where every aspect of the prescribing process is managed electronically. The reasons for this relatively low uptake of E-Prescribing are many, including the lack of universally accepted standards for all aspects of E-Prescribing, the lack of incentives for adopting the technology, and the lack of overwhelming evidence that adoption of E-Prescribing dramatically improves the prescribing process relative to the costs involved.

The issues of aligning incentives and creating evidence for the use of E-Prescribing are beyond the scope of this use case. Instead, this use case focuses on the set of technical standards that, if fully developed and widely adopted, would result in true E-Prescribing becoming a reality. Some of the standards required for E-Prescribing are already well established, and they do not need significant modification in order to reach this desired state. But there are several known gaps in the suite of standards supporting E-Prescribing. This use case contains three primary scenarios, each focusing on one of these gaps. In this manner, the use case can be a means to identify areas where the refinement of current standards or the development of new standards would bring us closer to the goal of the widespread adoption of true E-Prescribing.

This E-Prescribing use case focuses primarily upon the outpatient setting. It assumes that an inpatient Computerized Physician Order Entry (CPOE) system is in place that can interface with the outpatient setting in certain circumstances as described in the scenarios that follow.
Use Case Scope:
We will work on this in greater detail after we have a more complete description of the scenarios.

This use case focuses primarily upon the outpatient setting. However, there are several instances where the inpatient setting plays a role in the scenarios described in this use case where the inpatient setting interfaces with the outpatient setting.

The following issues are contained within or are closely connected to the domain of true E-Prescribing. These issues should be addressed in future or separate use cases, but are out of scope for this current use case:
- E-Prescribing of controlled substances
- E-Prescribing in the long-term care setting
- Electronic reporting of adverse events by the healthcare provider
- Inclusion of computable clinical criteria (indications, contraindications, warnings, dosing instructions, etc.) in the Structured Product Label of prescription drugs for the purpose of adapting them for use in prior authorization
- Distribution of model clinical guidelines for the use of prescription drugs to payers for the purpose of adapting them for use in prior authorization
- Detection and reporting of potential fraud and abuse
- Provision of contextually sensitive literature references, clinical guidelines, dosing calculation tools, and other decision support tools at the point of care during the E-Prescribing process
- Delivery of contextually sensitive patient and caregiver educational materials that improve patient understanding of the purpose, dosing instructions and potential side effects of a medication during the prescribing and dispensing process

Strategic Healthcare Improvement Goals:
The strategic goals of this use case are to improve healthcare delivery – reducing errors, improving patient safety, reducing costs, and increasing efficiency throughout the system (for patients, prescribers, dispensers, and payers) – through the efficient exchange of information related to the selection, prescribing, dispensing and claims processing of medications in the ambulatory care setting.

Expected Outcomes:
The successful implementation of this use case and the included scenarios should result in the following outcomes:
• Improvements in the relative comprehensiveness and accuracy of medication history available to healthcare providers at the point of care
• Reduction in the number and relative significance of gaps in the standards and standardized vocabularies required for achieving true E-Prescribing
• Improvements in prescription clarity – i.e. the extent to which the prescriber’s intent is captured and ambiguity is avoided during the prescribing process
• Reduction in the “Semantic Loss Ratio” – the degree to which the original meaning of the information exchanged during the prescribing process is retained when it reaches its final destination
• Reduction in the frequency of medication errors and subsequent adverse drug events
• Increase in the efficiency of the prior authorization process for both the prescriber and the payer
• Reduction in the frequency with which the administrative burden imposed by the prior authorization process results in a reluctance among providers to prescribe the most clinically appropriate medications for their patients
• Reduction in the amount of “rework” that is required in order to successfully complete a prescription transaction – i.e. a reduction in callbacks from the pharmacy regarding clarifications of prescription content, resolution of formulary issues, discussion of potential interactions, etc.
• Improvements in patient compliance with and adherence to prescribed therapies
• Reduction in the administrative costs related to the prescribing process
• Reduction in the costs related to adopting and utilizing E-Prescribing tools by prescribers
• Reduction in the difficulties associated with and the time required for implementing E-Prescribing systems in the outpatient setting
• Increase in participation in E-Prescribing among all stakeholders
• Reduction in the requirement to maintain dual processes - one paper-based and one electronic – in order to fulfill all aspects of the prescribing process
• Increase in overall ambulatory practice efficiency and pharmacy dispensing efficiency with respect to the prescribing and dispensing process
• Increase in the prevalence of “achieved interoperability” – i.e. the extent to which entities are able to more predictably implement E-Prescribing solutions that can transmit and receive information from external sources without extensive customization
• Increase in patient convenience and satisfaction in the prescribing process
• Increase in patient and caregiver understanding of current medications and medication history

Stakeholders:

The following is a list of the stakeholders for this use case:

• Patients
• Prescribers (Physicians and others with prescriptive authority - Hospital-based, ambulatory, LTC)
• Dispensers (Pharmacists and others with dispensing authority)
• Payers (PBMs, Health Plans, Employers, etc.)
• Vendors (eRx point-of-care vendors, Pharmacy information system vendors, Drug
Knowledgebase vendors, EHR Vendors, PHR vendors)
- Networks (Pharmacy networks, payer networks, NHIN participants)
- Healthcare Providers (Physicians and others using prescription information in the provision of care – hospital-based, ambulatory, LTC)
- Laboratory
- Ancillary staff (front office, physician support, etc.)
**Interoperability Scenarios included in E-Prescribing:**

The following scenarios will be part of this use case:

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<th>Scenario I</th>
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**Year 1 Scope:**

The following scenarios will have completed implementation guidelines published during Year 1:

1. UC1S1 – Comprehensive Patient Medication History Exchange
2. UC1S2 – E-Prescribing Interoperability
3. UC1S3 – Electronic Processing of Prior Authorization in E-Prescribing
UC1S1- Comprehensive Patient Medication History Exchange

Scenario Description:

We often use analogies such as jumbo jets falling out of the sky on a daily basis to provide a sense of the scale for the national impact of medical errors in the US. The catastrophic destruction unleashed by Hurricane Katrina’s wrath and its continuing aftermath has served as a profound example of our nation’s desperate need for a robust health information system that can weather major calamities like Katrina. The sobering reality is that our current information infrastructure is not adequate for the task of keeping our citizenry connected with their health information when the traditional channels of information flow are disrupted or unavailable.

Such a nationwide health information network, once in place, can not only help us minimize the adverse health consequences of a major disaster or terrorist attack, it can also provide that same level of protection for the personal disasters and disruptions we all experience at various times in our lives: when we move, when we change doctors, when we change insurance providers, when the only copy of our old immunization records are lost in a fire, or when we lose that copy of our medication list we keep in our wallets.

Collectively, these small tragedies that happen thousands of times each day across America, likely exceed the total damage to our population’s health meted out by Katrina. But they don’t rise to the top of our national consciousness or make headlines for weeks on end because they appear more as background noise than seminal events.

In the days immediately following Hurricane Katrina, pharmacies throughout the affected areas worked together with SureScripts, an electronic prescribing networking company, and ONCHIT to generate medication histories for more than 800,000 people displaced by the storm. They accomplished this task in less than 10 days by aggregating data from dispensing records stored electronically by the chain and independent pharmacies, and then matching these data using demographic information contained within the records. These medication histories are now available to healthcare providers caring for Gulf Coast residents living in shelters throughout the country.

While such an effort is laudable in its creative and rapid application of technology to a dire emergency, we have an opportunity to develop a more robust and enduring solution that will help us prepare for the next, inevitable catastrophic event as well as for those everyday, individual emergencies that disrupt the delivery of care.

NCPDP recently successfully balloted SCRIPT version 8.0, which contains segments that enable entities to exchange medication history information with one another. This standard was adapted from a proprietary medication history exchange methodology offered by RxHub, which has used this messaging protocol to deliver medication history based upon payer and PBM prescription claims data to hospitals, emergency care
facilities, and doctors using E-Prescribing tools. While these claims data do capture a useful set of medication history information, this data set does not always fully reflect the patient’s entire medication history. Patients who pay cash for their prescription medicines and who receive drug samples from their doctors in the office. Medication history is also found in hospital records that use HL7-based data repositories. Additionally, past medication histories are often lost when a patient changes insurance providers.

The Comprehensive Patient Medication History Exchange scenario examines the use of the use of the Medication History messaging protocol contained with NCPDP SCRIPT 8.0 standard for exchanging medication history and patient allergy information from multiple sources to multiple entities, including a patient-controlled medication history record that can be shared with providers via the internet with appropriate authorization. This scenario will also employ the NCPDP-HL7 mapping guidance document described in Scenario UC1S1 to capture medication history information found in the hospital record.

The successful refinement of existing standards and processes along with the addition of any necessary new standards and processes would enable the following scenario:

A patient on vacation experiences a sudden but temporary loss of consciousness, which leaves her somewhat disoriented. She is taken to a local hospital where an Emergency Department physician examines her, but is unable to ascertain an obvious cause for her syncopal event. The doctor gains access to the patient’s personal health record by activating the emergency access authorization procedure described on a card in the patient’s wallet. After authenticating on the system, the doctor is able to retrieve the patient’s medication and allergy history that includes information from the following sources:

- Three pharmacies local to her area
- Chemotherapy treatments administered at a tertiary care hospital
- Starter (sample) medications provided by her primary care physician and recorded in his E-Prescribing application
- Over-the-counter medications and herbal remedies recorded by the patient in her Personal Health Record.

By having access to this information, the doctor is able to identify a possible cause of her problem and orders lab tests to confirm his hypothesis. The patient is then treated and released.

[We will need to flesh out this scenario with a more specific course of clinical events, diagnosis and outcome. We will also want to think about including a related scenario where medication history information is exchanged between a primary care physician and a specialist to whom a patient is referred. This scenario could be linked to the chronic disease management or care coordination use cases.]
UC1S2 – Electronic Prescribing Interoperability

Scenario Description:

The E-Prescribing Interoperability scenario focuses on a known interoperability issue related to the interface between the inpatient and outpatient settings. In the ambulatory care setting, E-Prescribing transactions are typically conducted using the NCPDP\(^1\) SCRIPT Standard Implementation Guide. Within an institution such as a hospital or integrated delivery network, medication orders are typically conducted using HL7\(^2\) standards. The HL7 standards were not specifically designed to manage transactions between prescribers and retail pharmacies. Because inpatient facilities use HL7 as their primary means for managing prescription information, there was a need to map HL7 to SCRIPT for the purposes of communicating with ambulatory pharmacies.

To meet this need, industry volunteers came together as part of an NCPDP-HL7 Electronic Prescribing Coordination Project in 2004. The goal was to create a requirements document to be used for the mapping of NCPDP SCRIPT Standard Implementation Guide with HL7 for electronic prescribing. The resulting NCPDP-HL7 Electronic Prescribing Coordination Mapping Document will soon be available for use by anyone permitted to use either standard.

The Mapping Document has been demonstrated twice in 2005 - at the Healthcare Information and Management Systems Society (HIMSS) Annual Conference and Exhibition and the NCPDP Annual Conference – and is now being implemented on a very limited basis by the Cleveland Clinic.

Through successful implementation of the Mapping Document, the following scenario would be enabled:

An Emergency Department (ED) physician in a hospital using an HL7-based CPOE system requests a medication history on a patient she is seeing. After treating the patient and in preparation for the patient’s discharge, she orders a new prescription, which is translated into an NCPDP SCRIPT message and delivered to the patient’s pharmacy of choice. The pharmacy receives the prescription request and submits a change request to the ED physician because the particular drug requested is not available but a therapeutically equivalent drug is available. The ED physician approves the request.

[The use case refinement process will be used to determine where the current mapping guidance document is incomplete and where additional standards may be necessary in order to fully support the electronic transmission of prescription information between prescribers and pharmacies in multiple settings.]

\(^1\) The National Council for Prescription Drug Programs, an ANSI-accredited Standards Development Organization that focuses primarily on pharmacy, and drug benefit-related information standards

\(^2\) Health Level 7, an ANSI-accredited Standards Development Organization that focuses on a wide range of clinical information standards
UC1S3 – Electronic Processing of Prior Authorization in E-Prescribing

Scenario Description:

Prior Authorization (PA) is a process employed by many payers and Pharmacy Benefit Managers (PBMs) to ensure the appropriate use of certain prescription drugs. Drugs requiring PA are often those that have a high potential for misuse or abuse, have complex prescribing or administration requirements, or are very costly. The current PA process is often quite burdensome to the prescriber and the prescriber's staff. It may involve the completion of extensive forms, which must then be faxed to the payer or PBM for review. Or it may require a series of phone conversations with the payer or PBM before benefit approval is received.

The Medicare Modernization Act of 2003 calls for the naming of standards for E-Prescribing for patients receiving outpatient prescription benefits under Medicare Part D. In its recommendations to the Secretary of DHHS, the National Committee on Vital and Health Statistics (NCVHS) recommended that the prior authorization process, including the workflow surrounding PA and the transaction standards required for electronically adjudicating the PA process, be supported and tested in the 2006 Medicare E-Prescribing pilots.

This analysis was undertaken beginning in November of 2004 by an NCPDP Task Group that includes participants from multiple stakeholder groups as well as representatives from HL7 and X12. To date, the task group has analyzed more than 300 paper-based PA forms and has sought to normalize the criteria contained within the forms in order to find common patterns and determine methods for structuring the criteria for more efficient management.

The ongoing project now involves several parallel efforts. Much work has already been completed in assessing the breadth and complexity of the processes involved in adjudicating PA. Through this work, the task group has found that multiple standards, vocabularies and code sets from multiple SDOs and other sources will be required in order to fully address the PA issue.

While some of these standards are well suited for their particular functions in the overall process, others will require significant enhancements. In many respects, prior authorization serves well as the "poster child" for why AHIC and HITSP are vital to the standards harmonization process, as these bodies can serve to both guide and support the efforts of the various SDOs toward a coordinated and successful end.

The general flow of the portions of the PA process we will address in this use case scenario is found in Figure X on Page 17.

The process begins with the delivery of the PA requirements from the payer or
PBM to the prescriber's E-Prescribing tool. These criteria can, in some simple instances, be delivered through the recently balloted NCPDP Formulary and Benefit standard. But many of these criteria and their accompanying rules are too complex to be delivered using the current standard.

The NCPDP Task Group, in conjunction with HL7’s Clinical Decision Support Special Interest Group, exploring the possible use of GELLO (Guideline Expression Language), which is an ANSI-accredited HL7 standard used to construct complex queries, expressions, and formulae. In this context, GELLO could be used as a means of expressing the clinical criteria contained within a prior authorization requirements set in a computable form. These GELLO statements could therefore be used to query a patient’s electronic health record in order to determine whether or not the patient meets the required criteria. Those remaining criteria for which there are insufficient supporting data in the electronic record could be answered by the prescriber by completing an electronic form.

Once all of the required information for addressing the prior authorization criteria has been collected, the resulting data can be sent to the payer using an HL7 attachment embedded in an ASC X12N 275 wrapper and accompanied by an ASC X12N 278 Request for PA Review and Response message. All of these standards are in various stages of development within their respective SDOs.

After the payer has reviewed the 278 message and accompanying data, a 278 response is sent to the prescriber along with a prior authorization approval code. This code is then sent along with the electronic prescription from the prescriber’s E-Prescribing tool to the patient’s pharmacy via the NCPDP SCRIPT standard.

Finally, the claim for the prescription, accompanied by the prior authorization approval code is communicated by the pharmacy to the payer via the NCPDP Telecommunications standard.

While the process just described is, admittedly, extremely complex, the successful creation of this standards-based framework for prior authorization would yield the following benefits:

- Improvement in the quality of patient care through the appropriate provision of needed medications
- Increase in prescriber compliance with evidence-based clinical protocols that are enforced through the prior authorization process
- Reduction of the burden of prior authorization that is imposed upon the prescriber

Note that there are a number of precursors leading to this step in the PA process, such as the inclusion of computable clinical criteria in a medication's Structured Product Label (SPL) and the development of model clinical guidelines (based in part on the SPL criteria) that can shape the individual payer's PA requirements. These precursors are out of scope of the current scenario, but could be addressed in future standards harmonization efforts.
in the current process

- Reduction in that portion of the health care spend that provides no additional clinical benefit to the patient through the optimization of the administrative process surrounding prior authorization for both payers and prescribers

In summary, the Prior Authorization scenario addresses the following functions:

- The delivery of prior authorization requirements from the payer to the prescriber
- The collection of answers to the prior authorization requirements through electronically accessing the patient’s clinical data
- The delivery of the prescriber’s prior authorization request and requirements response to the payer
- The delivery of the payer response to the prior authorization request to the prescriber
- The delivery of the prior authorization approval code from the prescriber to the pharmacy

The claims processing of a prior authorization medication between the pharmacy and the payer
UC1S3 Process Flow Diagram

Figure X is below:

Standard eRx Prior Authorization Process Flow

9/16/2005    HL7 Conference - San Diego
What is the proposed workflow?

**PATIENT**
Visits Physician

**PRESCRIBER**
- Writes Prescription
- Completes a structured Q&A
- Submits PA Request
- Transmits Prescription

Drugs can be flagged as requiring PA, and simple rules applied via NCPDP Formulary & Benefit Standard

**PAYER**
- Determines PA Status
- Determines Criteria, Rules
- Processes PA Requests
- Processes Drug Claims

Submit Required Patient Information via X12N-278 X12N-275 with HL7 Attachment

**PHARMACY**
- Obtains Pharmacy PA
- Dispense Drugs
- Files Drug Claims

Prescriptions are submitted via NCPDP SCRIPT

Drug Claims are Submitted via NCPDP Telecommunication

Pharmacy PAs are Submitted via NCPDP Telecommunication