U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Medication Gaps

Draft AHIC Extension/Gap

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1.0 Preface and Introduction

1.1 Background

In April and June of 2008, the American Health Information Community (AHIC) approved a recommendation to develop documents that address extensions/gaps from the use cases published between 2006 and 2008. One of the extensions/gaps prioritized for subsequent processing in the national health agenda activities in 2009 was Medication Gaps. AHIC specifically requested that the Medication Gaps Extension/Gap address the electronic exchange of medication information between Electronic Health Record (EHR) systems, pharmacy systems, and other related systems. AHIC also requested the document address electronic prescribing (e-prescribing) and interoperability needs related to medications in a long term care setting.

This extension/gap document is being developed by Office of the National Coordinator for Health Information Technology (ONC) to represent the AHIC priorities and provide context for the national health agenda activities, beginning with the selection of harmonized standards by the Health Information Technology Standards Panel (HITSP). Components that need to be considered during the standards identification and harmonization activities include standardized data sets, data elements, vocabularies, naming conventions, capabilities, and technical standards that support the information needs and processes of clinicians, pharmacists, long term care staff, and healthcare payors. During the development of the document, there will be an opportunity for review and feedback by interested stakeholders within both the public and private sectors.

1.2 Progress to Date

To date, the national health agenda, including the activities of AHIC and HITSP, has not fully addressed all of the interoperability requirements for medication-related information exchange for e-prescribing and long term care medication uses.

Previously published AHIC use cases incorporate several concepts that have been evaluated by HITSP and could be leveraged during standards harmonization for this extension/gap.

- The 2007 Medication Management Use Case describes needs for communicating medication information between clinicians and pharmacists in inpatient and ambulatory settings; and

- The 2008 Consultations and Transfers of Care Use Case describes needs for communicating medication information between facilities and clinicians during these transitions in care.

2.0 Overview and Scope

2.1 Document/Request Overview

This extension/gap document is focused on information needs to facilitate the electronic exchange of medication information. The Medication Gaps Extension/Gap Document is divided into the following sections:

- Section 1.0, Preface and Introduction, describes the progress to date, the additional priorities identified by the AHIC, the resulting extensions/gaps, and their purpose;
- Section 2.0, Overview and Scope, describes the sections of an extension/gap document, the request being made to HITSP, and the scope of that request;
- Section 3.0, Functional Needs, describes the combination of end-user needs and system behaviors which support interoperability and information exchange;
- Section 4.0, Stakeholder Communities, describes individuals and organizations that participate in activities described in this extension/gap;
- Section 5.0, Issues and Obstacles, describes issues and obstacles which may need to be planned for, addressed, or resolved to achieve the capabilities described in the extension/gap;
- Section 6.0, References to Use Case Scenarios, describes various scenarios and information exchanges which assist in the communication of information. Scenarios may re-used from previously published 2006 – 2008 Use Cases and/or new scenarios may be described;
- Section 7.0, Information Exchange, describes information exchange capabilities which are needed to support the scenarios and the high-level role of information exchange;
- Section 8.0, Data Set Considerations, identifies specific information opportunities relevant to this extension/gap document that may support future identification, development, and harmonization of standards;
- Appendix A, Glossary, provides contextual descriptions of key concepts and terms introduced in this extension/gap document; and
- Appendix B, Analysis and Examples, describes current public and private efforts to enable interoperable e-prescribing.

2.2 Scope

Medication Gaps can be described as those areas where existing medication regulations and standards are unable to meet the functional needs of clinicians and pharmacists who participate in medication-related information exchange. Therefore, requirements for Medication Gaps can be summarized as:

- The ability to expand and implement standards for electronic prescribing to support wider implementation; and
- The ability to expand and implement standards to support the specialized needs of long term care medications.

The identification, development, and harmonization of standards to support medication-related information exchange are underway. Although this work is progressing, additional standardization needs are required for the identification, development, harmonization, and implementation of these standards. As mentioned in Section 1.0, these needs have not yet been fully addressed by the national health agenda's standardization efforts. Examples of gaps in industry standards are outlined in the upcoming sections of this extension/gap document.

3.0 Functional Needs

This section describes a combination of end-user needs and system behaviors considered necessary to support users during the exchange of medication information between EHR, pharmacy, and other systems. Rather than an all-inclusive list of functional interoperability requirements, key capabilities are outlined below with associated functionalities. The descriptions in this section are not intended to prescribe policy nor propose architectures required to implement capabilities.

A. The ability to electronically conduct real-time eligibility, benefits, and prior-authorization activities that incorporate formulary restrictions established by the payor

    i. While making prescribing decisions, a clinician may need the ability to review a payor's medication formulary information to determine the formulary and financial coverage available to the patient. Similarly, when filling a prescription, a pharmacist may need the same ability to understand the payor's formulary. In each case, formulary information may include the recommended use of medication brands, generics, medication substitutions, and alternatives.

        a. During coverage determination, some medication choices may be available that are identified as requiring prior-authorization from the payor before they can be prescribed, dispensed, or included as a part of the patient's pharmacy benefit. Clinicians and pharmacists may benefit from improved real-time interactions with the payor to request and receive prior-authorization for the use of these medications.

B. The ability to describe patient instructions regarding the use of a medication in a structured, interoperable SIG within an electronic medication prescription

    i. A clinician provides patient medication instructions, such as how a drug is to be taken, through details in a SIG (for Signatura), a component of a prescription. This SIG is communicated to the pharmacist as part of a prescription. When fulfilling the prescription, the Pharmacist reviews the SIG and determines how to best convey the instructions to the patient. Additional considerations may be made by the pharmacist during this activity.

C. The ability to integrate medication data from multiple clinicians to form a comprehensive view of the patient's medication regime at the facility since the long term care (LTC) setting includes the roles of facility nurses, clinicians, dispensing pharmacists, and consulting pharmacists.

i. Clinicians, who conduct medication reconciliation when a patient is admitted, may need the ability to communicate patient demographic and medical information to a dispensing pharmacy.

ii. Consulting pharmacists, who regularly review a patient's medication regime, may need the ability to review all medication-related documentation for a patient within the LTC EHR. They may also need to provide notes and observations for the facility staff and clinicians through the LTC EHR.

iii. Pharmacies supporting LTC facilities may need the ability to provide patient-specific medication administration instructions to facility staff.

iv. Since the LTC setting requires coordinated communication on the availability of medications within the facility inventory, this communication may need to support: the reordering of patient medications; other communications regarding medication inventory; and communications regarding discontinued and unused medications.

4.0 Stakeholder Communities

Examples of stakeholders who may be directly or indirectly involved in the exchange of medication information have been listed below. Specific descriptions of each type of stakeholder can be found in the previous 2006 – 2008 AHIC Use Cases.

Stakeholders that may be directly involved in the exchange of medication information may include: Clinicians, Pharmacists, Clinical Support Staff, and Healthcare Payors.

Stakeholders that may assist in medication information communication may include: EHR System Suppliers, Pharmacy System Suppliers, and Pharmacy Benefits System Suppliers.

Stakeholders that may be sources or recipients of medication information may include: Pharmacy Benefit Managers, Medication Network Intermediaries, Healthcare Entities, Patients, and Consumers.

5.0 Issues and Obstacles

A number of issues in today's health information technology environment are obstacles to achieving the full potential of electronic health information exchange (HIE). Some general issues were described within the 2006 – 2008 AHIC Use Cases. Examples of specific issues and obstacles related to the Medication Gaps discussed in this document are outlined below.

A. Medication Terminology and Standardization:

i. A standardized medication terminology vocabulary that supports the needs of clinicians and pharmacists may be needed. Existing terminology vocabularies may not have sufficient compatibility and clinicians may have unmet needs for a clinical drug terminology. Pharmacist terminology vocabulary may be adequate for interactions with drug manufacturers, but efficient communications governing clinician-pharmacist interactions may benefit from a stronger terminology standard that supports a comprehensive medication vocabulary. Other aspects of medication information flow would also be served by an improved standard in this area.

   a. Without a standardized medication vocabulary, many aspects of medication-related information exchange will continue to be impeded, which may negatively affect interoperability and patient health.

B. Financial Barriers and Incentives:

i. One of the principal obstacles to wider adoption of electronic medication systems is the cost of acquiring and maintaining these systems. Appropriate financial incentives to promote the adoption and use of these systems may be needed.

   a. If electronic systems supporting medication have limited adoption, the benefits to overall healthcare costs and patient care will not be realized.

C. Clinician and Pharmacist Workflow:

i. Many aspects of clinician and pharmacist workflow rely on detailed yet concise communication. When additional efforts such as avoidable phone calls, inefficient prior-authorization processes, or workflows that require multiple tools or systems are required, clinician and pharmacist productivity suffers. Efficient, concise, and timely communications of medication information may be needed.

   a. As long as workflow requirements include inefficient or avoidable processes, clinician and pharmacist acceptance and implementation of HIT will be limited.

ii. In addition within a clinician's office, there are obstacles that relate to the communication and workflow handoffs between clinicians and clinical staff. Where medication-related system communications are intended to be directed to the prescriber, there may be instances where a clinical staff member is actually the recipient of a message if that workflow model has been adopted.

    a. If a system design assumption does not match a clinician workflow implementation, implementation of HIT will be limited.

D. Allergy and Medication Intolerances Terminology and Standardization:

i. As medication terminology is improved, similar standardization and vocabulary efforts related to allergies and medication intolerances will support the next generation of medication decision support tools. A concise, comprehensive allergies and intolerances vocabulary may be needed.

    a. If allergy and medication intolerance vocabularies are not standardized, medication-related decision support benefits will not be realized.

E. E-Prescribing of Controlled Substances:

i. The Drug Enforcement Agency (DEA) currently has a proposed rule available for public comment. The proposed change in regulations addresses potential clinician use of e-prescribing of controlled substances. If e-prescribing of controlled substances is not allowed, e-prescribing will continue to have limited adoption.

    a. If e-prescribing adoption is limited or not applicable to prescribing of controlled substances, many of the benefits of e-prescribing will not be realized.

6.0 References to Use Case Scenarios

The Medication Gaps Document focuses on the exchange of medication information between clinicians, pharmacists, and healthcare payors in inpatient, ambulatory, and long term care settings. Specific events and information exchanges have been selected from previous use cases for contextual purposes.

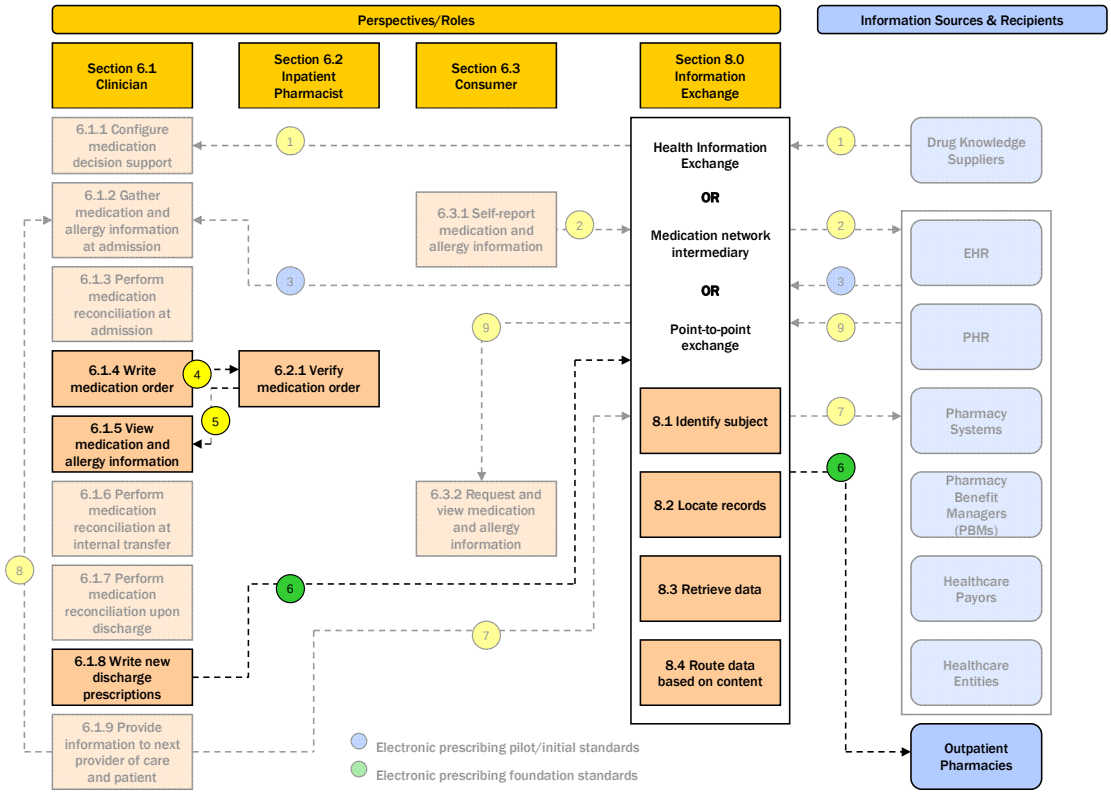
The 2007 Medication Management Use Case contains scenarios that describe the communication of medication information by various entities and the incorporation of medication-related requirements into EHRs and other clinical systems. Section 6 of this document includes applicable copies of the scenarios and information flows from the Medication Management Use Case.

In addition, during the final public feedback period of the 2007 Medication Management Use Case, several long term care entities provided feedback and suggestions for modifications that could be made to more fully address the interoperability and standardization needs of the long term care community. This Medication Gaps Draft Document provides a previously unpublished information flow diagram (Figure 6-3) that highlights several particular information exchanges that may benefit from additional standards harmonization activities.

The events and information flows that are pertinent to the Medication Gaps Extension/Gap document are shown in bold. All other events and information flows have been faded out.

6.1 Reference to Prior Use Case: 2007 Medication Management Use Case (Scenario 1 – Inpatient Medication Reconciliation)

Figure 6-1. Medications in an Inpatient Setting

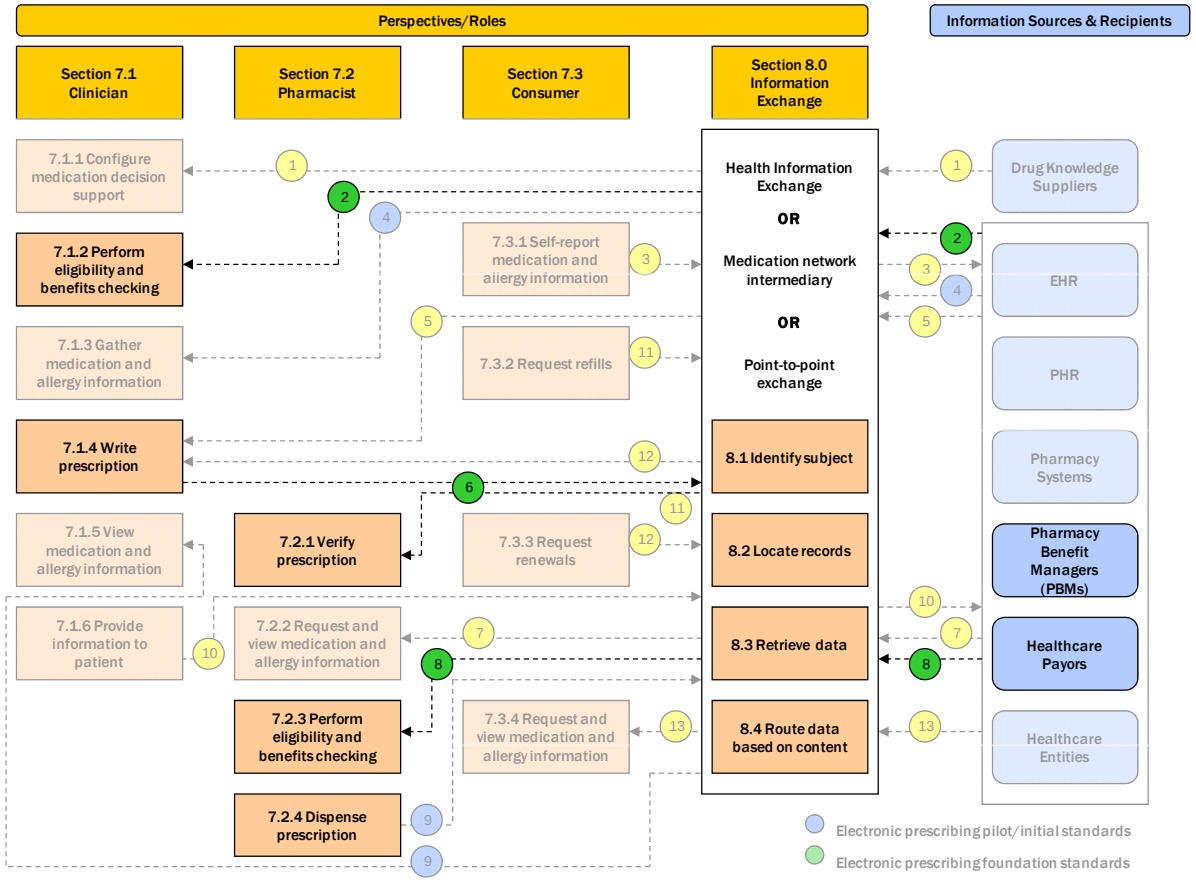


As expressed in the 2007 Medication Management Use Case events 6.1.4, 6.2.1, and 6.1.5 and information flows 4 and 5, clinicians write medication orders which are acted upon by an inpatient pharmacist and pharmacist provide verification information back to the ordering clinician. Similarly, as expressed in event 6.1.8 and information flow 6, clinicians write discharge prescriptions that are communicated to the patient's preferred pharmacy.

For the purposes of this Medication Gaps Extension/Gap document, the events and information flows surrounding flows 4 and 5 would benefit from an improved medication terminology. In addition, the event and information flow surrounding flow 6 may benefit from improved medication terminology as well as improved standards for formulary, prior-authorization, and SIG. Therefore, information flows 4, 5, and 6 should be referenced when addressing Medication Gaps.

6.2 Reference to Prior Use Case: 2007 Medication Management Use Case (Scenario 2 – Ambulatory Medication Management)

Figure 6-2. Medications in an Ambulatory Setting

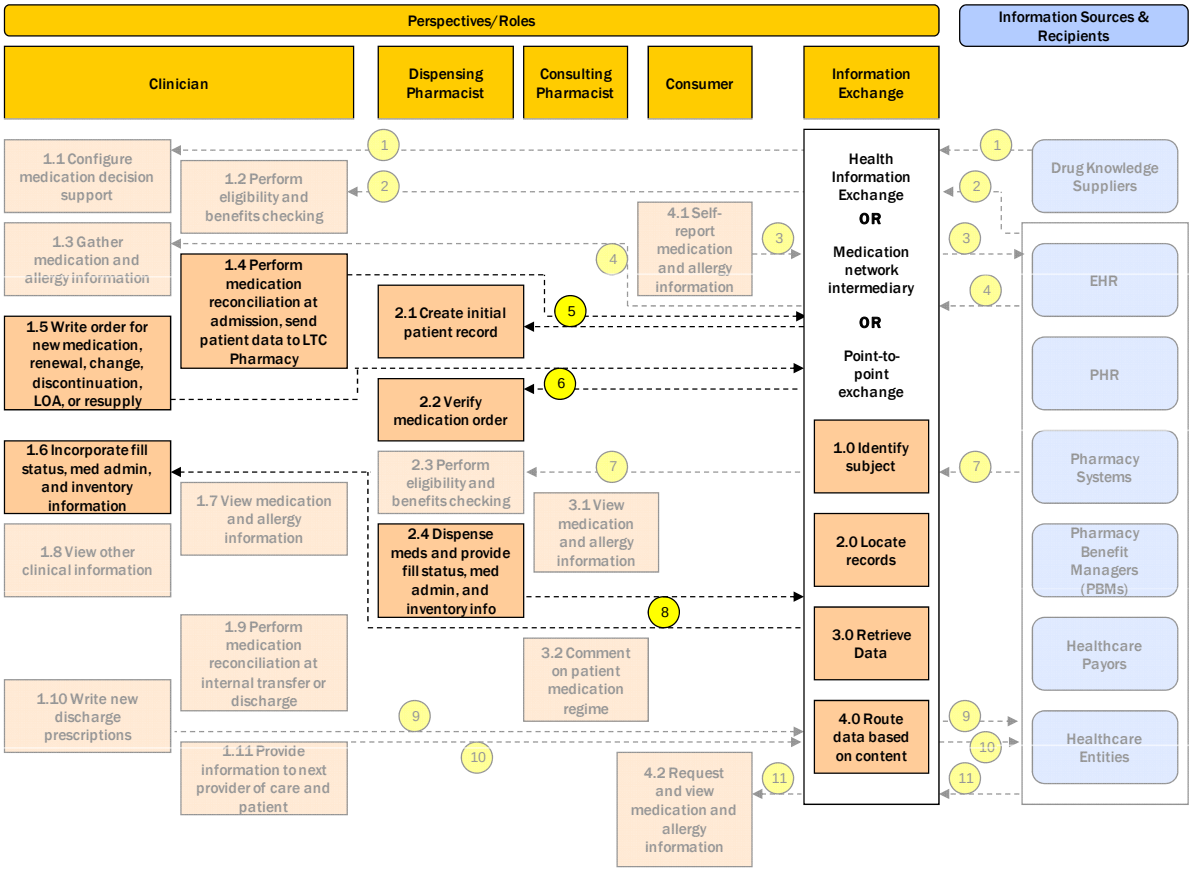


As expressed in the 2007 Medication Management Use Case events 7.1.2 and 7.2.3 and information flows 2 and 8, clinicians and pharmacists perform patient eligibility, pharmacy benefits, formulary, and prior-authorization activities to support medication prescribing and dispensing. Healthcare payors and pharmacy benefits managers provide support for these activities. Similarly, as expressed in event 7.1.4, 7.2.1, and 7.2.4 and information flows 6 and 9, clinicians and pharmacist document prescriptions by including patient instructions in a "SIG" which is given to patients when medication is dispensed.

For the purposes of this Medication Gaps document, the events and information flows surrounding flows 2 and 8 would benefit from an improved medication terminology as well as improved standards for formulary and prior-authorization. Similarly, the event and information flow surrounding flow 6 would benefit from an improved medication terminology as well as improved standards for prior-authorization and SIG. Finally, the Dispense Prescription event would benefit from an improved SIG standard. Therefore, information flows 2, 6, and 8 should be referenced when addressing medication gaps.

6.3 Addendum to Prior Use Case: 2007 Medication Management Use Case (Long Term Care Medication Scenario)

Figure 6-3. Medications in a Long Term Care Setting



This information flow diagram was developed based on input received from Long Term Care entities who commented on the 2007 Medication Management Use Case. This information flow diagram has not been previously published and should be viewed as an addendum to the 2007 Medication Management Use Case. While many of the above events and information flows are similar to those described in the 2007 Medication Management Use Case, several were identified as having significant additional needs specific to the Long Term Care setting.

Through events 1.4 and 2.1 and information flow 5, clinicians communicate relevant patient demographic information to LTC pharmacies to begin appropriate patient recordkeeping within the pharmacy. Through events 1.5 and 2.2 and information flow 6, clinicians communicate medication orders to LTC pharmacists that may also include orders related to medication inventory at the LTC facility or to support a patient leave of absence. This information flow may also support communications related to discontinued or unused medications. Through events 2.4 and 1.6 and information flow 8, pharmacists communicate

medication information to LTC pharmacists that may include medication administration and inventory information. Therefore, information flows 5, 6, and 8 should be referenced when addressing Medication Gaps.

7.0 Information Exchange

The information exchange requirements for the effective selection and communication of medication information may comprise:

- The ability to communicate and route formulary information requirements;
- The ability to communicate and route prior-authorization information requirements;
- The ability to communicate and route medication order information requirements that include appropriate terminology and SIG standards;
- The ability to communicate and route LTC medication information requirements; and
- The ability to unambiguously maintain a relationship between patients, clinicians, pharmacists, pharmacies, healthcare delivery organizations, and healthcare payors.

Examples of information exchange capabilities described above and in Section 3.0 may include: Data Delivery, Routing, Data Retrieval, and Subject Data Matching. Descriptions of each of these are in the previous 2006 – 2008 Use Cases.

The functional capabilities may be provided fully or partially by a variety of organizations including: free-standing or geographic health information exchanges (e.g., Regional Health Information Organizations), integrated care delivery networks, provider organizations, health record banks, medication network intermediaries, specialty networks, and others.

While not described in this section, health information exchange and point-to-point exchanges assist in the completion of the processes described in this extension/gap. Examples of these exchanges can be found in the previous 2006 – 2008 AHIC Use Cases.

8.0 Medication Gaps Dataset Considerations

The following non-exhaustive information categories and limited examples illustrate some of the information needs outlined in this extension/gap document. Examples of medication information relevant for this extension/gap are included in Appendix B.

Patient and Clinician Identification – Regardless of the clinical purpose of prescription order, standard information is needed to identify a prescription order when it is communicated. Standard prescription identification information may be required or optional depending on the order and the needs of the receiving entity and federal, state and local regulations. Patient and clinician identification information may include:

- **Required and Optional Patient Information**
    - Patient Identification Information
    - Name
    - Address
- **Required and Optional Clinician Information**
    - Provider Identification Information
    - Name
    - Location(s) of prescriber
    - Patient and Institution Privileges
    - Credentials/Licensing Information
    - Alternative Phone/Fax Number
    - DEA Number

Prior-Authorization - Based on payor and/or regulatory constraints, approval to order or dispense a prescription may be contingent on required or optional information. This information may include:

- **Required and Optional Information**
    - Patient Identification Information
    - Physician Identification Information

- Medication Requested
- Diagnosis
- Frequency
- Dose
- Demonstration of Conditional Requirements

Formulary and Benefits - Specific information that assists in the payment and authorization of prescriptions may be considered. This information may include:

- **Required and Optional Information**
  - Formulary Identification
  - Product Name Information
  - Formulary Conditions and Restrictions
  - Drug Reference Information
  - Pharmacy Type and Identification Information
  - Payment Information
  - RxNorm Code/Qualifier
  - Source Identification Information

Long Term Care Medication - Prescription orders for long term care patients may have distinctive information requirements which may be considered. This information may include:

- **Required and Optional Information**
  - Ordering Facility
  - Point of Contact Provider
  - Address of Patient
  - Bed/Room Location of Patient
  - Address of Patient Representative

- Consultant Pharmacist
- Delivery Method
- Packaging Information for LTC Use, Home Use, or Leave of Absence Use
- Additional Information Specific to LTC Needs

SIG (*Signatura* – patient instructions) - To effectively communicate prescription compliance instructions to a patient specific information may be considered. This information may include:

- **Required and Optional Information**
  - Provider Identification
  - Dose Form/Calculations/Restrictions
  - Route
  - Site
  - Frequency
  - Strength
  - Medication Administration Timing
  - Medication Administration Duration
  - Medication Stop Date or Stop Criteria

Appendix A: Glossary

The 2006 – 2008 AHIC Use Cases contained general terms and their contextual descriptions. Listed below are the new terms that are specific to this extension/gap.

Prior-Authorization: In pharmacy, a cost-containment procedure that requires a prescriber to obtain permission to prescribe a medication prior to prescribing it. It is also known as "prior approval."

Signatura: Also known as "SIG." This is the portion of a prescription that provides instructions to the patient on how, how much, when, and how long a drug is to be taken.

RxNorm: RxNorm is a standard for the electronic exchange of clinical health information. It provides a standard nomenclature for clinical drugs (active ingredient + strength + dose form) and for dose forms as administered to a patient. It also provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. NDCs (National Drug Codes) for specific drug products are linked to that product in RxNorm. RxNorm links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, thereby mediating messages between systems not using the same software and vocabulary. RxNorm is maintained by the National Library of Medicine (NLM).

National Drug Code (NDC): The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by them for commercial distribution. Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. FDA inputs the full NDC number and the information submitted as part of the listing process into a database known as the Drug Registration and Listing System (DRLS). Several times a year, FDA extracts some of the information from the DRLS data base (currently, properly listed marketed prescription drug products and insulin) and publishes that information in the NDC Directory.

Appendix B: Analysis and Examples

The purpose of this appendix is to list examples of the types of information appropriate for this extension/gap. As noted in the previous sections, prior-authorization, SIG, and LTC medications are the topics of focus for this extension/gap but other related examples are also included. This example and analysis is included for discussion purposes and may or may not be included in the final document.

Prior-Authorization

- Five standards are recommended for this function along with multiple payor requirements, including X12 278, X12 275, HL7 PA, LOINC, and XML;
- This functionality was not specifically addressed in HITSP IS07 document; and
- In a recent pilot study, the Center for Medicare and Medicaid Services (CMS) determined that the Prior-Authorization standard was technically "unable" to support Medicare, Part D prescribing.

SIG (for *Signatura*)

- A SIG standard was tested in a recent CMS pilot study and was determined technically "unable" to support Medicare, Part D prescribing. The National Council for Prescription Drug Programs (NCPDP) is working with CMS to improve the standard;
- HITSP mentioned SIG in HITSP IS07 data requirements, but no standard was offered, nor was a gap identified;
- The SIG standard pilot tested by CMS was the NCPDP Structured, Codified SIG v.1 standard; additional work may be needed in the areas of field definition, clarifications for field use, field use examples, and naming conventions; also, some fields may contradict other structured fields, and limitations may exist on capturing topical drug directions; and
- FDA's work on Structured Product Labeling (SPL) is also contributing to the development of the SIG. Additional work is needed in the area of dispensed drug labeling and patient medication guides where there is no standard for consumer terminology or catalogues.

Long Term Care

- There are e-prescribing needs that are unique to the LTC setting;
- E-prescribing for LTC was discussed in HITSP IS07 document but there was no specific request to focus on the unique needs of LTC;
- In a recent pilot study, CMS indicated e-prescribing standards would work for LTC but would require modification; and
- The LTC community worked with HITSP to address some of these needs, but additional work is needed.

Eligibility and Benefits Determination and Formulary

- No standard exists for identifying participants (patients, providers, health plans); much of the information available to link patients/providers with health plans is proprietary;
- Need standards to identify sender and receiver;
- NCPDP incompatibility with X12 on optional versus required elements; and
- NCPDP Formulary and Benefits v.1.0 was tested in a CMS pilot study and considered technically "able" to meet Medicare Part D prescribing needs but problems were identified with matching patients to health plans (patient identification may be different within each system); NCPDP Formulary and Benefits v.1.0 allows prescriber to make Point of Care decisions.

E-Prescribing of Controlled Substances

- HITSP IS07 acknowledged that there is a gap in this area;
- CMS acknowledges this gap and is working with the DEA to address the issue; and
- DEA has offered a proposed rule.

Terminology

- There are many on-going efforts in this area. Terminology appears to be top priority area to enable e-prescribing interoperability;
- There are at least five relevant perspectives for this issue: drug manufacturers; drug database vendors; FDA (NDC); other terminology sources (e.g., UMLS, SNOMED-CT, RxNorm); and Federal health partners;

- There exists a need for wider coordination between all industry stakeholders. In the absence of a developed standard, independent solutions are being developed by both private and public entities;
- HITSP IS07 attempted to map NCPDP with Federal Medical Terminology (FMT) and RxNorm but identified incompatibilities; and
- In recent pilot studies, CMS tested RxNorm and found it currently technically "unable" to support Medicare, Part D prescribing. Shortcomings exist in unresolved synonymy and in conveying information about drug delivery devices and packages. There are currently efforts underway to improve RxNorm.