U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Consumer Adverse Event Reporting

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 Consumer Adverse Events Reporting. AHIC specifically requested that the Consumer Adverse Events Reporting Extension/Gap address the standards and interoperability needs related to the ability for consumers and patients to report adverse events related to drugs, vaccines, medical devices, nutritional products, and cosmetics that occur outside of clinical trials.

This extension/gap document is being developed by the Office of the National Coordinator for Health Information Technology (ONC) to represent AHIC priorities and provide context for the national health agenda activities, beginning with the selection of harmonized standards by the Healthcare Information Technology Standards Panel (HITSP). Components that need to be considered during the standards identification and harmonization activities include standardized vocabulary, data elements, datasets, and technical standards that support the information needs and processes related to consumer adverse events reporting. This document is the Final AHIC Extension/Gap. Feedback received on the Draft AHIC Extension/Gap has been considered and incorporated into this document where applicable. HITSP has the opportunity to reuse standards, where applicable, from those previously recognized by the Secretary of Health and Human Services, to specify and constrain how standards are to be used to advance interoperability and to work with standards development organizations to see that gaps in standards are filled.

1.2 Progress to Date

To date, the national health agenda, including the activities of AHIC and HITSP, has not formally addressed all of the interoperability considerations for the communication of adverse events reported by consumers.

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 2008 Public Health Case Reporting Use Case includes the processes and standards for clinician reporting of adverse events when specific reporting criteria are met. This use case also describes the communication of adverse

event reporting criteria, as well as the communication of public health case reporting criteria for incorporation into EHR systems for utilization by clinicians;

- The 2008 Immunizations and Response Management Use Case includes some of the needs related to vaccine use and related connection to active surveillance for adverse events reporting; and
- The 2007 Consumer Access to Clinical Information Use Case includes capabilities that enable consumers to have direct access to clinical information and to provide information that can then be reviewed and used by other people supporting the health care system.

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 adverse events information reported by consumers. The 2009 Consumer Adverse Events Reporting 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 that 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 that 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 that assist in the communication of information. Scenarios may be from previously published 2006 – 2008 Use Cases and/or new scenarios may be described.
- Section 7.0, Information Exchange, describes information exchange capabilities needed to support the scenarios and the high-level information exchanges.
- Section 8.0, Dataset Considerations, identifies specific opportunities for identification of information and/or data relevant to this extension/gap document. These opportunities 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.

- Appendix B, Analysis and Examples, identifies specific data types, datasets, data elements, vocabularies, naming conventions, capabilities, and technical standards that may support future industry efforts in the identification, development, and harmonization of standards.

2.2 Scope

Consumer Adverse Events Reporting includes consumers identifying potential adverse events and communicating relevant information about these events to relevant organizations, providers, and other entities such as manufacturers. Therefore, requirements for the 2009 Consumer Adverse Events Reporting Extension/Gap document can be summarized as:

- The ability for consumers to report adverse events to appropriate organizations using Personal Health Records (PHRs) or other systems;
- The ability for relevant organizations to send standardized consumer adverse event reporting information and specifications to PHRs and other systems; and
- The ability for PHRs and other systems to receive standardized consumer adverse event reporting information and specifications from appropriate organizations, and incorporate and use this information within PHRs and other systems.

This document discusses the need for incorporation of adverse event reporting capabilities into PHRs and other systems to enhance the communication between consumers' PHRs and the systems that support organizations concerned with potential adverse events. The communication of adverse events from a consumer to various stakeholders will depend on standardized data elements, datasets, message structures, and message transport considerations.

The identification, development, and harmonization of standards to support the processes associated with consumer adverse event reporting is progressing but will require additional work with standards and professional organizations, care delivery organizations, and organizations providing information technology services and products to the healthcare industry. As mentioned in Section 1.0, the needs expressed here 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 to support the exchange of information regarding potential consumer adverse events between consumers and others. Support for this exchange includes the development of interoperability standards for vocabularies, data elements, datasets, and other technical components that are implicit in these functional needs. Rather than an all-inclusive list of functional requirements, key capabilities are outlined below. The descriptions in this section are not intended to prescribe policy nor propose architectures required to implement capabilities.

These capabilities highlight what potential adverse events may be reportable as well as information exchange and standardization efforts needed to support consumer adverse event reporting. "Appropriate organizations" refers to those organizations that are concerned with tracking and/or responding to potential adverse events and may include but not be limited to: providers, manufacturers, public health, government agencies, knowledge suppliers, and other organizations.

A. The ability for consumers to report adverse events to appropriate organizations using PHRs or other systems.

    i. Consumers may need the ability to report adverse events related to one or more of: drugs, vaccines, medical devices, nutritional products, food, and cosmetics and interactions between them. Potential adverse events associated with clinical trials are addressed through approaches and mechanisms different than what is included here. Consumers may need the ability to report potential adverse events without requiring them to differentiate the cause or the organizations that may conduct follow-up activities.

    ii. Consumers may need the ability to make direct reports of potential adverse events through PHRs, internet websites, or other systems to appropriate organizations. This reporting capability is focused on the exchange of information related to adverse event reporting and may include initial reporting as well as follow-up information exchange activities.

B. The ability for appropriate organizations to send standardized consumer adverse event reporting information and specifications to consumers' PHRs and other systems.

    i. Information that helps consumers identify potential adverse events may be sent from appropriate organizations to support the capability to recognize and/or report potential adverse events. PHRs may use these specifications to help the consumer identify, understand, and develop a potential adverse event report.

ii. Information regarding potential adverse events may also include guidance for reporting adverse events to members of a consumer's healthcare team, manufacturers, and other appropriate organizations.

C. The ability to receive standardized consumer adverse event reporting information and specifications from appropriate organizations and incorporate and use this information within consumers' PHRs and other systems.

i. Information that helps consumers identify potential adverse events may be received from appropriate organizations to give them the capability to report in a consistent manner.

ii. This information can provide guidance to assist in the identification of appropriate information that could support potential adverse event reporting and may already be contained within a PHR, such as demographic information, medical history, names of medications taken by a consumer, or medical device identification information.

iii. This information may also include specifications on the use of code sets, vocabularies, or other mechanisms to help consumers report potential adverse events using structures that will support their subsequent management, follow-up, and resolution.

iv. Standardized reporting information and specifications may assist in the communication of information that could support potential follow-up investigational activities as described in the 2008 Public Health Case Reporting Use Case.

4.0 Stakeholder Communities

Examples of stakeholders who may be directly or indirectly involved in the exchange of consumer adverse event reporting 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 consumer adverse event reporting information may include: Patients, Consumers, Providers, Manufacturers/Distributors, Government Agencies, and other appropriate organizations.

Stakeholders that may assist in consumer adverse event reporting information may include: PHR System Suppliers, Health Information Exchange Organizations, Clinicians, Healthcare Entities, and Knowledge Suppliers.

Stakeholders that may be sources or recipients of consumer adverse event reporting information may include: Patients, Consumers, Providers, Manufacturers/Distributors, Government Agencies, and other appropriate organizations.

5.0 Issues and Obstacles

A number of issues in today's health information technology environment are obstacles to achieving the healthcare data standardization and interoperability to promote patient safety, reduce healthcare costs, and increase the value of electronic health information exchange. Some general issues were described within the 2006 – 2008 AHIC Use Cases. Examples of specific issues and obstacles related to Consumer Adverse Event Reporting are outlined below.

A. Adverse Event Reporting Standards:

i. Some standards are in development to support adverse event reporting. A number of efforts are ongoing to help address gaps in existing standards, but more work is needed in this area.

a. Without sufficient standards for adverse event reporting, consumers, providers, and organizations that share adverse event reporting information will not be able to efficiently and accurately communicate complete information to enable an thorough understanding of potential adverse events.

b. Efforts to establish an adverse event report vocabulary and terminology are underway but have not yet been completed. There may be benefits in referencing clinician adverse event reporting vocabulary and terminology when addressing consumer adverse event reporting.

B. Consumer Understanding of Adverse Events:

i. For consumers to effectively report potential adverse events, they may need guidance described in terms which the consumer can readily understand rather than the medical terminology of clinicians.

a. Although clinical judgement is needed to determine or confirm an actual adverse event, consumers should be given guidance to reduce the risk of under-reporting or over-reporting of adverse events.

C. Adverse Events Reporting Language:

i. For consumers to make accurate adverse event reports, instructional language may need to be given in layperson terms that avoid the use of technical or clinical jargon as part of adverse event reporting criteria.

a. Without including language that is understandable to consumers as part of the adverse event report, adverse events may be incompletely or inaccurately reported by consumers.

D. Significant Change in the Quantity of Adverse Events Reports:

i. When consumers are given increased access to systems that support consumer adverse event reporting, significantly more adverse events may be reported.

a. With this capability, adverse events reporting may increase significantly, causing additional workload for organizations involved in adverse event reporting investigation and follow-up activities.

b. There may be duplicate reports related to a single adverse event that would benefit from an ability to identify a specific adverse event.

E. Patient Confidentiality, Privacy, and Security

i. Adverse event reporting should consider patient needs for confidentiality, privacy, and security to guard against the possibility of retailiation from an identified clinician or facility.

a. Without appropriate considerations of patient confidentiality, privacy, and security, consumers may choose not to report potential adverse events.

F. Standardized, Coded Adverse Event Categorization Terminology:

i. Adverse event reporting management and follow-up may benefit from a standardized, coded terminology set for categories of adverse events to allow for aggregation, reporting, and management. This could enable analysis and response by organizations receiving adverse event reports.

a. Without a standardized, coded terminology set for categories of adverse events, effective response to adverse event reports may be difficult.

6.0 References to Use Case Scenarios

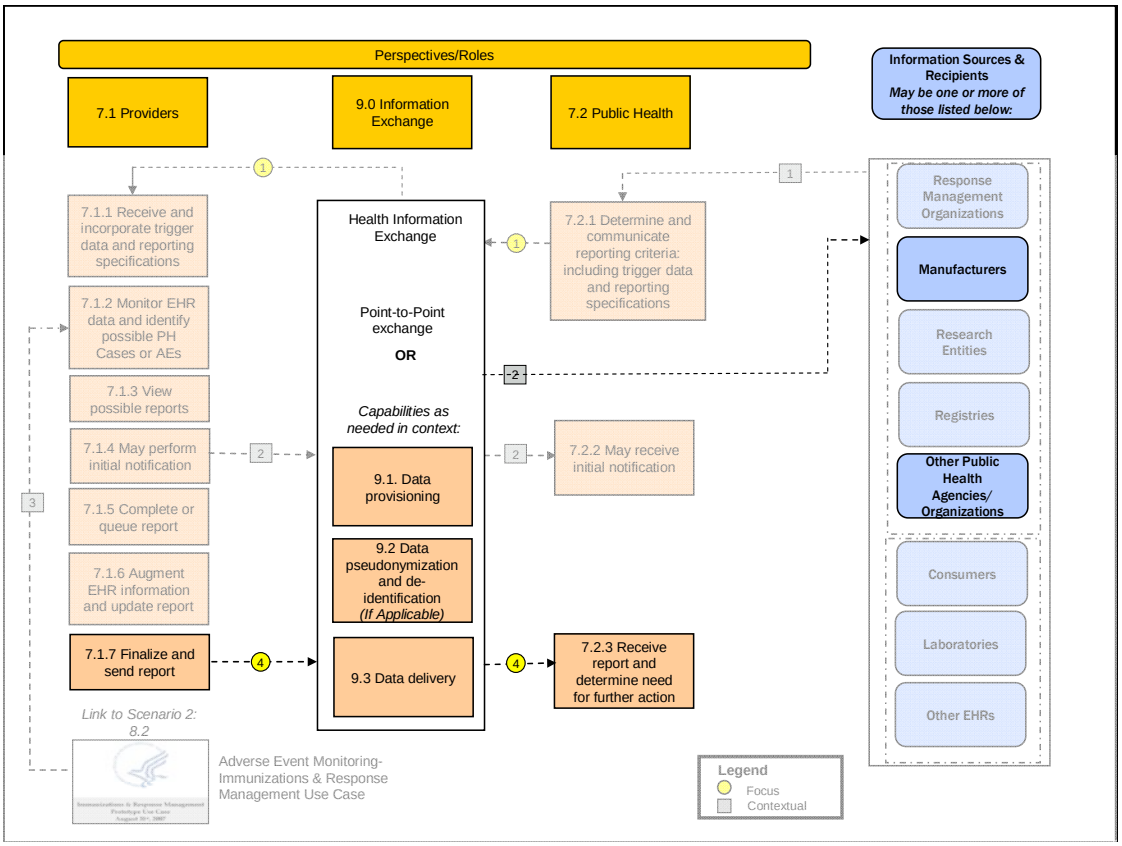
The 2009 Consumer Adverse Events Reporting Extension/Gap Document focuses on the exchange of adverse event information between consumers and other entities. Specific events and information exchanges have been selected from previous use cases for contextual purposes.

The 2008 Public Health Case Reporting Use Case contains a scenario that describes the communication of adverse event information from various care settings and the incorporation of related information into Electronic Health Records (EHRs). Analogous information flows can be constructed to support consumer adverse event reporting. This 2009 Consumer Adverse Event Reporting Extension/Gap provides a previously unpublished information flow diagram (Figure 6-2) that highlights several functions that may benefit from additional standards harmonization activities and electronic system capabilities. Below is a copy of the applicable scenario with information flows from the Public Health Case Reporting Use Case and a similar scenario that shows relevant flows for consumer adverse event reporting.

The events and information flows that are pertinent to the Consumer Adverse Events Reporting Extension/Gap are shown in bold. All other events and information flows have been faded out.

6.1 Reference to Prior Use Case: 2008 Public Health Case Reporting (Scenario 1)

Figure 6-1. Reporting from EHRs

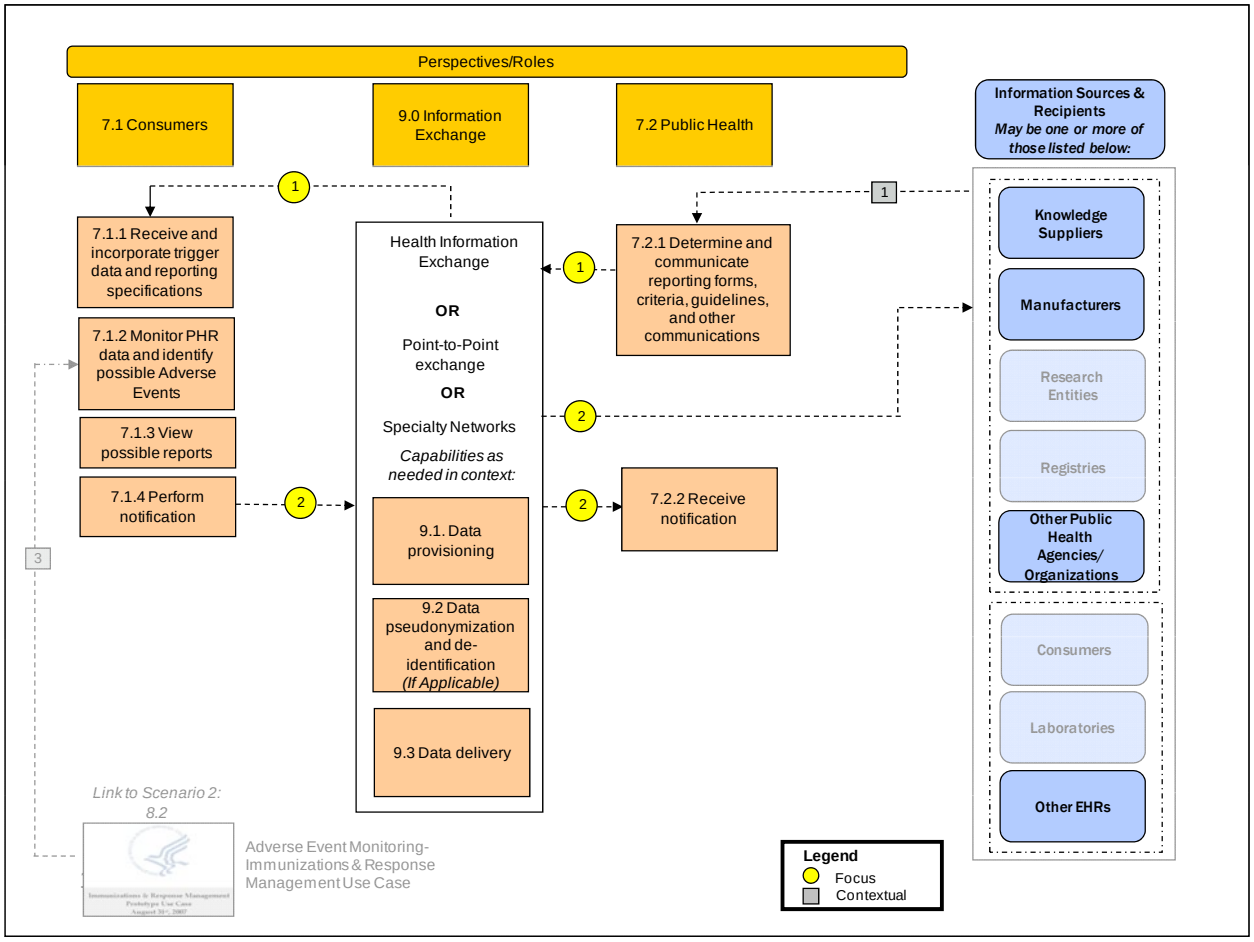


As expressed in the 2008 Public Health Case Reporting Use Case, events 7.1.7, 7.2.3 and information flow 4, adverse event reports can be communicated from EHRs to various entities. Adverse event reports are completed by providers and communicated via information exchange to Public Health where a determination is made regarding the need for further action.

In the case of the consumer adverse event reporting, a similar capability for communicating adverse event reports from PHRs or other systems may be needed to allow consumers to complete a potential adverse event report and communicate it via information exchange to appropriate organizations. This similar capability is depicted in Figure 6-2 in the following section.

6.2 Reference to Prior Use Case: Addendum to 2008 Public Health Case Reporting Use Case (Scenario 1)

Figure 6-2. Reporting from PHRs



Related to what was expressed in the 2008 Public Health Case Reporting Use Case, in this previously unpublished information flow diagram, events 7.1.1, 7.2.1, and information flow 1 show how various appropriate organizations may communicate standardized consumer adverse event reporting information and specifications to PHRs and other systems that assist in consumer adverse event reporting.

Events 7.1.2, 7.1.3, 7.1.4, and 7.2.2 and information flow 2 show how a consumer can consider potential adverse events, use a PHR to help complete a report, and notify others of a potential adverse event for potential follow-up and investigation. This communication could be directed to the appropriate organizations such as providers, manufacturers, public health, government agencies, and other organizations.

Therefore, information flows 1 and 2 should be referenced when addressing consumer adverse event reporting.

7.0 Information Exchange

The information exchange requirements for the effective selection and communication of consumer adverse event reporting information may comprise:

- The ability for consumers to report adverse events to appropriate organizations using PHRs or other systems;
- The ability for relevant organizations to send standardized consumer adverse event reporting information and specifications to PHRs and other systems; and
- The ability to receive standardized consumer adverse event reporting information and specifications from appropriate organizations and incorporate and use the information within PHRs and other systems.

Examples of information exchange capabilities described above and in Section 2.0 may include: Data Provisioning, Routing, Data Pseudonymization and De-identification (if applicable), and Data Delivery. Descriptions of each of these are in the previous 2006 – 2008 AHIC Use Cases.

The functional capabilities may be provided fully or partially by a variety of organizations including: health information exchange organizations, integrated care delivery networks, provider organizations, health data banks, public health networks, specialty networks, and others.

While not described in this section, Health Information Exchange (HIE) and Point-to-Point exchanges assist in the completion of the processes described in this extension/gap. Examples of HIEs and Point-to-Point exchanges can be found in the previous 2006 – 2008 AHIC Use Cases.

8.0 Consumer Adverse Event Reporting Dataset Considerations

The following non-exhaustive information categories and limited examples illustrate some of the information needs from this extension/gap document. Examples of relevant adverse event activities, which may serve as starting points to facilitate consumer adverse event reporting, are included in Appendix B.

A. Patient Information

a. Patient Identification Information

b. Patient Name

c. Patient Address

d. Patient Contact Information

B. Demographics

a. Sex

b. Age at time of event

C. Event Information

i. Outcomes Attributed to Adverse Event

ii. Date of Event

iii. Date of Report

iv. Body Site of Adverse Event

D. Description of Problem

i. Adverse Event

a. Death

b. Life Threatening

c. Disability

d. Other Health Problems or Outcomes

ii. Product Use Error

E. Product Problem

i. Suspected Contamination

ii. Problem with Different Manufacturer of Same Medicine

iii. Other Product Problems

F. Description of Problem

G. Product Type

i. Medication

ii. Vaccine

iii. Cosmetic

iv. Other

H. Product Availability for Evaluation

I. Event Reporter Information

i. Name and Contact Information for Reporter

ii. Patient Name and Other Identification Information

iii. Occupation of Reporter (e.g., Consumer, Patient, Family Member, Risk Manager, Attorney, Other)

iv. Reporter's Primary Health Provider

v. Additional Information Related to this Event and Reporter

J. Event Report Recipient Information

i. Type of Recipient (e.g., Physician, Manufacturer, Health Department, Consumer Product Safety Commission, Food and Drug Administration, Other)

ii. Name and Contact Information for Recipient

iii. Relevant Report Dates (e.g., Receive Date, Acknowledged Date)

iv. Additional Information Related to this Event Report

K. Consent to Release Reporter's Information to Manufacturer

L. Responsible Physician

i. Clinician Identification Information

ii. Clinician Contact Information

M. Dispenser

N. Pharmacists

O. Relevant Tests/Laboratory Data

P. Relevant Medical History

i. Other Vaccines/Rx Administered at Date Given

ii. Other Vaccines/Rx Given Within 4 Months Prior

iii. Relevant Vaccine/Rx Information for Family Member

Q. Prescription Information

i. Medication Identification Information (e.g., NDC #)

ii. Dose, Amount, Frequency, Route

iii. Dates of Use

iv. Event Follow-up (e.g., Reappeared After Reintroduction, Resolved After Discontinuation)

v. Additional Detail on Medication Use (e.g., Number of Doses Before Event Occurred)

R. Device Information

i. Brand Name

ii. Common Device Name

iii. Product Class

iv. Manufacturer Name, City, State

v. Unique Identifying Device Information

vi. Expiration Date

vii. Operator of Device

viii. Implanted/Explanted Date

ix. Single Use Device

x. Reprocessed

xi. Reused

xii. Address of Reprocessor

Appendix A: Glossary

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

Adverse Events: Outcomes such as diagnosis, sign, symptom, and/or injury that can be related to the use of a biopharmaceutical product or device. An adverse event can be either expected or unexpected (in terms of nature, severity, specificity, or outcome).

Consumers: Members of the public that include patients as well as caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient receiving or potentially receiving healthcare services.

Government Agencies: Federal, state, local, territorial, or tribal departments within the government responsible for the oversight and administration of a specific function; government agencies may include: Department of Health and Human Services (DHHS), Food & Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), Department of Veterans Affairs (VA), Indian Health Services (IHS), and Department of Homeland Security (DHS).

Health Information Exchange (HIE): The electronic movement of health-related data and information among organizations according to specific standards, protocols, and other agreed criteria. These 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 (RHIOs)), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, and others supporting these capabilities. This term may also be used to describe the specific organizations that provide these capabilities such as RHIOs and Health Information Exchange Organizations.

Manufacturers/Distributors: Entities which may be involved in research, development, testing, production, storage, distribution, surveillance, and communication regarding medical/healthcare products at the community, regional, state, and national level, such as pharmaceutical manufacturers, drug wholesalers, and medical device suppliers.

Medical Devices: Devices used by consumers to support their health needs with coordinated assistance from clinical and other health support personnel. An example of a medical devices might be a glucometer.

Patients: Members of the public who receive healthcare services.

Providers: Providers are the healthcare personnel within healthcare delivery organizations with direct patient interaction in the delivery of care, including physicians, nurses,

psychologists, clinicians, dentists, oral surgeons, and other professionals. This can also refer to healthcare delivery organizations.

Appendix B: Analysis & Examples

An analysis of the information exchange components associated with consumer adverse event reporting and examples of potential mechanisms are included in this appendix. These examples are not intended to be inclusive of all activities in this area.

MedWatch: The Food and Drug Administration (FDA) manages a website that allows for mandatory and voluntary reporting of serious adverse events for human medical products associated with FDA-regulated drugs, biologics, medical devices, and special nutritional products and cosmetics.

MedWatch Plus: FDA is working with the National Institute of Health (NIH) to develop a "portal through which adverse event, consumer complaint, and product problem reports are received and processed to make the information available to adverse event analysis systems." Based on the HL7 Individual Case Safety Report (ICSR) data exchange standard, this portal is intended to include a "Rational Questionnaire" that consumers could use to complete an online form that has imbedded logic to improve quality, accuracy, and timeliness of reporting and support the distribution of adverse event reports to appropriate government agencies. The NIH Federal Adverse Event Task Force supports this effort and includes participation from multiple government agencies.

HL7 v3.0 Individual Case Safety Report: The ICSR is currently being considered as a base standard for much of the standardization needs related to the MedWatch Plus effort. The HL7 ICSR message supports the exchange of data and other safety reporting requirements between various public health and patient safety organizations — specifically, reporting of adverse events or product problems associated with the use of drugs, therapeutic biologics, vaccines, and devices. Currently, work is under way to expand the scope of the message to support other types of products such as food, dietary supplements, cosmetics, or veterinary products and services. The ICSR message is specifically designed to support individual case safety reports and does not support population-based case reporting for disease surveillance or outbreak events. The message can support international safety reporting between public health organizations

AHRQ's Common Formats for Patient Safety Event Reporting: The Agency for Healthcare Research and Quality (AHRQ) is currently administering the provisions of the Patient Safety and Quality Improvement Act of 2005 that support Patient Safety Organizations. One aspect of this activity is the development of Common Formats for use with patient safety event reporting. The Common Formats describe technical requirements, common definitions, reporting specifications, and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety events. AHRQ convened an interagency Federal Patient Safety Work Group to guide the development of the Common Formats. As part of this process, AHRQ viewed materials from 64 reporting systems, working with 55 organizations. Details of the Common Formats

(including metadata and technical specifications) are being developed and will be contained within the United States Health Information Knowledgebase (USHIK).

Vaccine Adverse Event Reporting System (VAERS): VAERS is a vaccine safety cooperative program of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is a post-marketing safety surveillance program, collecting information about adverse events that occur after the administration of US licensed vaccines.

Personal Health Record System – Functional Model (PHR-S FM): This HL7 document identifies the features and functions necessary to create and manage an effective PHR. Some of these features and functions could support Consumer Adverse Event Reporting.