U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Immunizations & Response Management

Detailed Use Case

March 21, 2008

Table of Contents

List of Figures

1.0 Preface

Use cases developed for the American Health Information Community (AHIC) are based on the priorities expressed by the AHIC, which include needs expressed by the AHIC Workgroups. These high-level use cases focus on the needs of many individuals, organizations, and systems rather than the development of a specific software system. The use cases describe involved stakeholders, information flows, issues, and system needs that apply to the multiple participants in these arenas.

The use cases strive to provide enough detail and context for standards harmonization, certification considerations, architecture specifications and detailed policy discussions to advance the national health information technology (HIT) agenda. These high-level use cases focus, to a significant degree, on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system.

During the January 2007 AHIC meeting, nine priority areas (representing over 200 identified AHIC and AHIC workgroup detailed issues and needs) were discussed and considered. Three of these areas (Consumer Access to Clinical Information, Medication Management, and Quality) were selected for use case development and the final 2007 Detailed Use Cases were published in June, 2007.

The remaining six priority areas from the January 2007 AHIC meeting (Remote Monitoring, Patient-Provider Secure Messaging, Personalized Healthcare, Consultations & Transfers of Care, Public Health Case Reporting, and Immunizations & Response Management) have been developed as the 2008 Use Cases which, will be processed in the national HIT agenda activities in 2008.

The 2008 Use Cases have been developed by the Office of the National Coordinator for Health Information Technology (ONC) with opportunities for review and feedback by interested stakeholders within both the private and public sectors. To facilitate this process, the use cases have been developed in two stages:

- The **Prototype Use Cases** describes the candidate workflows for the use case at a high level, and facilitates initial discussion with stakeholders; and
- The **Detailed Use Cases** documenst all of the events and actions within the use case at a detailed level.

This document is the Detailed Use Case. Feedback received on the Detailed Use Case has been considered and incorporated where applicable into this document.

This Detailed Use Case is divided into the following sections:

- Section 2.0, Introduction and Scope, describes the priority needs identified by one or more AHIC workgroups and includes draft decisions made regarding the scope of the use case.
- Section 3.0, Use Case Stakeholders, describes individuals and organizations that participate in activities related to the use case and its components.
- Section 4.0, Issues and Obstacles, describes issues or obstacles which may need to be resolved in order to achieve the capabilities described in the use case.
- Section 5.0, Use Case Perspectives, describes how the use case combines similar roles (or actors) to describe their common needs and activities. The roles are intended to describe functional roles rather than organizations or physical entities.
- Section 6.0, Use Case Scenarios, describes how various perspectives interact and exchange information within the context of a workflow. Use case scenarios provide a context for understanding information needs and are not meant to be prescriptive.
- Sections 7.0 and 8.0 provide a greater level of detail for each scenario and include information flows. Specific events and actions for each perspective and scenario are presented and discussed. These are also not intended to be prescriptive.
- Section 9.0, Information Exchange, describes the role of information exchange in the use case at a high level.
- Section 10.0, Dataset Considerations, identifies specific information opportunities relevant to this use case that may support future standardization and harmonization activities.
- Appendix A, the Glossary, provides draft descriptions of key concepts and terms contained in the detailed use case.

2.0 Introduction and Scope

In July 2007, AHIC approved a recommendation to develop a use case which addresses the exchange of information supporting the distribution and administration of medications, vaccinations, and other specific medical prophylaxis and treatment methods. The Immunizations and Response Management Detailed Use Case focuses on the information needs of consumers, clinicians, registries, public health and inventory managers carrying out routine care activities associated with immunizations. The use case recognizes that portions of the needs during non-routine or emergency situations, as well as those necessary to support public health outcomes, could be accomplished using the same infrastructure. This use case, however, does not address all capabilities required for public health response planning or response management in emergency situations.

AHIC prioritized needs related to this use case include:

- Automated integration of Electronic Health Records (EHRs) with related registries, such as immunization registries, registries of emergency response volunteers, registries of individuals given other prevention and treatment interventions, and registries supporting long-term follow-up will support case management activities.

- The ability to exchange information such as the need to administer resources, the availability of resources and their actual administration (including isolation and quarantine) in coordinating response activities, and managing available medical resources during a public health emergency.

- The integration of supply chain information from public and private sectors to provide data to support informed decision making as well as support response and treatment activities.

The Immunizations and Response Management Detailed Use Case focuses on: 1) access to information about individuals who need to receive specific vaccines, drugs, or other interventions; 2) the ability to report, track, and manage administration of vaccines, drugs, isolation and quarantine; 3) the ability to identify and electronically exchange information describing the treatment or prophylaxis status of populations; 4) the ability to exchange specific resource and supply chain data from public and private sectors. The draft detailed use case describes these activities within the context of two scenarios:

- **Vaccine and Drug Administration and Reporting.** This scenario describes the process of identifying individuals and populations with needs for, and the administration of vaccines or drugs based on routine schedules, or by priorities dictated by emergency response. Additionally, this scenario describes the exchange of data necessary to support countermeasure and response administration of prophylaxis and treatment modalities, and the supply of data between appropriate

registries and other sources of data to support clinical care and public health follow-up activities.

- **Vaccine and Drug Inventory Reporting.** This scenario describes how information regarding the need for, and availability of, vaccines and/or drugs is collected and exchanged to support coordinated delivery of care.

Associations between the scenarios in this use case and the Public Health Case Reporting Use Case are also described.

This use case assumes the developing presence of electronic systems such as EHRs, Personal Health Records (PHRs), and other local or web-based solutions supporting consumers and clinicians, while recognizing the issues and obstacles associated with these assumptions. This approach helps promote the development of longer-term efforts.

3.0 Use Case Stakeholders

Figure 3-1. Immunizations & Response Management Use Case Stakeholders Table

Stakeholder	Contextual Description
Clinicians	Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, psychologists, pharmacists, and other licensed and credentialed personnel involved in treating patients.
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.
Electronic Health Record (EHR) / Personal Health Record (PHR) System Suppliers	Organizations which provide specific EHR and/or PHR solutions to clinicians and patients such as software applications and software services. These suppliers may include developers, providers, resellers, operators, and others who may provide these or similar capabilities.
Geographic Health Information Exchange / Regional Health Information Organizations	A multi-stakeholder entity, which may be a free-standing organization (e.g., hospital, healthcare system, partnership organization) that supports health information exchange and enables the movement of health-related data within state, local, territorial, tribal, or jurisdictional participant groups. Activities supporting health information exchanges may also be provided by entities that are separate from geographic health information exchanges/Regional Health Information Organizations including integrated delivery networks, health record banks, and others.
Government Agencies	Federal, state, local, territorial, or tribal departments within the United States 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).

Stakeholder	Contextual Description
Healthcare Entities	Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health programs, school health programs, dental clinics, psychology clinics, care delivery organizations, pharmacies, home health agencies, hospice care providers, airport clinics, mass vaccination sites, public health agencies, retail store clinics, and other healthcare facilities.
Healthcare Payors	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.
Inventory Managers	Individuals, from public or private organizations, who are responsible for coordinating inventory resources to support the delivery of care. These individuals determine the needs and coordinate logistics (including interacting with suppliers and vendors) to support the delivery of care.
Knowledge Providers	Associations of public health individuals/organizations who provide technical and clinical advice/guidance and assistance to state and local health agencies in a broad range of areas including: occupational health, chronic diseases, injury control, and maternal and child health.
On-site Care Providers	On-site care providers are the initial personnel to deliver medical care at the scene of an incident. While this would typically be emergency medical technicians (EMTs), it can also include medically trained fire, law enforcement, and uniformed services medical personnel and civilian disaster medical assistance teams (DMATs).
Patients	Members of the public who receive healthcare services.
Providers	The healthcare clinicians within healthcare delivery organizations with direct patient interaction in the delivery of care, including physicians, nurses, psychologists, and other clinicians. This can also refer to healthcare delivery organizations.

Stakeholder	Contextual Description
Public and Private Immunology, Vaccine Response, and Adverse Event Experts	Governmental organizations, and physician associations which make decisions or recommendations on issues including: licensing vaccines, establishing effective and safe dosages, establishing schedules for vaccine administration based on immunology principles, pre- or post- exposure prophylactics, proper handling of vaccines, reporting of adverse events, and defining adequate documentation of vaccination events for coverage assessments and recall of patients or vaccine lots.
Public and Private Sector Supply Chain	Entities involved in the production, storage, and distribution of medication and immunization products at the community, regional, and national level, such as pharmaceutical or vaccine manufacturers, drug and vaccine wholesalers/distributors, and pharmacies and retail delivery organizations.
Public Health Agencies/Organizations (federal/state/local/territorial/tribal)	Federal, state, local, territorial, and tribal government organizations and clinical care personnel that exist to help protect and improve the health of their respective constituents. These organizations are also involved in the coordination of ordering and distributing resources such as vaccines.
Registries	Organized systems for the collection, storage, retrieval, analysis, and dissemination of information to support health needs. This also includes government agencies and professional associations which define, develop, and support registries. Immunization Information Systems (IISs) as well as other types of health registries are included within this group.
Response Management Organizations	Organizations that are responsible for emergency evaluation and response to natural disasters (e.g., public health and emergency management organizations (Federal Emergency Management Agency, Red Cross, etc.)).
Schools	Organizations that provide education and can also serve in a public health support role. Educational facilities may have vaccination requirements for matriculation. In some instances, schools have been delegated to input vaccination status/history into IISs.

4.0 Issues and Obstacles

Realizing the full benefits of HIT is dependent on overcoming a number of issues and obstacles in today's environment. Inherent is the premise that some of these issues and obstacles will be cross-cutting and therefore shown in all use cases, while others are unique to this specific use case. Some of these topics will appear in both the cross-cutting and use case-specific sections so that, in addition to the shared characteristics of the issue, considerations specific to a use case may be addressed.

Issues and Obstacles which are applicable across use cases appear below in problem and consequence form:

- **Confidentiality, privacy, and security:**
    - In order for consumers to accept electronic health records, appropriate privacy and security protections may be needed to manage access to personal health information. Consumers may also want to decide who will view and communicate their personal health information. Privacy and security controls and the means of restricting data access are not standardized or regulated.
        - Without adequate permissions and controls, consumer participation in the act of electronic health information exchange may be limited.
    - There are regulations concerning the storage, transmission, or destruction of electronic health information. These regulations are inconsistent across federal, state, and local jurisdictions, or may specifically prohibit access in certain situations (e.g. the Family Educational Rights and Privacy Act (FERPA)
        - Without consistent standards, the viewing, accessing, or transmitting of electronic health information may be inhibited.
- **Information integrity, interoperability, and exchange:**
    - Incomplete, inaccurate, or proprietarily-formatted information prevents efficient health information exchange activities or utilization of electronic health information.
        - Without data standards that promote compatibility and interoperability, longitudinal patient medical records may be incomplete or of questionable integrity.
- **EHR and HIT adoption:**
    - The processes identified in the use cases rely upon successful integration of EHRs into clinical activities. Because this integration may not align with

current workflow and may require additional upfront costs, it may not be widely pursued or implemented.

    - Low adoption of HIT, particularly within small physician practices, rural areas and long-term care settings, may create disparate service levels and may adversely affect healthcare for these populations.

- **Lack of business model and infrastructure:**

    - Financial incentives are not currently sufficient to promote the business practices necessary for sustainable HIT.

        - If sufficient reimbursement policies and other financial incentives are not established, HIT adoption may be difficult or unsustainable.

    - Activities involving health information exchange (HIE) will require additional technical infrastructure, functionality, and robustness, beyond what is currently available.

        - Unless the requisite infrastructure for HIE capabilities is established, improved upon, and sustained, these capabilities may have limited success and provide few benefits.

- **Clinical Decision Support:**

    - The capabilities, requirements, and standards needed for consistent development, implementation, and maintenance of Clinical Decision Support within EHRs have not been identified.

        - The utility and benefits of Clinical Decision Support cannot be fully realized without the development of workflows and standards demonstrating benefits for consumers, patients, and providers.

In addition to the cross-cutting issues and obstacles described above, several other issues or obstacles exist that are specific to this use case and include:

- Harmonized standards have not been fully adopted and there is limited availability of information exchange capabilities.

    - The lack of agreed-upon standards and limited capabilities hinders the exchange of immunization information exchange between clinicians and registries.

- Individual patient immunization information may be spread across multiple sources, with no single source containing the entire set of information.

  - It is difficult to provide a complete immunization history to a clinician or accurately determine the immunization status of an individual.

- Variations exist in the manual process of entering vaccine administration information into registries and IISs.
  - These variations can result in duplicate immunization entries or attributing the data to the incorrect individual.
- Immunization schedules, as well as local, school and state interpretations of published schedules, vary between jurisdictions and are not available in an electronically interoperable form for inclusion in EHRs, PHRs, and registries.
  - This schedule variability and lack of electronic interoperability limits the ability for clinicians to efficiently identify immunizations needed, missing doses, etc.
- In most instances consumer-supplied immunization information is not currently accepted by clinicians or registries unless it can be attributed to a clinically verified source.
  - As personally controlled health records evolve, it is possible that the consumer's PHR or health data bank may contain immunization information supplied directly by a clinician; however the standards by which that information can be properly attributed are not currently harmonized.
- Non-routine or emergency situations have similar information needs which are not readily supported by the routine care infrastructure including:
  - The ability for those in public health roles to gather information describing the immunization status of individuals or populations from multiple sources.
  - The ability to electronically communicate information to clinicians about the individuals or populations needing prioritized intervention.
  - The ability to electronically distribute intervention criteria and schedules to EHRs and registries.
  - The ability for clinicians to electronically communicate administration of prophylaxis, treatment, isolation, or quarantine interventions to appropriate registries.
  - The ability for those in public health roles to monitor and manage inventory usage and availability of prophylaxis and treatment interventions, including resources to support those in isolation or quarantine.

- From state to state, policies vary regarding patient consent regarding treatment and the release of immunization information in the event of a public health emergency.
    - These inconsistencies limit the ability to exchange immunization information across state borders for routine care as well as during non-routine situations.
- Protocols for vaccine research protocols may require that the actual vaccine not be identified in the clinical documentation (e.g. a blinded study).
    - Special requirements for identifying the actual vaccine administered may be required if the information is to be reported to IISs and other registries.

5.0 Use Case Perspectives

The Immunizations and Response Management Detailed Use Case describes the information exchanges associated with vaccine and drug administration and reporting as well as inventory management from the perspectives of the clinician, registries, consumers, public health, inventory managers, and information exchange. The perspectives included in the use case are intended to indicate roles and functions, rather than organizations or physical locations. In most instances, the role and function is described within the context of routine care activities, with some additional discussion about roles and functions in non-routine or emergency situations. Each perspective is described below:

- **Clinician**

  The clinician perspective includes physicians, advanced practice nurses, physician assistants, nurses, pharmacists, psychologists, and other personnel involved in administering to and treating patients. For individuals needing routine prevention or treatment interventions, clinicians administer the associated vaccines or drugs and ensure that the administration information is reported to the appropriate registries and/or public health entities. Clinicians may perform these roles in routine care settings as well as non-routine settings including, but not limited to, physician offices, hospitals, clinics, field medical stations, pharmacies, incident locations, etc. Clinicians are also involved in monitoring for immunization effectiveness and adverse events resulting from the interventions administered. This role includes clinicians who are responsible for administering prophylaxis or treatment in a public health clinic or other care settings.

- **Registry**

  The registry perspective includes those organizations performing the functional activities of gathering and providing information that describe the immunization status and history of individuals and populations. Within the context of this use case, the registry perspective encompasses the role of IISs which are a specific type of registry and other types of registries which utilize data describing prophylaxis and treatment interventions including isolation and quarantine. Registry capabilities may be provided by federal, state, territorial, tribal, or local public health entities, healthcare delivery entities, public or private organizations with a specific focus, or emergency response entities. Registries may provide immunization history, immunization status or notifications of immunization needs of individuals or populations to clinicians, consumers, schools and similar entities, other registries, or those in public health roles.

- **Consumer**

The consumer perspective includes individuals who need or have received immunizations or other prevention and treatment interventions. Within the context of this use case, the consumer perspective includes individuals as well as family members (or surrogates) who are responsible for the healthcare of the individual. Consumers need access to their immunization history and need the ability to provide clinically verified immunization history or immunization status electronically to their clinicians, schools, public health organizations, other registries, etc.

- **Public Health**

The public health perspective includes federal, state, territorial, tribal and local public health organizations with responsibility to monitor the health status of populations or individuals. This role may also be present within healthcare delivery organizations or other entities having responsibility to monitor the health status of specific populations or individuals. Public health provides prevention and treatment guidelines to clinicians, evaluates the effectiveness of prevention and treatment interventions, and identifies prioritized intervention such as prophylaxis, treatment, isolation or quarantine for specific populations or individuals in non-routine or emergency situations. Public health may also have specific roles related to the recall of vaccines or drugs. The public health role that is at times associated with administering prophylaxis or treatment is included in the clinician perspective rather than the public health perspective. The public health role associated with procuring and distributing vaccines and drugs is described in the inventory manager perspective.

- **Inventory Reporting**

The inventory reporting perspective includes those roles within registries, clinical care organizations, public health organizations, and the pharmaceutical supply chain which are responsible for procuring, apportioning, distributing, monitoring, and reporting the status and usage of vaccines and drugs. During routine care activities of vaccine and drug administration, the reporting functions are typically conducted by care delivery organizations, pharmaceutical suppliers, distributors and/or registries. During non-routine or emergency situations, public health may be more directly involved in the decisions affecting apportionment, and distribution of prophylaxis and treatment interventions including, at times, the use of stockpiled resources. In non-routine or emergency situations individuals serving in inventory reporting roles may also monitor the availability and usage of resources to support those in isolation or quarantine, including the distribution of resources to those affected. In some situations, registries also support these activities.

- **Information Exchange**

The information exchange perspective may include 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, etc. These entities may support specific functional capabilities which assist in facilitating health information exchange activities. These perspectives are the focus of the events detailed in scenarios described in Section 6.0.

6.0 Use Case Scenarios

The scenarios in the Immunizations & Response Management Detailed Use Case describe the exchange of immunization and drug administration information between clinicians, registries, consumers, those individuals in public health roles, and those who report information describing the inventory status of vaccines and drugs. The scenarios describe ways in which processes and systems used during routine daily care activities could also be leveraged in emergency response situations. While the scenarios focus on the activities associated with routine vaccinations, they also incorporate additional activities which may be applicable in non-routine or emergency situations, such as countermeasure administration to include prophylaxis and treatment or support for isolation or quarantine. The scenarios are not intended to be comprehensive or limiting.

- **Vaccine and Drug Administration and Reporting**

  The Vaccine and Drug Administration and Reporting scenario focuses on the bi-directional exchange of immunization and drug administration information between clinicians, registries, and consumers during both routine and non-routine or emergency care activities. The scenario describes the flow of vaccination information from a clinician to the appropriate registries, as well as the mechanisms for registries to provide immunization status and history information to clinicians, consumers, schools, and public health officials. This scenario also describes processes by which registries or EHRs can inform clinicians about the specific immunization needs of their patients based on published immunization schedules. A process by which registries could retrieve information from other registries in order to provide a complete immunization history or immunization status is also included.

  This scenario also incorporates the flow of information coming from public health organizations when specific individuals have been identified as needing intervention based on public health case investigations. Also, if an adverse event is identified by a clinician following administration of a vaccine or drug, the use case describes the relationship to the adverse event reporting process which is described separately in the Public Health Case Reporting Detailed Use Case.

- **Vaccine and Drug Inventory Reporting**

  The Vaccine and Drug Inventory Reporting scenario focuses on the exchange of information regarding the availability, usage, and needs for vaccines and drugs at dispensing locations. The scenario describes the routine flow of information regarding vaccine and drug usage and processes for reporting the availability and usage of vaccines and drugs to public health. The process for identifying inventory needs in non-routine or emergency situations is also described.

7.0 Scenario 1: Vaccine and Drug Administration and Reporting

Figure 7-1. Vaccine and Drug Administration and Reporting

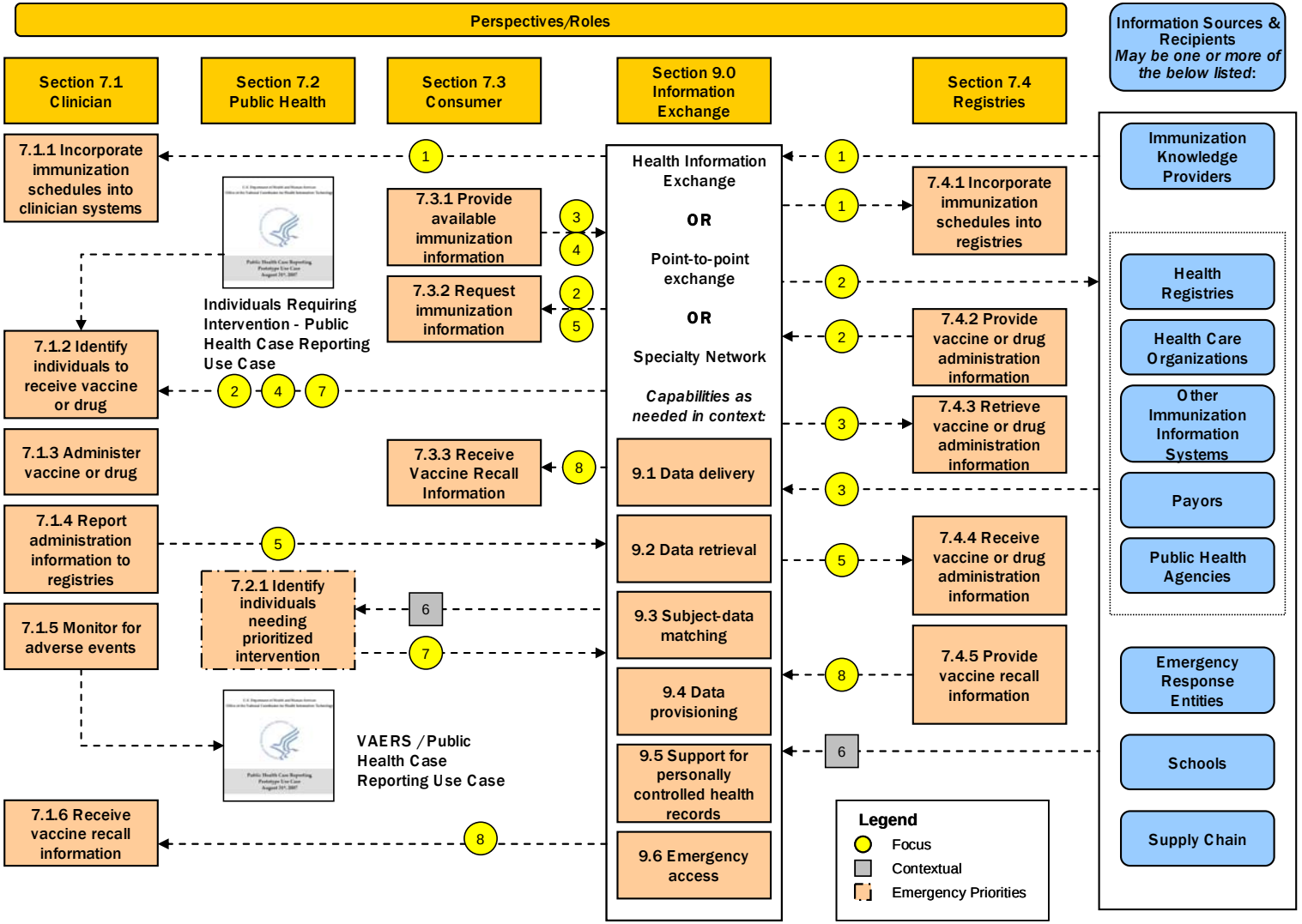

Figure 7-2. Vaccine and Drug Administration and Reporting Scenario Flows

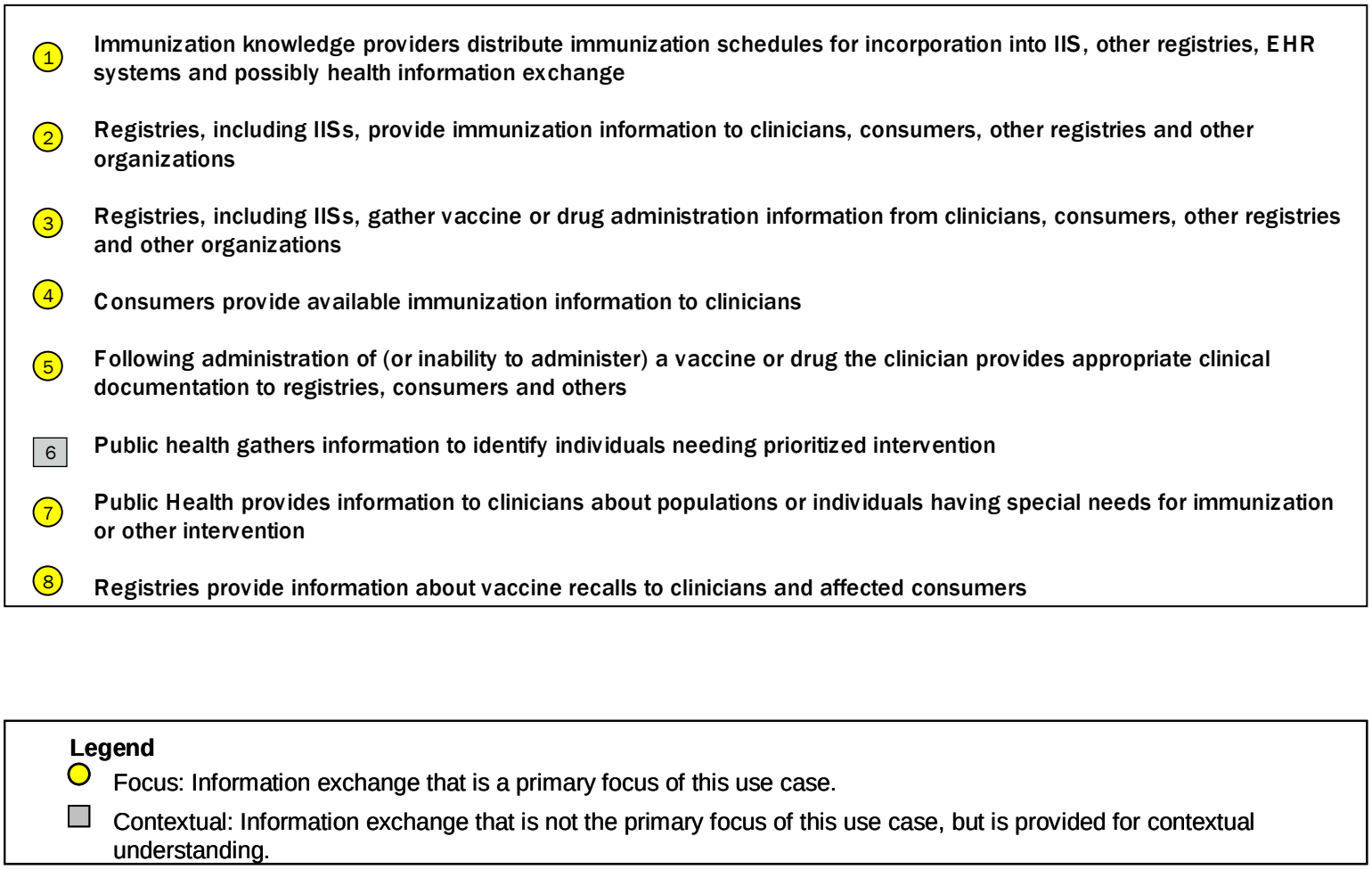

Figure 7-3. Clinician Perspective -Vaccine and Drug Administration and Reporting

Code	Description	Comments
7.1.1	**Event:** Incorporate immunization schedules into clinician systems	**Figure 7-1, Flow 1**
7.1.1.1	**Action:** Receive immunization schedules.	Immunization guidelines and schedules developed by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP),the Centers for Disease Control (CDC) as well as other federal, state, territorial, tribal and local public health organizations provide guidance to clinicians about the immunization needs of specific patient populations. Today these are available to clinicians in the form of published documents, web pages, or downloadable reference documents. In emergency situations, public health may also publish additional guidelines related to immunizations or administration of drugs, which need to be rapidly acted upon by clinicians. This use case assumes that knowledge suppliers will, in the future, be able to provide the schedules and related clinical criteria in an electronically interoperable form to clinicians and registries using various technical approaches that may include information delivered via messaging or file transfer or retrieved from a service.
7.1.1.2	**Action:** Incorporate immunization schedules into the clinician's EHR.	The electronic guidelines and schedules are incorporated into the EHR to provide decision support capabilities to the clinician. The use case does not propose that a specific technical approach be utilized for this activity. The intent may be accomplished in various ways, to include manually configuring the system, loading files containing standardized decision support algorithms and related vocabularies, or accessing an external service. Discussion about incorporating the schedules into an IIS is included in Event 7.4.1

Code	Description	Comments
7.1.2	**Event:** Identify individuals to receive vaccine or drug	**Figure 7-1, Flows 2, 4, 7**
7.1.2.1a	**Alternative Action**: Identify individuals needing immunization or drug.	Clinicians identify individuals who need to receive immunizations by referring to published immunization schedules, by receiving decision support guidance via their EHR, by receiving notifications from immunization registries, or by querying registries or consumer PHRs for immunization history or status. This information may also be available from administrative sources such as pharmacy benefits data or claims data. Using decision support capabilities, registries compare the immunization status of individuals to published immunization guidelines and schedules. The registries then send notifications to the appropriate clinician and/or patient about the immunizations that are needed. To support this activity, the registry may need to retrieve information from multiple sources as described in 7.4.3 in order to provide the requesting clinician with a complete immunization history for an individual.

Code	Description	Comments
7.1.2.1b	**Alternative Action**: Receive information about individuals needing prioritized intervention.	In non-routine or emergency situations, the clinician may receive information from public health which identifies population characteristics for those requiring special attention such as the elderly, emergency care providers, or other at-risk groups. This may include lists of specific individuals needing immunizations or other interventions. Public health may also identify individuals needing specific interventions based on possible or confirmed public health case reports as described separately in action 7.1.2 of the Public Health Case Reporting Detailed Use Case. Public health or others using information available within registries may also notify clinicians of individuals affected by vaccine or drug recalls, which is described in 7.1.6. of this use case.
7.1.3	**Event:** Administer vaccine or drug	
7.1.3.1	**Action:** Administer vaccine or drug to patient.	After completing any necessary clinical evaluation, contraindication checks, review of the patient's immunization history, and other medication safety activities, the clinician administers the vaccine or drug to the patient. The focus of this use case is on vaccines and drugs which would be administered by a clinician in a clinical care setting for routine care and to support most emergency situations. Some non-routine or emergency vaccines or drugs may be prescribed or dispensed to the patient, but not administered by the clinician. In those instances, some of the actions in 7.1.3.2 and 7.1.3.3 may be abbreviated or not occur as described.

Code	Description	Comments
7.1.3.2	**Action:** Record vaccine or drug administration information.	The clinician records information describing the administration activity including, but not limited to, patient information, site of administration, the vaccine or drug manufacturer, lot number, expiration date, and date administered in the clinical system. Portions of this information may have been previously gathered during the medication safety activities in action 7.1.3.1. A more complete discussion of the data needs is included in Section 10. In the case of a contraindication, the clinician documents the reason the vaccine or drug was not administered or why the administration schedule was modified. If the administration cannot be accomplished due to a shortage of the vaccine or drug, the clinician may also document this information.
7.1.4	**Event:** Report administration information to registries	**Figure 7-1, Flow 5**

Code	Description	Comments
7.1.4.1	**Action:** Report administration information to registries.	The clinician communicates the vaccine or drug administration information gathered in action 7.1.3.2 to appropriate registries, which may include IISs as well as other healthcare registries (e.g. emergency responder registries). The clinician or designee may carry out this activity using various information exchange capabilities such as, but not limited to, a web portal provided by the registry, interoperable messages communicated from the local EHR to the relevant registries, point-to-point communications, or other information exchange methods. In some situations, the designee may be a school, public health entity, prison, or similar organization which has gathered clinically verified information and provides it to the registry. This information may also be used by individuals involved in inventory reporting to update the information systems which monitor and report vaccine and drug usage and availability. In addition, information identifying expired doses, lost doses, etc., may need to be reported separately by the clinician perspective. At times it may be useful to report available doses which have been committed (or reserved) for a specific patient but have not yet been administered. There may be specific inventory reporting requirements for some programs (e.g. Vaccines for Children Program). In non-routine situations, information describing clinician orders for isolation or quarantine could also be communicated to registries in order for public health to identify those individuals affected and monitor their needs. Although not the focus of this use case, some registries use similar processes to gather other health status or screening information such as lead testing, hearing evaluations, EPSDT, anemia, etc.
7.1.5	**Event:** Monitor for adverse events	

Code	Description	Comments
7.1.5.1	**Action:** Monitor for adverse events.	Following administration of the vaccine or drug, the clinician monitors the patient for possible adverse events. Decision support may be available to the clinician to identify possible adverse events based upon patient clinical data recorded within the clinician's EHR and information incorporated into the EHR as described in the 2008 Public Health Case Reporting Detailed Use Case.
7.1.5.2	**Action:** Report adverse events.	If the clinician detects a possible adverse event, appropriate care is provided. Subsequently, the appropriate reporting procedures to various regulatory organizations are completed, utilizing VAERS or other public health case reporting capabilities as appropriate. This process is described separately in events and actions associated with 7.1 and 8.2.3 of the 2008 Public Health Case Reporting Detailed Use Case. Consumer self-reporting of vaccine adverse events is out-of-scope for the 2008 Immunizations and Response Management use case.
7.1.6	**Event:** Receive vaccine recall information	**Figure 7-1, Flow 8**
7.1.6.1	**Action:** Receive vaccine recall information from registries.	An IIS may identify individual consumers affected by a specific vaccine or drug recall. The registry notifies the consumer that a vaccine recall has been issued which may require a follow-up clinical evaluation. The focus of this notification is to inform the consumer of the clinical situation associated with the recall and provide appropriate guidance to the consumer (e.g. monitor for specific symptoms, initiate follow-up with their clinician, etc.). The process for notifying the clinician is described separately in Event 7.1.6. The mechanisms for communicating recalls from appropriate public health organizations and/or manufacturers to the IIS are out of scope for this use case.

Figure 7-4. Public Health Perspective - Vaccine and Drug Administration and Reporting

Code	Description	Comments
7.2.1	**Event:** Emergency Situations: Identify individuals needing prioritized intervention	**Figure 7-1, Flows 6 , 7**
7.2.1.1	**Action:** Conduct analysis to determine intervention priorities.	Based on the nature of the emergency situation, those in public health roles gather information to determine health status and characteristics of populations and individuals at-risk. This action and flow 5 has been included to provide context for subsequent activities. It is not a focus area for this use case.
7.2.1.2	Action: Notify clinicians of individuals or population characteristics needing prioritized intervention.	As represented by flow 7 those in public health roles may communicate information about specific individuals, or population characteristics of those who require prioritized intervention, to clinicians and/or registries.

Figure 7-5. Consumer Perspective - Vaccine and Drug Administration and Reporting

Code	Description	Comments
7.3.1	Event: Provide available immunization information	**Figure 7-1, Flows 3, 4**

Code	Description	Comments
7.3.1.1	**Action:** Provide available immunization information via a personally controlled health record.	Consumers may retain their immunization information in a personally controlled health record, such as a PHR or health record bank. This information may have been provided electronically by a clinician or registry, and also may include self-reported immunization information which has been supplied by the consumer. The consumer's immunization information is provided to clinicians or registries at the direction of the consumer, or in response to a query from a clinician or registry with appropriate consumer permissions. The consumer's immunization information may also be provided to schools and other entities with appropriate consumer permissions. The information provided may include a complete immunization history or the status of specific immunization(s). The original source of the information is identified to distinguish between a clinically verifiable source vs. consumer-entered data in order for the receiving clinician or registry to properly identify the source during subsequent activities.
7.3.2	**Event:** Request immunization information	**Figure 7-1, Flows 2, 5**
7.3.2.1	**Action:** Request available immunization information.	Consumers receive their immunization information from registries or EHRs and store it in their personally controlled health record. This process may occur automatically based on pre-defined consumer preferences for delivery of their health information, or as a result of a consumer-initiated query. This information may also be retrievable from administrative sources such as pharmacy benefits data or claims data.
7.3.3	**Event:** Receive vaccine recall information	**Figure 7-1, Flow 8**

Code	Description	Comments
7.3.3.1	**Action:** Receive vaccine recall information from registries.	An IIS may identify individual consumers affected by a specific vaccine or drug recall. The registry notifies the consumer that a vaccine recall has been issued which may require a follow-up clinical evaluation. The focus of this notification is to inform the consumer of the clinical situation associated with the recall and provide appropriate guidance to the consumer (e.g. monitor for specific symptoms, initiate follow-up with their clinician, etc.). The process for notifying the clinician is described separately in Event 7.1.6. The mechanisms for communicating recalls from appropriate public health organizations and/or manufacturers to the IIS are out of scope for this use case.

Figure 7-6. Registries Perspective - Vaccine and Drug Administration and Reporting

Code	Description	Comments
7.4.1	Event: Incorporate immunization schedules into registries	**Figure 7-1, Flow 1**
7.4.1.1	Action: Receive immunization schedules.	Immunization guidelines and schedules developed by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP),the Centers for Disease Control (CDC) as well as other federal, state, territorial, tribal and local public health organizations provide guidance to clinicians about the immunization needs of specific patient populations. Today these are available in the form of published documents, web pages or downloadable reference documents. In emergency situations, public health may also publish additional guidelines related to immunizations or administration of drugs, which need to be rapidly acted upon by clinicians. This use case assumes that knowledge suppliers will, in the future, be able to provide the schedules and related clinical criteria in an electronically interoperable form to clinicians and registries using various technical approaches that may include information delivered via messaging, file transfer or retrieved from a service.
7.4.1.2	Action: Incorporate immunization schedules into the registry.	The electronic guidelines and schedules are incorporated into the registry to provide decision support to the registry functions and users. The use case does not propose that a specific technical approach be utilized for this activity. The intent may be accomplished in various ways at times including manually configuring the system, loading files containing schedules or retrieving information from a service.

Code	Description	Comments
7.4.2	Event: Provide vaccine or drug administration information	**Figure 7-1, Flow 2**
7.4.2.1	Action: Provide vaccine or drug administration information.	A registry provides immunization or drug administration information to authorized requestors by means of a portal, by responding to an interoperable query message, or by proactively sending notifications about needed immunizations which have been generated by decision support evaluating the patient data contained within the registry. Registries could also distribute notifications to advise clinicians of specific individuals affected by a vaccine or drug recall as described in 7.4.5. Requests for information may be initiated by clinicians, public health, consumers, schools, or other entities which need to confirm the immunization status of an individual. The information provided may include a complete immunization history, status of specific immunization(s), or exceptions such as missed vaccinations or doses. As described in event 7.4.3, a registry may need to request information from other registries or other sources in order to construct a complete immunization history or status.
7.4.3	Event: Retrieve vaccine or drug administration information	**Figure 7-1, Flow 3**

Code	Description	Comments
7.4.3.1	Action: Retrieve vaccine or drug administration information from external sources.	A registry may need to gather immunization or drug administration information from other sources such as other registries, EHRs, personally controlled health records, pharmacies, healthcare payors, etc. This could be in response to a query received by the registry, or proactively initiated by the registry based on predefined business rules. While the query would typically relate to a specific individual, at times the query may request immunization or drug administration information about more than one person. The requesting registry queries the external sources, receives the responses, confirms that the patient-matching criteria have been met, and incorporates the information into the registry.
7.4.4	Event: Receive vaccine or drug administration information	**Figure 7-1, Flow 5**
7.4.4.1	Action: Receive information describing the administration of a vaccine or drug.	The registry receives vaccine or drug administration information from a clinician's EHR as described in event 7.1.4. The registry receives the information, confirms the patient-matching information, and updates the registry information with the vaccine or drug administration information. If the patient is unknown to the registry, it may initiate a new record for the patient, or carry out other actions to confirm the identity of the patient before updating the registry.

8.0 Scenario 2: Vaccine and Drug Inventory Reporting

Figure 8-1. Vaccine and Drug Inventory Reporting

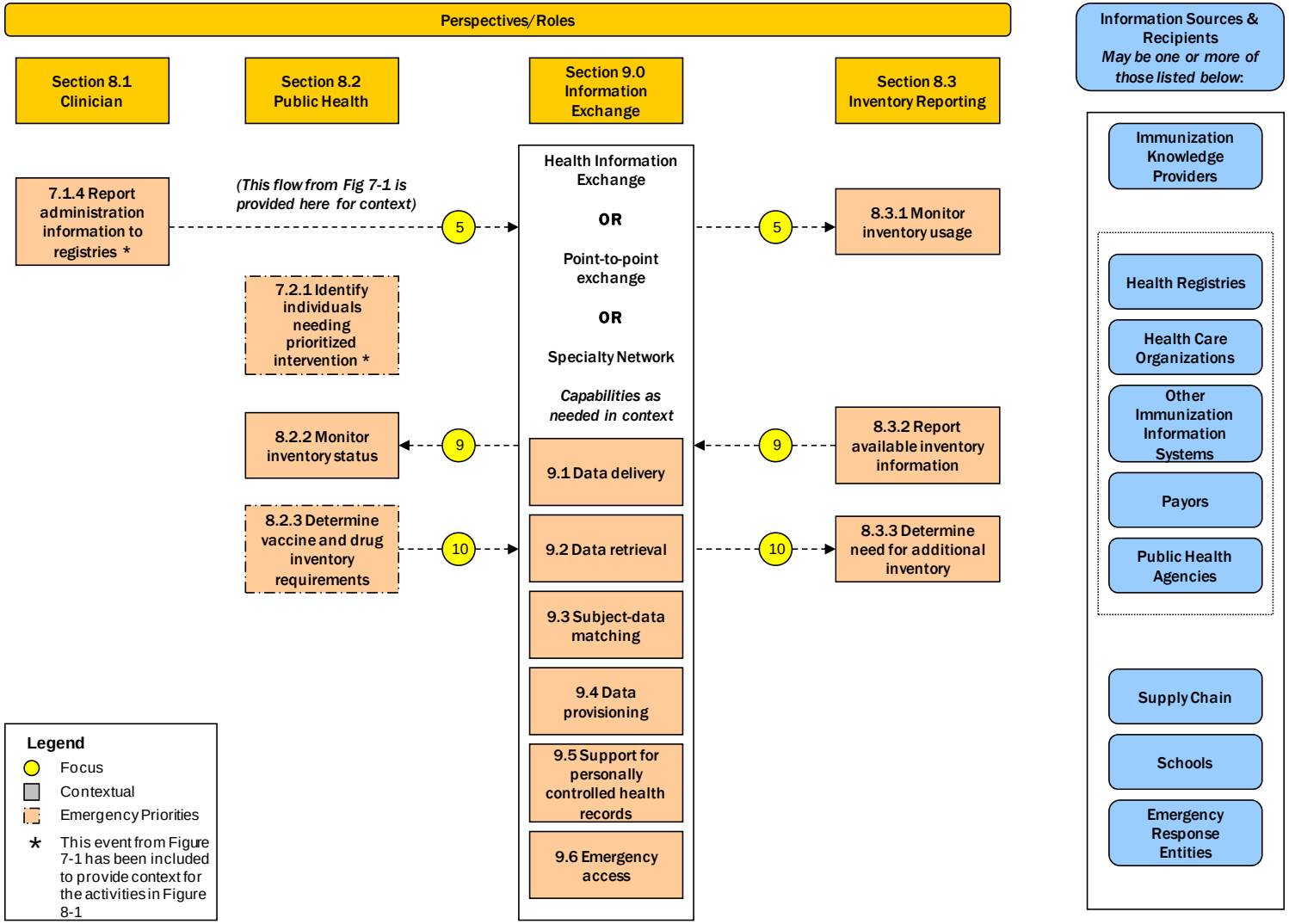

Figure 8-2. Vaccine and Drug Inventory Reporting Scenario Flows

5 Following administration of (or inability to administer) a vaccine or drug the clinician provides appropriate clinical documentation to registries, consumers and other system. This same information is communicated to the Inventory Reporting perspective. In addition, information about expired doses, lost doses, etc. would be communicated to Inventory Reporting.

9 Inventory Reporting communicates inventory availability and usage information to public health.

10 Public Health communicates vaccine and drug inventory needs.

Legend

- Focus: Information exchange that is a primary focus of this use case.
- Contextual: Information exchange that is not the primary focus of this use case, but is provided for contextual understanding.

Figure 8-3. Clinician Perspective - Vaccine and Drug Inventory Reporting

Code	Description	Comments
7.1.4	**Event**: Report administration information to registries	**This Event was introduced in Figure 7-1 and described in Figure 7-3. It has been included in Figure 8-1 along with flow 5 in order to provide context for event 8.3.1.**
7.1.4.1	**Action**: Report administration information to registries.	The clinician communicates the vaccine or drug administration information gathered in Figure 7-1 Event 7.1.3 to the appropriate registries, which may include IISs as well as other healthcare registries (e.g. emergency responder registries). The clinician, or designee, may carry out this activity using various information exchange capabilities such as, but not limited to, a web portal provided by the registry, interoperable messages communicated from the local EHR to the relevant registries, point-to-point communications or other information exchange methods. In some situations, the designee may be a school, public health entity, prison or similar organization which has gathered clinically verified information and provides it to the registry This information may also be used by individuals involved in inventory reporting to update the information systems which monitor and report vaccine and drug usage and availability. In addition, information identifying expired doses, lost doses, etc., may need to be reported separately by the clinician perspective. At times it may be useful to report available doses which have been committed (or reserved) for a specific patient but have not yet been administered. There may also be specific inventory reporting requirements for some programs (e.g. Vaccines for Children Program). Notification of recalled doses is described separately in Figure 7-1 flow 7 event 7.4.5

Figure 8-4. Public Health Perspective - Vaccine and Drug Inventory Reporting

Code	Description	Comments
7.2.1	**Event:** Emergency Situations: Identify individuals needing prioritized intervention	**This event was previously introduced in Figure 7-1 and described in Figure 7-4. It has been included in the Vaccine and Drug Inventory Reporting information flow in order to provide context for events 8.2.2 and 8.2.3**
7.2.1.1	**Action:** Identify individuals needing prioritized intervention.	In a non-routine or emergency situation, those in public health roles may identify individuals who need to be prioritized for immunization or drug administration. This step is included to provide context for subsequent steps in the use case. The information needs and processes for conducting this activity are outside of the scope of this use case.
8.2.2	**Event:** Monitor inventory status	**Figure 8-1, Flow 9**
8.2.2.1	**Action:** Receive and monitor inventory status information.	Those individuals in public health roles receive inventory information from those involved in inventory reporting activities describing the locations, types, quantities, manufacturers, lot numbers and expiration dates of the available vaccines and drugs. Information about the usage of vaccines and drugs may also be included. At times it may be useful to report available doses which have been committed (or reserved) for a specific patient but have not yet been administered. There may also be specific inventory reporting requirements (e.g. Vaccines for Children Program). This information may be provided routinely as described in event 8.3.2, or upon request (e.g. a query) initiated by public health.
8.2.3	**Event:** Emergency Situations: Determine vaccine and drug inventory requirements	**Figure 8-1, Flow 10**

Code	Description	Comments
8.2.3.1	**Action:** Determine vaccine and drug inventory requirements.	In an emergency situation, public health officials may identify individuals who need to be prioritized for immunization or drug administration as described in Event 7.2.1. In order to provide an adequate supply of vaccine or drug at the appropriate locations, public health officials may use this information to estimate the inventory requirements needed to meet the emergency situation. As described in event 8.2.2 Flow 9, public health officials receive inventory status information from inventory reporting, which can be used to identify the availability of vaccines or drugs to meet the emergency need at the required locations. Public health officials use the inventory status information and the estimated inventory requirements to determine the additional inventory needed at a specific location or where inventory can be redeployed to meet the need at a different location.
8.2.3.2	**Action:** Communicate inventory requirements to the inventory reporting perspective.	Public health officials communicate the inventory requirements to those involved in inventory reporting and management. The information communicated could include the type of vaccine or drug, quantity, delivery location(s), and delivery instructions, including redeployment instructions if appropriate.

Figure 8-5. Inventory Reporting Perspective - Vaccine and Drug Inventory Reporting

Code	Description	Comments
8.3.1	**Event:** Monitor inventory usage	**Figure 8-1, Flow 5**
8.3.1.1	**Action:** Monitor inventory usage.	The vaccine or drug administration information communicated to registries in Event 7.1.4 is also communicated to the inventory reporting perspective in order to update inventory usage and availability information. Information identifying expired doses, lost doses, etc, may also need to be reported by the clinician perspective. At times it may be useful to report available doses which have been committed (or reserved) for a specific patient but have not yet been administered. Notification of recalled doses is described separately in Figure 7-1 Event 7.4.5
8.3.2	**Event:** Report available inventory information	**Figure 8-1, Flow 9**
8.3.2.1	**Action:** Report available inventory information.	The inventory reporting perspective reports information describing the locations, types, quantities, manufacturers, lot numbers and expiration dates of the available vaccines and drugs. Information about the usage of vaccines and drugs may also be included. At times it may be useful to report available doses which have been committed (or reserved) for a specific patient but have not yet been administered. There may also be specific inventory reporting requirements (e.g. Vaccines for Children Program). This information may be provided routinely or upon request (e.g. a query) from public health
8.3.3	**Event:** Determine need for additional resources	**Figure 8-1, Flow 9**
8.3.3.1	**Action:** Receive inventory requirements information.	The inventory perspective receives information from public health describing the inventory requirements for vaccines or drugs. This information may include the specific vaccine or drug required, the quantity required, the location(s) needing the vaccine or drug and details about delivery requirements.

Code	Description	Comments
8.3.3.2	**Action:** Determine need for additional inventory of vaccines or drugs.	The inventory reporting perspective evaluates the available inventory of vaccines or drugs in order to determine whether the requirements received from public health can be met by the existing inventory. The information exchanges and related processes for ordering additional inventory are out-of-scope for this use case.

9.0 Information Exchange

This section highlights selected information exchange capabilities which enable the scenarios described in this use case. These functional capabilities may be provided fully or partially by a variety of organizations including free-standing or geographic health information exchanges (e.g. RHIOs), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, and others supporting these capabilities.

Figure 9-1. Immunizations & Response Management Information Exchange Capabilities

Code	Capability	Comments
9.1	Data delivery – including secure data delivery, data receipt including confirmation of delivery to EHRs, personally controlled health records, other systems and networks	Capability to securely deliver data to the intended recipient and confirm delivery, including the ability to route data based on message content if required. For example, routing may be applicable to identify the clinician who should receive notification from a registry that a patient is due for a scheduled immunization.
9.2	Data retrieval – including data lookup, retrieval and data location registries	Capability to locate and retrieve requested data subject to consumer access decisions and local policies. For example, responding to a clinician's request for an individual's immunization history information involves identifying the appropriate registry(ies) to query as well as delivery of the available information to the requestor.
9.3	Subject-data matching	Capability to match available data to the appropriate person during retrieval or routing. For example, when a clinician makes a request for immunization history information for a specific person, the systems, processes and policies facilitating information exchange are utilized to confirm that the data available for retrieval match the person of interest to the clinician.

Code	Capability	Comments
9.4	Data provisioning – including support for secondary uses; data provisioning and distribution of data transmission parameters	Capability to distribute pre-defined data reporting specifications, data filtering or triggering criteria, logical algorithms, reporting vocabularies, or similar information to target systems so that these systems can implement the associated capabilities to gather and report information for secondary uses. The Immunizations & Response Management Detailed Use Case implements a portion of this capability, specifically the ability to distribute interoperable immunization schedules and guidelines to EHRs and IISs. This same capability could be used by public health in non-routine situations to distribute information about the needs of special populations such as the elderly, emergency responders, or those with special needs.
9.5	Support for personally controlled health records – including managing consumer-identified locations to store their personally controlled health information; support consumer requests for information as well as routing of information to the consumer's preferred personally controlled health record	Capability to maintain and implement information identifying the consumer's preferred personally controlled health record (e.g. a PHR or health record bank) to support data routing and retrieval. For example, vaccination information provided by a clinician could be delivered to the consumer's preferred personally controlled health record through this process. Similarly, a consumer could retrieve and retain their immunization history in their personal health record.

Code	Capability	Comments
9.6	Emergency access – including capabilities to support appropriate individual and population emergency access needs	Capability to enable access to health information in extraordinary situations in which an individual may need emergency care but due to their health status is incapable of granting access permissions, or in the case of a public health emergency during which the health status of a population needs to be determined. For example this need could arise if an individual who has elected to not participate in network exchange of their information subsequently experiences a health situation which needs emergency care while incapacitated or unconscious. In emergency situations, public health officials may need to access immunization status information in order to identify populations or specific individuals at-risk.

While not described in this section, other capabilities support information exchange including data integrity and non-repudiation checking; subject and user identity arbitration with like identities during information exchanges; access logging and error handling for data access and exchange; consumer review of disclosure and access logs; and routing consumer requests to correct data.

Health information exchange (HIE): For the purpose of this use case, the functional capability to exchange health information between networks in order to exchange the health information of individuals or populations. These functional capabilities may be provided fully or partially by a variety of organizations including free-standing or geographic health information exchanges (e.g. RHIOs), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, and others supporting these capabilities.

Specialty Network – may provide all, or a portion of the capabilities needed to accomplish the activities involved in the exchange of health information. Specialty networks may focus on the exchange of specific types of health information, may focus on specific patient populations, may focus on the capabilities needed to support specific types of healthcare activities, or may perform a combination of information exchange activities and other services.

Point-to-Point Exchange: For the purposes of this use case, point-to-point exchange includes direct interactions between two systems which do not involve intermediary information exchange functions to route and deliver the data. Representative architectures

could include point-to-point messaging, service-oriented-architectures, or information exchange among participants using a common application platform.

10.0 Immunizations and Response Management Data Set Considerations

The Immunizations and Response Management Detailed Use Case describes the exchange of information to support the needs of consumers, clinicians, public health, registries, and inventory reporting. Work has been done in several organizations, including AIRA, CDC and HL7, to develop the detailed information requirements necessary to support these activities. Information needs for medications are also described in the 2007 Medication Management Detailed Use Case.

This section summarizes, at high level, the types of data which may need to be exchanged to support the interactions described in the use case. The listing is intended to be representative, not exhaustive nor limiting.

Data set considerations for this use case include:

- Vaccination information describing the individual receiving the vaccination, the vaccine, manufacturer, lot number, expiration date, dosage amount, dilutent, date/time and method of administration, the organization and clinician administering the vaccine. This may also include reasons that a vaccine could not be administered, such as the presence of a contraindication for the patient, documented immunity, or non-availability of the required vaccine. The source of this information would need to be identified as coming from a clinically verifiable source, self-reported by a consumer, or provided from another non-clinically verifiable source. For certain vaccine programs, there may additional reporting requirements such as vaccine payment type, VCF eligibility status Administration of drugs or other prophylaxis or treatment intervention may include similar types of information.

- Immunization history information describing all vaccinations received by an individual, including the dates administered, administering clinician, manufacturer and lot number, etc. The source of this information would need to be identified as coming from a clinically verifiable source, self-reported by a consumer, or provided from another non-clinically verifiable source. History of administration of drugs or other prophylaxis or treatment interventions may include similar types of information.

- Immunization status includes information describing the presence or absence of a specific immunization based upon published immunization schedules or other criteria. Status of the administration of drugs or other prophylaxis or treatment interventions may include similar types of information.

- Information identifying individuals needing prioritized intervention includes the population characteristics of those individuals needing intervention, or may include information describing specific individuals needing intervention.

- Inventory usage information includes detailed information identifying the quantity of vaccine utilized in a specific period of time, by location, by clinician, or by other geographic or non-geographic identifiers. Inventory usage information may also include manufacturer, lot number, expiration date, and other indicators relevant to the process of managing the pharmaceutical supply chain.

- Inventory availability information includes detailed information identifying the quantity of vaccine or drugs available at a specific point in time, by location, or by other geographic or non-geographic identifiers. Information about on-hand inventory which has been committed or reserved for a specific use would also be included. Inventory availability information also includes manufacturer, lot number, expiration date, and other indicators relevant to the process of managing the pharmaceutical supply chain.

Appendix A: Glossary

These items are included to clarify the intent of this use case. They should not be interpreted as approved terms or definitions but considered as contextual descriptions. There are parallel activities underway to develop specific terminology based on consensus throughout the industry.

AHIC: American Health Information Community; a federal advisory body chartered in 2005, serving to make recommendations to the Secretary of the U.S. Department of Health and Human Services regarding the development and adoption of health information technology.

Care: Relieving the suffering of individuals, families, communities, and populations by providing, protecting, promoting, and advocating the optimization of health and abilities.

CCHIT: The Certification Commission for Healthcare Information Technology; a recognized certification body for electronic health records (EHR) and their networks, as well as an independent, voluntary, private-sector initiative. CCHIT's mission is to accelerate the adoption of health information technology by creating an efficient, credible, and sustainable certification program.

Clinicians: Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, psychologists, pharmacists, and other licensed and credentialed personnel involved in treating patients.

CMS: Centers for Medicare & Medicaid Services; a federal agency within the Department of Health and Human Services that administers Medicare, Medicaid, and the State Children's Health Insurance Program.

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.

Decision Support: An activity that enables improved analysis and conclusions based on related information, recent research, algorithms, or other resources. In a clinical environment, decision support can help clinicians make more informed care decisions based on these resources. Clinical decision support is a related activity with specific components such as best practice guidelines, medication contraindication information, and access to recent research.

Department of Health and Human Services (HHS): The United States federal agency responsible for protecting the health of the nation and providing essential human services with the assistance of its operating divisions that include: Administration for Children and Families (ACF), Administration on Aging (AOA), Agency for Healthcare Research and Quality

(AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Services (IHS), National Institutes of Health (NIH), Program Support Center (PSC), and Substance Abuse and Mental Health Services Administration (SAMHSA).

Electronic Health Record (EHR): An electronic, cumulative record of information on an individual across more than one health care setting that is collected, managed, and consulted by professionals involved in the individual's health and care. This EHR description encompasses similar information maintained on patients within a single care setting (a.k.a., Electronic Medical Record (EMR)).

Electronic Health Record (EHR) System Suppliers: Organizations which provide specific EHR solutions to clinicians and patients such as software applications and software services. These suppliers may include developers, providers, resellers, operators, and others who may provide these or similar capabilities.

FDA: Food and Drug Administration; a federal agency within the Department of Health and Human Services responsible for the safety regulation of foods, dietary supplements, vaccines, drugs, medical devices, veterinary products, biological medical products, blood products, and cosmetics.

Geographic Health Information Exchange/Regional Health Information Organization: A multi-stakeholder entity, which may be a free-standing organization (e.g., hospital, healthcare system, partnership organization) that supports health information exchange and enables the movement of health-related data within state, local, territorial, tribal, or jurisdictional participant groups. Activities supporting health information exchanges may also be provided by entities that are separate from geographic health information exchanges/Regional Health Information Organizations including integrated delivery networks, health record banks, and others.

Government Agencies: Federal, local, state, territorial, or tribal departments within the United States 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.

Health Record Banks: Entities/mechanisms for holding an individual's lifetime health records. This information may be personally controlled and may reside in various settings such as hospitals, doctor's offices, clinics, etc.

Healthcare Entities: Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health programs, school health programs, dental clinics, psychology clinics, care delivery organizations, pharmacies, home health agencies, hospice care providers, airport clinics, mass vaccination sites, public health agencies, retail store clinics, and other healthcare facilities.

Healthcare Payors: Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.

HITSP: The American National Standards Institute (ANSI) Healthcare Information Technology Standards Panel; a body created in 2005 in an effort to promote interoperability and harmonization of healthcare information technology through standards that would serve as a cooperative partnership between the public and private sectors.

Inventory Managers: Individuals, from public or private organizations, who are responsible for coordinating inventory resources to support the delivery of care. These individuals determine the needs and coordinate logistics (including interacting with suppliers and vendors) to support the delivery of care.

Knowledge Providers: Associations of public health individuals/organizations who provide technical and clinical advice/guidance and assistance to state and local health agencies in a broad range of areas including: occupational health, chronic diseases, injury control, and maternal and child health.

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

On-site Care Providers: On-site care providers are the initial personnel to deliver medical care at the scene of an incident. While this would typically be emergency medical

technicians (EMTs), it can also include medically trained fire, law enforcement, and uniformed services medical personnel and civilian disaster medical assistance teams (DMATs).

ONC: Office of the National Coordinator for Health Information Technology; serves as the Secretary's principal advisor on the development, application, and use of health information technology in an effort to improve the quality, safety, and efficiency of the nation's health through the development of an interoperable harmonized health information infrastructure.

Patients: Members of the public who receive healthcare services.

Personal Health Record (PHR): An electronic, cumulative record of health-related information on an individual, drawn from multiple sources, that is created, collected, and managed by the individual or an agent acting for the individual. The content of and rights of access to the PHR are controlled by the individual or agent. The PHR is also known as the electronic Personal Health Record (ePHR).

Personal Health Record (PHR) System Suppliers: Organizations which provide specific PHR solutions to clinicians and patients such as software applications and software services. These suppliers may include developers, providers, resellers, operators, and others who may provide these or similar capabilities.

Pharmacies: Organizations that dispense pharmaceuticals to consumers, utilize data to check for contraindications and allergies, and potentially participate as an intermediary or sub-network provider of data on dispensed medications or provide PHR services.

Pharmacists: Health professionals and clinicians who are licensed to prepare and dispense medication pursuant to the request of authorized prescribers. The practice of pharmacy includes, but is not limited to, the assessment, monitoring, and modification of medication and the compounding or dispensing of medication. Direct care activities that pharmacists can perform include patient education, patient assessment, and consultation.

Point-to-Point Exchange: Point-to-point exchange includes direct interactions between two systems which do not involve intermediary information exchange functions to route and deliver the data. Representative architectures could include point-to-point messaging, service-oriented-architectures, or information exchange among participants using a common application platform.

Providers: The healthcare clinicians within healthcare delivery organizations with direct patient interaction in the delivery of care, including physicians, nurses, psychologists, and other clinicians. This can also refer to healthcare delivery organizations.

Public and Private Immunology, Vaccine Response, and Adverse Event Experts: Governmental organizations, and physician associations which make decisions or

recommendations on issues including: licensing vaccines, establishing effective and safe dosages, establishing schedules for vaccine administration based on immunology principles, pre- or post- exposure prophylactics, proper handling of vaccines, reporting of adverse events, and defining adequate documentation of vaccination events for coverage assessments and recall of patients or vaccine lots.

Public and Private Sector Supply Chain: Entities involved in the production, storage, and distribution of medication and immunization products at the community, regional, and national level, such as pharmaceutical or vaccine manufacturers, drug and vaccine wholesalers/distributors, and pharmacies and retail delivery organizations.

Public Health Agencies/Organizations (federal/state/local/territorial/tribal): Federal, state, local, territorial, and tribal government organizations and clinical care personnel that exist to help protect and improve the health of their respective constituents. These organizations are also involved in the coordination of ordering and distributing resources such as vaccines.

Public Health Knowledge Providers: Associations of public health individuals/organizations who provide technical advice and assistance to state and local health agencies in a broad range of areas including: occupational health, infectious diseases, immunization, environmental health, chronic diseases, injury control, and maternal and child health.

Registries: Organized systems for the collection, storage, retrieval, analysis, and dissemination of information to support health needs. This also includes government agencies and professional associations which define, develop and support registries.

Resource Managers: Individuals who are responsible for coordinating resources to support the delivery of care. These individuals determine the needs and coordinate logistics to support the delivery of care.

Response Management Organizations: Organizations that are responsible for emergency evaluation and response to natural disasters (e.g., public health and emergency management organizations (Federal Emergency Management Agency, Red Cross, etc.)).

Schools: Organizations that provide education and can also serve in a public health support role. Educational facilities may have vaccination requirements for matriculation. In some instances, schools have are delegated to input vaccination status/history into data repositories such as Immunization Information Systems (IISs).