U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Immunizations & Response Management

Draft Detailed Use Case

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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) are now being developed into the 2008 Use Cases which will be processed in the national HIT agenda activities in 2008.

The 2008 Use Cases are being 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 are being developed in two stages:

- The **Prototype Use Cases** describe the candidate workflows for the use case at a high level, and facilitate initial discussion with stakeholders; and

- The **Detailed Use Cases** document all of the events and actions within the use case at a detailed level.

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

This Draft 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 draft detailed use case.

Following receipt of feedback from interested stakeholders, ONC will develop a final 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 medication, vaccinations, and other specific medical prophylaxis and treatment methods. The Immunizations and Response Management Draft 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, recognizing that portions of the needs during non-routine or emergency situations and to support public health outcomes could be accomplished using the same infrastructure. This use case 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 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 regarding 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 Draft 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 status of populations relative to having received treatment or prophylaxis; 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 and the administration of vaccines or drugs based on routine schedules, or priorities dictated by emergency response. Additionally, this scenario describes the exchange of data necessary to support the administration of prophylaxis and treatment modalities, and the supply

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

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

There are associations between the scenarios in this use case and the scenarios in the Public Health Case Reporting Draft Detailed Use Case.

This use case assumes the developing presence of electronic systems such as electronic health records (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, and other 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.
Geographic Health Information Exchange/Regional Health Information Organizations	A multi-stakeholder entity, which may be a free-standing organization (i.e., hospital, healthcare system, partnership organization, etc.) that supports health information exchange and enables the movement of health-related data within state, local, territorial, 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	Local, state, territorial, or federal departments within the United States government responsible for the oversight and administration of a specific function; government agencies may include: Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), and Department of Homeland Security (DHS), Department of Homeland Security, and the National Guard.
Healthcare Entities	Organizations that are engaged in, or support the delivery of, healthcare. These organizations could include ambulatory clinics, airport clinics, care delivery organizations, community-based healthcare organizations, dental clinics, employers/occupational health, hospitals, long-term care facilities, mass vaccination sites, pharmacies, psychology clinics, public health agencies, retail store clinics, school health, and other healthcare facilities.
Healthcare Payros	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.

Stakeholder	Contextual Description
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.
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 principals, defining "take" responses, 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, and pharmacies and retail delivery organizations.
Public Health Agencies/Organizations (local/state/territorial/federal)	Local, state, territorial and federal 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.

Stakeholder	Contextual Description
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).

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.

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

- **Confidentiality, privacy, and security:**

    o   Consumers may require privacy controls for personal health information that govern how patient data is accessed, viewed, and communicated. Privacy controls and the means of restricting data access, which are available for paper-based records, are not currently available for electronic records.

        - Without permissions and controls, consumer participation in the act of electronic health information exchange may be limited.

    o   There are regulations concerning the storage, transmission, or destruction of electronic health information. These regulations are inconsistent across federal, state, and local jurisdictions.

        - Without consistent standards, the viewing, accessing, or transmitting of electronic health information may be inhibited.

- **Information integrity, interoperability, and exchange:**

    o   Incomplete, inaccurate, or proprietarily-formatted information prevents efficient exchange 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:**

    o   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 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:**

    o 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.

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

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

- **Clinical Decision Support:**

    o The capabilities, requirements, and standards needed for consistent development and implementation of Clinical Decision Support 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.

    o 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.

- Without an aggregated data set of immunization information, it is difficult to assemble a complete immunization history or accurately determine 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 vary between jurisdictions and are not available in an electronically interoperable form for inclusion in EHRs 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 nor 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 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 gather information describing the intervention status of individuals or populations from multiple sources.

  - 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 and the release of immunization information in the event of a public health emergency.

  o This inconsistency limits the ability to exchange immunization information across state borders for routine care as well as during non-routine situations.

5.0 Use Case Perspectives

The Immunizations and Response Management Draft 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, and inventory managers. 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, 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 and reporting immunization "take" or effectiveness of, and adverse events from, the interventions administered. This role includes clinicians who are responsible for administering prophylaxis or treatment in a public health clinic or other care setting.

- **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 immunization information systems (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, 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, 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 Manager**

The inventory manager perspective includes those roles within 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. Within routine care activities of vaccine and drug administration, these functions are carried out by the care delivery organizations and their pharmaceutical suppliers. During non-routine or emergency situations, public health may be more directly involved in the decisions affecting procurement, apportionment, and distribution of prophylaxis and treatment interventions. In non-routine or emergency situations inventory managers 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 support this activity by providing usage information to inventory managers.

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 Draft 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 manage the inventories 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 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 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 Draft Detailed Use Case.

- **Vaccine and Drug Inventory Management**

  The Vaccine and Drug Inventory Management 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 vaccine and drug usage information to the inventory manager 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, as is a mechanism for informing the vaccine or drug suppliers or distributors of the needs.

7.0 Scenario 1: Vaccine and Drug Administration and Reporting

Figure 7-1. Vaccine and Drug Administration and Reporting
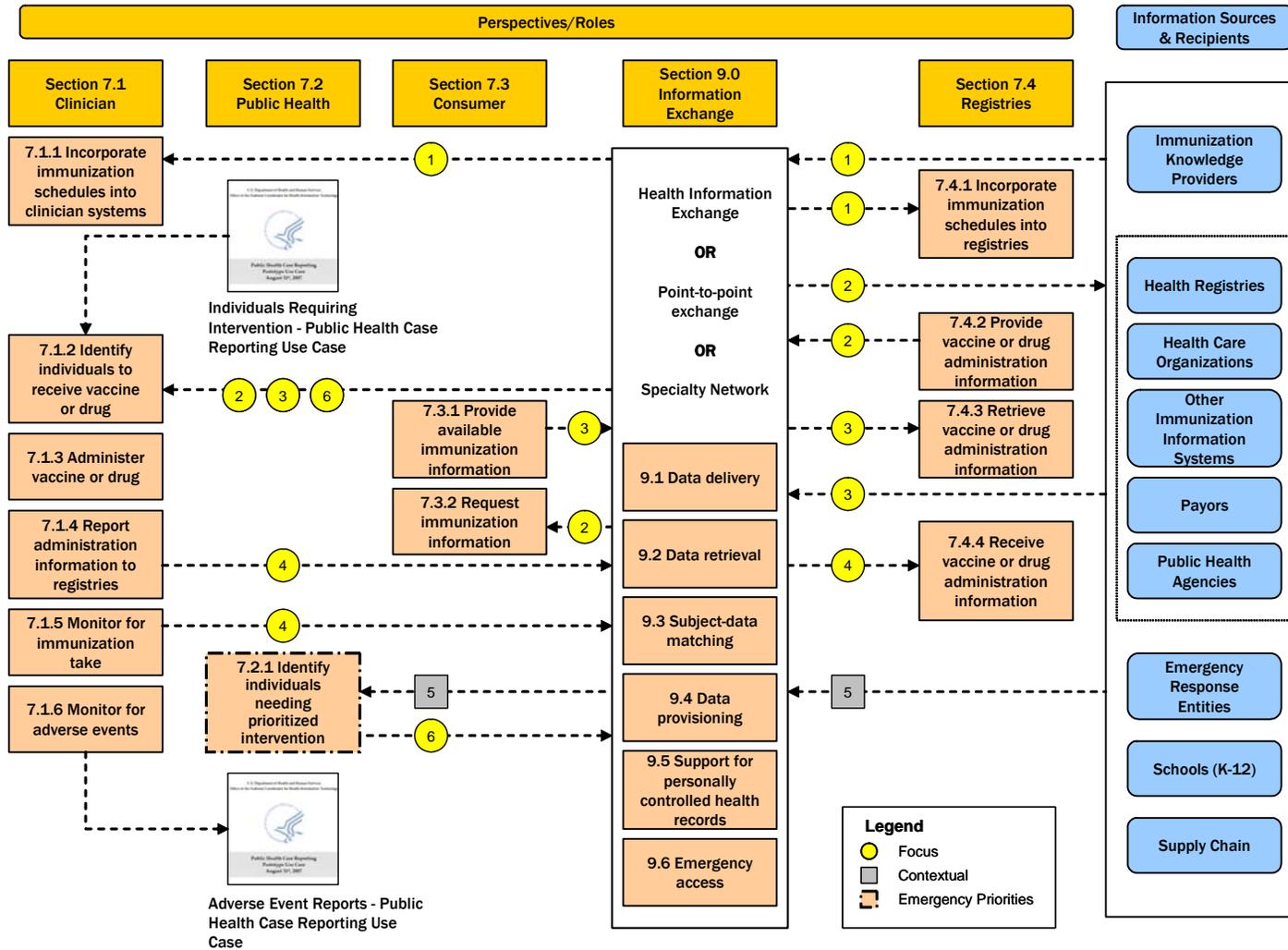
Figure 7-2. Vaccine and Drug Administration and Reporting Scenario Flows

1. Immunization knowledge providers distribute immunization schedules for incorporation into registries and EHR systems.

2. Registries, including IISs, provide immunization to clinicians, consumers, other registries and other organizations

3. Registries, including IISs, gather vaccine or drug administration information from clinicians, consumers, other registries and other organizations.

4. Following administration of (or inability to administer) a vaccine or drug the clinician provides appropriate clinical documentation to registries, consumers and others including subsequently reporting immunization "take" if appropriate.

5. Public health gathers information to identify individuals needing prioritized intervention.

6. Public health provides information to clinicians about populations or individuals having special needs for immunization or other intervention.

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

Code	Description	Comments
7.1.1	**Event:** Incorporate immunization schedules into clinician systems	
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), and federal, state, territorial, 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. In the future, these schedules and guidelines could be incorporated into the clinician's EHR system as well as an IIS in order to provide decision support guidance and reminders to clinicians regarding the immunization needs of their patients. This use case assumes that knowledge suppliers will, in the future, provide the schedules and related clinical criteria in an electronically interoperable form to clinicians and registries in processes similar to that currently in place to provide clinical guidelines for drug:allergy and drug:drug interaction checking.
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. This may be accomplished by manually configuring the system or by loading files containing standardized decision support algorithms and related vocabularies.
7.1.2	**Event:** Identify individuals to receive vaccine or drug	

Code	Description	Comments
7.1.2.1a	**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 from their EHR, by receiving notifications from immunization registries, or by querying registries for immunization history or status. At times information may also be available from administrative sources such as pharmacy benefits data or claims data. A registry may need to query other registries in order to provide a complete immunization history of an individual to the requesting clinician. Utilizing decision support capabilities, registries evaluate the immunization status of individuals and compare them to published immunization guidelines and schedules. The registries then send notifications to the appropriate clinician of the immunizations that are needed.
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 immunization or other intervention. Population characteristics information could also be incorporated into the clinician's EHR or an IIS as described in actions 7.1.1.1 and 7.1.1.2. Public health may also identify individuals needing specific interventions based on possible or confirmed public health case reports as described separately in action 7.1.7.2 of the Public Health Case Reporting Draft Detailed Use Case. Public health or others using information available within registries may also notify clinicians of individuals affected by vaccine or drug recalls.
7.1.3	**Event:** Administer vaccine or drug	

Code	Description	Comments
7.1.3.1	**Action:** Administer vaccine or drug to patient	After completing any necessary clinical evaluation, contraindication checks, and medication safety activities, the clinician administers the vaccine or drug to the patient.
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 (e.g. using barcode technologies). 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	

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 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 a web portal provided by the registry or communication from the clinician's EHR to the relevant registries. In some situations, the designee may be a school, public health entity, prison or similar organization which has gathered clinically verified information and wishes to provide it to the registry. This information may also be used by inventory managers to update the systems which monitor and report vaccine and drug usage and availability. 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 also use similar processes to gather other health status or screening information such as lead testing, hearing evaluations, EPSTD, anemia, etc.
7.1.5	**Event:** Monitor for immunization "take"	
7.1.5.1	**Action:** Monitor for immunization "take"	Based on appropriate and relevant clinical guidance that pertain to the specific vaccine administered, the clinician monitors for specific clinical indications that confirm "immunization take", and records the outcome. "Immunization take" in the context of this use case encompasses the activities related to determining whether the vaccination accomplished intent without clinical confirmation. The use of this term does not encompass specific clinical activities that determine seroconversion, immunity, or vaccine response. The activities that this term does describe include visual examination of the administration site, and identification of adverse events.

Code	Description	Comments
7.1.5.2	**Action:** Report immunization "take" results to registries	At times the clinician may need to communicate the vaccine take information gathered in action 7.1.5.1 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 a web portal provided by the registry or by initiating interoperable messages from the local EHR to the relevant registries.
7.1.6	**Event:** Monitor for adverse events	
7.1.6.1	**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 in action 7.1.1.1.
7.1.6.2	**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. This process is described separately in actions 7.3.6.1 and 7.3.6.2 of the Public Health Case Reporting Draft Detailed 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	
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 step 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	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. This information could be communicated utilizing web portals or interoperable messages to the clinician's EHR or an IIS as described in action 7.1.1.1.

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

Code	Description	Comments
7.3.1	Event: Provide available immunization information	

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 data bank. This information may have been provided electronically by a clinician and also may include self-reported immunization information which has been supplied by the consumer. The consumer's immunization information is sent to clinicians or registries at the direction of the consumer, or in response to a query from a clinician or registry with appropriate consumer consent. The consumer's immunization information may also be provided to schools and other entities to verify their immunization status. The information provided may include a complete immunization history or the status of specific immunization(s). The original source of the information will be 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	
7.3.2.1	**Action:** Request available immunization information	Consumers may retrieve 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, or as a result of a consumer-initiated query. At times this information may also be retrievable from administrative sources such as pharmacy benefits data or claims data.

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

Code	Description	Comments
7.4.1	Event: Incorporate immunization schedules into registries	
7.4.1.1	Action: Receive immunization schedules	Immunization guidelines and schedules developed by ACIP, AAP, AAFP, and federal, state, territorial, 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. In the future, these schedules and guidelines could be incorporated into the clinician's EHR system as well as an IIS in order to provide decision support guidance and reminders to clinicians regarding the immunization needs of their patients. This use case assumes that knowledge suppliers will, in the future, provide the schedules and related clinical criteria in an electronically interoperable form to clinicians and registries in processes similar to that currently in place to provide clinical guidelines for drug:allergy and drug:drug interaction checking.
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 capabilities to the registry functions and users. This may be accomplished by manually configuring the system or by loading files containing standardized decision support algorithms and related vocabularies.
7.4.2	Event: Provide vaccine or drug administration information	

| Code	Description	Comments
7.4.2.1	Action: Provide vaccine or drug administration information	A registry may provide 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 algorithms evaluating the patient data contained within the registry. Registries could also use notifications to advise clinicians of specific individuals affected by a vaccine or drug recall. 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	
7.4.3.1	Event: Retrieve vaccine or drug administration information from external sources	At times 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 person matching criteria have been met, and incorporates the information into the registry.

Code	Description	Comments
7.4.4	Event: Receive vaccine or drug administration information	
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 Management

Figure 8-1. Vaccine and Drug Inventory Management
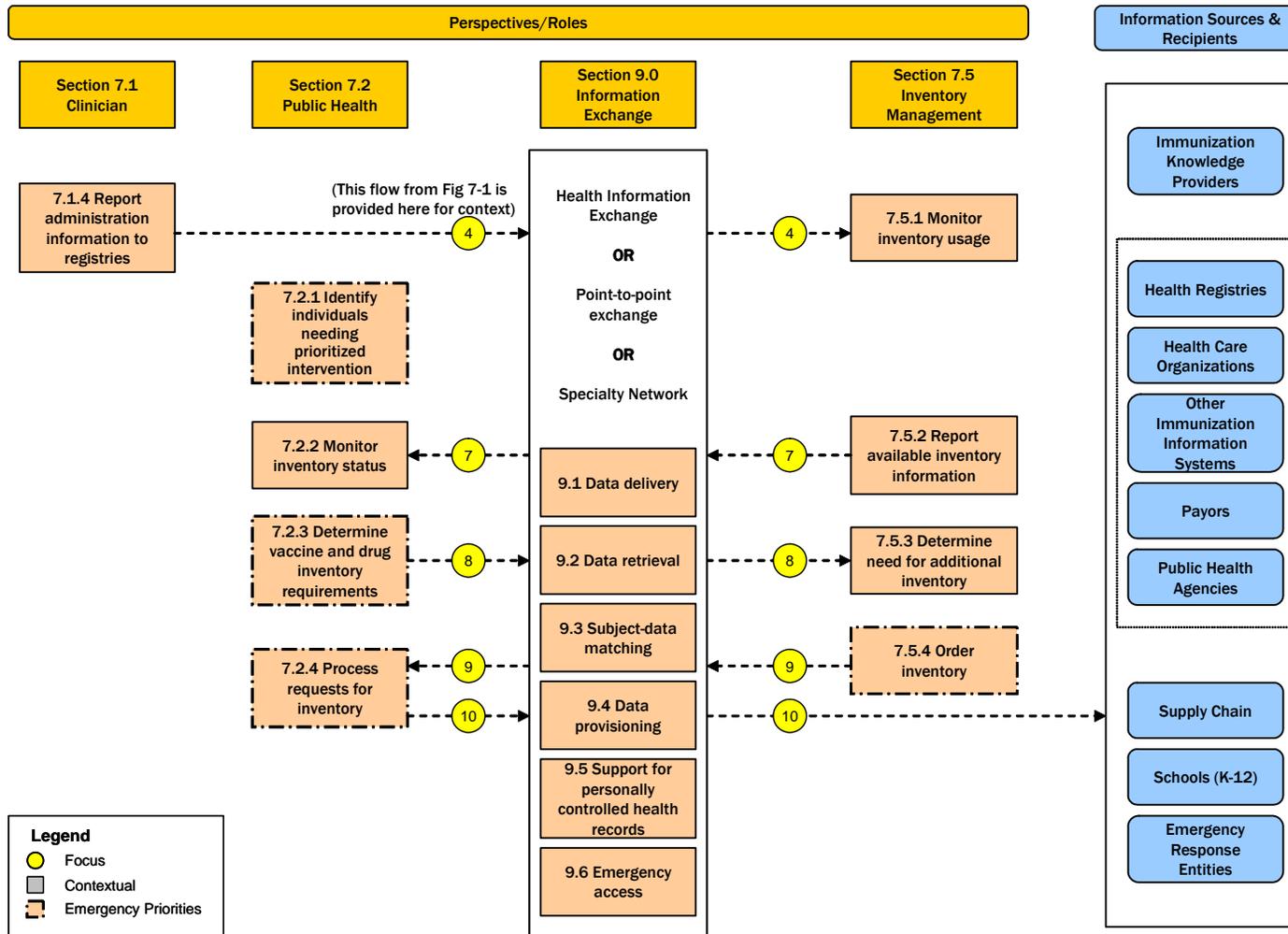
Figure 8-2. Vaccine and Drug Inventory Management Scenario Flows

④ Following administration of (or inability to administer) a vaccine or drug the clinician provides appropriate clinical documentation to registries, consumers and other system including subsequently reporting immunization "take" if appropriate. This same information is communicated to the inventory manager.

⑦ The inventory manager reports inventory availability and usage information to public health.

⑧ Public health communicates vaccine and drug inventory requirements based on clinical need.

⑨ The inventory manager communicates inventory needs (orders) based on inventory status and expected needs.

⑩ Public health communicates request for additional inventory through the public and private supply chains as applicable.

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

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 the Vaccine and Drug Inventory Management information flow in order to provide context for event 7.5.1.
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 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 a web portal provided by the registry or by initiating interoperable messages from the local EHR to the relevant registries.

This information may also be used by inventory managers to update their systems which monitor and report vaccine and drug usage and availability. |

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

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 Management information flow in order to provide context for event 7.2.3
7.2.2.1	**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.

Code	Description	Comments
7.2.2	**Event:** Monitor inventory status	
7.2.2.1	**Action:** Receive and monitor inventory status information	Those in public health roles receive inventory information from inventory manager(s) 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. This may be provided routinely by inventory managers as described in event 7.5.2, or upon request (e.g. a query) initiated by public health.
7.2.3	**Event:** Emergency Situations: Determine vaccine and drug inventory requirements	
7.2.3.1	**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 7.2.1, public health officials receive inventory status information from inventory managers, 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. |
| **7.2.3.2** | **Action:** Communicate inventory requirements to inventory managers | Public health officials communicate the inventory requirements to inventory managers. The information communicated could include the type of vaccine or drug, quantity, delivery location(s), and delivery instructions including redeployment instructions if appropriate. |

Code	Description	Comments
7.2.4	**Event:** Emergency Situations: Process requests for inventory	
7.2.4.1	**Action:** Receive requests for vaccines or drugs	In emergency situations, inventory managers may need to send requests for supplies of vaccines or drugs to public health officials for processing or approval. Public health officials evaluate the requests as described in action 7.3.2.1.
7.2.4.2	**Action:** Communicate inventory orders to supplier(s)	Public health officials communicate inventory orders for vaccines or drugs to the appropriate supplier(s) along with the relevant delivery instructions.

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

Code	Description	Comments
7.5.1	**Event:** Monitor inventory usage	
7.5.1.1	**Action:** Monitor inventory usage	The vaccine or drug administration information communicated to registries in event 7.1.4 is also communicated to the inventory manager in order to update inventory usage and availability information.
7.5.2	**Event:** Report available inventory information	
7.5.2.1	**Action:** Report available inventory information	The inventory manager reports the usage and availability of vaccines and drugs to public health. The information reported may include the quantity of vaccines or drugs available (or used) at each inventory storage location along with the manufacturer, lot number, and expiration date.
7.5.3	**Event:** Determine need for additional resources	

Code	Description	Comments
7.5.3.1	**Action:** Receive inventory requirements information	The inventory manager 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.
7.5.3.2	**Action:** Determine need for additional inventory of vaccines or drugs	The inventory manager 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.
7.5.4	**Event:** Order inventory	
7.5.4.1	**Action:** Order additional vaccines or drugs	If additional vaccines or drugs are required, the inventory manager places an order with the appropriate supplier(s) via public and private supply chains. In emergency situations, or in the case of certain vaccine inventories managed by public health, the order may be forwarded to public health for confirmation before it is sent to the appropriate supplier(s).

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, 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 involved in the information exchange 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 Draft 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 extra-ordinary 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 they are 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: A direct link or communication connection with defined endpoints.

10.0 Immunizations and Response Management Data Set Considerations

The Immunizations and Response Management Draft Detailed Use Case describes the exchange of information to support the needs of consumers, clinicians, public health, registries, and inventory managers. Discussions are underway in several settings to develop the information requirements in detail as represented by the *IIS Codebook1* developed by the American Immunization Registry Association (AIRA). The Codebook, developed by the AIRA Data Definitions Workgroup, illustrates and documents the collected data items used in the IIS community.

This section summarizes 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, dilutent, date/time of administration, the organization and clinician administering the vaccine, and details about vaccine "take" if applicable. This may also include reasons that a vaccine could not be administered, such as the presence of a contraindication for the patient 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. 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, and "take" information if applicable. 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.

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1 This document can be downloaded from the AIRA website at:
http://www.immregistries.org/docs/IIS_Data_Codebook_101607.xls.

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 available at a specific point in time, by location, or by other geographic or non-geographic identifiers. 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.

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, and other 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 discipline with specific components such as best practice guidelines, medication contraindication information, and access to recent research.

Department of Health and Human Services (HHS): Department of Health and Human Services; 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): The electronic health record is a longitudinal electronic record of patient health information generated in one or more encounters in any care delivery setting. This information may include patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory information, and radiology reports.

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 (i.e., hospital, healthcare system, partnership organization, etc.) that supports health information exchange and enables the movement of health-related data within state, local, territorial, 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: Local, state, territorial, or federal departments within the United States government responsible for the oversight and administration of a specific function; government agencies may include: Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), and Department of Homeland Security (DHS), Department of Homeland Security, and the National Guard.

Health Information Exchange (HIE): 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.

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, 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.

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 nations health through the development of an interoperable harmonized health information infrastructure.

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.

Personal Health Record (PHR): A health record that can be created, reviewed, annotated, and maintained by the patient or the caregiver for a patient. The personal health record may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history, or communications with healthcare providers.

Pharmacies: The organizations that dispense pharmaceuticals to consumers, utilizes data to check for contraindications and allergies, may participate as an intermediary or subnetwork provider of data on dispensed medications, or even as a provider of 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: A direct link or communication connection with defined endpoints.

Providers: The healthcare clinicians within healthcare delivery organizations with direct patient interaction in the delivery of care, including physicians, nurses, 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 principals, defining "take" responses, 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, and pharmacies and retail delivery organizations.

Public Health Agencies/Organizations (local/state/territorial/federal): Local, state, territorial and federal 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).