

ILLINOIS HEALTH INFORMATION EXCHANGE

# Immunization Use Case v1.1

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The Illinois Immunization Registry and Health Information Exchange

**Illinois Health Information Exchange Public Health Work Group**

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## 1.0 Executive Summary

This Use Case is a product of the Public Health Work Group (PHWG) of the Illinois Health Information Exchange (HIE) Advisory Committee. The Illinois HIE Advisory Committee was constituted as the diverse public healthcare stakeholder body providing input and recommendations on the creation of the Illinois HIE Authority (“the Authority”) as the Illinois vehicle for designing and implementing electronic health information exchange in Illinois. The establishment of the Authority marks the formal transition of the work of the HIE Advisory Committee and the Work Groups into alignment with the provisions of Illinois Public Act 096-1331, the Illinois Health Information Exchange and Technology Act.

Generally, the mission of the PHWG is to provide guidance and recommendations to the HIE Advisory Committee or its successors on the exchange of data relevant to public health between HIEs that operate in Illinois and Illinois public health agencies. This will be advanced by

- encouraging the adoption of electronic health records (EHRs) and the use of health information technology (health IT) to improve both individual and population health status and public health outcomes;
- assuring standards-based interoperability and workable data sharing between the public health system and HIEs in Illinois, including the Illinois HIE, local exchanges, and institution-based EHR systems;
- demonstrating and documenting the mutual benefit to public health and healthcare providers in the development of the Illinois HIE;
- assuring policy compatibility with the goals of public health for the use of individual and population health data;
- communicating to and educating the public health system about the value and applications of the Illinois HIE and promoting participation in the HIE by state and local health departments and the broader public health community; and
- promoting the identification of resources for public health to fully participate in HIE planning.

The Illinois Office of Health Information Technology (OHIT) will provide administrative and implementation support to the Authority as it moves forward with the development of the Illinois HIE. It is the intention of OHIT to release a request for proposals in early 2011 that will detail the requirements for the initial design of the Illinois HIE. **The purpose of this Use Case is to document and describe the current state of information flows regarding immunizations in Illinois, and to document and describe the ideal state in a future system that includes expanded electronic health information systems and**

**HIE.** The PHWG expects that the Use Case will be one of many inputs into the upcoming RFP process, and will be a scored element of the process to award the contract to design and build the Illinois HIE.

Making a priority of integrating Illinois' immunization registry in Illinois' HIE planning is justified by its specific inclusion in the federal rules for Meaningful Use under the EHR Incentive Programs, including the criterion for "electronic submission to immunization registries". Because the Illinois immunization registry is already employing federal health information technology funding to upgrade the registry, now is the right time to work to integrate it with the emerging HIE development plans. Additionally, supporting bi-directional communications between the registry and healthcare providers has the following benefits:

- Reduces death, morbidity, disability
- Enables stakeholders to meet Meaningful Use
- Enriches clinical records to enhance decision support for providers
- Increases patient safety and quality of care
- Increases system efficiency, reduces redundancy and repetition of services
- Which in turn decreases overall cost of providing immunization services
- Results in a more complete description of population-level health outcomes
- Which in turn allows for better allocation of public resources to support more effective immunization practices
- Increases capacity to prevent vaccine-preventable diseases
- Provides a structural model for other governmental public health systems to be integrated with EHR/HIE

The PHWG Immunization Use Case addresses several aspects of immunization information, including: immunization status for specific populations as well as the general population; the automated integration of electronic immunization data into Illinois' immunization registry and case management databases; vaccine supply management and the automated integration of immunization and vaccine information into supply chain and product management tracking functions; and automated functionalities related to Illinois statutory requirements regarding elementary school attendance.

This Use Case is divided into the following Sections:

- 2.0 Introduction
- 3.0 Scope
- 4.0 Use Case Stakeholders
- 5.0 Issues and Obstacles

- 6.0 Use Case Pre-Conditions
- 7.0 Use Case Post-Conditions
- 8.0 Detailed Scenarios/Technical Specifications
- 9.0 Information Exchange
- 10.0 Dataset Considerations
- 11.0 Validation and Certification

## **2.0 Introduction**

Vaccines save lives routinely and in times of outbreaks – they are one of the ten great Public Health Achievements of the last century. From a variety of perspectives, including medical and financial, the public benefits when the whole population is vaccinated against disease are immense; providing individual and population level protection against illness and death caused by infectious diseases. Simplifying the reporting, tracking, and monitoring of immunizations in the population through use of a registry that is interoperable with the clinical EHR, will pay off in helping to ensure that appropriate immunizations are administered to everyone.

Immunizations are a proxy measure for the overall health of the population; the idea being that if people are appropriately immunized they are also receiving other preventive and primary care. As such they are an important quality indicator for public health departments, health care organizations, and consumers to monitor for continuous improvement.

The PHWG chose to provide a clear pathway for interoperability between clinical providers and the Illinois immunization registry, the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE). The secure exchange of this data will allow Illinois to increase the number of children and adults participating in the immunization registry, eliminate double entry of immunization data by providers, reduce the risk of care interruption, and ensure widespread use of the registry to establish greater accuracy on Illinois and national immunization levels. Eventually the immunization registry may become part of the public health node on the Illinois HIE.

I-CARE is an immunization registry application developed by the Illinois Department of Public Health (IDPH), allowing health care providers to share immunization records of Illinois residents. I-CARE is designed to help providers collect, store, analyze, and report their patients' immunization data as well as access patient records for information about immunizations administered outside their practices. I-CARE currently stores

immunization information on approximately 4 million patients and contains nearly 40 million records.<sup>1</sup>

Among the functionality available to I-CARE users is the capability to: forecast immunization due dates; prevent duplicate immunizations; follow CDC's immunization schedule for children and adults; produce a health record and pre-printed school physical forms; record patient contraindications, adverse reactions, and immunities; track vaccine inventory; collect patient demographic data and insurance eligibility; maintain running progress notes; and schedule appointments as well as track and notify patients of upcoming due dates. I-CARE has also incorporated additional data fields to track and record body mass index, height and weight, blood pressure, and blood lead screenings.

I-CARE can accept data from Cornerstone (the statewide data management information system developed to effectively measure health outcomes and facilitate the integration of community maternal and child health services provided to Illinois residents by the Illinois Department of Human Services) through daily batch flat file transfers. Data entered directly into the I-CARE web-portal is available in real-time. IDPH is currently working with providers to enable secure messaging directly between a provider's EHR and I-CARE. I-CARE is able to accept HL7 data, in versions 2.31 and 2.51, from outside sources and is prepared to accept batch data through a secure STP site, which it will use to populate the registry. IDPH anticipates implementing 2-way real time patient data exchange in early 2011.

This immunization registry Use Case focuses on the needs of consumers, clinicians, registries, and public health carrying out routine care activities associated with immunizations. This Use Case also recognizes that the technical infrastructure for the immunization registry supports routine immunizations by governmental public health and other healthcare providers as well as emergency situations arising from outbreaks, epidemics and natural disasters. This Use Case does not address all the operational possibilities of the immunization registry – but will focus on universality, the functionality of providers receiving real time feedback regarding immunization status, reminder recalls, vaccine and drug administration reporting, immunization monitoring, vaccine and drug inventory reporting, and reporting and notification of adverse events.

### **3.0 Scope**

Since widespread adoption of the EHR and meaningful use of that record is the goal of the national and statewide health IT agenda, this Use Case for immunization data exchange

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<sup>1</sup> Illinois Department of Public Health, 2010.

between the clinical provider's EHR and I-CARE will provide clinicians, technology vendors, and the State the opportunity to align the technical specifications for exchange. The Use Case will present the public health workflow, perspectives, pre and post conditions, and include the actions required to exchange specific patient care data between clinical providers and state and local public health departments through I-CARE. This Use Case also outlines how, as the HIEs becomes operational, they will facilitate bi-directional exchange. The PHWG Use Case for the Illinois immunization registry addresses the following:

- Access to information about who receives or needs to receive specific vaccines, including:
  - Patient demographics, physician orders, vaccine administration data, and adverse events data
- The ability to report and track vaccines, including:
  - Measuring and reporting immunizations with a minimum burden assessed on the provider
  - The aggregation of health information for the purpose of public health reporting of immunizations
  - Recall data and supply management data
- Documentation of vaccine administration
- Ability to provide reminders about immunization to patients
- Ability to provide aggregate reports of immunizations in a practice
- Ability to expand I-CARE beyond traditional medical and healthcare settings
- Ability to identify and electronically exchange information describing the immunizations of the population, both routine and emergency. This gives both providers and public health the capability to request real time information from the registry.

### **3.1 Criteria for Meaningful Use for Public Health in Illinois**

The value of the creation and implementation of criteria for Meaningful Use for public health is in the promotion of unified standards, the development of interoperable data stores, and the establishment of a foundation for future efforts to leverage information technology for public health practice in Illinois.

The PHWG recognizes the challenges inherent in implementation of new methods and workflows for data sharing. These challenges may include a) development of interface engines or web service engines that message data b) harmonization of semantic knowledge into a common format c) allocation of limited IT resources to accomplish technical implementation tasks d) incorporation of security and consents in health information

exchange and e) maintenance and certification of the accuracy of electronically detected and transmitted data.

To that end, this document will summarize the recommendations for messaging of data to public health as a part of the HIE and in the effort to meet the Stage 1 Meaningful Use criteria for public health. The two initial Use Cases to be developed by the PHWG will be the transmission of data to the state immunization registry and electronic laboratory reporting. It is not coincidental that these two Use Cases correspond to existing robust reporting systems at the state level: I-CARE and I-NEDSS. The general philosophy in the development of infrastructure to support the public health Use Cases is to leverage existing implementation guides and standards to promote a short term/current state messaging implementation framework, while also looking forward to the future for a longer term/future state framework to be developed in parallel. We will provide these two paths to enable use of existing systems while also providing a roadmap for the future of public health surveillance infrastructure. We will also give some examples of ways these standards can be implemented to permit sustainability, auditing and certification, and minimal impact on existing public health work processes.

#### 4.0 Use Case Stakeholders

The primary stakeholders for HIE for immunizations are listed below and defined by their functional role related to either submitting and/or retrieving immunization information electronically through EHRs and HIEs.

Stakeholder	Working Definition of Role
Patient	Members of the public who require immunizations. May also include a person who can act on behalf of the patient, such as a parent. Patient consent is required to participate in I-CARE.
Clinician	Health care providers with direct patient care responsibilities, including ordering clinicians and providers of care in all health care delivery settings. Eligible professionals participating in the Medicare and Medicaid EHR Incentive Programs. Programs demonstrating fulfillment of the immunization objective.  Providers would both submit and retrieve data.
Health care delivery organization	All health care delivery organizations that provide vaccines to children and adults. Examples of healthcare organizations include hospitals, physician practices, Federally Qualified Health Centers, and long term care facilities that manage the delivery of care and



	<p>maintain personal health records with immunizations.</p> <p>Health care delivery organizations would both submit and retrieve data.</p>
Local health department	<p>Public health agencies that manage delivery of immunizations, maintain personal immunization records, and enter immunization record for individual patients into Cornerstone or I-CARE. Uses population-based immunization coverage levels for the purpose of improving immunization rates in the population.</p> <p>Local health departments would both submit and retrieve data.</p>
Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE)	<p>The Illinois Department of Public Health’s web-based immunization registry application housing information on public and private patients receiving immunizations.</p>
Local Health Information Exchange	<p>Local conduit for sharing electronic health information among certified participants in exchange and the Illinois Health Information Exchange.</p>
State Health Information Exchange	<p>State conduit for sharing electronic health information among local HIEs, interstate exchanges, certified participants in exchange, and state and federal data sources.</p>

There are a number of secondary stakeholders who use immunization data in a wide variety of ways but who would primarily be accessing the data through the I-CARE system rather than the HIE. These include: community-based organizations, family case management services, schools and daycare centers, Cornerstone, the Department of Healthcare and Family Services (State Medicaid), and public and privacy vaccine experts. Additionally, secondary stakeholders in public and population health may access aggregated data from either I-CARE or the HIE to support assessment, assurance and advocacy. This functional aspect of HIE will be more fully addressed in subsequent Use Case documents.

## 5.0 Issues and Obstacles

Realizing the full benefits of health IT 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 will apply to all the Use Cases developed by the PHWG, while others are unique to this specific Use Case. This Use Case promotes the standardization of data messaging either directly to I-CARE or to the proposed public health node on the Illinois HIE.

Generally, the issues and obstacles applicable across all Use Cases are related to the adoption of health IT and the concerns of clinical workflow integration and workforce education, and the use of standards to promote data interoperability and facilitate HIE. These issues, while critical to the success and widespread implementation to the exchange of immunization data, are outside the scope of this Use Case and, are being addressed by the multiple federally funded programs to encourage the widespread use of health IT and HIE created under the Health Information Technology for Economic and Clinical Health Act of 2009.

In addition to the cross-cutting issues and obstacles identified above, several issues or obstacles exist that are specific to this Use Case and include:

- Immunization schedules, as well as local, school and state interpretations of published schedules, vary between jurisdictions and are not available in an electronic interoperable form for inclusion in EHRs, Personal Health Records (PHRs), or registries.
- 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.
- It is acceptable for providers to accept patient's self-report as long as it is documented as such in the medical record.
- 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.
- I-CARE is a web-based registry and can be used by providers without an EHR. Therefore, providers may choose not to adopt or upgrade their EHRs with an immunization/I-CARE module.

## 6.0 Use Case Pre-Conditions

Pre-conditions are the conditions that must be in place before the start of the use case.

This includes, but is not limited to, the state of a stakeholder, data that must be available somewhere, or an action that must have occurred.

- Health care provider has completed the I-CARE registration process, including the user agreement
- Health care provider is located in Illinois and has administered an immunization
- Health care provider has the consent of the patient, or a child's parent or guardian, to participate in I-CARE
- Data system technical specifications
  - Provider's EHR will be able to record data elements required by I-CARE
    - See I-CARE HL7 Specs for data field requirements for HL7 messaging to I-CARE
  - Messaging will adhere to I-CARE approved data exchange file specifications; EHR technology supporting HL7 2.3.1 or 2.5.1 messaging standards
    - See HL7 2.3.1 and HL7 2.5.1 implementation guides, available online
- Memo of Understanding between the Authority and IDPH for implementation, routing and query functions using the Illinois HIE

## 7.0 Use Case Post-Conditions

Post-conditions are the conditions that will result or be the output from the Use Case. This includes, but is not limited to, the state of the stakeholder upon conclusion of the Use Case, data that was created or now available, and identification of actions that may serve as pre-conditions for other Use Cases.

### Systems

1. Local, state and federal public health agencies will have higher quality data and can develop effective programming to improve immunization rates in targeted populations and ensure prevention of vaccine preventable diseases.
2. In a public health emergency, central storage of immunization data would improve the ability to track vaccinations given and where vaccine is needed.
3. Vaccine experts will have more usage data to draw on for future decisions/recommendations.

### Individual

1. Patient receives needed immunization at appropriate time and can check PHR to know when future immunizations are due.

2. Clinician has access to previous immunizations given and can make appropriate clinical decisions on what additional immunizations are needed.

## 8.0 Details Scenarios/Technical Specifications

I-CARE is the immunization registry in use by IDPH. This system has a web-based interface that permits manual entry of client information. In addition to the web-based system, there is the capability to receive HL7 messages from stakeholders of vaccine recipients and incorporate this information into the registry. The necessary fields are listed in the I-CARE HL7 Specs.

Much as with electronic laboratory reporting, messaging is currently planned to occur using HL7 2.3.1, and sent to the registry using Secure FTP to the MoveIT system at the state level. It is anticipated that future standards will incorporate the use of XML based methods of data transfer, and a web services model to enable transmission of data.

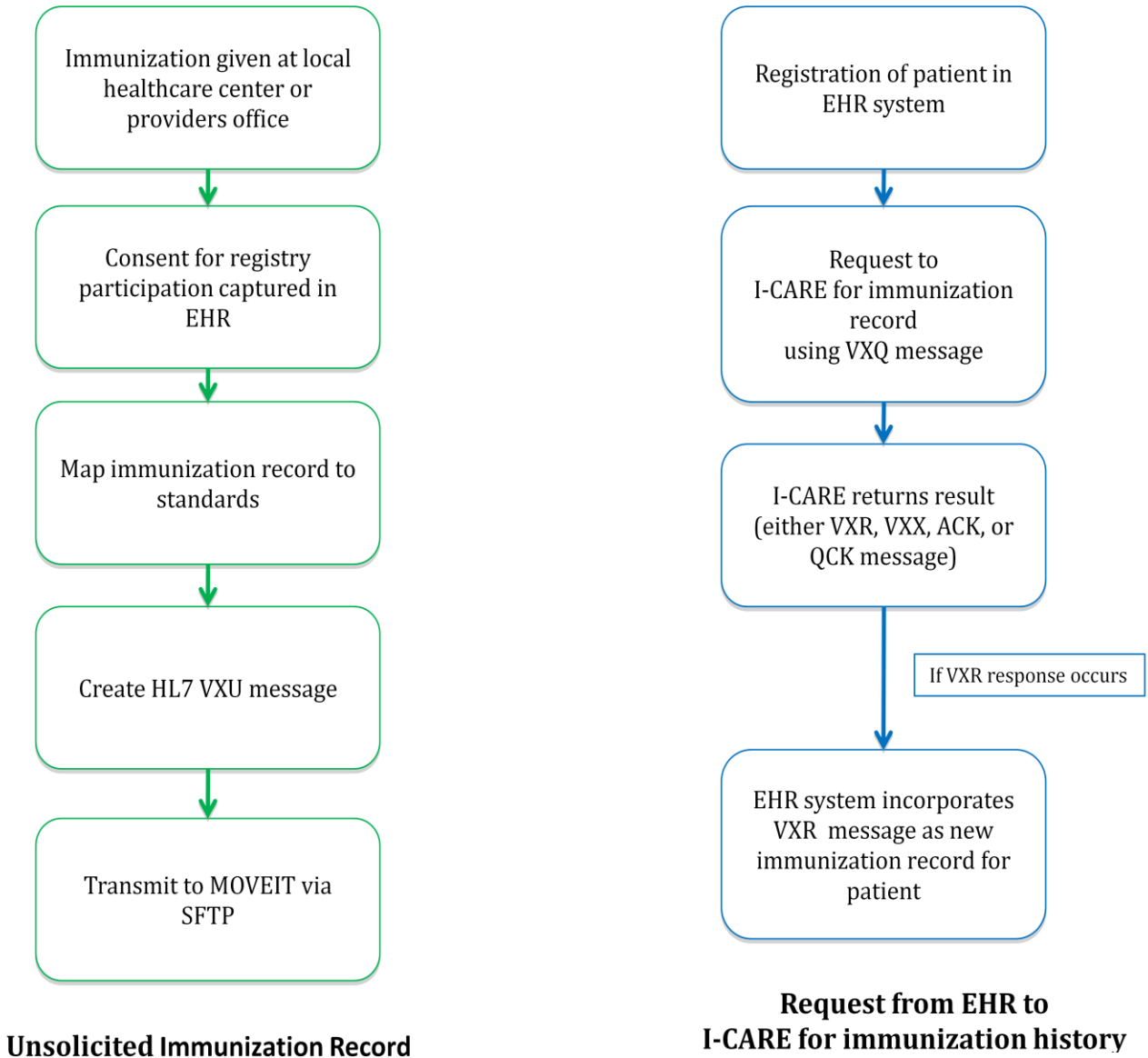
For Stage 1 Meaningful Use, the focus of data sharing will be unsolicited messages to the state immunization registry, I-CARE. It is anticipated that bidirectional, real-time data transmission will be achievable to I-CARE in 2011. Future stages of Meaningful Use will incorporate these features. Vendors and developers are asked to refer to the following implementation guides with the full description of immunization messaging standards for HL7 2.3.1 and HL7 2.5.1:

- HL72.3.1  
<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide.pdf>
- HL7 2.5.1  
<http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7-guide2010-508.pdf>

Messages to the immunization registry shall be sent as VXU message types (i.e., unsolicited vaccination record update). Infrastructure to support the ACK response to a VXU message type should also be planned with modifications possible at the vendor site with a repeat send of message. Examples of methods of implementation are shown below (Figure 7-1).

It is anticipated that as national standards mature for the transmission of data to governmental agencies, new standards will emerge. For example, a candidate for a new standard that already is in use on the federal level in some domains of data exchange is the National Information Exchange Model (or NIEM) model. As there is maturation in the exchange of health information, new standards will be discussed with stakeholders and pursued where appropriate.

**Figure 7-1 Methods of Implementation**



## 9.0 Information Exchange

Messaging to the state I-CARE registry can be viewed as a current state, and a future state. The current state consists of all existing methods of messaging to registries, and is what will be leveraged for Stage 1 Meaningful Use for public health. The future state

encompasses possible and desirable systems of data exchange that can fully leverage new technologies like XML, web services, and novel security paradigms.

In the current state, the use of Secure FTP to the MoveIT system will be recommended for transmission of HL7 messages to the State. Daily batch uploads will be sufficient, though real time transmission of data are supported. The MoveIT system is available at [www.idphnet.com](http://www.idphnet.com). Potential users can follow a registration process to access the IDPH Health Alert Network web portal, as well as to obtain credentials to enable Secure FTP uploads. Facilities seeking to transmit data to I-CARE will need to transmit data using the Secure FTP protocol and develop the appropriate institutional infrastructure (e.g. Secure FTP clients, firewall, and network modifications) to permit transmission in this manner.

For the future state, we will seek input from stakeholders and anticipate some support of web services and SaaS models to enable transmission of data.

### **9.1. Examples of Models of Standards-Based Reporting to I-CARE**

It is anticipated that, with the opportunity presented through Stage 1 Meaningful Use, that opportunities for sustainable systems will be maximized. The following section provides non-prescriptive examples of methods to deploy reporting systems.

- 1 EHR based, vendor provided solutions. In this scenario, health care systems will utilize software products provided by the EHR vendor to enable compliance with the Meaningful Use criteria. Vendors will be expected to comply with Illinois guidance for messaging to I-CARE, including use of standard vocabularies as suggested by the HL7 specification in use in Illinois, transport mechanisms suggested for data transmission, and implementation of consent and other workflow processes necessary for a working system.
- 2 Middleware, on-site solutions. It is anticipated that health care providers, particularly hospital systems, may select middleware software providers for data transmission to the immunization registry. For example, point-to-point interfaces from EHR systems to middleware systems on-site at hospitals might provide the capability for transmission of immunization dosing to I-CARE.
- 3 A third party, off-site solution. A third option is the use of a neutral third party entity to which data are sent, whose responsibility is to receive data from providers, map the data to standards, create HL7 messages, and transmit to I-CARE. The third party could perform auditing functions, standardize mapping approaches, and achieve economies of scale in the transmission of data to I-CARE.

- 4 HIE. When the Illinois HIE has matured in Illinois, this might serve as a method to simplify and streamline data transmission to I-CARE. In this scenario, providers and healthcare systems will send data to the HIE, which will then be responsible for data transmission to I-CARE.

## 10.0 Dataset Considerations

**The mandatory fields regarding the immunization event in an immunization VXU message are:**

Patient Identifier List (segment PID 3.1)

Patient Name(segment PID 5.1)

Date of Birth (PID 7)

Sex (PID 8)

Patient Address (Street: PID 11.1; Other designator: PID 11.2; City: PID 11.3; State: PID 11.4; Zip Code: 11.5)

Route (RXR 1)

Date/Time of Administration (start: RXA 3; end: RXA 4)

Administered Code/Amount (RXA 5: Administered Code)

Lot Number (RXA 15)

Manufacturer (RXA 17)

**Optional, but desirable fields are:**

Cornerstone ID (PID 4)

Medical Record ID (PID 4)

State Master Patient Locator Number (PID 4)

Race (PID 10)

County Code (PID 12)

Phone Number – Home (PID 13)

Phone Number – business (PID 14)

SSN number – patient (for identification– PID 19)

Driver's License Number –patient (for identification – PID 20)

Ethnic Group (PID 22)

Ordering Provider (ORC 12)

Call back phone number (ORC 14)

Entering Organization (ORC 17)

Ordering Facility Name (ORC 21)

Ordering Facility Phone Number (ORC 23)

Ordering Provider Address (ORC 24)

Administration Site (RXR 2)

Administration Method (RXR 4)

Administered Units (RXA 7)

Administered Dosage Form (RXA 8)

Administering Provider (RXA 10)

Administered-at Location (RXA 11)

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Administered strength (RXA 13)  
Administered strength units (RXA 14)  
Substance Expiration Date (RXA 16)  
Substance Refusal Reason (RXA 18)  
Indication (RXA 19)  
Completion Status (RXA 20)  
System Entry Date/Time (RXA 22)

## **11.0 Validation and Certification**

Some aspects of exchange of data with public health agencies require the application of business logic rules to detect cases of interest. It is anticipated that a useful approach to implementation of this Use Case will be the creation of a third party entity/entities that will serve several functions: a) enforcement of standardization in data mapping b) application of public health business rules c) audit and validation of application of mapping terms and d) audit and validation of the rule sets used for public health surveillance. Such entity/entities will be developed, it is expected, under the supervision of or as agents of OHIT or HFS; possible opportunities for auditing and validation are at the time of integration testing of new interfaces, or before the initiation of transmission of data to I-CARE.