

## Consolidated Health Informatics

### Standards Adoption Recommendation

#### Immunizations

##### Index

1. **Part I – Sub-team & Domain Scope Identification** – basic information defining the team and the scope of its investigation.
2. **Part II – Standards Adoption Recommendation** – team-based advice on standard(s) to adopt.
3. **Part III – Adoption & Deployment Information** – supporting information gathered to assist with deployment of the standard (may be partial).

## Summary

### Domain: Immunizations

### Standards Adoption Recommendation: Health Level Seven<sup>®</sup> (HL7<sup>®</sup>) Version 2.3.1+

#### SCOPE

The implementation of a data standard for the storage and exchange of immunization data would provide an organized and streamlined means of communicating between Federal partners by offering a real-time means of transferring information regarding immunization encounters, vaccine events, patient records and other immunization-related information important to immunization registries.

#### RECOMMENDATION

Health Level Seven<sup>®</sup> (HL7<sup>®</sup>) for immunization registry terminology, more specifically the CVX (clinical vaccine formulation) and MVX (manufacturer) codes.

#### OWNERSHIP

The Immunization Data Transactions, Version 2.3.1 of the HL7<sup>®</sup> Standard Protocol, Version 2.0 has been promulgated as the primary standard for immunization data transactions by CDC in the National Immunization Program (NIP). HL7<sup>®</sup> has designated the CDC as the maintenance agency for the CVX and MVX codes.

#### APPROVALS AND ACCREDITATIONS

HL7<sup>®</sup> is an ANSI-accredited Standards Developing Organization. This standard has been approved by full organizational ballot voting.

#### ACQUISITION AND COST

There is no use license with this standard; it is available for any healthcare organization to use. An implementation guide for the HL7<sup>®</sup> standard with respect to immunization data transactions can be found on the National Immunization Program website:

<http://www.cdc.gov/nip/registry>.

**Part I – Team & Domain Scope Identification**

**Target Vocabulary Domain**

*Common name used to describe the clinical/medical domain or messaging standard requirement that has been examined.*

Immunizations/Vaccinations Data Transactions and supporting terminology

*Describe the specific purpose/primary use of this standard in the federal health care sector (100 words or less)*

The implementation of a data standard for the exchange of immunization data would provide an organized and streamlined means of communicating between Federal partners by offering a real-time means of transferring information regarding immunization encounters, vaccine events, patient records and other immunization-related information important to immunization registries. Additionally, use of a common vocabulary would allow direct interfacing with multiple facilities within the Federal sector, regardless of location or size. This would enhance immunization registry and surveillance activities; give more robust data with respect to coverage levels, immunization histories, vaccine decision support, record exchange and patient/parent reminders, standardize communication to/from providers/users of vaccine information such as primary care physicians and schools; and provide an up-to-date standardized method of communication to keep vaccination records current and complete.

**Sub-domains** *Identify/dissect the domain into sub-domains, if any. For each, indicate if standards recommendations are or are not included in the scope of this recommendation.*

Domain/Sub-domain	In-Scope (Y/N)
None identified	

**Information Exchange Requirements (IERS)** *Using the table at appendix A, list the IERS involved when using this vocabulary.*

Customer Demographic Data
Encounter )Administrative Data)
Beneficiary Financial/ Demographic Data
Customer Risk Factors
Beneficiary Tracking Information
Provider Demographics
Customer Health Care Information
Care Management Information
Tailored Education Materials
Case Management Information
Population Member Health Data

Population Risk Reduction Plan
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**Team Members** *Team members' names and agency names with phone numbers.*

Name	Agency/Department
<b>Jason Goldwater (Team Lead)</b>	CMS/CMSO/FSBG/DSS
Terry Boyd	CDC
Scott Steins	USAID
Bette Goldman	FDA
Nancy Orvis	DoD
Eugene DeLara, M.D.	DoD
Stanley Griffith	IHS
Katherine Hollinger	FDA
Randy Levin	FDA
Lise Stevens	FDA
Robert Wise	FDA

**Work Period** *Dates work began/ended.*

Start	End
February 4 <sup>th</sup> , 2003	July 31, 2003

## Part II – Standards Adoption Recommendation

**Recommendation** *Identify the solution recommended.*

For the messaging standard, HL7<sup>®</sup> 2.3.1, and future versions, as defined by CDC in the Implementation Guide for Immunization Data Transactions using Version 2.3.1. of the Health Level Seven<sup>®</sup> (HL7<sup>®</sup>) Standard Protocol – Implementation Guide Version 2.1 (September 2002) available at <http://www.cdc.gov/nip/registry>. For immunization registry terminology, the recommendation supports the use of CVX (clinical vaccine formulation) and MVX (manufacturer) codes from HL7<sup>®</sup>. This recommendation will be revisited within 12-18 months to determine whether an appropriate, and sufficiently robust, terminology exists to update those data needs. The Immunizations/Vaccinations Team recommendations for product related terminology will be aligned with the Medications workgroup as described below. The recommendation for the messaging standard described here will be reviewed in 12-18 months to assess its updating of the current HL7<sup>®</sup> adverse event message with the HL7<sup>®</sup> Version 3.0 Electronic MedWatch Message for adverse events that is currently under development.

**Ownership Structure** *Describe who “owns” the standard, how it is managed and controlled.*

Health Level Seven<sup>®</sup> (HL7<sup>®</sup>) is one of several ANSI-accredited Standards Developing Organizations (SDOs) operating in the healthcare arenas. Their mission is, “To provide standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems.” HL7<sup>®</sup> is like most of the other SDOs in that it is a not-for-profit volunteer organization. Its members – providers, vendors, payers, consultants, government groups, and others who have an interest in the development and advancement of clinical and administrative standards for healthcare – develop the standards. HL7<sup>®</sup> adheres to a strict and well-defined set of operating procedures that ensures consensus, openness and balance of interest.

Members of HL7<sup>®</sup> are known collectively as the Working Group, which is organized into technical committees and special interest groups. The technical committees are directly responsible for the content of the Standards. Special interest groups serve as a test bed for exploring new areas that may need coverage in HL7<sup>®</sup>'s published standards. The organization is managed by a Board of Directors, which is comprised of eight elected positions and three appointed positions. The *Technical Committees* and *Special Interest Groups* are responsible for defining the HL7<sup>®</sup> standard protocol. Two or more co-chairs chair each Technical Committee and Special Interest Group. Collectively, the co-chairs comprise the Technical Steering Committee, which votes on issues related to the

standard. Votes of the Technical Steering Committee are passed as recommendations to the Board of Directors, who make the final decision. HL7<sup>®</sup> members are encouraged to participate in all of these committees.

**Summary Basis for Recommendation** *Summarize the team's basis for making the recommendation (300 words or less).*

The Immunization Data Transactions, Version 2.3.1 of the HL7<sup>®</sup> Standard Protocol, Version 2.0 has been promulgated as the primary standard for immunization data transactions by CDC in the National Immunization Program (NIP), and is currently used nationally by many immunization registries, on local, state and federal levels. This standard is a mandatory functional requirement for states receiving federal matching funds. The Indian Health Service, within their Resource Patient Management System (RPMS,) and the Veteran's Administration also use the same transaction standard. The HL7<sup>®</sup> standard is also recommended for use when reporting adverse events associated with immunization adverse events. The HL7<sup>®</sup> messaging standard for Vaccine Adverse Event Reporting System (VAERS) has been recommended by the American Academy of Pediatricians and the National Vaccine Advisory Board. Currently, the CVX and MVX codes are utilized within the immunization and VAERS messaging standard. It is believed that recommending a different standard than the one currently used, with great effectiveness, in the status quo, would be akin to "reinventing the wheel" and thus would be counter-productive to the overall efforts of the CHI project. Note that for the purposes of global harmonization of regulatory and industry product safety surveillance, FDA is planning to use MedDRA in its VAERS system as the standard terminology for postmarketing adverse event reporting. This is part of an agreement made with the International Conference on Harmonisation (ICH) with private industry and regulators from the US, EU and Japan to achieve consistency of reported adverse event data between industry and ICH regulatory authorities.

**Conditional Recommendation** *If this is a conditional recommendation, describe conditions upon which the recommendation is predicated.*

No conditions apply to this recommendation.

The recommendation is based on the following:

From 1995 through the spring of 1999, the National Immunization Program, Centers for Disease Control and Prevention, worked with Kaiser Permanente, Indian Health Service, and several states with immunization registries, including California, Georgia, Illinois, Michigan, and New York, to develop a standardized way for handling immunization data exchange within HL7<sup>®</sup> version 2.3.1. This culminated in the publication of the "Implementation Guide for Immunization Data Transactions using

Version 2.3.1 of the Health Level Seven<sup>®</sup> (HL7<sup>®</sup>) Standard Protocol,” initially in June 1999, subsequently updated as version 2.1 in September 2002. This implementation guide details several message formats, a core data set, and mentions several external code sets (including clinical vaccine formulation and manufacturer codes – CVX and MVX codes, respectively). These components are intended to allow the electronic sharing of immunization data between separate and otherwise disparate entities (the need specifically described in the CHI Immunization Team’s purpose statement). In addition to coordinating the development of the implementation guide and promoting its use in various states and organizations, CDC has been designated by the HL7<sup>®</sup> organization as the “keeper” of the CVX and MVX code sets.

This HL7<sup>®</sup>-based system, including both messaging and vocabulary standards, is now widely implemented. In these implementations, the HL7<sup>®</sup> messaging and vocabulary standards have been found to be sufficient to allow various organizations, public and private, to share immunization data, improving our ability to assess the vaccination status of individuals and population groups and to keep vaccination records current and complete. Because of this, the CHI immunization team recommends that CHI adopt the HL7<sup>®</sup> messaging standards *and* CVX and MVX external code sets for immunizations.

The workgroup acknowledges that while the HL7<sup>®</sup> code sets and the domains they address are sufficient today for the limited purpose of exchanging immunization information, they will not be adequate to completely meet future needs as defined by the NCVHS Subcommittee on Standards and Security in its Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information, July 6, 2000. To meet these more ambitious purposes (e.g., to facilitate the development of decision support; reduce the costs of developing and implementing healthcare applications; ensure more consistent interpretation of categorizations and term relationships both within and among organizations, as well as across applications; facilitate our ability to assess immunization coverage for populations; allow healthcare organizations to better integrate their various IT applications into one system; etc.) and to address the full informational content of the immunization realm, this information will need to be subsumed within a more comprehensive and fully configured drug reference terminology.. The CHI cannot recommend a more replete terminology such as this for current adoption, however, because one is not yet sufficiently developed.

Additionally, the CHI Immunizations Group also believed that the immunization-messaging standard applied specifically to the encounter, while the vocabulary directly applied to the drug/biologic used in the immunization delivery. Drugs are defined as those products intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, manifestations or symptoms of disease or alter structure/function of the body were considered the area of initial interest<sup>2</sup>. This definition covers a vast array of products from simple chemical structures to more complex molecular entities such as biologicals, including vaccines. As such, the CHI Immunizations workgroup should align itself with the Medications workgroup where product related information standards are being developed. Regulations on labeling, adverse events and other product

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<sup>2</sup> FD&C Act Section 201(g)(1)

information are being increasingly harmonized for drugs and biologics.

For immunization registry terminology, the recommendation supports the use of CVX (clinical vaccine formulation) and MVX (manufacturer) codes from HL7<sup>®</sup>. This recommendation will be revisited within 12-18 months to determine whether an appropriate, and sufficiently robust, terminology exists to update those data needs. The Immunizations/Vaccinations Team recommendations for product related terminology would be aligned with the Medications workgroup as described below. The recommendation for the messaging standard described here will be reviewed in 12-18 months to assess its updating of the current HL7<sup>®</sup> adverse event message with the HL<sup>®</sup>7 Version 3.0 Electronic MedWatch Message for adverse events that is currently under development. The new version of the adverse event message will be adopted for widespread use in reporting. The AHRQ National Patient Safety Network will use the new message for transmission of regulated product adverse events, including vaccines and other biologics.

The CHI Medications group reviewed a large number of potential candidate terminologies for representing drug product information. One criterion, respect for existing regulatory authority, bears special mention. The FDA is the United States regulatory authority for approving the safe and effective use of drug and biologic products in the US, and is collaboratively responsible for national and international harmonization of a number of drug-related issues. Product information, including the naming and coding of medications and their associated products, packaging, and other descriptive information is an FDA regulatory responsibility. The CHI medications group, as well as the Immunizations group, recommendations reflect this authority. While a number of medication-related terminologies include FDA determined and sanctioned names, selecting non-FDA terminologies, as government standards would effectively usurp FDA's legal role. CHI medication group selections that are not solely administered by FDA, such as LOINC<sup>®</sup> names for label section headers, have significant FDA input nonetheless. Therefore, these recommended standards should be revisited in 12-18 months when the FDA electronic information models have been further developed.

### **Approvals & Accreditations**

Indicate the status of various accreditations and approvals:

Approvals & Accreditations	Yes/Approved	Applied	Not Approved
Full SDO Ballot	X		
ANSI	X		

**Options Considered** *Inventory solution options considered and summarize the basis for not recommending the alternative(s). SNOMED<sup>®</sup> must be specifically discussed.*

SNOMED CT<sup>®</sup> was not among the terminologies selected by the Immunizations group for a number of reasons. First, the FDA is the legal regulatory authority for medication-related terminology in the U.S. As described above, selecting SNOMED CT<sup>®</sup> would conflict with FDA's regulatory mission and authority related to vaccines, other biologics and drugs. The government license specifically excluded the portion of SNOMED CT<sup>®</sup> related to medications. Secondly, SNOMED CT<sup>®</sup>'s medication terminology is a relatively less developed component of the product. Finally, SNOMED CT<sup>®</sup>'s update frequency is measured in months. This interval is far too infrequent given the rate of change in certain components medication-related terminology.

### **Current Deployment**

***Summarize the degree of market penetration today; i.e., where is this solution installed today?***

HL7<sup>®</sup> 2.3.1 is recommended as the National Immunizations Program standard for immunization data transactions. It is utilized within immunization registries and other systems, on the local, state and federal levels.

***What number of or percentage of relevant vendors have adopted the standard?***

State and local Health departments and other entities that administer or operate immunization registries, or similar systems, use the HL7<sup>®</sup> standard for transmission and storage of immunization records. The National Immunization Program of CDC, the American Academy of Pediatricians and the National Vaccine Advisory Commission endorse this standard.

***What number or percentage of healthcare institutions have adopted the standard?***

A significant number of healthcare institutions that electronically submit data to an immunization registry, or similar system, use the HL7<sup>®</sup> standard. Immunization registries must meet the HL7<sup>®</sup> requirement in order to meet the certification requirements established by the National Immunization Program. Additionally, a significant number of institutions have also adopted the CVX and MVX code sets that support this standard.

***What number or percentage of federal agencies have adopted the standard?***

CDC, CMS, IHS and the VA have all adopted the standard.

***Is the standard used in other countries?***

Yes, HL7<sup>®</sup> is used worldwide, although it is difficult to ascertain how prevalent it is with respect to immunization data transactions.

***Are there other relevant indicators of market acceptance?***

As previously stated, the HL7<sup>®</sup> recommendation has been promulgated by CDC as the primary data standard for immunization data transactions, and has also been endorsed by CMS as a necessary functional standard in order for federal matching funds to be received by a state for the design, development and implementation of their immunization registry,

### Part III – Adoption & Deployment Information

*Provide all information gathered in the course of making the recommendation that may assist with adoption of the standard in the federal health care sector. This information will support the work of an implementation team.*

#### **Existing Need & Use Environment**

*Measure the need for this standard and the extent of existing exchange among federal users. Provide information regarding federal departments and agencies use or non-use of this health information in paper or electronic form, summarize their primary reason for using the information, and indicate if they exchange the information internally or externally with other federal or non-federal entities.*

- Column A: Agency or Department Identity (name)  
 Column B: Use data in this domain today? (Y or N)  
 Column C: Is use of data a core mission requirement? (Y or N)  
 Column D: Exchange with others in federal sector now? (Y or N)  
 Column E: Currently exchange paper or electronic (P, E, B (both), N/A)  
 Column F: Name of paper/electronic vocabulary, if any (name)  
 Column G: Basis/purposes for data use (research, patient care, benefits)

<b>Department/Agency</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>
Department of Veterans Affairs						
Department of Defense						
HHS Office of the Secretary						
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)	Y	Y	Y	B		
Centers for Medicare and Medicaid	Y	Y	N		N/A	FFP

<b>Department/Agency</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>
Services (CMS)						
Food and Drug Administration (FDA)	Y	Y	Y	B		Public health surveillance/ research
Health Resources and Services Administration (HRSA)						
Indian Health Service (IHS)	Y	Y	Y	B	HL7	Patient care, public health care, research
National Institutes of Health (NIH)						
Substance Abuse and Mental Health Services Administration (SAMHSA)						
Social Security Administration						
Department of Agriculture						
State Department						
US Agency for International Development						
Justice Department						
Treasury Department						
Department of Education						
General Services Administration						
Environmental Protection Agency						
Department of Housing & Urban Development						
Department of Transportation						
Homeland Security						

**Number of Terms**

*Quantify the number of vocabulary terms, range of terms or other order of magnitude.*

The Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven<sup>®</sup> 2.3.1 (HL7<sup>®</sup>) Standard Protocol lists the following message types as part of the standard:

VXQ – Query for Vaccination Record  
 VXR – Response to Vaccination Query Returning the Vaccination Record  
 VXX – Response to Vaccination Query Returning Multiple PID Matches  
 VXU – Unsolicited Vaccination Record Update  
 ORU – Unsolicited Transmission of an Observation  
 ACK – General Acknowledgement  
 OCK – Query General Acknowledgment (no matching records)

Each message type will have various segments relevant to information essential to that particular segment. For example:

(VXQ) Query for a Vaccination Record

Definition: When a health care provider participating in an immunization registry needs to obtain a complete patient vaccination record, he/she will send a query (using a V01 trigger event) to the immunization registry for the definitive (last updated) immunization record.

The query follows this format:

<u>VXQ</u>	<u>Vaccination Query</u>	<u>H7 Chapter</u>
MSH	Message Header Segment	2
QRD	Query Definition Segment	2
[QRF]	Query Filter Segment	2

**VXQ Example #1 (Query with Many Identifiers)**

```
MSH|^~\&||GA000||MA000|199705221605||VXQ^V01|19970522GA40|T|2.3.1|||NE|AL|<CR>
QRD|199705221605|R|I|19970522GA05|||25^RD|^KENNEDY^JOHN^FITZGERALD^JR|
VXI^VACCINE INFORMATION^HL70048|^SIIS|<CR>
QRF|MA000|||256946789~19900607~MA~MA99999999~88888888~KENNEDY^JACQUELINE^
LEE^BOUVIER~898666725~KENNEDY^JOHN^FITZGERALD~822546618|<CR>
```

In this query, the Georgia state registry (GA0000) is sending a request to the Massachusetts state registry (MA0000) for the immunization record of John Fitzgerald Kennedy, Jr., who was born on June 7, 1990. The request is being sent on May 22, 1997, at 4:05 p.m. All known patient identifiers are included in the sample query for use in matching records. These identifiers are defined by their position in the QRF segment. The responding system is expected to return all query items in its response.

***How often are terms updated?***

Other defined messages can be found in the implementation guide. The terms are updated in subsequent versions of the standard (i.e. HL7<sup>®</sup> Version 3.0)

The lists of CVX and MVX codes sets are attached to this document as Appendixes B and C, respectively.

### **Range of Coverage**

***Within the recommended vocabulary, what portions of the standard are complete and can be implemented now? (300 words or less)***

The HL7<sup>®</sup> standard for immunization data transactions, as promulgated by CDC, is complete. They have defined the immunization messages described above, and organizations using this standard have removed “Z” segments from their data transactions. This removes the possibility of uniquely defined elements being removed from the transaction, which limits flexibility with the standard, but creates a common vocabulary that is interoperable with any system. The standard can be implemented at the present time. Additionally, CDC, working with HL7<sup>®</sup> is responsible for maintenance and updates of the CVX and MVX code sets that are utilized in this immunization message standard.

### **Acquisition: *How are the data sets/codes acquired and use licensed?***

HL7<sup>®</sup> is created through a consensus-based method in which a group of volunteers representing interested parties works in an open process to create a standard. The data standards are created and refined in subsequent versions. HL7<sup>®</sup> Version 1.0 was published in September 1987; Version 2.3.1, which is currently used with immunization data transactions, was published in March 1997. There is no use license with this standard; it is available for any healthcare organization to use.

### **Cost**

***What is the direct cost to obtain permission to use the data sets/codes? (licensure, acquisition, other external data sets required, training and education, updates and maintenance, etc.)***

There is no cost to examine or assess the HL7<sup>®</sup> standard. The only cost would be the use and/or possible development of a tool or parser in order to utilize the messaging. At this time, it is difficult to estimate the cost of other reference terminologies until such vocabularies are identified, recommended and adopted.

***Guidance: What public domain and implementation and user guides, implementation tools or other assistance is available and are they approved by the SDO?***

An implementation guide for the HL7<sup>®</sup> standard with respect to immunization data transactions can be found on the National Immunization Program website: [www.cdc.gov/nip/registry](http://www.cdc.gov/nip/registry). The HL7<sup>®</sup> protocol has been refined into a series of messages specific to the transmission of immunization-specific data. The standard, promulgated by CDC, has been endorsed by HL7<sup>®</sup> and is in current use among many systems.

***Is a conformance standard specified? Are conformance tools available?***

The implementation guide details the HL7<sup>®</sup> standard messages that must be applied to immunization data transactions. It describes a consensus-based standard that has widespread approval.

***Maintenance: How do you coordinate inclusion and maintenance with the standards developer/owners?***

As the HL7<sup>®</sup> standard continues to evolve, both CDC and assorted stakeholders will incorporate those changes into the latest versions of the implementation guide for immunization data transactions. Note that this recommendation requires review and updating of the standard and terminology within 12-18 months.

***What is the process for adding new capabilities or fixes?***

New messages, content, or terminology can be brought to the HL7<sup>®</sup> quarterly meetings for possible inclusion in the latest standard. Additions to the specific standard for immunizations can also be suggested to CDC directly.

***What is the average time between versions?***

HL7<sup>®</sup> Version 1.0 – September 1987

HL7<sup>®</sup> Version 2.0 – September 1988

HL7<sup>®</sup> Version 2.1 - June 1990

HL7<sup>®</sup> Version 2.2 – December 1994

HL7<sup>®</sup> Version 2.3 – March 1997

***What methods or tools are used to expedite the standards development cycle?***

The HL7<sup>®</sup> standard is defined through a consensus process and thus, it is not possible to utilize any tools or methods to expedite the development cycle.

***How are local extensions, beyond the scope of the standard, supported if at all?***

There are no local extensions with the HL7<sup>®</sup> immunization data standard as all users have agreed to remove all “Z” codes (local elements) and adhere to a national standard.

**Customization:** *Describe known implementations that have been achieved without user customization, if any.*

All known implementations have been done without any specific customization to the standard, as all users have agreed to adhere to one consensus-based standard without adding any additional local elements.

*If user customization is needed or desirable, how is this achieved? (e.g, optional fields, interface engines, etc.)*

### Mapping Requirements

*Describe the extent to which user agencies will likely need to perform mapping from internal codes to this standard.*

HL7<sup>®</sup> has been the endorsed standard for immunization record exchange from the early stages of the program at CDC. Use of this standard may require mapping from this standard message to other messages that are in use.

*Identify the tools available to user agencies to automate or otherwise simplify mapping from existing codes to this standard.*

None at this time.

### Compatibility

*Identify the extent of off-the-shelf conformity with other standards and requirements:*

Conformity with other Standards	Yes (100%)	No (0%)	Yes with exception
NEDSS requirements			<b>X</b>
HIPAA standards	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
HL7 2.x	<b>X</b>		

### Implementation Timeframe

*Estimate the number of months required to deploy this standard; identify unique*

***considerations that will impact deployment schedules.***

This standard is already in use and new institutions adopting this standard would assess the timeframes for implementation based upon their resources and needs. An implementation guide is currently available, and many agencies already adhere to this standard. Additionally, HL7<sup>®</sup> is free for messaging use, as are the CVX and MVX terminologies, and available to any system developer, as well as being platform-independent.

***If some data sets/code sets are under development, what are the projected dates of completion/deployment?***

HL7<sup>®</sup> 2.4 is the current version being used. It is expected that potential revisions to the implementation guide will occur based on this latest version.

**Gaps*****Identify the gaps in data, vocabulary or interoperability.***

Currently, there are minimal gaps within the messaging standard. It matches current data needs with respect to immunization registries. Gaps related to terminology exist, as they do not harmonize with product information standards that are currently under development. Data needs will evolve potentially requiring more robust clinical content from a standard vocabulary. The committee analyzed this issue and it was determined that the CVX and MVX codes from HL7<sup>®</sup> be adopted, but that this issue be revisited in 12-18 months. Additional research needs to be done to assess those future data needs, and whether the specific reference terminologies could address those issues. Regardless, the standard for the seamless transmission of immunization messages is a tested and readily implementable standard for use in immunization registries.

**Obstacles*****What obstacles, if any, have slowed penetration of this standard? (technical, financial, and/or cultural)***

There have been few obstacles in regard to this standard, as it has been adopted by many health data organizations, as well as state and federal data agencies.

Appendix A**Information Exchange Requirements (IERs)**

<b>Information Exchange Requirement</b>	<b>Description of IER</b>
Beneficiary Financial / Demographic Data	Beneficiary financial and demographic data used to support enrollment and eligibility into a Health Insurance Program.
Beneficiary Inquiry Information	Information relating to the inquiries made by beneficiaries as they relate to their interaction with the health organization.
Beneficiary Tracking Information	Information relating to the physical movement or potential movement of patients, beneficiaries, or active duty personnel due to changes in level of care or deployment, etc.
Body of Health Services Knowledge	Federal, state, professional association, or local policies and guidance regarding health services or any other health care information accessible to health care providers through research, journals, medical texts, on-line health care data bases, consultations, and provider expertise. This may include: (1) utilization management standards that monitor health care services and resources used in the delivery of health care to a customer; (2) case management guidelines; (3) clinical protocols based on forensic requirements; (4) clinical pathway guidelines; (5) uniform patient placement criteria, which are used to determine the level of risk for a customer and the level of mental disorders (6) standards set by health care oversight bodies such as the Joint Commission for Accreditation of Health Care Organizations (JCAHO) and Health Plan Employer Data and Information Set (HEDIS); (7) credentialing criteria; (8) privacy act standards; (9) Freedom of Information Act guidelines; and (10) the estimated time needed to perform health care procedures and services.
Care Management Information	Specific clinical information used to record and identify the stratification of Beneficiaries as they are assigned to varying levels of care.
Case Management Information	Specific clinical information used to record and manage the occurrences of high-risk level assignments of patients in the health delivery organization..
Clinical Guidelines	Treatment, screening, and clinical management guidelines used by clinicians in the decision-making processes for providing care and treatment of the beneficiary/patient.

Cost Accounting Information	All clinical and financial data collected for use in the calculation and assignment of costs in the health organization .
Customer Approved Care Plan	The plan of care (or set of intervention options) mutually selected by the provider and the customer (or responsible person).
Customer Demographic Data	Facts about the beneficiary population such as address, phone number, occupation, sex, age, race, mother's maiden name and SSN, father's name, and unit to which Service members are assigned
Customer Health Care Information	All information about customer health data, customer care information, and customer demographic data, and customer insurance information. Selected information is provided to both external and internal customers contingent upon confidentiality restrictions. Information provided includes immunization certifications and reports, birth information, and customer medical and dental readiness status
Customer Risk Factors	Factors in the environment or chemical, psychological, physiological, or genetic elements thought to predispose an individual to the development of a disease or injury. Includes occupational and lifestyle risk factors and risk of acquiring a disease due to travel to certain regions.
Encounter (Administrative) Data	Administrative and Financial data that is collected on patients as they move through the healthcare continuum. This information is largely used for administrative and financial activities such as reporting and billing.
Improvement Strategy	Approach for advancing or changing for the better the business rules or business functions of the health organization. Includes strategies for improving health organization employee performance (including training requirements), utilization management, workplace safety, and customer satisfaction.
Labor Productivity Information	Financial and clinical (acuity, etc.) data used to calculate and measure labor productivity of the workforce supporting the health organization.
health organization Direction	Goals, objectives, strategies, policies, plans, programs, and projects that control and direct health organization business function, including (1) direction derived from DoD policy and guidance and laws and regulations; and (2) health promotion programs.
Patient Satisfaction Information	Survey data gathered from beneficiaries that receive services from providers that the health organization wishes to use to measure satisfaction.

Patient Schedule	Scheduled procedure type, location, and date of service information related to scheduled interactions with the patient.
Population Member Health Data	Facts about the current and historical health conditions of the members of an organization. (Individuals' health data are grouped by the employing organization, with the expectation that the organization's operations pose similar health risks to all the organization's members.)
Population Risk Reduction Plan	Sets of actions proposed to an organization commander for his/her selection to reduce the effect of health risks on the organization's mission effectiveness and member health status. The proposed actions include: (1) resources required to carry out the actions, (2) expected mission impact, and (3) member's health status with and without the actions.
Provider Demographics	Specific demographic information relating to both internal and external providers associated with the health organization including location, credentialing, services, ratings, etc.
Provider Metrics	Key indicators that are used to measure performance of providers (internal and external) associated with the health organization.
Referral Information	Specific clinical and financial information necessary to refer beneficiaries to the appropriate services and level of care.
Resource Availability	The accessibility of all people, equipment, supplies, facilities, and automated systems needed to execute business activities.
Tailored Education Information	Approved TRICARE program education information / materials customized for distribution to existing beneficiaries to provide information on their selected health plan. Can also include risk factors, diseases, individual health care instructions, and driving instructions.