Conformance Clarification for EHR Certification of Immunization Messaging

VXU MESSAGES V04

HL7 Version 2.5.1

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Addendum to HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.4)

Centers for Disease Control and Prevention

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HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.4)—Addendum

Conformance Clarification for Electronic Health Record (EHR) Certification of Immunization Messaging

The Office of the National Coordinator for Health Information Technology's (ONC's) 2014 Edition EHR Certification Criterion "§170.314(f)(2)" specifies Standards and Implementation Specifications in "§170.205(e)(3) (HL7 2.5.1)" that designates HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4; and in "§170.207(e)(2)" that designates HL7 Standard Code Set CVX -- Vaccines Administered, updates through July 11, 2012.

This addendum consolidates the Implementation Guide information that clarifies the conformance requirements for EHR certification. This supplement does not specify additional requirements; it just clarifies existing ones. Conformance statements and conditional predicates that clarify message requirements for EHR certification are presented below. Value set requirements, general clarifications, and Immunization Implementation Guide errata are also provided in this addendum.

1.0 GENERAL CLARIFICATIONS

The scope of the conformance requirements will only address sender behavior. All actions on the part of the receiver, including acknowledgements, are not covered by the conformance requirements.

The conformance requirements do not specify transport in order to give state and local public health agencies the flexibility to specify their preferred means of transport.

CVX codes are used in several message components. They indicate the vaccine of interest for the component. In the case of RXA-5, they indicate the vaccine administered. This should be the most specific vaccine known. In the case of a historical record of an immunization, this may be the general vaccine type. For instance, it could be CVX code 45, Hep B, unspecified formulation. If the immunization was administered by the reporter, it should reflect the more specific vaccine actually administered. (e.g. CVX 43, Hep B, Adult). The other place CVX codes are used in observations (OBX). For instance, the observation about the vaccine type for Vaccine Information Statements (VIS) relies on the "unspecified formulation" CVX codes, since the statement applies to any of the specific vaccines. In the case where Hep B adult was administered, the RXA-5.1 would be populated with 43. OBX-5.1 for the document type observation would be populated with 45.

http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=vg

Table 1-Clarifications

Location	Field Name	Existing	Clarification
PID-22	Ethnic Group	Definition: This field further defines the patient's ancestry. Refer to User-defined Table 0189 - Ethnic Group. The second triplet of the CE data type for ethnic group (alternate identifier, alternate text, and name of alternate coding system) is reserved for governmentally assigned codes.	HL7 table 0189 displayed in the Implementation Guide refers to two values sets. The US ethnicity codes are actually from the CDCREC table. They should be identified as CDCREC. The HL7 2.4 codes are the actual values in HL70189 and should be labeled accordingly. In addition it is not clear which one is meant by "reserved for governmentally assigned codes" in the implementation guide. Therefore, either is acceptable. That is, the first triplet of PID.22 may contain a code from either value set given in table 0189 or CDCREC. In addition, the second triplet may also be valued with a code from either value set given in table 0189 or CDCREC. The order in which the codes appear is not significant. Examples for Hispanic or Latino include "H^Hispanic or Latino^HL70189", "2135-2^Hispanic or Latino^CDCREC", "H^Hispanic or Latino^HL70189^2135-2^Hispanic or Latino^CDCREC", and so on.

2.0 ERRATA

There are additional errata identified in Release 1.4 of the Immunization Messaging Implementation Guide. These will be brought to the attention of the public health IIS community as a next release of the Immunization Messaging Implementation Guide is produced. For EHR certification purposes, these errata are documented and corrected below.

Table 2-Errata

Location	Field Name	Change	Existing	Corrected
PID-1	Set ID	**Note:** This Set ID numbers the repetitions of the segments. Only one patient per message is supported for meaningful use certification. Literal value: "1"	Usage RE. Cardinality [0..1]	Usage R. Cardinality [1..1] PID-1 (Set ID) **SHALL** have the Literal Value of '1' when the message type is VXU
MSH-21	Message Profile ID	This field will not be tested during certification.	Usage RE	Usage C(R/X) **Conditional Predicate:** If MSH-9.1 is populated with "QBP" or "RSP"
VXU Orders Group		Usage specified.	Usage is blank	Usage shall be RE.
RXA-6	Administered amount		**NOTE:** If RXA-6 (administered amount) is not known or meaningful, use "999."	New conformance statement: **IZ-33:** If RXA-9.1 is not valued "00" then RXA.6 SHALL BE valued "999".
ORC-12		Clarification		If the first occurrence of RXA-9.1 is valued "00" and RXA-20 is valued "CP" or "PA"
RXA-15	Substance lot number	Clarification	If the value in RXA-9.1 (Administration Notes) is valued "00"	If the first occurrence of RXA-9.1 is valued "00" and RXA-20 is valued "CP" or "PA"
RXA-17	Manufacturer	Clarification	If the value in RXA-9.1 (Administration Notes) is valued "00"	If the first occurrence of RXA-9.1 is valued "00" and RXA-20 is valued "CP" or "PA"

RXA-20	Refusal reason	Correct text	**IZ-32:** If the RXA-18 (Refusal Reason) is populated, this field SHALL be valued to “RE”.	**IZ-32:** If the RXA-18 (Refusal Reason) is populated, RXA-20 (Completion Status) SHALL be valued to “RE”.
RXA-20	Completion Status	New conformance statement	If this RXA has a CVX of 998 (no vaccine administered) then this shall be populated with NA.	**IZ-34:** If RXA-5.1 (vaccine administered) has a CVX of 998 (no vaccine administered) then RXA-20 shall be populated with “NA.”
CE.4-6	Data type	Change usage from RE to O	Usage is RE	Change usage to O
VIS Conformance Statement	OBX conformance statements	Clarification	IZ-23: If RXA-9.1 (Administration Note.code) is “00” then the message SHALL include an OBX segment associated with the RXA with OBX-3.1 shall equal “64994-7” . This OBX will indicate the Patient Eligibility Category for Vaccine Funding Program.	IZ-23: If RXA-20 is valued "CP" or "PA" and the first occurrence of RXA-9.1 (Administration Note.code) is “00” then the message SHALL include an OBX segment associated with the RXA with OBX-3.1 shall equal “64994-7” . This OBX will indicate the Patient Eligibility Category for Vaccine Funding Program.
VIS Conformance Statement	OBX conformance statements	Clarification	**IZ-24:** If RXA-9.1 is valued “00” and RXA-5.1 is valued with a CVX code from table PHVS_VISVaccines_IIS (See Appendix A) then there SHALL be: • an OBX segment with OBX-3.1 valued “64764-9” (bar coded) **and** one OBX with OBX-3.1 valued “29769-7” (presentation /delivery date) associated. Both OBX shall have the same value in OBX-4 **OR** • an OBX segment with OBX-3.1 valued “30956-7” (vaccine type) and an OBX segment with OBX-3.1	**IZ-24:** If RXA-20 is valued "CP" or "PA" and the first occurrence of RXA- 9.1 is valued “00” and RXA-5.1 is valued with a CVX code from table PHVS_VISVaccines_IIS (See Appendix A) then for each vaccine information statement that was shared there SHALL be: • one OBX segment with OBX-3.1 valued “69764-9” (bar coded) **and** one OBX with OBX-3.1 valued “29769-7” (presentation /delivery date) associated. Both

			valued “29768-9” (version date) and one OBX with OBX-3.1 valued “29769-7” (presentation /delivery date) associated. Both OBX shall have the same value in OBX-4	OBX shall have the same value in OBX-4 **OR** • one OBX segment with OBX-3.1 valued “30956-7” (vaccine type) and one OBX segment with OBX-3.1 valued “29768-9” (version date) and one OBX with OBX-3.1 valued “29769-7” (presentation /delivery date) associated. All three OBX shall have the same value in OBX-4 **Note that 30956-7 (vaccine type) is preferred over the alternative** 38890-0 (Component Vaccine Type) even when the vaccine administered is a combination vaccine. For this reason, the test will compare to the 30956-7 value.
IN1		Changed usage from O to R since the IN1 segment is required if the group is present (per the base standard).	Usage O	Usage R
PID-29	Death Date conditional predicate	Correction	If PID-30 (patient death date) is valued “Y”	If PID-30 (patient death indicator) is valued “Y”
Version ID Data type	VID.2 and VID.3	Correct typo	Data type is set to (CO/O)	Data type is CE
CE data type	CE.4-CE.6	Change usage	Usage is RE	Change usage to O
XTN data type	XTN.4	Correct conditional predicate	If the XTN-2 (telecommunication type code) is valued “NET”	If the XTN-2 (telecommunication use code) is valued “NET”

XTN data type	XTN.6, XTN.7	Correct conditional predicate	If the XTN-2 (telecommunication type code) is not valued “NET”	If the XTN-2 (telecommunication use code) is not valued “NET”
HD data type use of OID	Data type specification note	Clarification	The use of OIDs in fields using this data type is encouraged.	The use of OIDs in fields using this data type is encouraged. **Note that either Namespace ID or Universal ID is required.**
EI Data Type		Correct typo	If EI.1 (Namespace ID) is not valued	If EI.2 (Namespace ID) is not valued
ORC-12	Change Usage to C(RE/O)	Document Conditional Predicate		If RXA-20 is valued "CP" or "PA" and the first occurrence of RXA-9.1 is valued “00”
OBX	Table page 112	Typo	Value set is listed as cdcgi1vis	Correct to cdcgs1vis
OBX-17	Change Usage to C(RE/O)	Document Conditional Predicate		If OBX-3.1 is “64994-7”
RXA-9	Admin Notes	Correct cardinality	Cardinality is [1..*], since is only required when RXA-20 is “CP” or “PA” changed to [0..*]	Change cardinality to [0..*]

3.0 VALUE SET REQUIREMENT CLARIFICATION

For conformance testing, the message elements summarized in the table below SHALL be valued with elements from the specified value sets. Value sets described in the guide for elements not in the table below will not be considered for conformance testing, as their associated message elements will not be constrained. (These unconstrained value sets in the guide are still worth consulting; they should be considered suggested usage, reflective of best and widespread practices, and may possibly become requirements in the future.) Value sets shown below are defined by their name in CDC vocabulary server - Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS), which may constrain the original Health Level Seven (HL7) tables and other code systems indicated. For EHR certification, PHIN VADS will be used as the source of truth to test content for these elements.

The National Institute for Standards and Technology (NIST) will depend on the CDC/PHIN VADS to ensure that the values are correct and current. PHIN VADS can be accessed at http://phinvads.cdc.gov. The NIST validation tool imports the value sets from CDC/PHIN VADS.

All the value sets associated with Immunization IG can also be downloaded using the following link:

http://phinvads.cdc.gov/vads/ViewView.action?name=Immunization Messaging - HL7 Version 2.5.1

The following table provides the mapping between the value set information present in immunization implementation guide and the VADS value set. More detailed version of this mapping table and all the value set concepts can be downloaded from PHIN VADS home page (http://phinvads.cdc.gov) under hot topics "**Immunization HL7 2.5.1**".

CDC vocabulary / PHIN VADS team can be contacted for support at PHINVS@CDC.GOV .

Table 3-Value Sets

Value set information from HL7 Implementation Guide			Vocabulary Source	Value set information from CDC Vocabulary Server (PHIN VADS)		
Data Element Name from HL7 IG	HL7 Segment - Field (location)	Value Set information from IG	Code System identifier (HL7 table 0396 Code)	PHIN VADS Value Set Name	PHIN VADS Hyperlinks & Value Set OID	Comments - Implementation notes
Sex	PID-8, NK1-15	User-defined Table 0001 - Sex, Value set OID : 2.16.840.1.113883.1.11.1	HITSP-CS-1	~~PHVS_Administrative Gender_HL7_V3~~	~~2.16.840.1.113883.1.11.1~~	~~V3 sex tables are being used in the guide. Next version of IG would remove the reference to Hl7 2.x Table 001.~~ PHVS_Administrative Gender_HL7_V3 specifies the value set for SEX as "M, F, and

						UN". Per the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 named in the ONC Final Rule, the HL70001 Administrative Sex table is to be used, and the relevant options in this table are "M, F, and U". The NIST Immunization Messaging Validation Tool will only accept "M, F, or U" when validating against HL70001.
Event type	MSH-9, second component	HL7-defined Table 0003 - Event type	HL70003	PHVS_EventType_IIS	2.16.840.1.114222.4.11.3362	
Patient class	PV1-2	User-defined Table 0004 - Patient class	HL70004	PHVS_PatientClass_IIS	2.16.840.1.114222.4.11.3363	
~~Race~~	~~PID-10, NK1-35~~	~~User-defined Table 0005 – Race, Value set OID: 2.16.840.1.114222.4.11.836~~	~~CDCREC~~	~~PHVS_RaceCategory_CDC~~	~~2.16.840.1.114222.4.11.836~~	~~Value Set OID in IG points to Race Category value set based upon CDC Race & Ethnicity. Next version of IG would remove reference to HL7 Table 0005 (Race)~~
Race	PID-10, NK1-35	User-defined Table 0005 – Race, Value set OID: 2.16.840.1.114222.4.11.836	CDCREC	FHIM_RaceCategory	2.16.840.1.113883.3.2074.1.1.3	Value Set OID in IG points to Race Category value set based upon CDC Race & Ethnicity. Next version of IG would remove reference to HL7 Table 0005 (Race)
Acknowledgment code	MSA-1	HL7-defined Table 0008 - Acknowledgment code	HL70008	PHVS_AcknowledgmentCode_HL7_2x	2.16.840.1.114222.4.11.958	
Physician ID	Use in all XCN data types; including PV1-7,8,9,17, RXA-10	User-defined Table 0010 - Physician ID		NPI		Each registry should establish a system of coding its reporting physicians. The National Provider Identifier (NPI) adopted for the HIPAA legislation may be used for this purpose.

Check digit scheme	Use in all CX data types; including PID-2,3,4,18,21	HL7-defined Table 0061 - Check digit scheme	HL70061	PHVS_CheckDigitScheme_HL7_2x	2.16.840.1.114222.4.11.3339	
Relationship	NK1-3, IN1-17	User-defined Table 0063 – Relationship	HL70063	PHVS_Relationship_IIS	2.16.840.1.114222.4.11.3365	HL7 table 0063 has been constrained for Immunization.
Financial class	OBX-5	User-defined Table 0064 - Financial class	HL70064	PHVS_FinancialClass_IIS	2.16.840.1.114222.4.11.3366	HL7 table 0064 has been constrained for Immunization.
Message type	MSH-9, first component	HL7-defined Table 0076 - Message type	HL70076	PHVS_MessageType_IIS	2.16.840.1.114222.4.11.3364	
Abnormal flags	OBX-8	HL7-defined Table 0078 - Abnormal flags	N/A	PHVS_AbnormalFlag_HL7_2x	2.16.840.1.114222.4.11.800	Use in OBX-8. Fields using this code set are expected to be empty. We have not included in VADS Immunization view yet as this is expected to be empty.
Observation result status codes interpretation	OBX-11	HL7-defined Table 0085 - Observation result status codes interpretation	HL70085	PHVS_ObservationResultStatus_IIS	2.16.840.1.114222.4.11.6062	
Query priority		HL7-defined Table 0091 - Query priority	HL70091	PHVS_QueryPriority_IIS	2.16.840.1.114222.4.11.3382	
Delayed acknowledgment type	MSA-5	HL7-defined Table 0102 - Delayed acknowledgment type	N/A			Fields using this code set are expected to be empty. So, we have not included in PHIN VADS.
Processing ID	MSH-11	HL7-defined Table 0103 - Processing ID	HL70103	PHVS_ProcessingID_HL7_2x	2.16.840.1.114222.4.11.1028	
Version ID	MSH-12	HL7-defined Table 0104 - Version ID	HL70104	PHVS_VersionID_IIS	2.16.840.1.114222.4.11.3367	
Source of comment	NTE-2	HL7-defined Table 0105 - Source of comment	N/A			Fields using this code set are expected to be empty.
Order Control Codes	ORC-1	HL7-defined Table 0119 – Order Control Codes	HL70119	PHVS_OrderControlCode_IIS	2.16.840.1.114222.4.11.3368	
Quantity limited request	RCP-2	HL7-defined Table 0126 - Quantity limited request	HL70126	PHVS_QuantityLimitedRequest_IIS	2.16.840.1.114222.4.11.3383	

Yes/No indicator	PID-24,30; PD1-12	HL7-defined Table 0136 - Yes/No indicator	HL70136	PHVS_YesNo_HL7_2x	2.16.840.1.114222.4.11.819	
Accept/Application acknowledgment conditions	MSH-15 and 16	HL7-defined Table 0155 - Accept/Application acknowledgment conditions	HL70155	PHVS_AcceptApplicationAcknowledgmentConditions_HL7	2.16.840.1.114222.4.11.3344	
Route of administration	RXR-1	HL7-defined Table 0162 - Route of administration	NCIT	PHVS_RouteOfAdministration_IIS	2.16.840.1.114222.4.11.3369	Uses HITSP recommended FDA route of administration based upon NCI thesaurus codes. Next version of IG would remove reference to HL7 table 0162.
Administrative site	RXR-2	HL7-defined Table 0163 - Administrative site	HL70163	PHVS_AdministrativeSite_IIS	2.16.840.1.114222.4.11.3370	
Ethnic Group	PID-22, NK1-28	User-defined Table 0189 - Ethnic Group	CDCREC	PHVS_EthnicityGroup_CDC_Unk	2.16.840.1.114222.4.11.3015	Ethnicity Group value set is based upon CDC Race & Ethnicity. Next version of IG would remove reference to HL7 Table 0189. This does have HL7 Null flavor concept which has a different code system OID.
Address type	use in all XAD data types; including PID-11	HL7-defined Table 0190 - Address type	HL70190	PHVS_AddressType_HL7_2x	2.16.840.1.114222.4.11.801	Recording of Birth State uses the BDL, birth delivery location code
Name type	Use in all XCN, XPN data types; including PID-5, 6, 9	HL7-defined Table 0200 - Name type	HL70200	PHVS_NameType_IIS	2.16.840.1.114222.4.11.3371	
Telecommunication use code	Use in all XTN data types including PID-13,14	HL7-defined Table 0201 - Telecommunication use code	HL70201	PHVS_TelecommunicationUseCode_HL7_2x	2.16.840.1.114222.4.11.818	
Telecommunication equipment type	Use in all XTN data types; including PID-13,14	HL7-defined Table 0202 - Telecommunication equipment type	HL70202	PHVS_TelecommunicationEquipmentType_HL7_2x	2.16.840.1.114222.4.11.817	
Identifier type	Use in all CX, XCN type codes; including PID-	User-defined Table 0203 - Identifier type	HL70203	PHVS_IdentifierType_IIS	2.16.840.1.114222.4.11.3372	

	2,3,4,18,21 and RXA-10					
Organizational name type	Use in all XON data types	User-defined Table 0204 - Organizational name type	HL70204	PHVS_OrganizationalNameType_IIS	2.16.840.1.114222.4.11.3373	
Processing mode	MSH-11	HL7-defined Table 0207 - Processing mode	N/A	PHVS_ProcessingMode_HL7_2x	2.16.840.1.114222.4.11.1029	Fields using this code set are expected to be empty. Not included in Immunization VADS view as this is supported to be empty.
Query response status	QAK-2	User-defined Table 0208 - Query response status	HL70208	PHVS_QueryResponseStatus_IIS	2.16.840.1.114222.4.11.3374	
Alternate character sets	MSH-18	HL7-defined Table 0211 - Alternate character sets	N/A	PHVS_AlternateCharacterSets_HL7_2x	2.16.840.1.114222.4.11.3347	Fields using this code set are expected to be empty.
Publicity code	PD1-11	User-defined Table 0215 - Publicity code	HL70215	PHVS_PublicityCode_IIS	2.16.840.1.114222.4.11.3384	
Living arrangement		User-defined Table 0220 - Living arrangement	N/A			Fields using this code set are expected to be empty.
Manufacturers of vaccines	RXA-17	HL7-defined Table 0227 - Manufacturers of vaccines	MVX	PHVS_ManufacturersOfVaccinesMVX_CDC_NIP	2.16.840.1.114222.4.11.826	
Census tract	Use in all XAD; including PID-11	User-defined Table 0288 - Census tract	N/A			Fields using this code set are expected to be empty.
County/parish	Use in all XAD; including PID-11	User-defined Table 0289 - County/parish, FIPS 6-4 county codes	FIPS6_4	PHVS_County_FIPS_6-4	2.16.840.1.114222.4.11.829	PHIN VADS link is included for FIPS 6-4 in IG
Codes for Vaccines administered	RXA-5	HL7-defined Table 0292 - Codes for Vaccines administered	CVX	PHVS_VaccinesAdministeredCVX_CDC_NIP	2.16.840.1.114222.4.11.934	
Language		User-defined Table 0296 - Language	ISO6392	PHVS_Language_ISO_639-2_Alpha3	2.16.840.1.114222.4.11.831	
CN ID source	Use in all XCN data types	User-defined Table 0297 - CN ID source	N/A			Use in all XCN data types. [locally-defined]

Namespace ID	Use in all EI, HD data types	User-defined Table 0300 - Namespace ID	N/A			Use in all EI, HD data types [locally-defined]
Universal ID type	Use in all HD data types	HL7-defined Table 0301 - Universal ID type	HL70301	PHVS_UniversalIDType_IIS	2.16.840.1.114222.4.11.6063	
Completion status	RXA-20	HL7-defined Table 0322 - Completion status	HL70322	PHVS_CompletionStatusForValidValues_HL7_2x	2.16.840.1.114222.4.11.821	
Action code	RXA-21	HL7-defined Table 0323 - Action code	HL70323	PHVS_ActionCode_IIS	2.16.840.1.114222.4.11.3375	
Message structure	MSH-9, third component	HL7-defined Table 0354 - Message structure	HL70354	PHVS_MessageStructure_IIS	2.16.840.1.114222.4.11.3376	
Alternate character set handling scheme	MSH-20	HL7-defined Table 0356 - Alternate character set handling scheme	N/A	PHVS_AlternateCharacterSetHandlingScheme_HL7_2x	2.16.840.1.114222.4.11.3350	Fields using this code set are expected to be empty.
Message error status codes	ERR-3	HL7-defined Table 0357 - Message error status codes	HL70357	PHVS_MessageErrorConditionCodes_HL7_2x	2.16.840.1.114222.4.11.974	
Degree	use in all XPN data types, including PID-5, 6, 9	User-defined Table 0360 – Degree	HL70360	PHVS_DegreeLicenseCertificate_HL7_2x	2.16.840.1.114222.4.11.808	
Application		User-defined Table 0361 – Application	N/A			No suggested values defined.
Facility		User-defined Table 0362 – Facility	N/A			No suggested values defined.
Assigning Authority		User-defined Table 0363 – Assigning Authority	N/A			Look at the IG for the starting set. We may include this in VADS later, if needed as this is user defined.
Coding system	Use in CE data types to denote the coding system used for coded values	User-defined Table 0396 – Coding system	HL70396	PHVS_CodingSystem_HL7_2x_Table0396	2.16.840.1.114222.4.11.3338	
Immunization registry status	PD1-16	User-defined Table 0441 - Immunization registry status	HL70441	PH_ImmunizationRegistryStatus_IIS	2.16.840.1.114222.4.11.3378	

Query Name		User-defined Table 0471 – Query Name	HL70471	PHVS_QueryName_IIS	2.16.840.1.114222.4.11.3379	
Error Severity	ERR-4	HL7 Table 0516 - Error Severity (use in ERR-4)	HL70516	PHVS_ErrorSeverity_HL7_2x	2.16.840.1.114222.4.11.993	
Application Error Code		User-defined Table 0533 – Application Error Code	N/A	Locally Defined Codes		There are no suggested values for this code. Local implementations need to create a table of local application error codes.
Immunization information source	RXA-9	CDC-defined NIP001 - Immunization information source	NIP001	PHVS_ImmunizationInformationSource_HITSP	2.16.840.1.113883.3.88.12.80.39	
Substance refusal reason	RXA-18	CDC-defined NIP002 - Substance refusal reason	NIP002	PHVS_SubstanceRefusalReason_IIS	2.16.840.1.114222.4.11.3380	
Observation identifiers	OBX-3	CDC-defined NIP003 - Observation identifiers	LN	PHVS_ObservationIdentifier_IIS	2.16.840.1.114222.4.11.3381	Look at the IG for mapping between Observation Identifier (OBX-3) and its associated observation values (OBX-5) for CE data type
Immunization Funding Source	OBX- 5	Immunization Funding Source	CDCPHINVS	PHVS_ImmunizationFundingSource_IIS	2.16.840.1.114222.4.11.3287	Few null flavor concepts are included in this value set.
Vaccination Contraindications	OBX- 5	Value Set Name – Vaccination Contraindications	SCT, CDCPHINVS	PHVS_VaccinationContraindication_IIS	2.16.840.1.114222.4.11.3288	Value set contains both SNOMED and CDCPHINVS coding system concepts
Vaccination Reaction	OBX- 5	Vaccination Reaction - IIS	SCT, CDCPHINVS	PHVS_VaccinationReaction_IIS	2.16.840.1.114222.4.11.3289	Value set contains both SNOMED and CDCPHINVS coding system concepts
Vaccination Special Indications	OBX- 5	Vaccination Special Indications - IIS	CDCPHINVS	PHVS_VaccinationSpecialIndication_IIS	2.16.840.1.114222.4.11.3290	
Immunization Profile Identifiers	MSH-21	Immunization Profile Identifiers - IIS	CDCPHINVS	PHVS_ImmunizationProfileIdentifier_IIS	2.16.840.1.114222.4.11.3291	

Immunization Schedule Identifiers	OBX-5	Immunization Schedule Identifiers - IIS	CDCPHINVS	PHVS_ImmunizationScheduleIdentifier_IIS	2.16.840.1.114222.4.11.3292	
Evidence of Immunity	OBX- 5	Evidence of Immunity - IIS	SCT	PHVS_EvidenceOfImmunity_IIS	2.16.840.1.114222.4.11.3293	
VIS Bar Codes	OBX-5	PHVS_VISBarcodes_IIS	cdcgs1vis	PHVS_VISBarcodes_IIS	2.16.840.1.114222.4.11.6041	Bar Codes content may not be populated in the message as implementers may not have implemented this new feature.
Funding Eligibility Observation Method	OBX- 17	Funding Eligibility Observation Method (IIS)	CDCPHINVS	PHVS_FundingEligibilityObsMethod_IIS	2.16.840.1.114222.4.11.6039	
VIS Vaccines	OBX-5	VIS Vaccines (IIS)	CVX	PHVS_VISVaccines_IIS	2.16.840.1.114222.4.11.6040	

4.0 APPENDIX A: CONFORMANCE STATEMENTS

For convenience the following table summarizes conformance statements for specific electronic immunization message elements.

Table 4-Data Type Conformance Statements

Data Type	Location	Conformance Statement
CQ	CQ-1	**IZ-1: CQ-1 (Quantity) SHALL be a positive integer.**
CQ	CQ-2	**IZ-2: CQ-2 (Units) SHALL be the literal value "RD".**
EI	EI-3	**IZ-3: If populated, EI-3 (Universal ID) shall be valued with an ISO-compliant OID.**
EI	EI-4	**IZ-4: If populated, EI-4 (Universal ID Type) shall contain the value "ISO"**
HD	HD-2	**IZ-5: If populated, HD-2 (Universal ID) SHALL be valued an ISO-compliant OID**
HD	HD-3	**IZ-6: If populated, HD-3 (Universal ID Type) SHALL be valued the literal value: "ISO"**
VID	VID-1	**IZ-7: VID-1 (Version ID) SHALL be valued with the literal value "2.5.1".**

Table 5-Field Level Conformance Statements

Location	Field Name	Conformance Statement
BHS	Batch Field Separator	**IZ-8: BHS-1 (Batch Field Separator) field SHALL be "|"**
BHS	Batch Encoding Character	**IZ-9: BHS-2 (Batch Encoding Character) field SHALL be "^~\\&"**
FHS	File Field Separator	**IZ-10: FHS-1 (Field Field Separator) field SHALL be "|"**
FHS	File Encoding Character	**IZ-11: FHS-2 (Field Encoding Character) field SHALL be "^~\\&"**
MSH-1	Field Separator	**IZ-12:** MSH-1 (Field Separator). **SHALL** have the Literal Value of '|'
MSH-2	Encoding Characters	**IZ-13:** MSH-2 (Encoding Characters) **SHALL** have the Literal Value of "^~\&"
MSH-7	Date/Time of Message	**IZ-14:** MSH-7 (Date/Time of Message) **SHALL** be expressed with a minimum precision of the nearest minute, and be represented in the following format: 'YYYYMMDDHHMM[SS[.S[S[S[S]]]]] [+/-ZZZZ]'.
MSH-9	Message Type	**IZ-17:** MSH-9 (Message Type) **SHALL** be constrained to be the value "VXU^V04^VXU_V04"

Location	Field Name	Conformance Statement
MSH-12	Version ID	**IZ-15**: MSH-12 (Version ID) **SHALL** have the Literal Value of '2.5.1'.
MSH-16	Application Acknowledgement Type	**IZ-16:** The value of MSH-16 SHALL be one of the following: AL-always, NE-never, ER-Error/reject only, SI-successful completion only**.**
OBX-1	Set ID	**IZ-20:** The Value of OBX-1 (Set ID-OBX) SHALL be valued sequentially starting with the value "1" within a given segment group.
OBX-2	Value Type	**IZ-21:** The value of OBX-2 (Value Type) SHALL be one of the following: CE, NM, ST, DT, ID or TS
OBX-5		**IZ-35:** If OBX-3.1 is "64994-7" and OBX-2 is "CE" then the value set for OBX-5 shall be HL70064.
OBX-5		**IZ-36:** If OBX-3.1 is "69764-9" and OBX-2 is "CE" then the value set for OBX-5 shall be cdcgi1vis.
OBX-5		**IZ-37:** If OBX-3.1 is "30956-7" and OBX-2 is "CE" then the value set for OBX-5 shall be CVX.
OBX-11	Observation Result Status	**IZ-22:** The value of OBX-11 (Observation Result Status) SHALL be "F"
ORC-1	Order Control	**IZ-25:** ORC.1 (Order Control) SHALL contain the value "RE "
PID-7	Birth Date	**IZ-26:** PID-7 (birth date) SHALL be accurate at least to the day. (YYYYMMDD)
RXA-1	Give Sub-id Counter	**IZ-28:** RXA-1 (Give Sub-id counter) SHALL be valued "0" Note that "0" is zero.
RXA-2	Admin Sub-id	**IZ-29:** RXA-2 (admin Sub-id) SHALL be valued "1 "
RXA-4	Date/time of administration End	**IZ-30:** If RXA-4 (Date time of admin end) is populated, then it SHALL be the same as Start time (RXA-3)
RXA-6	Administered Amount	IZ-33: If RXA-9.1 is not valued "00" then RXA.6 SHALL BE valued "999".
RXA-9.1	Administration Notes	**IZ-31:** If RXA-20 is valued "CP" or "PA" then RXA-9.1 (admin notes) SHALL be valued one of the codes listed in NIP001 in the first occurrence of this field. Support for repetition of this field is optional. See "Known Issues" in the test tool documentation section for further clarification.

Location	Field Name	Conformance Statement
		Note that NIST certification will only test for the presence of the first occurrence of RXA-9. Additional occurrences will be ignored.
RXA-20	Completion Status	**IZ-32:** If the RXA-18 (Refusal Reason) is populated, RXA-20 (completion Status) SHALL be valued to “RE”.
RXA-20	Completion Status	**IZ-34:** If RXA-5.1 (vaccine administered) has a CVX of 998 (no vaccine administered) then RXA-20 shall be populated with “NA”

4.1.1.1 Application Conformance Statement:

There are a number of core data elements that are important to support a complete immunization history and the functional requirements of an Immunization Information System (IIS). Some of these utilize the OBX to carry their data. The following table lists the data elements and the usage responsibilities.

Table 4-Application Conformance Statements

Core Data Element	Description	Observation Identifier (OBX-3)	Observation Value Set (OBX-5)	Conformance Statements
Patient Eligibility Category for Vaccine Funding Program	This value represents the funding program that should pay for a given immunization. It is determined based on characteristics of the patient/client and the type of vaccine administered.	64994-7	HL70064	**IZ-23:** If RXA-20 is valued “CP” or “PA” and the first occurrence of RXA-9.1 (Administration Note.code) is “00” then the message SHALL include an OBX segment associated with the RXA with OBX-3.1 shall equal “64994-7” . This OBX will indicate the Patient Eligibility Category for Vaccine Funding Program.
Vaccine Information Statement (VIS) document type	This value represents the vaccine type that the statement provides information about.	69764-9	cdcgi1vis	See VIS related Conformance Statements below
Vaccine Information Statement (VIS) version date	This value represents the date the presented VIS was published	29768-9		See VIS related Conformance Statements below
VIS vaccine type	This value represents the vaccine type that the statement provides information about	30956-7	CVX	
Vaccine Information Statement (VIS) delivery date	This value represents the date the document was presented to the patient/responsible person.	29769-7		See VIS related Conformance Statements below

NOTE: There are three things that need to be recorded for documenting VIS:

1. Date VIS was shared with patient or parent
2. Vaccine that the VIS refers to
3. Edition Date of VIS

VIS Conformance Statements:

Location	Conformance Statement
RXA/OBX	**IZ-24:** If RXA-20 is valued "PA" or "CP" and the first occurrence of RXA-9.1 is valued "00" and RXA-5.1 is valued with a CVX code from table PHVS_VISVaccines_IIS (See Appendix A) then for each vaccine information statement that was shared there SHALL be: • one OBX segment with OBX-3.1 valued "69764-9" (bar coded) **and** one OBX with OBX-3.1 valued "29769-7" (presentation /delivery date) associated. Both OBX shall have the same value in OBX-4 **OR** • one OBX segment with OBX-3.1 valued "30956-7" (vaccine type) and one OBX segment with OBX-3.1 valued "29768-9" (version date) and one OBX with OBX-3.1 valued "29769-7" (presentation /delivery date) associated. All three OBX shall have the same value in OBX-4

5.0 APPENDIX B: CONDITION PREDICATES

For convenience this section clarifies and formalizes the format in which condition predicates are specified. For data type condition predicates, the name of the data type is appended with the sequence number. The first entry in the table below can be interpreted as follows: If the first component of PID.10 (i.e., PID.10.1—in this context we refer to the element as CE.1 since the data type for PID.10 is CE-coded element) is valued, then PID.10.3 is required to be supported (i.e., the effective usage is RE). Note that only conditional predicates that will be tested in Meaningful Use Certification are included below.

Table 7-Data Type Conditional Predicates

Data Type	Component	Usage	Condition Predicate
CWE	CWE.3	C(R/X)	If CWE.1(Identifier) is valued
CWE	CWE.5		If CWE.4 (Alternate Identifier) is valued
CWE	CWE.6		If CWE.4 (Alternate Identifier) is valued
EI	EI.2	C(R/O)	If EI.3 (Universal Id) is not valued
EI	EI.3	C(R/O)	If EI.1 (Namespace ID) is not valued
EI	EI.4	C(R/X)	If EI.3 (Universal Id) is valued
ERL	ERL.4	C(R/X)	If ERL.3 (Field Position) is valued
HD	HD.1	C(R/O)	If the HD.2 (Universal ID) is not valued
HD	HD.2	C(R/O)	If the HD.1 (Namespace ID) is not valued
HD	HD.3	C(R/X)	If the HD.2 (Universal ID) is valued
XCN	XCN.1	C(R/RE)	If XCN.2.1 (Surname) and XCN.3 (Given Name) are not valued

Data Type	Component	Usage	Condition Predicate
XCN	XCN.9	C(R/X)	If the XCN-1 (id number) is valued
XON	XON.6	C(R/O)	If XON.10 is valued
XON	XON.7	C(R/X)	If XON.10 is valued
XON	XON.10	C(R/RE)	If XON.1 is not valued
XTN	XTN.4	C(R/X)	If the XTN-2 (telecommunication type code) is valued “NET”
XTN	XTN.6	C(RE/X)	If the XTN-2 (telecommunication type code) is valued not “NET”
XTN	XTN.7	C(R/X)	If the XTN-2 (telecommunication type code) is valued not “NET”

Table 5-Field-level Conditional Predicates

Location	Field Name	Sender Usage	Derived Condition Predicate
OBX-6	Units	C(R/RE)	If OBX-2(Value Type) is valued “NM” or “SN” Note: If there is not a unit of measure available while the Condition Predicated is true, then the value “NA” SHALL be used in CWE.1 and “HL70353” in CWE.3.
OBX-17	Observation Method	C(R/O)	If OBX-3.1 is “64994-7”

Location	Field Name	Sender Usage	Derived Condition Predicate
ORC-12	Ordering Provider	C(RE/O)	If RXA-20 is valued “CP” or “PA” and the first instance of RXA-9.1 is valued “00”
PD1-13	Protection Indicator Effective Date	C(RE/X)	If PD1-12 (Protection Indicator) is valued
PD1.17	Immunization Registry Status Effective Date	C(RE/X)	If the PD1-16 (Registry Status) field is valued.
PD1.18	Publicity Code Effective Date	C(RE/X)	If the PD1-11 (Publicity Code) field is valued.
PID.25	Birth Order	C(RE/O)	If PID-24 (Multiple Birth Indicator) is valued “Y “
PID.29	Patient Death Date and Time	C(RE/X)	If PID-30 (patient death date) is valued “Y”
RXA-7	Administered Units	C(R/O)	If Administered Amount is not valued “999”
RXA.9	Administration Notes	C(R/O)	If RXA-20 is valued “CP” or “PA”
RXA-15	Substance Lot Number	C(R/O)	If the first occurrence of RXA-9.1 is valued "00" and RXA-20 is valued "CP" or "PA"
RXA-16	Substance Expiration Date	C(RE/O)	If the RXA-15 (lot number) is valued
RXA-17	Substance Manufacturer Name	C(R/O)	If the first occurrence of RXA-9.1 is valued "00" and RXA-20 is valued "CP" or "PA"
RXA-18	Substance/Treatment Refusal Reason	C(R/X)	If the RXA-20 (Completion Status) is valued “RE “