

Context: Significant progress has been made across IIS jurisdictions to more closely align with a standard messaging format. However, some variations are driven by local public health law/policy that may be well out of the reach of IIS to impact/modify. IIS data are used for a broad range of purposes, including vaccine management, school law, generation of practice and jurisdictional coverage rates, clinical decision support at the point of care, and more. As interoperability testing expands, EHRs should be sensitive to the jurisdictional differences that may be driven by public health or private partner/stakeholder business needs.

Topic	Law/policy/program impacting local IIS requirements	How this law/policy/program can manifest itself in an IIS
Consent	While most IIS have “opt out” laws allowing data to flow into IIS freely in the absence of intervention, some states require individuals to “opt in”, or to actively consent to being included in the registry.	<p>The two concepts of opt-in and opt-out can manifest themselves differently due to the law which must be supported by the IIS. For the majority of the IIS, consent can be dealt with through the use of PD1-12 (Protection Indicator) in the patient demographic section of an HL7 V2 message sent from a clinical site to an IIS. However, depending upon local law, this can vary.</p> <p>Here is an example list of the different ways an individual jurisdiction’s consent law may be required to be supported, and how it may ultimately impact the IIS:</p> <ul style="list-style-type: none"> • Patients must be part of the IIS. The IIS will ignore PD1-12. • Opting out of the IIS must be documented as a physically signed form. The IIS will ignore PD1-12. • Patients must consent to be part of the IIS. The IIS requires that PD1-12 be valued “N” to be accepted. • Patient consent must be declared. Either value (“Y” or “N”) in PD1-12 is fine, but consent must be explicitly messaged. • Patients who wish to opt-out cannot be viewed by the Public Health Agency and therefore must not be sent to the IIS. The IIS is not allowed to see or know about these patients.

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		<ul style="list-style-type: none"> Patients born before a date specified in law must provide consent (opt-in). Patients born on or after a date specified in law do not (opt-out). <p>Finally, an IIS may be required to support different consent laws for children vs. adults. That is, the IIS may be required to support one of the above for child records and a different one for adult records.</p> <p>More information on consent can be found in the following Confidentiality and Privacy Considerations document:</p>
Vaccine eligibility codes (also known as Vaccine for Children or VFC codes)	Many states require providers receiving publicly funded vaccine to account for their vaccine in an IIS. Vaccine eligibility codes (or Vaccines for Children/VFC codes) track a patient's eligibility for receiving publicly or privately funded vaccine. Some states may require state-specific codes as part of this process. Vaccine eligibility codes may also be used to infer Funding Source (see below).	<p>As noted in the National HL7 2.5.1 Release 1.5 Implementation Guide for Immunization Messaging and subsequent Addendum, each IIS may be required to support local programs which are above and beyond the nationally defined set of codes. This can happen when a local jurisdiction has funds to supply vaccines to patients meeting program requirements. The vaccine eligibility codes are used to properly track a patient's eligibility for a given vaccine. The local programs – based on funding – will come and go over time so EHRs should be prepared to extend and manage the National HL7 IG values to support the varying programs both nationally and locally.</p> <p>More information on vaccine eligibility can be found in the following Modeling of Immunization Registry Operations workgroups (MIROW) chapter on IIS Collaboration with the Vaccines for Children Program: Mini-Guide Full Chapter</p>
Funding Source	Whereas vaccine eligibility codes record the patient's eligibility for a particular vaccine, Funding Source records what stock of vaccine (public-VFC, public-317, private, etc.) was used to immunize a patient. Funding	As noted in the National HL7 2.5.1 Release 1.5 Implementation Guide for Immunization Messaging and subsequent Addendum , the IIS may require funding source be tracked to support both national and locally funded vaccines. This can

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	<p>Source may be required to appropriately account for vaccine or to appropriately deduct administered doses from inventory.</p>	<p>manifest itself in essentially three different types of vaccine storage models to align with the funding program which financially supplied the vaccine.</p> <p>The storage models range from a “one-stock model” to a “multi-stock” model. Each model has considerations and different code systems which may need to be supported and messaged.</p> <ul style="list-style-type: none"> • One-Stock: In this model, the state may universally purchase all public and private vaccine, or may have developed specific contracts or agreements to replace private vaccine administered to VFC-eligible patient with public vaccine. In these and other cases, funding source may be inferred from the vaccine eligibility codes • Two-Stock: In this model, the vaccines are split into two categories (i.e., public and private). These are messaged using the following HL7 codes for funding source referenced in the observation (OBX) segment of an HL7 v2 message: <ul style="list-style-type: none"> ○ PHC70 – Private ○ VXC50 – Public • Three-Stock: In this model, the IIS must separate the vaccine which was funded by VFC program from the vaccine which was funded by some other local program. These are messaged using the following HL7 codes: <ul style="list-style-type: none"> ○ PHC70 – Private ○ VXC51 – Public VFC ○ VXC52 – Public non-VFC • Multi-Stock: In this model, the IIS must manage each local program which funded the vaccine. These are message using the following HL7 codes: <ul style="list-style-type: none"> ○ PHC70 – Private ○ VXC51 – Public VFC ○ Locally defined codes

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		<p>More information on funding source can be found in the following MIROW chapter on Decrementing Inventory via Electronic Data Exchange:</p> <p>Mini-Guide Full Chapter (with particular attention to pp: 19-23)</p>
School Entry/ Official Imm. Records	In many jurisdictions, the consolidated record from the IIS is considered to be the “Official Immunization Record” for school law purposes. Parents and/or individuals may need this Official Record for school entry, camp entry, or similar purposes.	This law doesn’t directly impact HL7 messaging, but may impact provider workflow. Historically, these official forms had to be hand-written or hand-entered. In many jurisdictions, the IIS is now able to generate the required entry forms using the consolidated immunization history in the IIS which eliminates the need for hand-written or hand-entered forms. To date, there is not a nationally defined electronic interface between the EHR and the IIS to eliminate the need for the provider from having to log into the IIS for this populated form.
Matching Rules, Single vs. Multiple Matches	Law or policy may govern how an IIS matches incoming submissions (VXUs) or queries (QBPs)	These law or policy differences may dictate whether a single exact match is necessary, or whether suggested matches can be returned to the requesting/sending system.
Insurance Information	Some jurisdictions may require the insurance segment for vaccine management purposes. This may be required by policy or law.	In these jurisdictions, collection of insurance information may be necessary to ensure accurate vaccine accountability and accurate decrementing from inventory.
Sensitive Fields	In select jurisdictions, a specific field may have policy restrictions. For example, some jurisdictions cannot, by law/policy, receive social security numbers (SSNs) due to particular security regulations.	These fields are rare, with the SSN example being the most oft-cited. In some cases, an IIS can receive the data element, but is unable to use or store the data element. In other cases, the IIS may request that the data element not be sent at all due to law/policy.

For more discussion on these and other topics, please contact the AIRA Technical Assistance Team at info@immregistries.org.