

Immunization Registry Minimum Functional Standards

This document represents the April 5, 2001 recommendations made by the National Immunization Program's Technical Working Group (TWG) on the minimum technical functions of immunization registries. These standards were identified through a process that involved an October 1997 survey of immunization program managers and registry developers regarding the technical functions that "at a minimum, state and community-based immunization registries must" implement. Functions that were identified by $\geq 75\%$ of respondents were discussed by breakout sessions at the 1997 Program Managers meeting to ensure consensus. Since that time, the core functions have been renamed "immunization registry minimum functional standards."

In November 1999, the TWG recommended that the minimum functional standards be used as a basis for voluntary registry certification. Though a certification body has not yet been identified to assume this responsibility, the TWG reviewed the functional standards in preparation for registry certification. As a result of this review, two standards were separated (Standard #5 and Standard #6) and two standards were merged (Standard #6 and former Standard #7-- Disaster recovery).

These standards were approved by the National Immunization Program on May 15, 2001.

Note: These standards only apply to records available in a population-based immunization registry (one that is designed to contain all children in the catchment area) that is operating in compliance with state/local laws and/or policies. For example, in a state where explicit consent is required by law or policy, these standards only apply to records where explicit consent has been obtained.

Standard #1

Electronically store data on all NVAC-approved core data elements

Definition The registry's computer database contains fields for all NVAC-approved core data elements. These elements are: patient name (first, middle, and last); patient birth date; patient sex; patient birth state/country; mother's name (first, middle, last, and maiden); vaccine type; vaccine manufacturer; vaccination date; and vaccine lot number.

Note: The core data elements comprise the basic set of data that registries will exchange with each other. They are designed to standardize a set of patient demographic and vaccine event elements that are considered core to record exchange between registries. The mother's name element refers to current legal mother (who may or may not be birth mother). To receive credit for the patient and mother names, at least a surname and one other name element must be valued.

Standard #2

Establish a registry record within 6 weeks of birth for each newborn child born in the catchment area

Definition Identifying information from a population-based data set (e.g., vital statistics) is regularly sent to or retrieved by the registry in a computer file format that requires little, if any, manipulation by registry staff for the data to be entered into the

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immunization registry. Such information is available in the registry within 6 weeks of birth.

Standard #3

Enable access to and retrieval of immunization information in the registry at the time of encounter

Definition The registry provides a means by which providers can access and retrieve immunization records prior to or at the time of a scheduled encounter.

Note: This standard accommodates registries that do not operate continuously (e.g. closed Sundays and holidays) and those that send and receive non-electronic records in order to allow access to users without electronic capabilities. For example, providers can request and receive the immunization record(s) needed from the registry prior to the scheduled encounter (can include printed patient lists, flags on charts, fax or phone requests).

Standard #4

Receive and process immunization information within 1 month¹ of vaccine administration

Definition The registry receives and processes immunization information within 1 month of vaccine(s) administration (e.g., can include fax or phone requests).

Standard #5

Protect the confidentiality of health care information

Definition The registry has written confidentiality policies and procedures in place and implemented, including administrative and technical practices to protect health care information.² The policies and procedures are consistent with applicable state and local laws, Federal law (HIPAA or other privacy law) when implemented, and with the recommended specifications and guidelines outlined in the updated “*Community Immunization Registries Manual: Chapter II: Confidentiality*,” except where they conflict with applicable legislation.

Standard #6

Ensure the security of health care information

Definition The registry has written security policies and procedures in place and implemented, including administrative and technical practices and physical safeguards to protect health care information. The policies and procedures are consistent with applicable state and local laws and with Federal law when implemented.

Note: Appendix D of the “Community Immunization Registries Manual: Chapter II: Confidentiality” will serve as the current recommended specifications and guidelines; however, HIPAA implementation may result in a change in the minimum specification.

Standard #7

Exchange immunization records using Health Level Seven (HL7) standards

¹ For the purposes of this calculation, one month equals 30 days.

² Health care information in this document refers to patient demographics, as well as medical conditions, care or services related to the health of the patient.

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Definition The registry has a function, at the central level, that creates, receives, and properly processes the HL7 messages, as specified in NIP's Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol, June 1999.

Standard #8

Automatically determine the routine childhood immunization(s) needed, in compliance with current ACIP recommendations, when an individual presents for a scheduled immunization

Definition The registry has an automated function, accessible at the provider level, that determines needed routine childhood immunizations, in compliance with current ACIP recommendations, given an individual's immunization history to date.

Standard #9

Automatically identify individuals due/late for immunization(s) to enable the production of reminder/recall notifications

Definition The registry has an automated function that produces a list of individuals who, as of a given date, are due or late for immunizations according to the registry's algorithm (see Functional Standard #8). The output from this function gives the ability to produce reminder or recall notices.

Standard #10

Automatically produce immunization coverage reports by providers, age groups, and geographic areas

Definition The registry has an automated function to assess immunization coverage (e.g., % of children "age-appropriately" immunized) as of a given date for an individual provider's practice, for the registry's entire catchment area, and for subgroups within a practice or the catchment area (e.g., children of a certain age).

Standard #11

Produce official immunization records

Definition The registry has a function that allows authorized users to produce an individual's immunization history that is accepted as an official immunization record.

Standard #12

Promote accuracy and completeness of registry data

Definition The registry has developed and implemented a data quality protocol to combine all available information relating to a particular individual into a single, accurate immunization record.