

10-144 DEPARTMENT OF HUMAN SERVICES

BUREAU OF HEALTH

Chapter 274: IMMUNIZATION INFORMATION SYSTEM (IIS) RULES

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1. Intent:

The Immunization Information System is intended to be a repository for accurate and up to date immunization records for all persons born, residing, or receiving vaccine in the State of Maine. The primary purpose of the system is to collect data related to vaccine administration, and to promote effective and cost efficient prevention of vaccine preventable diseases. This rule is issued pursuant to the statutory authority of the Department of Human Services under 22 M.R.S.A. §1064. Administration of the system shall be performed by the Department's Immunization Program.

2. Scope:

These Rules apply to all Immunization Providers and other entities who have a contract or Memorandum of Agreement with the Department to participate in the vaccine distribution system, the Immunization Information System or to provide related support services.

3. Definitions:

- A. "Authorized Users" means employees of (1) the Department, (2) Immunization Providers and (3) other entities which have a contract or memorandum of understanding with the Department to distribute and administer vaccine, participate in the Immunization Information System, or provide related support services. Such employees must execute a user agreement in form satisfactory to the Department, and their access to system information will be based upon their respective assigned user roles.
- B. "User Role" means the collection of permissions which define the individual's area of responsibility, access to the system and access to specific functions.
- C. "User Agreement" means an agreement signed by the end user that documents knowledge and acceptance of his or her responsibilities as a user, including a confidentiality statement and penalties for violations.
- D. "Commissioner" means the Commissioner of the State of Maine Department of Human Services.
- E. "Department" means the State of Maine Department of Human Services.
- F. "Demographic Information" means current vital statistics for a Patient, including without limitation, the Patient's full name, date of birth, physical address, mailing address, phone

number, social security number, Medicaid identification number, insurance provider, and insurance identification number. When a Patient is a minor, Demographic Information includes the vital statistics for the Patient's parent or guardian.

- G. "Immunization Information System" (IIS) means the electronic database and associated interfaces used to collect and store immunization data.
  - H. "Immunization Record" means the information that indicates the immunization status of an individual which may include, without limitation, the immunization received by the individual; vaccine type; manufacturer of the vaccine; date of administration of the vaccine; lot number of the vaccine administered; route and site of injection; name, initials and signature of the person administering the vaccine; and the revision date of the Vaccine Information Sheet given to the individual for review.
  - I. "Minor" means any individual under the age of eighteen (18) years who is not emancipated as defined by Title 15, section 3003, subsection 6.
  - J. "Patient" means any person who receives an immunization within the State of Maine or has been associated in the system with a Maine immunization provider/practice. When any such person is a minor, Patient shall include the minor's parent or guardian.
  - K. "Immunization Provider" is an organization which receives and administers state supplied vaccine and has a Provider Identification Number (PIN) assigned by the Department's Immunization Program.
  - L. "Vaccine Fraud" means any intentional misuse of state-supplied vaccines. Vaccine Fraud includes, without limitation, administration to inappropriate age groups, the sale of state-supplied vaccines, and the submission of pharmaceutical reimbursement claims to Medicaid or any other third party payer.
4. Establishment Of The Immunization Information System:
- A. All children born in Maine and registered in the Electronic Birth Certificate system shall have their demographic data entered into the Immunization Information System (hereinafter referred to as the "IIS").
  - B. The Department may use any birth record, Medicaid record, school record, or immunization record for the purposes of obtaining an individual's Immunization and Demographic Information and entering that Information into the IIS.
  - C. An Immunization Provider who administers immunizations with vaccines provided by the Department shall record or report all immunizations administered directly into the Immunization Information System, or through other methods as approved by the Department, within five (5) working days of administering the immunization.
  - D. All Patients will be informed during an initial immunization encounter with an Immunization Provider of the inclusion of their immunization record and demographic information into the IIS, and will be provided with the opportunity to opt-out of the IIS. All Patients will automatically have their immunization and demographic information

maintained in the IIS, unless a Patient states in writing on a form prescribed by the Department, that he or she wants to opt out of the IIS.

5. Confidentiality Of The Immunization Information System

- A. Identifying information contained in the IIS shall only be disclosed to Authorized Users and the individual that it identifies, except in the case of an authorized exchange (as specified in Section 10-C), or in the event of a public health emergency, as defined by statute.
- B. Authorized Users must sign a user agreement in a form prescribed by the Department that sets forth the terms for using the IIS. Any such Agreement shall include a confidentiality clause, as well as provisions related to penalties for unauthorized disclosure.
- C. Authorized Users shall not disclose information from the IIS about an individual except to another Authorized User when allowed by these rules, or by state and federal laws addressing patient confidentiality.

6. Individual's Right To Opt Out Of The Immunization Information System

- A. Any individual may choose to be excluded from the IIS, thereby limiting future access to his or her Immunization Records and Demographic Information from the IIS, by submitting a signed and witnessed document to his or her Immunization Provider on a form prescribed by the Department. The Department's form shall contain, at a minimum, the following information:
  - (1) the Patient's name;
  - (2) the Patient's address;
  - (3) the Patient's date of birth;
  - (4) the Patient's signature;
  - (5) the Witness's signature
  - (6) the Patient's reason for the requested exclusion; and
  - (7) the Department address.
- B. The Patient is responsible for notifying any Immunization Provider at each encounter of the decision to be excluded from the IIS. No Immunization Provider or health plan shall be liable for entering a previously excluded Patient into the Registry if that Patient did not provide that Immunization Provider or health plan with written notice of the exclusion. This rule does not relieve the excluded Patient from the obligation to comply with current immunization requirements set forth in State Law.

- C. Upon being notified that a Patient wants to be excluded from the IIS, the Immunization Provider is responsible for opting out that Patient from the IIS, and continues to be responsible for the maintenance of appropriate immunization record keeping for the Patient.
- D. In the event that an individual does not have an Immunization Provider, that Patient shall notify the Department directly in writing on the prescribed form of his or her decision to be excluded from the IIS.

#### 7. Individual Access To The Immunization Information System

- A. An individual may review his or her individual Demographic Information and Immunization Record contained in the IIS by requesting a copy from his or her Immunization Provider.
- B. In the event an individual discovers an error in his or her Immunization Record or Demographic Information, or in the event the Demographic Information changes, the individual is responsible for providing the correct information to the Immunization Provider. The Immunization Provider is responsible for making any such corrections or updates to the individual's Record.
- C. In the event that an individual does not have an Immunization Provider, that individual shall make any requests to review or correct his or her Demographic Information or Immunization Record directly to the Department in a manner prescribed by the Department.
- D. Requests for changes to Immunization Records must be supported by official immunization documentation as deemed acceptable by the Department.

#### 8. Authorized User Access To The Immunization Information System

- A. As a condition of using the IIS, Immunization Providers and contracted entities shall submit to the Commissioner or his designee, on an annual basis, a signed agreement on a form prescribed by the Department. Signing these forms binds the Provider to the terms and conditions of these rules and to such other terms and conditions as deemed appropriate by the Commissioner or his designee.
- B. All authorized users shall maintain the confidentiality of their individual access codes and passwords, and shall not share or exchange such codes with any other person, regardless of whether or not that other person is an Authorized User.
- C. Immunization Providers and contracted entities must immediately inform the Department when any person in their organization with a user code and password leaves employment, and when any other changes in staffing require corresponding changes in user permissions.
- D. Use of the IIS by authorized users will be limited by user roles that are assigned on an individual need-to-know basis.

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9. Department Access To The Immunization Information System

- A. Except as otherwise provided herein, the Commissioner or his designee may access an individual's Demographic Information and Immunization Records only in the following circumstances:
- (1) at the request or with permission of an Immunization Provider;
  - (2) at the written and notarized request of the individual;
  - (3) for the purpose of investigating vaccine fraud;
  - (4) for the purposes of preventing and controlling outbreaks of vaccine preventable communicable disease;
  - (5) for the purposes of assuring data quality and providing aggregate data as specified in section 10;
  - (6) for the purpose of providing reminder/recall and other health related services;
  - (7) when deemed necessary by the Commissioner in the event of a public health emergency; or
  - (8) as deemed necessary by the Department to perform repairs, maintenance and updates of the Immunization Information System.

10. Collection And Release Of Information

- A. The Department may require Immunization Providers to provide and report certain information from Patients' Immunization Records. The Department shall determine, from time to time, what information must be provided to the IIS, and shall determine the means by which such information must be provided. The Department may require all Immunization Providers to submit such information in an electronic format compatible to the IIS.
- B. The Department may require Immunization Providers to provide information from a Patient's demographic information. Information provided must include, without limitation, such information necessary to send reminder calls to, place telephone calls to, or personally contact a Patient. The Department shall determine, from time to time, what contact information must be provided to the IIS, and shall determine the means by which such information must be provided. The Department may require all Immunization Providers to submit such information in an electronic format.
- C. The Department may exchange information with other immunization registries and/or immunization databases maintained by health maintenance organizations and health insurance companies. The Department may share information with other entities only if the Commissioner or his designee determines that each other specific registry or database has confidentiality protections equal to or surpassing the standards set forth in these Rules.

- D. The Department may release and publish information from the IIS only in an aggregate form that does not identify an individual either directly or indirectly.
- E. The Commissioner, or his designee, may provide analyses and compilations of Demographic Information and Immunization Records to any interested party upon request, when such information does not identify a Patient, either directly or indirectly. Such requests must be made in accordance with procedures adopted by the Department.
- F. The Commissioner, or his designee, may provide analyses and compilations of Demographic Information and Immunization Records to a researcher, when such information does not identify a Patient, either directly or indirectly. The researcher must submit a research protocol describing, at a minimum:
  - (1) the intended use of the data;
  - (2) the methodology of the research project;
  - (3) why access to the information is necessary, and
  - (4) approval by an official Institutional Review Board.

#### 11. Liability, Penalties, And Protections

- A. Intentional or knowing violation of any of these rules by an Immunization Provider may result in a request for disciplinary action by the appropriate licensing and regulatory board which has regulatory authority over the Immunization Provider.
  - B. Whoever violates any of these rules or fails, neglects or refuses to perform any duties imposed upon that person by these rules is subject to criminal prosecution under Title 22 M.R.S.A. Section 47.
  - C. Nothing in these rules shall be construed to authorize the imposition of civil penalties upon any Immunization Provider which in good faith engages in an unauthorized disclosure of Immunization Information System information.
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STATUTORY AUTHORITY: 22 M.R.S.A. §1064

EFFECTIVE DATE:

April 16, 2002

NON-SUBSTANTIVE CORRECTIONS:

May 13, 2002 - corrected the spelling of DEPARTMENT in header, page 1

May 10, 2004 - corrected the spelling of "Commissioner" in Section 3(D)