

**RULEMAKING NOTICE FORM**

Notice Number 2015-203

Rule Number He-P 307

1. Agency Name & Address:

**Department of Health and Human Services  
Division of Public Health Services  
Immunization Section  
29 Hazen Dr.  
Concord, NH 03301**

2. RSA Authority: RSA 141-C:20-f, VI

3. Federal Authority: \_\_\_\_\_

4. Type of Action:

Adoption X

Amendment \_\_\_\_\_

Repeal \_\_\_\_\_

Readoption \_\_\_\_\_

Readoption w/amendment \_\_\_\_\_

5. Short Title: **Immunization/Vaccination Registry**

6. (a) Summary of what the rule says and of any proposed amendments:

**He-P 307, Immunization/Vaccination Registry, is being proposed to put back into place a rule which previously expired in 2007. While there were previously effective rules, the Division of Public Health Services did not have a functional immunization/vaccination registry but is now in the implementation stages of creating one.**

**The New Hampshire immunization/vaccination registry, created pursuant to RSA 141-C:20-f and the proposed rule, is for the purpose of aiding, coordinating, and promoting effective and cost-efficient disease prevention and control efforts. The registry will track vaccinations that health care providers administer to patients in New Hampshire in order for important vaccination information to be shared among health care providers, schools, child care agencies, pharmacists, licensed public health departments, and state agencies in a secure and confidential manner.**

**This rule describes:**

- **The establishment and maintenance of the immunization/vaccination registry;**
- **Content and submission of vaccination event reports;**
- **Procedures for patients to opt-out of the registry;**
- **Procedures for patients to withdraw from participation in the registry and have all information removed from the registry;**
- **Procedures for patients to reverse a previous decision to opt-out of the registry;**
- **Procedures for reviewing and correcting information contained in the registry; and**
- **Procedures for request of registry data for research purposes.**

**This rule, and the existence of the registry, do not affect in any way a person's obligation to comply with current immunization/vaccination requirements set forth in RSA 141-C:20-a, or a person's right to exemptions from receiving immunizations pursuant to RSA 141-C:20-c. Furthermore, this rule, and the existence of the registry, do not require health care providers or individual patients to participate in this registry.**

6. (b) Brief description of the groups affected:

**This rule affects immunization/vaccination providers, patients who receive immunizations/vaccinations, authorized users of the web-based immunization registry (including health care providers, schools, and licensed child care agencies), and those individuals or entities who request de-identified data from the registry for research purposes.**

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

<b>Rule</b>	<b>Specific State Statutes the Rule Implements</b>
He-P 307.01 – 307.11	RSA 141-C:20-f

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Michael Holt** Title: **Rules Coordinator**  
Address: **Dept. of Health and Human Services** Phone #: **271-9234**  
**Administrative Rules Unit** Fax#: **271-5590**  
**129 Pleasant St.** E-mail: [michael.holt@dhhs.state.nh.us](mailto:michael.holt@dhhs.state.nh.us)  
**Concord, NH 03301**

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

**The proposed rules may be viewed and downloaded at:**  
<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Friday, January 29, 2016**

Fax  E-mail  Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Friday, January 22, 2016 at 10:30 a.m.**

Place: [\*\*DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH\*\*](#)

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # 15:222, dated 12/21/15

**1. Comparison of the costs of the proposed rule(s) to the existing rule(s):**

The previous rules expired in 2007. While the rules were previously effective from 1999 through 2007, the Department did not have a functional immunization/vaccination registry in place during that time, and so in practice the rules were never implemented. For this reason, although the proposed rules differ from the expired rules in several respects, a cost comparison is not feasible.

**2. Cite the Federal mandate. Identify the impact of state funds:**

No federal mandate, no impact on state funds.

**3. Cost and benefits of the proposed rule(s):**

While there were previously effective rules from 1999 to 2007, the Department did not have a functional immunization/vaccination registry during that time. With respect to costs, the Department notes that in 2016, its budget for hosting and maintaining the system is \$215,000. With the exception of (C) below, any cost associated with the proposed rule is attributable to RSA 141-C:20-f, Immunization Registry.

**A. To State general or State special funds:**

None.

**B. To State citizens and political subdivisions:**

None.

**C. To Independently owned businesses:**

Participation in the immunization/vaccination registry by health care providers is voluntary. Insofar as a healthcare provider chooses to participate in the program and regardless of the number of employees, that provider may experience indeterminable costs associated with reporting immunization information to the registry.

For a provider which has an electronic health record (EHR) system, that system may be required to be updated in order for immunization information to be submitted via the provider's EHR system or in order to prevent a patient's information who does not want to participate in the registry from being sent to the registry. The cost to connect the two systems, and to prevent unwanted patient information from being sent, would be based on the EHR system currently used, the version of the system, and the features which may need to be "turned on or off" within the system. Such costs may be mitigated by potential "meaningful use" financial incentives available through the Medicare and Medicaid EHR Incentive Programs to those providers that meet the requirements for meaningful use. If functionality to prevent the sending of unwanted patient information is not possible or is too costly to build into the current EHR, the participating provider will be required to enter immunization/vaccination information for participating patients manually.

Those providers without EHRs will be able to enter immunization information directly into the registry through the currently existing internet connections with no additional information technology cost. In either case, there may be costs associated with the personnel time required to enter the vaccination information into the registry.

Similarly, provisions in the rule for opting out of the registry, correcting immunization/vaccination records, reversing the decision to opt out, and withdrawing a decision to participate will require the provider to track these statuses for their patients either in their EHR or by paper. The registry is prohibited from receiving this information. This may result in additional indeterminable administrative costs for the provider and possibly require the provider upgrade their EHR.

Students are required to be up to date on required immunizations/vaccinations, and schools are required to verify that their students are up to date on required immunizations/vaccinations. Participation in the web-based immunization/vaccination registry by schools is voluntary, but such participation by private schools may create an indeterminable fiscal benefit in the administrative work required by private schools to verify and report student immunizations/vaccinations as compared to current practices. Similarly, licensed child care agencies, to the extent that they participate in the registry, may experience a similar indeterminable benefit as described for private schools.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

**The proposed rule creates a new program or responsibility, but does not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore does not violate Part I, Article 28-a of the N.H. Constitution.**

**Adopt He-P 307, previously effective 1/30/99 (Document #6941), and expired 1/30/2007, to read as follows:**

PART He-P 307 IMMUNIZATION/VACCINATION REGISTRY

He-P 307.01 Purpose. These rules implement the procedures of the department pursuant to RSA 141-C:20-f relative to the establishment and maintenance of a New Hampshire immunization/vaccination registry (registry) for children and adults to aid, coordinate, and promote effective and cost-efficient disease prevention and control efforts. The information contained in the registry shall be used for the following purposes:

- (a) To remind registrants to receive all required immunizations/vaccinations in a timely manner by providing access to the registrant's immunization/vaccination record and to provide registrants with information about recommended immunizations/vaccinations;
- (b) To assure appropriate management and use of vaccines distributed by the department; and
- (c) To control communicable diseases by assisting in the identification of individuals who require immediate immunization/vaccination in the event of a disease outbreak.

He-P 307.02 Definitions.

(a) "Administering health care provider" means a health care provider whose medical focus is limited to completing a screening checklist for contraindications and administering a vaccination.

(b) "Authorized user" means a person or entity which is authorized to enter information into or access certain information contained in the registry, including:

- (1) Administering, current, and former health care providers;
- (2) Health care providers;
- (3) Schools;
- (4) Licensed child care agencies;
- (5) The department's division of public health services; and
- (6) Designated individuals of (1)-(5) above.

(c) "Commissioner" means the commissioner of the New Hampshire department of health and human services, or his or her designee.

(d) "Current health care provider" means a health care provider who the patient has chosen for ongoing health care and who maintains a complete medical history of the patient.

(e) "Department" means the New Hampshire department of health and human services.

(f) "Former health care provider" means a health care provider that is no longer a patient's current health care provider.

(g) “Health care provider” means any person who or entity which provides health care services including, but not limited to, hospitals, medical clinics and offices, physicians, naturopaths, pharmacists, dentists, registered or other nurses and nurse practitioners, medical assistants, paramedics, and emergency medical technicians.

(h) “Immunization” means “immunization” as defined in RSA 141-C:2, XI-a, namely, “inoculation with a specific antigen to promote antibody formation in the body.”

(i) “Managed care organization” means an entity which offers a managed care plan, as defined in RSA 420-J:3, XXV, namely, “a health benefit plan that either requires a covered person to use, or creates incentives, including financial incentives, for a covered person to use health care providers managed, owned, under contract with, or employed by the health carrier.”

(j) “New Hampshire immunization/vaccination registry (registry)” means a single repository of accurate, complete, and current immunization records to aid, coordinate, and promote effective and cost-efficient disease prevention and control efforts for New Hampshire residents.

(k) “Opt out” means the process an individual follows to elect not to participate in the registry and, after which, one’s immunization/vaccination record will not be provided to the registry.

(l) “Patient” means an individual who receives an immunization/vaccination or other health care services.

(m) “Public health purpose” means a population-based activity or individual effort primarily aimed at the prevention of injury, disease, or premature mortality, or the promotion of health in the community.

(n) “Read-only rights” means the ability of the data to be accessed but not entered or modified.

(o) “Read/write rights” means the ability of the data to be accessed, entered, or modified.

(p) “Registrant” means the patient whose immunization record is contained in the registry.

(q) “Vaccination event” means an immunization/immunoglobulin administration, exemption, refusal, adverse reaction. For the purposes of this definition “refusal” means refusal of a vaccination, and not refusal to participate in the registry.

#### He-P 307.03 Establishment and Maintenance of the Immunization/Vaccination Registry.

(a) The department shall implement and maintain a computerized immunization/vaccination registry as established in RSA 141-C:20-f in compliance with other applicable state statutes.

(b) Information in the registry may be transferred to or from the registry through a health information organization, as defined in RSA 332-I:1, II(c), provided that no such information shall be retained by the health information organization.

#### He-P 307.04 Authorized User Access to the Registry.

(a) The following authorized users, and their designated individuals, shall have read/write rights to the registry:

- (1) Administering, current, and former health care providers

(2) The department's division of public health services.

(b) The following authorized users, and their designated individuals, shall have read-only rights to the registry:

- (1) Health care providers who are not listed in (a)(1) above;
- (2) Schools, only for named individuals in their care;
- (3) Licensed child care agencies, only for named individuals in their care; and
- (4) Local public health entities.

(c) Access to the registry for all entities in (a) and (b) above, except (a)(2) and (b)(4), shall be limited to patients in their care.

He-P 307.05 Content and Submission of Vaccination Event Reports.

(a) For each patient who, after being given the opportunity to opt out of participating in the registry in accordance with He-C 307.06, does not exercise the option to opt out, an administering or current health care provider who is participating in the registry shall report vaccination events to the registry within 7 business days of the event through an electronic web-based interface.

(b) For each vaccination event, immunization providers shall report to the registry such data listed in the Centers for Disease Control (CDC) Core Data Elements for Immunization Information Systems, listed as Appendix B in HL7 Version 2.5.1: Implementation Guide for Immunization Messaging Release 1.5 (October 1, 2014) found at <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>.

(c) For each vaccination event, immunization providers shall also report to the registry the following types of registrant information:

- (1) The registrant's insurer information as held by the immunization provider; and
- (2) Date of death, if applicable and if known.

He-P 307.06 Procedures for Patients to Opt Out of the Registry.

(a) No patient, or the patient's parent or guardian if the patient is a minor, shall be required to participate in the immunization/vaccination registry.

(b) No patient's immunization/vaccination information shall be entered into the registry without that patient, or the patient's parent or guardian if the patient is a minor, being given the opportunity to opt out of the registry.

(c) No health care provider shall provide to the department or to the registry the name of, or any immunization/vaccination information relating to, any patient who opts out of participating in the registry, except required by RSA 141-C:9.

(d) A health care provider shall not provide information relating to immunizations/vaccinations contained in a former patient's medical record without that patient, or the patient's parent or guardian if the patient is a minor, first requesting that such information be reported to the registry.

(e) A patient, or the patient's parent or guardian if the patient is a minor, shall be provided an opportunity to opt out of the registry as follows:

- (1) At the time of immunization/vaccination by an administering health care provider; and
- (2) Prior to or at a face-to-face encounter with a current health care provider by the current health care provider.

(f) An administering or current health care provider, including the physicians and nurses in the administering or current health care provider's professional practice or medical group, shall be required to provide notice of the opportunity to opt out of the registry to the same patient, or the patient's parent or guardian if the patient is a minor, only once.

(g) The opportunity to opt out of the registry shall be provided in writing in a clear, succinct, and conspicuous manner, in simple language, and in a form, style, and size easily readable by the average adult, via the "Choose not to Participate in the New Hampshire Immunization/Vaccination Registry" form (11/15 edition).

(h) The opportunity to opt out of the registry in (e)(2) above may be provided by a current health care provider by sending a written communication to the patient, or the patient's parent or guardian if the patient is a minor, that meets the requirements in (g) above and that is individually directed and in which opting out is the sole subject of the communication.

(i) The option to opt out of the registry shall be exercised by the patient, or the patient's parent or guardian if the patient is a minor, by dating and signing the "Choose not to Participate in the New Hampshire Immunization/Vaccination Registry" form (11/15 edition) and providing that form to the administering or current health care provider.

(j) The "Choose not to Participate in the New Hampshire Immunization/Vaccination Registry" form in (i) above shall be maintained and documented within the patient's medical records.

(k) Nothing in this rule shall relieve the patient, or the patient's parent or guardian if the patient is a minor, who chooses to opt out of participation in the registry, from the obligation to comply with current immunization/vaccination requirements set forth in RSA 141-C:20-a or He-P 301.14.

He-P 307.07 Procedures for Patients to Withdraw from Participation in the Registry.

(a) A patient, or the patient's parent or guardian if the patient is a minor, may withdraw from participation in the registry at any time, including the removal of information contained in the registry, as follows:

- (1) The patient, or the patient's parent or guardian if the patient is a minor, shall complete the patient information section of "Withdraw and Remove Information from the New Hampshire Immunization/Vaccination Registry" (11/15 edition);

- (2) The current health care provider shall complete the provider information section of “Withdraw and Remove Information from the New Hampshire Immunization/Vaccination Registry” (11/15 edition);
  - (3) The current health care provider shall submit the completed “Withdraw and Remove Information from the New Hampshire Immunization/Vaccination Registry” (11/15 edition) to the department; and
  - (4) The department shall remove all patient information from the registry.
- (b) If the patient does not have a current health care provider, a former health care provider may complete and submit “Withdraw and Remove Information from the New Hampshire Immunization/Vaccination Registry” (11/15 edition) in accordance with (a) above.
- (c) If a patient, or the patient’s parent or guardian if the patient is a minor, requests withdrawal from participation in accordance with (a) or (b) above, then no information relating to the patient shall remain in the registry, and no record of the transaction, including the request itself, shall be kept by either the department or the health care provider.
- (d) It shall be the responsibility of the patient, or the patient’s parent or guardian if the patient is a minor, to inform his or her other health care providers of his or her decision to withdraw from participation in the registry. In order to ensure that no future immunization/vaccination information is reported to the registry, such patient, or the patient’s parent or guardian if the patient is a minor, shall be required to complete a “Choose not to Participate in the New Hampshire Immunization/Vaccination Registry” form (11/15 edition) with each of the patient’s current and administering health care providers.
- (e) Nothing in this rule shall relieve the patient, or the patient’s parent or guardian if the patient is a minor, who chooses to remove his or her information from the registry, from the obligation to comply with current immunization/vaccination requirements set forth in RSA 141-C:20-a or He-P 301.14.

He-P 307.08 Procedures for Patients to Review and Correct Information Contained in the Registry.

- (a) A patient, or the patient’s parent or guardian if the patient is a minor, may review and correct information contained in the registry by making a request through their health care provider or through the department in accordance with this section.
- (b) A request under (a) above for a registry record review to the department shall be via the completion and submission of a “Request for Immunization/Vaccination Record” (11/15 edition), including a notarized signature of the patient or the patient’s parent or guardian if the patient is a minor.
- (c) A request under (a) above for a registry record review to a health care provider shall be by a method to be determined by the health care provider, but shall not require a notarized signature of the patient or the patient’s parent or guardian if the patient is a minor.
- (d) No record of the transaction in described in (b) and (c) above, including the request itself, shall be maintained by the department or the health care provider in any way.
- (e) A request to correct information contained in the registry shall be as follows:
- (1) A patient, or a patient’s parent or guardian if the patient is a minor, shall:

- a. Complete the “Correction to Immunization/Vaccination Record” form (11/15 edition), available on the department’s web site and at the current health care provider’s office;
  - b. Return the completed form to the current health care provider; and
  - c. Provide the current health care provider with authenticated evidence of a laboratory test result or immunization.
- (2) Upon receipt of the materials in (1) above, and upon verification from the patient’s health care provider of the correct information, the health care provider shall make any such corrections or updates to the patient’s record within 7 business days;
- (3) Only the corrected information shall remain in the registry; and
- (4) No record of the transaction in described in (1) and (2) above, including the request itself, shall be maintained by the health care provider in any way.

He-P 307.09 Procedures for Patients to Reverse Decision to Opt Out of the Registry.

(a) A patient, or the patient’s parent or guardian if the patient is a minor, may reverse the decision to opt out of participation in the registry at any time by completing and submitting the “Reverse Previous Decision not to Participate in the New Hampshire Immunization/Vaccination Registry” form (11/15 edition) to the patient’s current or administering health care provider.

(b) It shall be the responsibility of the patient, or the patient’s parent or guardian if the patient is a minor, to inform his or her other health care providers of his or her decision to reverse his or her decision to opt out of participation in the registry. In order to ensure that past, current, and future immunization/vaccination information is reported to the registry, such patient, or the patient’s parent or guardian if the patient is a minor, shall be required to complete “Reverse Previous Decision not to Participate in the New Hampshire Immunization/Vaccination Registry” forms (11/15 edition) and submit them with each of the patient’s current and administering health care providers.

(c) The “Reverse Previous Decision not to Participate in the New Hampshire Immunization/Vaccination Registry” form in (a) above shall be maintained and documented within the patient’s medical records.

He-P 307.10 Requests for Registry Data for Research or Other Purposes.

- (a) Only de-identified data from the registry shall be released for research purposes.
- (b) Release of aggregated statistical data shall not include data that would allow constructive identification of individuals.
- (c) A “New Hampshire Immunization Program Request for Data” form (edition date) shall be completed by the researcher, submitted to the division’s immunization section, and approved before any data shall be released.
- (d) The completed “New Hampshire Immunization Program Request for Data” form shall be mailed to:

Department of Health and Human Services  
 Division of Public Health Services  
 Immunization Section – Data Request  
 29 Hazen Drive  
 Concord, NH 03301-6504

(e) If the request is not complete, the department shall notify the applicant in writing within 10 business days specifying any information or supporting documentation required to be submitted before the request can be processed.

(f) If after written notice in (e) above the applicant fails to provide the missing information or supporting documentation, within 30 days of such notice, the application shall be considered incomplete and shall not be processed.

(g) Persons fraudulently requesting data shall be subject to penalty for unsworn falsifications in accordance with RSA 641:3.

(h) The department shall approve applications for the use of registry data if:

(1) The application is complete; and

(2) It is determined that the study, if carried out according to the request submitted, will serve a public health purpose as defined in He-P 307.02(i).

(i) The department shall deny an application when it has been determined that one or more of the requirements of (h) above have not been met.

He-P 307.11 Procedures for Managed Care Organizations to Obtain Summary Statistics of Immunization Information on Members. The department shall provide annual summary statistics of immunization information to managed care organizations.

#### APPENDIX A: Incorporation by Reference Information

Rule	Title	Publisher; How to Obtain; and Cost
He-P 307.05(b)	Core Data Elements for Immunization Information Systems, listed as Appendix B in HL7 Version 2.5.1: Implementation Guide for Immunization Messaging Release 1.5 (October 1, 2014).	Available free of charge at the US Department of Health and Human Services, Centers for Disease Control and Prevention website: <a href="http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf">http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf</a>

#### APPENDIX B

Rule	RSA Implemented
He-P 307.01 – 307.11	RSA 141-C:20-f