

APPENDIX II-C

RULEMAKING NOTICE FORM

Notice Number	2021-81	Rule Number	He-P 307
1. Agency Name & Address: Dept. of Health & Human Services Division of Public Health Services Bureau of Infectious Disease Control 29 Hazen Drive Concord, NH 03301		2. RSA Authority: RSA 141-C:20-f, VI 3. Federal Authority: _____ 4. Type of Action: Adoption _____ Repeal _____ Readoption _____ Readoption w/amendment X	
5. Short Title: Immunization/Vaccination Registry			

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

He-P 307 is the New Hampshire immunization/vaccination registry established pursuant to RSA 141-C:20-f. He-P 307 was established to aid, coordinate, and promote effective and cost-efficient disease prevention and control efforts. The registry tracks 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, public health departments, and state agencies in a secure and confidential manner.

The Department of Health and Human Services (Department) is proposing to readopt with amendment He-P 307. The amendments to He-P 307 in this proposal include:

- **Updating He-P 307.01 on the purpose of the immunization/vaccination registry;**
- **Updating He-P 307.02 on definitions by:**
 - **Adding the terms “birthing facility”, “New Hampshire immunization record”, and “remainder or recall module”; and**
 - **Amending the terms “current health care provider” and “health care provider”;**
- **Updating He-P 307.04 on authorized user access to the registry by amending who has read/write access and who has read-only access to the immunization/vaccination registry;**
- **Updating He-P 307.05 on content and submission of vaccination event reports to include manual data entry as a form of reporting and to add requirements surrounding birthing facilities and newborns;**
- **Updating He-P 307.06 on procedures for patients to opt-out of the registry;**

- Updating He-P 307.07 on procedures for patients to withdraw from participation in the registry and have all information removed from the registry;
- Updating He-P 307.08 on procedures for patients to review and correct information contained in the registry;
- Updating He-P 307.09 on the procedures for patients to reverse their decision to opt-out of the registry;
- Updating He-P 307.10 on requests for registry data for research or other purposes to allow the request to be submitted to the Department via mail or email;
- Updating He-P 307.11 on the procedures for managed care organizations to obtain summary statistics of immunization information on members; and
- Adding new section He-P 307.12 on the security of immunization vaccination data.

He-P 307 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 immunization registry, and any individual or entity who requests data from the immunization/vaccination registry.

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

RULE	RSA/FEDERAL CITATION
He-P 307.01 – 307.12	RSA 141-C:20-f

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

Name:	Allyson Zinno	Title:	Administrator- Administrative Rules Unit
Address:	Dept. of Health and Human Services Administrative Rules Unit 129 Pleasant Street, 2nd Floor Concord, NH 03301	Phone #:	(603) 271-9604
		Fax#:	(603) 271-5590
		E-mail:	Allyson.E.Zinno@dhhs.nh.gov

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: **Wednesday, September 15, 2021**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Wednesday, September 8, 2021 at 3:00pm.**

Place: **DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH**

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

FIS # 21:065 , dated June 29, 2021

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

When compared to the existing rule, the proposed rule may decrease costs for independently-owned businesses by an indeterminable amount.

2. Cite the Federal mandate. Identify the impact on state funds:

No federal mandate, no impact on state funds.

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

Except for the potential savings described in (3) below, any costs associated with the rule are attributable to RSA 141-C:20-f, which establishes the state immunization registry.

A. To State general or State special funds:

None.

B. To State citizens and political subdivisions:

None.

C. To independently owned businesses:

The Department of Health and Human Services states that by simplifying reporting requirements and creating a web-based immunization/vaccination registry, the proposed rule may result in an indeterminable cost savings for healthcare providers, licensed childcare agencies, and private schools.

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

The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties, or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution.

Readopt with amendment He-P 307, effective 5-1-17 (Document #12163), 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~~ and shall serve as the single repository of immunization records 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 support healthcare providers' efforts in maintaining appropriate patient records to ensure timely administration of vaccines and meeting public health requirements;

(c) To document that required immunizations have been provided as required for school or child care admission;

(db) To ensure appropriate management and use of vaccines distributed by the department; and

(ee) To control communicable diseases by monitoring vaccine coverage levels and 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) "Birthing facility" means a health care facility that provides birthing and newborn care services and includes birth centers.

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

(ed) "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.

(fe) “Department” means the New Hampshire department of health and human services.

(gf) “Former health care provider” means a health care provider that is no longer a patient’s current health care provider.

(h) “Health care provider” means ~~the following~~any persons who or entities which provide health care services: ~~such as~~ hospitals, medical clinics and offices, physicians, naturopaths, pharmacists, dentists, registered or other nurses and nurse practitioners, medical assistants, paramedics, and emergency medical technicians.

(ih) “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.”

(ji) “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.”

(kj) “New Hampshire immunization record” means a paper or electronic copy of a participant’s immunization and preventive health screening information that is a true and accurate representation of the information contained in the NHIIS and shall be considered official documentation for the purposes of documenting vaccines required for participation in childcare, school, and other activities.

(l) “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.

(mk) “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.

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

(om) “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.

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

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

(rp) “Refusal” means the act of not receiving a vaccination on a particular day or at a particular medical appointment, for such reasons as, wanting to delay the vaccination to another time, not wanting a particular vaccination at that time, behavioral or medical issues at the time of vaccination, or a religious exemption from a particular vaccination. This term does not include refusal to participate in the registry.

(sq) “Reminder or recall module” means the subsystem within the NHIIS designed to prompt an authorized user with access to this module, that has elected to use this module, to perform outreach to a parent of a minor participant, or a participant if 18 years of age or over, to foster the completion of an immunization series, or the conduct of preventive health screenings in a timely manner.

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

(uf) “Vaccination event” means an immunization/immunoglobulin administration, exemption, refusal as defined in (p) above, adverse reaction.

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) Health care providers, only for registrants whom they have claimed in the registry as their patient or to whom they are currently providing health care services, or both Administering, current, and former health care providers; and

(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, childcare centers, colleges, and universities, only for named individuals in their care registrants that they have enrolled or are in the process of enrolling into their institutions;~~

~~(3) Licensed child care agencies, only for named individuals in their care; and Managed care organizations, only for registrants that they have enrolled as a member or beneficiary of their health coverage plan or as set forth at He-P 307.11; and~~

~~(4) Local public health entities, which are administered by the cities of Manchester and Nashua, New Hampshire.~~

(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 or through manual data entry at <https://nhiis-prod.dhhs.nh.gov/nhiis/Login.aspxwww.vaxnh.org>.

(b) Birthing facilities shall enroll all newborns in the registry through submittal of the electronic birth certificate (EBC) to the Division of Vital Records Administration Registration/Certification.

(c) When enrolling a newborn, birthing facilities shall record and report information about any vaccine or biological administered at the birthing facility on the EBC prior to the discharge of the newborn.

(d) If the birth of a newborn takes place outside of a birthing facility and the newborn is then transferred to a birthing facility, the receiving birthing facility shall enroll the newborn in, and inform the parent about the registry.

(e) For each vaccination event, administering or current health care providers who are participating in the registry shall report to the registry such data listed in the Centers for Disease Control (CDC) Core Data Elements for Immunization Information Systems, listed in the functional standards document (<https://www.cdc.gov/vaccines/programs/iis/core-data-elements/iis-func-stds.html>) and in the 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>, available as noted in Appendix A.

(f) For each vaccination event, administering or current health care providers who are participating in the registry shall also report to the registry the following types of ~~registrant~~ participant information:

(1) The ~~registrant~~ participant's insurer information as held by the administering or current health care provider; ~~and~~

(2) Any doses of vaccinations previously administered to the participant by the health care provider that may not have been reported to the NHIIS or for which there is documentation; ~~and~~

(3) Date of death, if applicable and if known.

(g) Administering or current health care providers who are participating in the registry shall report only verified and accurate information to the registry.

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 as 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.~~

(be) 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 who is participating in the registry; ~~and/or~~

(2) Prior to or at a face-to-face encounter with a current health care provider by the current health care provider who is participating in the registry; ~~and-~~

(3) Prior to a former healthcare provider reporting historical immunization/vaccination information to the registry.

(~~cf~~) In all cases described in (~~be~~) above, 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, and by providing the patient, or the patient's parent or guardian if the patient is a minor, the "Choose not to Participate in the New Hampshire Immunization/Vaccination Registry" form (~~XXXX 20213/16 edition~~).

(~~dg~~) If the opportunity to opt out of the registry is provided by a current health care provider prior to a face-to-face encounter with the current health care provider, as described in (~~be~~)(2) above, that provider shall send a written communication to the patient, or the patient's parent or guardian if the patient is a minor, which meets the requirements in (~~cf~~) above in form and substance, ~~which is individually directed, and in which opting out is the sole subject of the communication.~~

(~~eh~~) 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 (~~XXXX 20213/16 edition~~) and providing that form to ~~each of the patient's administering and current health care providers who are participating in the registry~~ their healthcare provider.

(~~di~~) The "Choose not to Participate in the New Hampshire Immunization/Vaccination Registry" form in (~~eh~~) above shall be maintained and documented by the ~~administering or current health care provider within the patient's medical records~~ healthcare provider that received the form.

(~~ej~~) An administering or current health care provider who is participating in the registry, including the physicians and nurses in the administering or current health care provider's professional practice or medical group, shall not 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, more than once.

(~~fk~~) 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" (~~XXXX 20213/16 edition~~);

(2) The current health care provider who is participating in the registry shall complete the provider information section of "Withdraw and Remove Information from the New Hampshire Immunization/Vaccination Registry" (~~XXXX 20213/16 edition~~);

(3) The current health care provider in (2) above shall fax or secure email the completed "Withdraw and Remove Information from the New Hampshire Immunization/Vaccination Registry" (~~XXXX 20213/16 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 who is participating in the registry may complete and submit “Withdraw and Remove Information from the New Hampshire Immunization/Vaccination Registry” (~~XXXX 20213/16 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 complete a “Choose not to Participate in the New Hampshire Immunization/Vaccination Registry” form (~~XXXX 20213/16 edition~~) ~~and provide to their healthcare provider, who in turn will provide a copy to the department with each of the patient’s current and administering health care providers who are participating in the registry.~~

(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 who is participating in the registry 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” (~~XXXX 20213/16 edition~~), including a notarized signature of the patient or the patient’s parent or guardian if the patient is a minor.

(c) Upon receipt of a complete request in (b) above, the department shall provide the patient, or the patient’s parent or guardian if the patient is a minor, a copy of the requested record by mail.

(d) A request under (a) above for a registry record review to a health care provider who is participating in the registry 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.

~~(e) No record of the transaction described in (b) and (d) above, including the request itself, shall be maintained by the department or the health care provider in any way.~~

~~(e)~~ (f) 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 (~~XXXX 20213/16 edition~~), available on the department’s web site and at the office of the current health care provider who is participating in the registry;

b. Return the completed form to the current health care provider who is participating in the registry; and

c. Provide the current health care provider who is participating in the registry 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 current health care provider who is participating in the registry 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 in any way by the current health care provider who is participating in the registry.~~

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 (~~XXXX~~ 20213/16 edition) to the patient's current or administering health care provider who is participating in the registry.

~~(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 who are participating in the registry 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 complete "Reverse Previous Decision not to Participate in the New Hampshire Immunization/Vaccination Registry" forms (3/16 edition) and submit them with each of the patient's current and administering health care providers.~~

~~(be) The "Reverse Previous Decision not to Participate in the New Hampshire Immunization/Vaccination Registry" form in (a) above shall be maintained and documented by healthcare provider that received the form. the current and administering health care provider who is participating in the registry 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 by the department 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 (July 2015) 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 submitted to:

Department of Health and Human Services
Division of Public Health Services
Immunization Section – Data Request

29 Hazen Drive
Concord, NH 03301-6504
[Email: nhiis.support@dhhs.nh.gov](mailto:nhiis.support@dhhs.nh.gov)

(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(m).

(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~~ Managed Care Organizations shall access statistics for registrants that they have enrolled as a member or beneficiary of their health coverage plan as an authorized user of the immunization registry ~~provide annual summary statistics of immunization information to managed care organizations.~~

He-P 307.12 Security of Immunization Vaccination Data. Authorized users shall maintain the confidentiality of information in the registry in the same manner as other medical record information with patient identification that they possess.

APPENDIX A

Rule	Title	Publisher, How to Obtain, Cost
He-P 307.05(e)	Core Data Elements for Immunization Information Systems, listed in the functional standards document and as Appendix B in HL7 Version 2.5.1: Implementation Guide for Immunization Messaging Release 1.5 (October 1, 2014).	<p>Publisher: US Department of Health and Human Services, Centers for Disease Control and Prevention</p> <p>Cost: Free of Charge</p> <p>Obtained at: https://www.cdc.gov/vaccines/programs/iis/core-data-elements/iis-func-stds.html; and http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf</p>

APPENDIX B

RULE	RSA/FEDERAL CITATION
He-P 307.01 – 307.12	RSA 141-C:20-f