1. Agency Name & Address:	2. RSA Authority:	RSA 141-C:6, XVIII; RSA 141-C:20-f, VI
Dept. of Health & Human Services Division of Public Health Services 29 Hazen Drive Concord, NH 03301	<ul> <li>3. Federal Authority:</li> <li>4. Type of Action: <ul> <li>Adoption</li> <li>Repeal</li> <li>Readoption</li> <li>Readoption w/s</li> </ul> </li> </ul>	X X amendment X
5 Short Title: Immunization Registr	Dl	

Rule Number

He-P 307

3. Short ride. Immunization Registry Rules

Notice Number

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

He-P 307 implements the procedures, pursuant to RSA 140-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 Department of Health and Human Services (Department) is proposing to adopt, readopt, or readopt with amendment all of the rules in He-P 307. A majority of these changes from the existing He-P 307 are to align with statutory changes from the 2022 legislative session, specifically HB 1606 (Chapter 207 of the Laws of 2022). The proposed changes include:

- Updating He-P 307.01 on the purpose of He-P 307 by deleting the word "vaccination" from "immunization/vaccination registry" for consistency of language used in RSA 141-C:20-f and replacing the term "registrant" with "participant". Both changes are being made here and throughout the proposed rule text;
- Updating He-P 307.02 on definitions by:
  - Amending the definition of "commissioner", "health care provider", and "patient";
  - Adding the definition of "opt-in", "participant", and "personal data"; and
  - Removing the definition of "registrant";
- Updating He-P 307.03 on establishment and maintenance of the immunization registry by deleting paragraph (b) as it refers to RSA 332-I:1, II(c), which has been repealed;
- Updating He-P 307.05 on content and submission of vaccination event reports by revising:
  - Paragraph (a) to ensure opt-in and explicit consent provisions are clearly indicated as precursors to reporting vaccination events to the registry and to clarify that reporting of vaccination events is only required when state or federally supplied vaccine is administered to a participant;
  - Paragraph (b) to update the link to the "Centers for Disease Control (CDC) Core Data Elements for Immunization Information System" and "Appendix B in HL7

- Version 2.5.1: Implementation Guide for Immunization Messaging Release 1.5" and to clarify that participating providers are only required to report data listed in the "CDC Core Data Elements for Immunization Systems" for participants who received state or federal supplied vaccine; and
- Paragraph (c) to add previously administered vaccination doses to the participant information that shall be reported by providers who are participating in the registry;
- Updating He-P 307.06 on procedures for patients to opt-out of the registry by amending the provisions of the registry and that it is now an opt-in or opt-out format, and that explicit consent is required. Additionally, He-P 307.06 is being updated in:
- Paragraph (e) to clarify that the opportunity to opt-in or opt-out shall be provided to each patient prior to or at a face-to-face encounter or at the time of vaccination unless the provider is able to confirm documentation of prior opt-in or opt-out in the patient's medical record;
- Paragraph (g) to require that the provider shall maintain documentation of the opportunity to opt-in or opt-out of the registry and explicit consent in the patient's medical record;
- Paragraph (h) to require the provider to inform, educate, and ensure that patients understand the various information provided to them;
- Paragraphs (i)-(j) to amend practice and procedures for individuals who change their decision to opt-in or opt-out of participating in the registry;
- Paragraph (k) to clarify that the opportunity to opt-in or opt-out shall be provided to each patient only once unless the provider is able to confirm documentation of prior opt-in or opt-out in the patient's medical record;
- Paragraph (l) to clarify that the opportunity to opt-in or opt-out shall not be required to be provided to individuals who have previously been given a chance to opt-out prior to July 1, 2023, and did not elect to opt-out unless there is a change to the participant's decision to opt-in or opt-out; and
- Paragraph (n) by adding that providers are obligated under Med 501.02(f)(8) and other state or federal regulations to maintain a record of vaccination within their own practice's patient medical record;
- Updating He-P 307.07 on procedures for participants to withdraw from participation in the registry to clarify updated processes to withdraw from participation in the registry, to update the incorporated "New Hampshire Immunization Information System (NHIIS) Withdrawal Form", and to ensure transactions of withdrawal of information are maintained in accordance with HIPAA record retention requirements pursuant to 45 CFR 164.530(j)(2) and 45 CFR 164.316);
- Updating He-P 307.08 on procedures for patients to review and correct information contained in the registry to revise the incorporated "Request for Immunization/Vaccination Record" and the required supporting documentation needed and to ensure the Department maintains a record of the transaction for participants to review and correct information

contained in the registry to maintain Department compliance with HIPAA record retention requirements pursuant to 45 CFR 164.530(j)(2) and 45 CFR 164.316);

- Updating He-P 307.09 on procedures for patients to reverse decisions to opt-in/opt-out of the registry to clarify procedures for individuals to reverse their decision to opt-in or opt-out of the registry;
- Update He-P 307.10 on requests for registry data for research or other purposes by clarifying what data shall not be released and revising the incorporated "New Hampshire Immunization Program Request for Data" form;
- Adopting new section He-P 307.11 on exchange of participant immunization/vaccination records that outlines the requirements to exchange participant immunization/vaccination records with other jurisdiction's registries in order to ensure a complete immunization record for all participants; and
- Renumbering the existing He-P 307.11 as He-P 307.12 on procedures for managed care organizations to obtain summary statistics of immunization information on members.
- 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 – He-P 307.12	RSA 141-C:20-f			

7. Contact person for copies and questions including requests to accommodate persons with disabi	
Toniaci person for copies and questions incliding requests to accommodate persons with disabi	

Name: Allyson Raadmae Title: Administrator- Administrative Rules Unit

Address: Dept. of Health and Human Services Phone #: (603) 271-9604

Administrative Rules Unit Fax#: (603) 271-5590 129 Pleasant Street, 2<sup>nd</sup> Floor

Concord, NH 03301 E-mail: Allyson.E.Raadmae@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:

https://www.dhhs.nh.gov/doing-business-dhhs/legal-services/administrative-rules/nh-administrative-rules-public-comment

8.		ission of materials in writing or, i Tuesday, October 10, 2023	f practicable for the agency, in the electronic
	⊠ Fax	🔀 E-mail	Other format (specify):

9. Public hearing scheduled for:

Date and Time: Tuesday, October 3, 2023 at 2:30pm

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

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

FIS # 23:164 , dated August 14, 2023

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

There is no difference in cost when comparing the proposed rules to the existing rules.

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):

Any costs or benefits are attributable to RSA 141-C:20-f, which was amended in 2022 to allow individuals the opportunity to opt into or opt out of the immunization registry.

A. To State general or State special funds:

None.

B. To State citizens and political subdivisions:

None

C. To independently owned businesses:

None.

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

The proposal modifies an existing 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.

### Readopt with amendment He-P 307.01 through He-P 307.03, effective 5-1-17 (Document #12163), cited and to read as follows:

#### PART He-P 307 IMMUNIZATION ACCINATION REGISTRY

He-P 307.01 <u>Purpose</u>. 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 <u>participants</u>registrants to receive all required immunizations/vaccinations in a timely manner by providing access to the registrant's immunization/vaccination record and to provide <u>participants</u> registrants with information about recommended immunizations/vaccinations;
  - (b) To ensure 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 <u>theirhis or her</u> 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 the following persons who or entities which provide health care services: hospitals, medical clinics and offices, physicians, naturopaths, pharmacists, dentists, registered or

other nurses and nurse practitioners, medical assistants, paramedics, other immunizing providers, 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-in" means the process an individual follows to elect to participate in the registry and, after which, one's immunization/vaccination record will be provided to the registry.
- (lk) "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.
  - (m) "Participant" means the patient/registrant whose immunization record is contained in the registry.
- (nl) "Patient" means an individual who receives an immunization/vaccination or other health care services in New Hampshire.
- (o) "Personal data" means a participant's name, date of birth, race, ethnicity, gender, address, contact information, and immunization or vaccination information.
- (pm) "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.
  - (qn) "Read-only rights" means the ability of the data to be accessed but not entered or modified.
  - (re) "Read/write rights" means the ability of the data to be accessed, entered, or modified.
- (SP) "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.
  - (q) "Registrant" means the patient whose immunization record is contained in the registry.
- ( $\underline{tr}$ ) "Vaccination event" means an immunization/immunoglobulin administration, exemption, refusal as defined in ( $\underline{sp}$ ) 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 all applicable state statutes.

Readopt He-P 307.04, effective 5-1-17 (Document #12163), to read as follows:

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; 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, 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, 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.

### Readopt with amendment He-P 307.05 and He-P 307.06, effective 5-1-17 (Document #12163), to read as follows:

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

- (a) For each patient who, after being given the opportunity to opt-in or opt-out of participating in the registry in accordance with He-C 307.06, and who has explicitly provided written or electronic consent to opt-in, does not exercise the option to opt out, an administering or current health care provider who is participating in the registry shall have report all vaccination events reported to the registry within 7 business days of the event through an electronic web-based interface or manual data entry at https://nhiis-prod.dhhs.nh.gov/nhiis/Login.aspx by a participating administering or current health care provider when a state/federally supplied vaccine is administeredat www.vaxnh.org.
- (b) For each vaccination event where a state or federal supplied vaccine was administered to a of participant, 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 and Prevention's (CDC), "Core Data Elements for an Immunization Information HistorySystems", listed in the functional standards document at <a href="https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html">https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html</a> and in as Appendix B in HL7 Version 2.5.1: Implementation Guide for Immunization Messaging Release 1.5 (October 1, 20142018) found

https://repository.immregistries.org/files/resources/5bef530428317/hl7 2 5 1 release 1 5 2018 updat e.pdf http://www.ede.gov/vaccines/programs/iis/technical\_guidance/downloads/hl7guide 1 5 2014 11.pdf, available as noted in Appendix A.

- (c) 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's participant's insurer information as held by the administering or current health care provider; and
  - (2) Any doses of vaccination(s) previously administered to the participant by the health care provider that may not have been previously reported to the registry for which there is documentation;
  - (3) Any doses of vaccination(s) previously administered to the participant by another health care provider that may not have been previously reported to the registry for which there is documentation provided unless the administering or current health care provider cannot manually or electronically transmit this information to the New Hampshire Immunization Information System (NHIIS); and
  - (24) Date of death, if applicable and if known.

#### He-P 307.06 Procedures for Patients to Opt-In or 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 <u>personal data immunization/vaccination information</u>-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 <u>opt-in or opt-out of</u> the registry <u>and providing written or electronic consent</u>.
- (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.
- (e) A patient, or the patient's parent or guardian if the patient is a minor, shall be provided an opportunity to <u>opt-in or</u> 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, unless the provider is able to confirm documentation of prior optin or opt-out in the patient's medical record; orand
  - (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, unless the provider is able to confirm documentation of prior opt-in or opt-out in the patient's medical record.
- (f) In all cases described in (e) above, the opportunity to <u>opt-in or opt-out</u> 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.
- (g) The provider shall maintain documentation of the opportunity to opt-in or opt-out of the registry and explicit consent, if applicable, in the patient's medical record.

, 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 (3/16 edition).

- (h) In all cases described in (e) above, the provider shall inform and educate the patient about the registry and ensure patient understanding of the following:
  - (1) Participation in the New Hampshire immunization/vaccination registry is voluntary;
  - (2) Immunization information for participants may be consolidated and used by authorized NHIIS users such as their health care provider, school nurse, licensed child care provider or NH Division of Public Health to provide notice about upcoming immunizations, overdue immunizations or identification of recommended immunization/vaccination in the event of a disease outbreak;
  - (3) The decision to opt-in or opt-out of the New Hampshire immunization registry shall not prevent them from receiving immunizations;
  - (4) Individuals may reverse their decision at any time by notifying their current health care provider(s);
  - (5) Individuals may remove all existing information from NHIIS by submitting a "New Hampshire Immunization Information System (NHIIS) Withdrawal Form" to their health care provider or by mailing or faxing a notarized "New Hampshire Immunization Information (NHIIS) Withdrawal for to:

Department of Health and Human Services
Division of Public Health Services
NH Immunization Program
29 Hazen Drive
Concord, NH 03301-6504
Attn: Registry Admin

Fax: (603) 696-3226

- (6) An individual's immunization information will not be released to the New Hampshire immunization/vaccination registry unless they have provided explicit electronic or written consent; and
- (7) The NHIIS may exchange immunization information with other state/territory Immunization Information Systems (IIS) for the purposes of ensuring completeness of record. In the event that an immunization record exists for individuals who participates in another state's/territory's registry, by choosing to participate they allow the transfer of their immunization record from another state/territory into the NHIIS. In the event that the participant receives immunization in another state/territory or there is a change of residence to another state/territory, by choosing to participate, they allow the transfer of their immunization record from the NHIIS to be exchanged with that other state's/territory's IIS."
- (ig) If the opportunity to <u>opt-in or opt-out</u> 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 (ed)(2) above, that provider shall send a written communication to the patient, or the patient's parent or guardian if the patient

- (h) 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 (3/16 edition) and providing that form to each of the patient's administering and current health care providers who are participating in the registry.
- (j) In the event a patient or the patient's parent or guardian if the patient is a minor, changes their decision from opt-in to opt-out or vice versa, the-participant, or the participant's parent or guardian if the participant is a minor, shall follow the process as described in He-P 307.09.
- (i) The "Choose not to Participate in the New Hampshire Immunization/Vaccination Registry" form in (hg) above shall be maintained and documented by the administering or current health care provider within the patient's medical records.
- (kj) 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-in or opt-out of the registry the to the same patient, or the patient's parent or guardian if the patient is a minor, more than once unless evidence of prior opt-in or opt-out cannot be confirmed via patient medical records.
- (l) 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 obtain explicit written or electronic consent to send personal data to the registry for any patient, or the patient's parent or guardian, who has previously been given a chance to optout prior to July 1, 2023 and did not elect to opt-out unless there is a change to participant's decision to optin or opt-out to the registry.
- (mk) 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.
- (n) Nothing in this rule shall relieve the provider from the obligation to maintain a record of vaccination within the practice's patient's medical record in accordance with Med 501.02(f)(8) and other state or federal regulations.

#### Readopt with amendment He-P 307.07, effective 3-28-23 (Document #13602), to read as follows:

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

- (a) A <u>patient participant</u>, or the <u>patient's participant's</u> parent or guardian if the <u>patient participant</u> 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 participant, or the participant's parent or guardian if the participant is a minor, shall follow the process as described in He-P 307.09 to withdraw from participation in the registry:
  - (2) The patientparticipant, or the patientparticipant's parent or guardian if the participantpatient is a minor, shall complete the vaccine recipient information section of the "New Hampshire Immunization Information System (NHIIS) Withdrawal of Information Form" (XXXX March 2023) and acknowledge that:

"I understand that this withdrawal from participation in the registry will not prevent me or my child from receiving immunizations/vaccinations.

I understand withdrawing will delete all existing vaccine information within the NHIIS for myself or for my child. This is a permanent deletion that cannot be undone.

I understand that it is my responsibility to inform my/my child's health care provider(s) of my decision to withdraw from the registry.

I understand that I may reverse my decision by completing a "Reverse Previous Decision not to Participate in the New Hampshire Immunization/Vaccination Registry" (3/2016) form with my current healthcare provider.

I understand that this withdrawal from NHIIS will not withdraw my/my child's information from another state's/territories IIS. It is my responsibility to contact any other state's/territories IIS in which I have received immunization to request withdrawal of immunization information from that state/territory as exchange of immunization information may have occurred.

<u>I understand that individuals Patients</u> who choose to withdraw from participation in the registry are not relieved from the obligation to comply with current immunization requirements set forth in RSA 141-C:20-a and He-P 301.14.";

- (32) The <u>participant patient</u>, or the <u>patient's participant's</u> parent or guardian if the <u>participant patient</u> is a minor, shall obtain <u>the</u> signature of a health care provider or a public notary on the "New Hampshire Immunization Information System (NHIIS) Withdrawal <u>of</u> Information Form" (XXXX<u>March</u> 2023);
- (43) The participantpatient, or the participantpatient's parent or guardian if the patient is a minor, or health care provider in (2a) above shall fax or mail the completed "New Hampshire Immunization Information System (NHIIS) Withdrawal of Information Form" (XXXX March 2023) to the department; and
- (54) The department shall remove all patient information from the registry.
- (b) If a <u>participant patient</u>, or the <u>participant patient</u>'s parent or guardian if the <u>participant patient</u> is a minor, requests withdrawal of information from the registry in accordance with (a) or (b) above, then no information relating to the <u>participant patient</u> shall remain in the registry.
- (c) The department or health care provider shall keep , and anyno record of the transaction, including the request itself, shall be kept by either the department or the health care provider in a HIPAA compliant system separate from the registry when subject to HIPAA record retention requirements.
- (c) 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 (3/16 edition) with each of the patient's current and administering health care providers who are participating in the registry.

### Readopt with amendment He-P 307.08 through He-P 307.10, effective 5-1-17 (Document #12163), to read as follows:

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 20233/16 edition) that, includes theing 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) ANo 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 wayto demonstrate department compliance with HIPAA record retention requirements.
  - (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 <u>NHIIS Immunization</u>/Vaccination Record" form (<u>XXXX 2023</u>3/16 edition), available on the department's web site <u>at https://www.dhhs.nh.gov/programs-services/disease-prevention/immunizations/nhimmunization-information-system/nhiis-1 andor at the office of the current health care provider who is participating in the registry;</u>
      - b. Return the completed form to the current health care provider who is participating in the registry or to the department via fax or mail,
      - c. If the completed form is being returned to the department, include the following supporting documentation for the information requested to be corrected:
        - 1. A valid state issued photo ID, passport, or birth certificate;
        - 2. Documentation of vaccination received, if a dose needs to be corrected, added, or deleted; and

- 3. Legal court documentation, if there has been a legal name change or as proof of guardianship for minors or medial proxy; and
- <u>de</u>. 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 requested to be corrected, the current health care provider who is participating in the registry entity who received the "Correction to Immunization/Vaccination Record" Correction to NHIIS Vaccination Record" form (XXXX 2023) 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) ANo record of the transaction in described in (1) and (2) above, including the request itself, shall be maintained in any way by the eurrent health care provider who is participating in the registryentity who received the "Correction to NHIIS Vaccination Record" form (XXXX 2023), in accordance with HIPAA record retention requirements.

#### He-P 307.09 Procedures for Patients to Reverse Decision to Opt-in/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 outopt-in or opt-out of participation in the registry at any time by informing completing and submitting the "Reverse Previous Decision not to Participate in the New Hampshire Immunization/Vaccination Registry" form (3/16 edition) to the patient's their current or administering health care provider who is participating in the registry of their decision to reverse their opt-in or opt-out status.
- (b) It shall be the responsibility of the The provider shall document the patient's, or the patient's parent or guardian if the patient is a minor, reversal of decision and explicit consent to opt-in, if applicable, in the patient's medical record. patient, or the patient's parent or guardian if the patient is a minor, to inform all of 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 outof 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 witheach of the patient's current and administering health care providers.

- (c) The provider shall ensure that past, current, and future immunization/vaccination information is or is not further reported to the registry in accordance with the patient's change in opt-in/opt-out status.
- (c) The "Reverse Previous Decision not to Participate in the New Hampshire Immunization/Vaccination Registry" form in (a) above shall be maintained and documented by the current and administering health care provider who is participating in the registry within the patient's medical records.

- (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 <u>direct-identifiers</u>, as <u>defined by HIPPA and in accordance with RSA 91-A:10, data</u> that would allow constructive identification of individuals. <u>The cell size shall not be released in any document where the numbers of counts are between 1 and 4.</u>
- (c) A "New Hampshire Immunization Program Request for <u>Non-Confidential</u> Data" form (<u>XXXX</u> <u>2023 July 2015</u>) 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 Non-Confidential Data" form shall be mailed or faxed to:

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

Fax: (603) 271-3850

- (e) If the request is not complete, the department shall notify the applicant in writing within 10 business days of receiving the request 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.

#### Adopt He-P 307.11 to read as follows:

He-P 307.11 Exchange of Participant Immunization/Vaccination Records.

(a) The department shall enter into data sharing agreements with other jurisdiction's immunization information systems (IIS) in order to ensure a complete immunization/vaccination record for all participants for the purposes as outlined in RSA 141-C:20-f,I, and V and He-P 307.01, and for other purposes as allowable under HIPAA and state and federal laws.

- (1) To create a single repository of accurate, complete and current immunization records to aid, coordinate, and promote effective and cost-efficient disease prevention and control efforts;
- (2) To ensure that participants receive all recommended immunizations in a timely manner by providing access to the registrant's immunization record and to provide participants with information about recommended immunizations/vaccinations;
- (3) To improve immunization rates by facilitating notice to participants of overdue or upcoming immunizations; and
- (4) To control communicable diseases by assisting in the identification of individuals who require immediate immunization in the event of a disease outbreak.

Readopt and renumber He-P 307.11, effective 5-1-17 (Document #12163), as He-P 307.12 to read as follows:

He-P 307.124 <u>Procedures for Managed Care Organizations to Obtain Summary Statistics of Immunization Information on Members</u>. The department shall provide annual summary statistics of immunization information to managed care organizations.

Rule	Title	Publisher; How to Obtain; and Cost
He-P 307.05(b)	Centers for Disease	Publisher: Centers for Disease Control and Prevention
	Control and	Cost: Free of Charge
	Prevention's, "Core	Cost. Free of Charge
	Data Elements for	The incorporated document is available at:
	Immunization	1.44//
	Information Systems,	https://www.cdc.gov/vaccines/programs/iis/technical-
	listed in the	guidance/hl7.html; or
	functional standards	
	document and in	https://repository.immregistries.org/files/resources/5bef5
	Appendix B in HL7	<u>30428317/hl7_2_5_1_release_1_5_2018_update.pdf</u>
	Version 2.5.1:	
	Implementation	
	Guide for	
	Immunization	
	Messaging Release	
	1.5" (October 2018)	

#### APPENDIX B

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



### New Hampshire Immunization Information System (NHIIS) Withdrawal of Information Form

Fax or mail this form to: New Hampshire Immunization Program, 29 Hazen Drive, Concord, NH 03301 Attn: Registry Administrator, fax: 603-696-3266

Vaccine Recipient Information (AS IT A	PPEARS IN NHIIS)	- To l	be comple	eted by the pa	rticip	ant or parents/	Legal guardian	
Name of the Vaccine Recipient/Participant (Print)		Dat	Date of Birth (MM/DD/YYYY) NHI		NHIIS Patient I	NHIIS Patient ID (If known)		
Street Address City			te	Zip code	Pho	Phone number or Email address		
Acknowledgement:  ❖ I understand that this withdrawal from participation immunizations/vaccinations.  ❖ I understand withdrawing will delete all existing vaccins is a permanent deletion that cannot be undone.  ❖ I understand that I may reverse my decision by complementary I understand that it is my responsibility to inform my registry so that no future immunization/vaccination  ❖ I understand that individuals Patients who choose to the obligation to comply with current immunization  ❖ I understand that this withdrawal from NHIIS will no my responsibility to contact any other state's/territorequest withdrawal of information from that state/toccurred.			nformation of the mation is draw from irements in draw information is draw information in the mation is and seel and seel	rse Previous Dent health care are providers reported to the participation set forth in RSA armation from the participations of a removal of a remova	HIIS to ecisic provestor of my e NH in the anotation and the anotation all m	for myself or for myself or for myself or for on not to Particivider.  y decision to with the registry are not concern the registry are not concern the received imming in information to my/my child's in	my child. This  pate in the New  chdraw from the  pt relieved from P 301.14.  itory's IIS. It is unization to may have	
Name of Parent or Legal Guardian (if participant <18 years old) (Print)	Relationship t participant		_	re of Participa an (sign in pro		_	Date of Request	
Healthcare Provider					Puhli	c Notary		
Name of the Facility or Clinic and Clinic ID			Subscrib	ed and sworn				
,					•			
Name of Healthcare Provider				_ Day of		(Month),	(Year)	
		OR	Notary's	s Signature an	d Sea	ıl		
Signature of Health Care Provider L	Date		Date My	/ Commission	Expir	es:		

**Note:** In the event that the NH Department of Public Health was the medical provider (i.e. State run COVID-19 clinic), a copy of vaccination(s) provided by the Department/Department's authorized agent will be retained in a separate HIPAA compliant system for a period of 7 years for adults and 7 years or until the minor reaches age 19 for minors in order to comply with Med 501.02(f)(8) and He P 802.06 (h). The Department is also obligated to maintain a record of transactions, separate from the registry, in accordance with HIPAA record retention requirements.



## New Hampshire Immunization Information System (NHIIS) Request for Immunization/Vaccination Record

An individual may obtain their/their child's Immunization Record from the NHIIS (if this information has been reported to the NHIIS) through the NHIIS Web Based portal <a href="https://www.vaccines.nh.gov/vaccination-record-instructions">https://www.vaccines.nh.gov/vaccination-record-instructions</a> or by completing this form.

Completed forms may be faxed to 603-696-3266 or mailed to:

<b>New Hampshire Immunization Pro</b>	ogram				
29 Hazen Drive					
Concord, NH 03301					
Attn: Registry Administrator					
PARTICIPANT NAME (Print):		Date of Birth:			
ADDRESS:					
CITY:	State:	ZIP Code:			
☐ I request a copy of my/my ch	nild's immunization/vaccinati	on record from the NHIIS for the			
	-	s (check if same as above address $\Box$ )			
ADDRESS:					
GITT.	State				
(Print)					
* PARENT/LEGAL GUARDIAN NAME, IF P					
		<del></del>			
SIGNATURE OF INDIVIDUAL REQUESTING	S NHIIS RECORD	DATE OF REQUEST			
•	_	al name change, please attach the appropriate nd applicable legal documentation is not			
For Department Use Only					
ID Verification Method:					
☐ State Issued Photo ID:					
☐ Passport					
☐ Birth Certificate					
☐ Other					
☐ Legal Documentation Verified	☐ Legal Documentation Not Ap	plicable			
Staff Name (Print)	Staff Title:				
Date:					



#### New Hampshire Immunization Information System (NHIIS) Correction to NHIIS Vaccination Record

Fax or mail this form to: New Hampshire Immunization Program, 29 Hazen Drive, Concord, NH 03301 Attn: Registry Administrator, fax: 603-696-3266

I have reviewed my/my child's current immunization/vaccination record contained in the New Hampshire immunization/vaccination registry <u>AND</u> present the attached supporting documentation (i.e. vaccine record, proof of to request correction of the immunization/vaccination record as it currently appears in the NHIIS for the following participant.

PARTICIPANT NAME (Print):	Date of Birth:			
ADDRESS:		<u> </u>		
CITY:	State:	ZIP Code:		
(Print)				
*PARENT OR LEGAL GUARDIAN NAME, IF F				
SIGNATURE OF INDIVIDUAL REQUESTING I	NHIIS RECORD CORRECTION	DATE OF REQUEST		
Please indicate information to be added (please see page 2 for instructions for so		ocumentation provided as evidence		
Change Requested:	Supporting Docu	mentation:		
* All record requests for minors or indi Parent/Guardian's proof of identity an of vaccine recipient.	•			
For State Internal Use Only:				
Change made and documented in the re				
☐ Change not made, supporting documen		·		
	that further documentation is nee			
(email/phone/oth	er)	(Date)		

#### **Instructions for supporting documentation:**

Copies of supporting documents are needed to have information corrected, see below for the type of documents needed for each type of request. All record requests for minors or individuals under Legal Guardianship or Medical Proxy must include Parent/Guardian's proof of identity and a birth certificate or legal documentation verifying guardianship of vaccine recipient.

#### A VALID STATE ISSUED PHOTO I.D. OR VALID PASSPORT OR BIRTH CERTIFICATE IS REQUIRED FOR THE FOLLOWING:

- Address, phone number or email additions or corrections.
- Adding or correcting vaccinations.
- Create an NHIIS record.
- Name spelling corrections.
- Date of birth corrections.
- Legal name change.
- Gender correction.

#### **DOCUMENTATION OF VACCINATION RECEIVED IS REQUIRED FOR THE FOLLOWING:**

- A dose needs to be corrected.
- A dose need to be added and/or deleted (including booster doses).

**AND MUST INCLUDE**: Vaccine recipient's name, date of birth, vaccine clinic name, administration date, name of vaccine and manufacturer of vaccine.

#### **LEGAL COURT DOCUMENTATION IS REQUIRED FOR THE FOLLOWING CHANGES:**

- Legal name change (EX: marriage).
- Proof of guardianship for minors or medical proxy.

#### Access to the NHIIS Public Portal:

Mobile phone number and/or email is needed to receive a verification code. Please include this
information on the form to access your verification code at <a href="https://nhiis-prod.dhhs.nh.gov/webiznet">https://nhiis-prod.dhhs.nh.gov/webiznet</a> nh public/Application/PublicPortal/Index



To request aggregated statistical data from the NH Immunization Program, in accordance with He-P 307.10, Pplease send your completed application materials to the following address:

New Hampshire Department of Health and Human Services
Division of Public Health Services
Immunization Section - Data Request Program Attn: Donna McKean
29 Hazen Drive
Concord, NH 03301-6504

You may also fax the form to (603) 271-3850, or e-mail it as an attachment todonna.m.mekean@dhhs.state.nh.us General data requests are filled within 10-15 business days, however, completion of the request may take longer depending on the complexity of the data search and/or analysis process. If you have any questions, please contacteall (603) 271-4482 or at-1-800-852-3345 ext. 4482 or email immunization@dhhs.nh.gov.

#### **L** Individual and Organization Requestor Information

1. Contact Person (person requesting data) Name and Title:
2. Organization/Office/Bureau:
3. Address:
4. Telephone Number:
5. Fax Number:
6. E-mail Address:
7. Name, Title, and Contact Information of person assigned to receive data (enter "same as requestor" if not applicable) Overall Responsible Party's Name and Title (if applicable):
8. Overall Responsible Party's Telephone Number (if applicable):
89. Date Request Made:
910. Date Information Needed:

Most simple data requests are filled within two weeks, however, completion of the request will



depend on the complexity of the data search and/or analysis process.

#### **II.** Description of Requested Data

Please complete the following; giving information that is as detailed as possible. The information you provide will serve as the criteria for the NH Immunization Program to respond to your data request. After receiving your request it will be reviewed for feasibility. You will be contacted if we have any questions or concerns.

#### A. Data Requested:

- 1. Please provide a title or brief description of the requested data (vaccine or immunization series of interest) and describe the overall aims of the project that this analysis is part of. NOTE: Data requests to release confidential information are not permitted.
- 2. Years Requested: For what year(s) are you requesting data or information?

  Note: It is sometimes necessary to combine data from multiple years to produce reliable statistics that do not conflict with confidentiality considerations. This is likely to be necessary for events that occur infrequently. Would your request still be useful to you if data from multiple years were grouped together?
- 3. Geographic Area Requested: What geographic area(s) are you interested in (statewide, all counties, a specific county, health service areas, a specific city/town, etc.)? If you are interested in data at the city/town level, please note that it may not be possible for us to release vaccination data at the town level, depending on the data set, the size of the city/town, and whether or not it would be acceptable to have multiple years of data combined, because of the need to maintain confidentiality. Would your request still be useful to you if data from multiple years were grouped together?
- 4. Data Elements Requested: Please describe as specifically as possible the information you would like to obtain from the data requested. Would you like the data broken down by any demographic variables (age, race, ethnicity, sex)? Would you like counts or vaccination rates?
- 5.4. Please provide any other details needed for us to complete your request.
- 6.5. Please describe how the data will be used and stored the format in which you would like to receive the analysis results (report, electronic document, e-mail, etc.).
- 7. What are the overall aims of the study or project that this analysis is part of?



#### III. Summary Description of Requested Data

Instructions for using following checklists:

- Check (✓) data being requested.
- Specify year(s) of data requested based on years of data available. Please note that years of available data vary for datasets.
- 1. Please indicate the type and timeframe of data requested:
- 2. Please indicate the specific diseases or conditions of interest and how you would like the data aggregated/stratified/broken down:

Please list Sspecific Vaccine/Immunizati on Series (please	1	Geographic Breakdown	1	Demographic Breakdown	✓	Type of data
<del>list)</del>		Statewide		Age:		Vaccination
		Statewide		rige.		counts
		County		single year, 5-year groups, other:		Vaccination rate
		Public Health Region		Sex		Other:
		City/town		Race/ethnicity		
		Other:		Other:		
3. Please indicate how you would like to receive the data:						
Media Type			File	Format		
CD-ROM				MS Access (please specify if 97 v	ersion	<del>or older)</del>
E-mail  MS Excel (please specify if 97 version or older)				<del>or older)</del>		
Hardcopy				Report (pdf file)		
Other:				Other:		

#### **Confidential Data Requests\***

\*Please contact the NH Immunization Program for more specific or detailed data requests and to obtain specific forms and process information. Thank you



<b>←</b>	Media Type
	E-mail:
	Other:
E	-mail:
0	Other: