

# NMAC Transmittal Form

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Volume:  Issue:  Publication date:  Number of pages:  (ALD Use Only)  Sequence No.

Issuing agency name and address:  Agency DFA code:

Contact person's name:  Phone number:  E-mail address:

Type of rule action: New  Amendment  Repeal  Emergency  Renumber  (ALD Use Only) Most recent filing date:

Title number:  Title name:

Chapter number:  Chapter name:

Part number:  Part name:

Amendment description (If filing an amendment):  Amendment's NMAC citation (If filing an amendment):

Are there any materials incorporated by reference? Yes  No  Please list attachments or Internet sites if applicable.

If materials are attached, has copyright permission been received? Yes  No  Public domain

## Concise Explanatory Statement For Rulemaking Adoption:

### Specific statutory or other authority authorizing rulemaking:

The requirements set forth herein are promulgated by the secretary of the department of health pursuant to the authority granted under Subsection E of Section 9-7-6 NMSA 1978. Sections 24-5-7 through 24-5-15 NMSA 1978, Subsection R of Section 24-1-3 NMSA 1978, and Section 24-1-21 NMSA

Notice date(s):  Hearing date(s):  Rule adoption date:  Rule effective date:

### Findings required for rulemaking adoption:

#### Findings MUST include:

- Reasons for adopting rule, including any findings otherwise required by law of the agency, and a summary of any independent analysis done by the agency;
- Reasons for any change between the published proposed rule and the final rule; and
- Reasons for not accepting substantive arguments made through public comment.

Please see attached Statement of Reasons for Adoption of Proposed New Mexico Statewide Immunization Registry Rule 7.5.5 NMAC.

Continued on next page

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**Findings required for rulemaking adoption:**  
continued



[Large empty rectangular box for findings]

Issuing authority (If delegated, authority letter must be on file with ALD):

Name: Kathryn GALLAGHER

Check if authority has been delegated

Title: CABINET SECRETARY

Signature: (BLACK ink only)  
Kathryn Gallagher

Date signed:  
10/4/18

**STATE OF NEW MEXICO  
BEFORE THE SECRETARY OF HEALTH**

**IN THE MATTER OF PROPOSED  
ADOPTION OF DEPARTMENT RULE PART 7.5.5 NMAC**

**STATEMENT OF REASONS FOR ADOPTION OF PROPOSED  
RULE 7.5.5**

Lynn Gallagher, Secretary for the New Mexico Department of Health, following a public hearing conducted on September 13, 2018 on the proposed adoption of the New Mexico Statewide Immunization Registry rule 7.5.5 NMAC, hereby adopts the proposed rule. This decision is based on the entire record in this matter, which includes a recording of the hearing and the Report and Recommendation of the Hearing Officer, Susan M. Hapka, Esq., dated September 28, 2018.

In further support of this action, the Secretary finds the following:

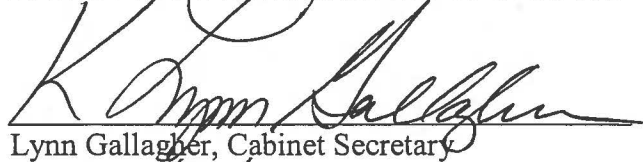
1. The Department of Health is authorized to adopt department promulgated regulations as may be necessary to carry out the duties of the Department and its division. NMSA 1978, Section 9-7-6(E).
2. By a letter dated July 6, 2018, the Cabinet Secretary, Lynn Gallagher, designated Ms. Hapka to serve as hearing officer for the purpose of conducting the hearing and submitting a recommendation regarding the proposed rule.
3. A Notice of Public Hearing, compliant with NMSA 1978, Section 14-4-5.2, for the proposed rule repeal was provided to the public pursuant to NMSA 1978, Section 14-4-2(E), through the following:
  - a. On July 11, 2018, the Notice of Public Hearing was electronically posted on the agency website at <https://nmhealth.org/publication/rules/>.

- b. On July 10, 2018, and July 24, 2018, the Notice of Public Hearing was published in the New Mexico Register.
  - c. On July 12, 2018, the Notice of Public Hearing was published in the Albuquerque Journal.
  - d. On July 11, 2018, the Notice of Public Hearing and proposed rule text was posted on the New Mexico Sunshine Portal website.
  - e. On July 16, 2018, the Notice of Public Hearing was emailed to Disability Rights New Mexico (DRNM) per their request for all notices of public hearings relating to Department of Health rules.
  - f. No person provided a postal address requesting notice of hearings regarding the subject of this rulemaking by mail, therefore the Notice of Public Hearing was not mailed to any person.
  - g. The proposed rule was sent to all persons who requested the rule text.
  - h. There are no other persons who participated in the repeal process who provided an electronic mail address to the agency.
  - i. On August 23, 2018, the Notice of Public Hearing was emailed to the New Mexico Legislative Council Service.
4. A public rule hearing was held in Santa Fe, New Mexico on September 13, 2018 pursuant to NMSA 1978, Section 9-7-6(E).
  5. Members of the public were afforded an opportunity to comment on the proposed rule at the hearing, and in writing prior to the hearing.
  6. No written comments were received prior to the hearing, and no oral comments were made at the rule hearing.

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7. The Hearing Officer has appropriately considered the entire record and the recommendations of the Hearing Officer are appropriate and well taken.
8. Subsections (A)-(G) of Section 24-3-11 of the Immunization Act provide that the Secretary of the Department shall adopt rules that address specific matters concerning the Registry, including implementation and maintenance, content and submission of reports, procedures, and limits on and methods of access.
9. The proposed rule, 7.5.5 NMAC, addresses the specific matters set out in subsections (A)-(G) of Section 24-5-11, is appropriate and consistent with law, and the rule is hereby adopted.

NEW MEXICO DEPARTMENT OF HEALTH

  
Lynn Gallagher, Cabinet Secretary

10/4/18  
Date

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**TITLE 7 HEALTH**  
**CHAPTER 5 VACCINES AND IMMUNIZATIONS**  
**PART 5 NEW MEXICO STATEWIDE IMMUNIZATION REGISTRY**

**7.5.5.1 ISSUING AGENCY:** Public Health Division, Department of Health.  
[7.5.5.1 NMAC - N, 10/30/2018]

**7.5.5.2 SCOPE:** These regulations govern the use of the New Mexico statewide immunization registry, a computerized repository of immunization information maintained by the New Mexico department of health.  
[7.5.5.2 NMAC - N, 10/30/2018]

**7.5.5.3 STATUTORY AUTHORITY:** The requirements set forth herein are promulgated by the secretary of the department of health pursuant to the authority granted under Subsection E of Section 9-7-6 NMSA 1978, Sections 24-5-7 through 24-5-15 NMSA 1978, Subsection R of Section 24-1-3 NMSA 1978, and Section 24-1-21 NMSA.  
[7.5.5.3 NMAC - N, 10/30/2018]

**7.5.5.4 DURATION:** Permanent.  
[7.5.5.4 NMAC - N, 10/30/2018]

**7.5.5.5 EFFECTIVE DATE:** October 30, 2018, unless a later date is cited at the end of a section.  
[7.5.5.5 NMAC - N, 10/30/2018]

**7.5.5.6 OBJECTIVE:** The objective of this rule is to describe implementation and maintenance, submission, reporting, participation, and limits on access to the registry portion of the New Mexico immunization program.  
[7.5.5.6 NMAC - N, 10/30/2018]

**7.5.5.7 DEFINITIONS:**

- A. "Authorized user"** means a person to whom the division has provided account credentials authorizing that person to access to the registry.
- B. "CDC"** means centers for disease control and prevention, the federal agency responsible for monitoring and protecting the United States of America from health, safety, and security threats related to diseases.
- C. "Data elements"** means the information required to be entered into the registry by providers as specified in these regulations or by official division publication.
- D. "Department"** means the department of health.
- E. "Division"** means the department of health, public health division.
- F. "Government issued identification"** means a legible, current credentialing document issued by a local, state or federal government entity that includes a photo.
- G. "Health information exchange"** means an arrangement that allows the sharing of health care information about individual patients among different health care institutions or unaffiliated providers.
- H. "Immunization"** means treatment of an individual with either a vaccine licensed by the U.S. food and drug administration for immunization and distribution in the United States, or an immune globulin product licensed by the U.S. food and drug administration and used for the purposes of producing or enhancing an immune response.
- I. "NDC"** means National Drug Code.
- J. "NMDOH"** means the New Mexico department of health.
- K. "NMSIIS"** means the New Mexico statewide immunization information system.
- L. "Provider"** means an individual or organization required to submit information to the registry pursuant to Section 24-5-8 NMSA 1978 including physicians, nurses, pharmacists, nurse practitioners, physician's assistants and other health care providers authorized by the division.
- M. "Patient"** means any person offered an immunization.
- N. "Registry"** means the New Mexico statewide immunization information system (NMSIIS), a computerized repository of immunization information maintained by the New Mexico department of health.
- O. "Vaccines for children program" or "VFC"** means the program operated by the division that provides federally funded vaccines to children ages 0-18 years who are uninsured, on medicaid, or are Alaska

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Native/American Indian.

[7.5.5.7 NMAC - N, 10/30/2018]

**7.5.5.8 IMPLEMENTATION AND MAINTENANCE OF THE REGISTRY:** The department is responsible for establishing guidelines as necessary regarding the implementation and maintenance of the registry.

**7.5.5.9 REPORTING REQUIREMENTS:**

**A.** Providers shall report all data elements to the registry for all immunizations they administer to a patient unless the patient or the patient's parent or guardian informs the provider that the patient declines to participate in the registry or does not wish to include a particular immunization in the registry.

**B.** Providers shall report all data elements to the registry within 10 days of administering an immunization. A provider may request an extension of 20 days from the division for large immunization events. Permission for extensions for these events are at the discretion of the division and providers must obtain pre-approval.

**C.** The following are the minimum data elements that must be reported to the registry:

- (1) Vaccination information, including:
  - (a) name of vaccine;
  - (b) manufacturer of vaccine;
  - (c) lot/serial number of vaccine;
  - (d) funding source of vaccine;
  - (e) expiration date of vaccine;
  - (f) NDC number of vaccine;
  - (g) date of administration of vaccine;
  - (h) dosage administered to patient;
  - (i) body site and route of administration.
- (2) Patient demographic information, including:
  - (a) last name;
  - (b) first name;
  - (c) middle name, if applicable;
  - (d) sex;
  - (e) date of birth;
  - (f) insurance status;
  - (g) insurance information;
  - (h) mailing address;
  - (i) physical address;
  - (j) contact information.

**D.** Providers will be notified through an official memo by the division of any additional required data elements for reporting not already included herein. Any included data elements published through an official memo to providers are incorporated herein by reference as required data elements.

[7.5.5.9 NMAC - N, 10/30/2018]

**7.5.5.10 SUBMISSION OF REPORTS OF IMMUNIZATION TO THE REGISTRY:**

**A.** All data elements shall be reported to the registry in a manner and format approved by the division.

**B.** Direct reporting:

- (1) Authorized users may directly review and submit data elements electronically through the registry website interface using individual account credentials assigned by the division.

- (2) Each user may only use their individual account credentials assigned to the authorized user.

- (3) Authorized user account credentials may not be shared.

**C.** Data exchange reporting:

- (1) Providers with electronic systems that are compatible with the division's data exchange program may request to receive approval to utilize the compatible system for reporting the required data elements.

- (2) Providers using data exchange reporting must utilize the file format approved by the division and are responsible for all associated costs.

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(3) Providers using data exchange reporting must update their systems to maintain compatibility with the divisions data exchange program as necessary to maintain the integrity of the data transfers.

D. A health information exchange may exchange information with the registry on behalf of a provider. When a health information exchange operates in this manner, the exchange is subject to the same rules as the provider.

E. To decrease duplication of patient records and duplicate vaccines, the division may utilize other information sources to populate the registry and perform data quality activities, such as birth certificates, adoption decrees, paper shot records, or medicaid enrollment information.

[7.5.5.10 NMAC - N, 10/30/2018]

#### 7.5.5.11 PROCEDURES TO DECLINE PARTICIPATION

A. At the time an immunization is offered or administered, if a patient, or a minor's parent or legal guardian notifies the provider that s/he chooses to decline participation in the registry or does not wish to have a specific immunization recorded in the registry, the provider shall document the patient's decision to opt-out as follows:

(1) The provider shall document the patient's opt-out decision using a form provided by the division, or the provider's own form provided the same information as the division's form is included.

(2) The provider will store all opt-out documentation in an accessible, orderly system so that in the event of a public health emergency, the department can review the opt-out data to inform emergency responses.

B. Patients must complete the opt-out process with each healthcare provider that offers immunization services to the patient, each time immunization services are provided. If the patient declines participation for certain immunizations only, the patient must complete the opt-out process for each immunization for which the patient opts out.

[7.5.5.11 NMAC - N, 10/30/2018]

#### 7.5.5.12 PROCEDURES FOR REVIEWING AND CORRECTING PATIENT RECORDS:

A. At the time an immunization is offered, the provider shall notify the patient of the procedures to review and correct information contained in the registry.

B. A patient, or a minor patient's parent or guardian, who wishes to review the patient's registry immunization record may request a copy from the patient's provider or from a department public health office, or through a department-approved online portal.

C. If a patient requests to correct any information in the registry, the patient shall submit a written request to the division, the NMDOH Helpdesk, to a department public health office, or to the patient's provider. The request shall identify the patient and the information to be corrected.

D. All requests for corrections must be accompanied by a copy of patient identification. If a patient is a minor, the request must be accompanied by a certified copy of the patient's birth certificate and a copy of identification for the submitter or the parent/guardian of the requesting patient. If the requester is a non-parent legal guardian, the guardian must also submit a copy of the guardian's legal appointment of guardianship.

E. If a patient requests to change the registry's record of the patient's date of birth, the patient must present a birth certificate or other legal documentation to verify the patient's correct date of birth. All such requests must be submitted to division staff via the NMDOH Helpdesk. Information on how to contact the NMDOH Helpdesk can be found on the NMSIIS webpage [https://nmsiis.health.state.nm.us/webiznet\\_nm/Login.aspx](https://nmsiis.health.state.nm.us/webiznet_nm/Login.aspx).

F. If the department bureau of vital records and health statistics provided the date of birth for a patient, the patient's date of birth may not be changed except through notification by vital records or a court order.

G. Only division staff are permitted to change a patient's name or date of birth on a patient record.

(1) Appropriate documentation as required by this section must be presented to division staff to have the patient's name changed, or spelling corrected or changed.

(2) If a court order for adoption requires a name change, the request for change must be submitted to division staff via the NMDOH helpdesk and must include copies of the patient's legal documentation supporting the request.

H. If a patient requests to change any other information in the registry, supporting materials such as medical records, should be attached to the patient's written request.

I. The division may make a change if the change is supported by appropriate documentation.

J. If the patient cannot be uniquely identified in the registry, or if the request is insufficiently supported, the division will contact the patient to obtain additional information.



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K. Upon making a determination, the division will notify the requestor of that decision. If the request is denied, the division will notify the patient of the reason(s) for denial. If the request is approved, the division will record the change in the registry.  
[7.5.5.12 NMAC - N, 10/30/2018]

#### **7.5.5.13 PROCEDURES TO WITHDRAW CONSENT AND REMOVE INFORMATION FROM REGISTRY:**

A. To remove a record from NMSIIS, a patient must submit by mail or hand delivery to the department a completed decision to remove NMSIIS record form. The decision to remove form can be obtained from a provider or printed from the department website at <https://nmhealth.org/about/phd/idb/imp/siis/>.

B. The patient's request to remove information must be accompanied by a copy of patient identification. If the patient is a minor, the request must be accompanied by a copy of the patient's birth certificate and a copy of identification for the submitter or parent/guardian of the patient. If the requester is a guardian, a copy of the legal appointment of guardianship will be required.

C. Upon receipt of the request, or upon receipt of any requested additional information, the division shall delete the patient's record from the registry. The division shall notify the patient when the record is deleted.  
[7.5.5.12 NMAC - N, 10/30/2018]

#### **7.5.5.14 LIMITS ON ACCESS TO THE REGISTRY:**

A. Access to the information in the registry shall be limited to primary care physicians, nurses, pharmacists, managed care organizations, school nurses, and other appropriate health care providers including nurse practitioners and physician assistants, or public health entities as designated by the secretary of health. A managed care organization may only access information for its enrollees.

B. Requests for access to the registry shall be made by a provider in writing to the division and access shall be determined by the division.

C. No person or automated system may access or attempt to access the registry without approval from the division.

D. At the division's discretion, access may be modified.

E. A patient, or a patient's parent or guardian if the patient is under the age of 18, may access the patient's records.

[7.5.5.13 NMAC - N, 10/30/2018]

#### **7.5.5.15 COMPLAINT INVESTIGATIONS:**

A. If the division receives a complaint or otherwise learns of noncompliance of a provider relating to these rules, an investigation will be initiated.

B. Upon completion of the investigation, the division will issue an investigative report substantiating or not substantiating the alleged noncompliance.

[7.5.5.14 NMAC - N, 10/30/2018]

#### **7.5.5.16 SANCTIONS AND NONCOMPLIANCE:**

A. A provider is in noncompliance if they fail to follow any of these regulations.

B. If noncompliance is substantiated, the department will issue the provider a written report of deficiencies which shall include a plan of correction.

(1) The provider must correct any deficiencies identified in the department's plan of correction within a fixed period of time.

(2) The period of time for a provider to correct deficiencies will be reasonably determined by the division and be based on the circumstances of the noncompliance. The time period will be specified in the plan of correction.

C. Upon expiration of the correction date as stated in the plan of correction, pursuant to Section 24-1-21 NMSA the division may impose a separate civil monetary penalty of one hundred dollars (\$100) for each repeated instance of noncompliance, including, but not limited to each invalid or improper entry. The division shall issue a written report detailing the repeated non-compliance and the civil monetary penalty. The civil monetary penalty shall not exceed five thousand dollars (\$5,000) per report.

[7.5.5.15 NMAC - N, 10/30/2018]

#### **7.5.5.17 ADMINISTRATIVE REVIEW:**

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**A.** If a provider wishes to appeal the issuance of a civil monetary penalty, the provider must submit a written request for an administrative review within 10 working days from the date of issuance of the civil monetary penalty.

**B.** An administrative review will be conducted by an assigned division bureau chief or designee within 30 days of the request for review. Additional time to conduct the administrative review may be granted if requested by the provider and good cause is shown.

(1) The provider may request a paper administrative review, limited to records and a written appeal, or may appear in person or through an advocate of the provider's choice and present evidence to refute the results of the investigation and the reason for the issuance of the civil monetary penalty during an administrative review.

(2) The assigned bureau chief or designee will complete their review and either overturn, modify, or uphold the civil monetary penalty in a written decision within 10 days of the completion of the administrative review.

[7.5.5.16 NMAC - N, 10/30/2018]

#### **7.5.5.18 ADMINISTRATIVE HEARING:**

**A.** If the provider wishes to appeal the result of the administrative review, the provider must submit a written request to the division within 10 working days from the date of issuance of the assigned bureau chief or designee's written decision.

#### **B. Hearing process:**

(1) Hearing will be conducted by a hearing officer appointed by the secretary.

(2) Hearings shall be conducted in Santa Fe, New Mexico, unless the appellant can show significant hardship sufficient to require the case be held in a different location.

(3) Due to federal and state laws regarding the confidentiality of protected health information, all hearings held pursuant to this section shall be closed to the public.

(4) The hearing shall be recorded on audio recording equipment. The hearing officer shall maintain the recording. No other recordings may be made except with the permission of the hearing officer.

(5) Any hearing provided for in this rule may be held telephonically, with the consent of the parties.

(6) A request for a telephonic hearing must be made no later than 10 business days prior to the date of the hearing; notice of the telephonic hearing shall be given to all parties and shall include all necessary telephone numbers;

(6) The department shall schedule and hold the hearing no later than 60 calendar days from the date the department receives the appellant's request for hearing. The hearing officer may extend the 60-day time period for good cause shown, or the parties may extend that period by mutual agreement.

(7) The department shall issue notice of the hearing at least fifteen days prior to the scheduled date of the hearing. The notice shall include a statement of the time, place, and nature of the hearing.

(9) An appellant's failure to appear at the hearing at the date and time noticed shall constitute a default unless good cause for the failure to appear is shown.

(10) All parties shall be given the opportunity to respond and present evidence and argument on relevant issues.

(11) A party may be represented by a person licensed to practice law in New Mexico or a non-lawyer representative or may represent himself or herself.

(12) The hearing officer shall create a record of the proceedings which shall include the following:

- (a) all pleadings, motions, and rulings;
- (b) evidence and briefs received or considered;
- (c) a statement of any matters officially noticed;
- (d) offers of proof, objections, and rulings thereon;
- (e) proposed findings and conclusions; and
- (f) any action recommended by the hearing officer.

(13) Unless the hearing officer determines a different procedure is appropriate, the hearing officer shall conduct the hearing as follows:

- (a) opening statements by the appellant and the department;
- (b) upon conclusion of the opening statements, the department shall present its case;
- (c) upon conclusion of the departments case, the appellant may present his or her

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case;

evidence; and

arguments.

(d) upon conclusion of either party's case, the opposing party may present rebuttal

(e) after presentation of the evidence by the parties, the parties may present closing

(14) The rules of evidence as applied in courts do not apply in the proceedings; any relevant evidence shall be admitted; irrelevant, immaterial, or unduly repetitious evidence may be excluded.

(15) The department shall be required to prove its case by a preponderance of the evidence.

(16) The parties may submit briefs including findings of fact and conclusions of law for consideration by the hearing officer. All briefs must be submitted 15 days after the conclusion of the hearing.

(17) No later than 30 calendar days after the last submission by a party, the hearing officer shall prepare and submit to the secretary a written recommendation of action to be taken by the secretary; the recommendation shall propose sustaining, reversing, or modifying the proposed action of the department.

(18) The secretary shall issue a final written decision accepting or rejecting the hearing officer's recommendation in whole or in part no later than 30 calendar days after receipt of the hearing examiner's recommendation; the final decision shall identify final action taken. Service of the secretary's final decision shall be made upon the appellant by registered or certified mail.

**History of 7.5.5 NMAC: [RESERVED]**