



# Notice of Intent to Adopt Rules

A copy of the proposed rules may be obtained at <http://rules.wyo.gov>

Revised November 2016

## 1. General Information

a. Agency/Board Name*		
b. Agency/Board Address	c. City	d. Zip Code
e. Name of Agency Liaison		f. Agency Liaison Telephone Number
g. Agency Liaison Email Address		
h. Date of Public Notice		i. Comment Period End Date
j. Public Comment URL or Email Address:		
k. Program		

\*  By checking this box, the agency is indicating it is exempt from certain sections of the Administrative Procedure Act including public comment period requirements. Please contact the agency for details regarding these rules.

## 2. Legislative Enactment

For purposes of this Section 2, "new" only applies to regular rules promulgated in response to a Wyoming legislative enactment not previously addressed in whole or in part by prior rulemaking and does not include rules adopted in response to a federal mandate.

a. Are these rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

No.  Yes. Please provide the Enrolled Act Numbers and Years Enacted:

## 3. Rule Type and Information

a. Provide the Chapter Number, Title, and Proposed Action for Each Chapter.  
Please use the Additional Rule Information form for more than 10 chapters, and attach it to this certification.

Chapter Number:	Chapter Name:	<input type="checkbox"/> New	<input type="checkbox"/> Amended	<input type="checkbox"/> Repealed
Chapter Number:	Chapter Name:	<input type="checkbox"/> New	<input type="checkbox"/> Amended	<input type="checkbox"/> Repealed
Chapter Number:	Chapter Name:	<input type="checkbox"/> New	<input type="checkbox"/> Amended	<input type="checkbox"/> Repealed
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Chapter Number:	Chapter Name:	<input type="checkbox"/> New	<input type="checkbox"/> Amended	<input type="checkbox"/> Repealed
Chapter Number:	Chapter Name:	<input type="checkbox"/> New	<input type="checkbox"/> Amended	<input type="checkbox"/> Repealed

**4. Public Comments and Hearing Information**

a. A public hearing on the proposed rules has been scheduled.  No.  Yes. Please complete the boxes below.

Date:	Time:	City:	Location:
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b. What is the manner in which interested persons may present their views on the rulemaking action?

By submitting written comments to the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: \_\_\_\_\_

A public hearing will be held if requested by 25 persons, a government subdivision, or by an association having not less than 25 members. Requests for a public hearing may be submitted:

To the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: \_\_\_\_\_

c. Any person may urge the Agency not to adopt the rules and request the Agency to state its reasons for overruling the consideration urged against adoption. Requests for an agency response must be made prior to, or within thirty (30) days after adoption, of the rule, addressed to the Agency and Agency Liaison listed in Section 1 above.

**5. Federal Law Requirements**

a. These rules are created/amended/revoked to comply with federal law or regulatory requirements.  No.  Yes. Please complete the boxes below.

Applicable Federal Law or Regulation Citation:
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Indicate one (1):

The proposed rules meet, but do not exceed, minimum federal requirements.

The proposed rules exceed minimum federal requirements.

Any person wishing to object to the accuracy of any information provided by the Agency under this item should submit their objections prior to final adoption to:

To the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: \_\_\_\_\_

**6. State Statutory Requirements**

a. Indicate one (1):

The proposed rule change *MEETS* minimum substantive statutory requirements.

The proposed rule change *EXCEEDS* minimum substantive statutory requirements. Please attach a statement explaining the reason that the rules exceed the requirements.

b. Indicate one (1):

The Agency has complied with the requirements of W.S. 9-5-304. A copy of the assessment used to evaluate the proposed rules may be obtained:

By contacting the Agency at the physical and/or email address listed in Section 1 above.

At the following URL: \_\_\_\_\_

Not Applicable.

**7. Additional APA Provisions**

a. Complete all that apply in regards to uniform rules:

These rules are not impacted by the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j).

The following chapters do not differ from the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j):

\_\_\_\_\_ (Provide chapter numbers)

These chapters differ from the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j) (see Statement of Principal Reasons).

\_\_\_\_\_ (Provide chapter numbers)

b. Checklist

The Statement of Principal Reasons is attached to this Notice and, in compliance with *Tri-State Generation and Transmission Association, Inc. v. Environmental Quality Council*, 590 P.2d 1324 (Wyo. 1979), includes a brief statement of the substance or terms of the rule and the basis and purpose of the rule.

If applicable: In consultation with the Attorney General's Office, the Agency's Attorney General representative concurs that strike and underscore is not required as the proposed amendments are pervasive (Chapter 3, *Types of Rules Filings*, Section 1, Proposed Rules, of the Rules on Rules).

**8. Authorization**

a. I certify that the foregoing information is correct.

<i>Printed Name of Authorized Individual</i>	
<i>Title of Authorized Individual</i>	
<i>Date of Authorization</i>	

Intent to Repeal Rules

Office of Rural Health

**CHILDHOOD IMMUNIZATION ACT**

Statement of Reasons

The Wyoming Department of Health proposes to repeal the following Rules pursuant to Wyo. Stat. Ann. §§ 14-4-116, 21-4-309, 35-1-240, 35-4-101, and 35-4-139.

**Rural Health**

<b>Chapter #</b>	<b>Chapter Name</b>
7	Childhood Immunization Act

Content from the repealed Chapters will be reflected in the **Wyoming Department of Health, Wyoming Immunization Program**, Chapters 1-5 that are being promulgated at the same time. Moving all of the immunization rules to one program will make it easier for the public and interested parties to find the rules. The rules are currently spread out among 3 programs.

**WYOMING CHILDHOOD IMMUNIZATION RULES**

**CHAPTER 7**

**COVERED SERVICES**

**[These rules are repealed]**

## WYOMING CHILDHOOD IMMUNIZATION RULES

### CHAPTER 7

#### COVERED SERVICES

##### Section 1. ~~Authority.~~

~~This Chapter is promulgated by the Department of Health pursuant to the Childhood Immunization Act at W.S. § 35-4-139 et seq. and the Wyoming Administrative Procedures Act at W.S. § 16-3-101 et seq.~~

##### Section 2. ~~Purpose and Applicability.~~

~~(a) This Chapter defines the process for determining the specific vaccines to be purchased to provide for the healthy development of children.~~

~~(b) This Chapter establishes the criteria required for Healthcare Providers to participate in the Wyoming Vaccines for Important People (WyVIP) program.~~

~~(c) This Chapter defines the Appeals process for Healthcare Providers who are made ineligible for the WyVIP program due to failure to comply with appropriate Rules and Regulations~~

~~(d) The Department may issue manuals or bulletins to providers and/or other affected parties to interpret the provisions of this Chapter. Such manuals or bulletins shall be consistent with and reflect the policies contained in the Chapter. The provisions contained in manuals or bulletins shall be subordinate to the provisions of this Chapter.~~

~~(e) The incorporation by reference of any external standard is intended to be the incorporation of that standard as it is in effect on the effective date of these rules.~~

##### Section 3. ~~General Provisions.~~

~~Except as otherwise specified, the terminology used in this Chapter is the standard terminology and has the standard meaning used in accounting, healthcare, the National Immunization Program and the Vaccines for Children Program.~~

##### Section 4. ~~Definitions.~~

~~The following definitions shall apply in the interpretation and enforcement of these rules. Where the context in which words are used in these rules indicates that such is the intent, words in the singular number shall include the plural and vice versa. Throughout these rules gender pronouns are used interchangeably. The drafters have attempted to utilize each gender pronoun in equal numbers, in random distribution. Words in each gender include individuals of the other gender.~~

~~(a) — “Cold Chain.” The system used for keeping and distributing vaccines in good condition is called the ‘cold chain’. This consists of a series of storage and transport procedures, all of which are designed to keep the vaccine at the correct temperature to ensure vaccine efficacy until it is administered. Different vaccines require different storage conditions, and what is correct for one vaccine may be dangerous for another, so it is vital to know the correct storage conditions for each vaccine used.~~

~~(b) — “Healthcare Provider.” Refers to individuals in a practice that is enrolled in the WyVIP program.~~

~~(c) — “Parent.” Refers to the biological parent, adoptive parent, or legal guardian of a minor child receiving an immunization.~~

~~(d) — “State Health Officer.” Refers to the individual appointed by the Governor to administer the Wyoming Department of Health, or designee.~~

~~(e) — “State Immunization Section Chief.” Refers to the individual appointed by the Wyoming Department of Health to manage the State Immunization Program.~~

~~(f) — “Vaccines for Children Program (VFC).” Refers to the federal program defined in 42 U.S.C. § 1396s(b)(2) or subsequent similar federal enactment(s).~~

~~(g) — “Wyoming Vaccines for Important People (WyVIP).” Refers to the Wyoming Department of Health Immunizations Program section that administers the ordering, distribution, vaccine handling, quality control and reporting for vaccines provided to Healthcare Providers.~~

~~(h) — “Child.” Refers to individuals who have not reached their nineteenth (19) birthday.~~

#### ~~Section 5. — Vaccine Advisory Board.~~

~~(a) — The State Health Officer or designee shall convene a Vaccine Advisory Board consisting of a representative of an organization representing physicians licensed in Wyoming, at least one (1) pediatric physician licensed in Wyoming and at least one (1) family physician licensed in Wyoming. Determination of vaccines that shall be purchased with State funds will be based on recommendations of the Vaccine Advisory Board and affirmed by the State Health Officer. The Vaccine Advisory Board will function to provide advice and recommendations to the State Health Officer including, but not restricted to:~~

~~(i) — Specific vaccine antigens to provide for the healthy development of the children of Wyoming;~~

~~(ii) — Specific vaccine brands of single antigen and/or combination antigens to be purchased;~~

~~(iii) Recommendations on the percentage of the legislative appropriation that is to be utilized for program operations and vaccine purchases;~~

~~(iv) Tier protocols for specific antigens/vaccine brands in the event that vaccines are not available for purchase or that appropriations will not be sufficient to provide Universal Vaccine coverage; and~~

~~(v) Recommendations to add newly developed and licensed vaccines to the formulary.~~

~~(b) The State Health Officer may consult other ad hoc professionals at his discretion to determine the most effective medical and economic decision.~~

~~(c) The State Health Officer or designee has the sole decisional authority for vaccine purchases, to include: antigen type and brand.~~

~~(d) After rendering a decision on the state vaccine purchase formulary, the State Health Officer shall authorize the Wyoming Immunization Section Chief to coordinate the purchase, ordering, distribution, vaccine storage and handling and accountability of vaccines in accordance with federal immunization program standards, or the prevailing processes for acquisition of vaccines purchased through the federal contract.~~

~~(e) The State Health Officer is empowered to convene the Vaccine Advisory Board and to amend the state vaccine formulary at will to address additional vaccines and/or vaccine combinations that receive federal Food and Drug Administration licenses.~~

~~Section 6. Healthcare Provider Eligibility and Requirements.~~

~~(a) All recipients of state purchased vaccines shall be enrolled in good standing with the Wyoming Vaccines for Important People (WyVIP) Program, the federal Vaccines for Children Program and Medicaid. Providers who are vaccine recipients shall renew their WyVIP and VFC enrollments on an annual basis.~~

~~(b) To the extent possible, all policies and procedures for the ordering, distribution, vaccine storage and handling, accountability and reporting by Healthcare Providers of state purchased vaccines shall be consistent with the policies and procedures required for federally purchased vaccines under the Vaccines for Children program.~~

~~(c) Healthcare Providers receiving and administering state purchased vaccines shall comply with prevailing Immunization Program policies, procedures and reporting requirements, to include but not be limited to:~~

~~(i) Ensure that Vaccine Information Statements (VIS) and appropriate vaccine education are provided to parents prior to the administration of any vaccines;~~

~~(ii) — Complying with generally recognized medical standards for administering and documenting immunizations;~~

~~(iii) — Complying with the Wyoming Immunization Program Fraud and Abuse Policy. Failure to comply with this policy may result in restitution for misused vaccines and/or prosecution;~~

~~(iv) — Determination of patient eligibility under either the VFC or state WyVIP program;~~

~~(v) — Providing standard vaccine inventory control procedures to include proper cold chain procedures and limiting vaccine waste to below 5%;~~

~~(vi) — Documenting and reporting Doses Administered and Vaccine Inventory data on a monthly basis;~~

~~(vii) — Documenting and reporting Temperature Logs on a monthly basis;~~

~~(viii) — Reporting vaccine adverse events in a timely manner to the national Vaccine Adverse Events Reporting System (VAERS);~~

~~(ix) — Provider fees assessed for the administration of vaccines may not exceed the regional vaccine administration cap as published by the federal government; and,~~

~~(x) — Complying with Wyoming Immunization Program procedures and addressing audit findings in a timely manner. Failure to comply with policies, procedures and timely reporting may result in delays in vaccine replacement or suspension from the WyVIP program. Healthcare Providers that cause the waste or spoilage of federal or state purchased vaccines through negligence or lack of adherence to WyVIP Policies and Procedures to ensure the proper handling and storage of vaccines, may be required to make financial restitution for the cost of the vaccines. The Wyoming Immunization Program will notify the provider in writing of any suspension or other administrative actions resulting from the lack of compliance with WyVIP policies and procedures. The notification shall include:~~

~~(A) — The reason for the action; and,~~

~~(B) — Requirements for the Healthcare Provider to resolve the temporary program suspension and become eligible for future vaccine shipments; or,~~

~~(C) — Process for the Healthcare Provider to appeal a permanent program suspension.~~

~~(d) — Healthcare Providers who receive sanctions for non-compliance shall have an Appeals Process for resolution.~~

~~Section 7. — Appeals Process.~~

~~(a) — In the event that a Healthcare Provider is subject to an administrative action by the WyVIP Program to include, but not be limited to program suspension:~~

~~(i) — The designated Healthcare Provider found out of compliance with Wyoming Immunization Program Rules and Regulations may request an administrative hearing.~~

~~(ii) — The request for an administrative hearing must be made to the State Health Officer in writing within 14 calendar days from the date of notification by the Wyoming Immunization Program of an administrative action.~~

~~(iii) — An administrative hearing will be conducted in accordance with the current *Rules For Contested Case Practice and Procedure Before the Office of Administrative Hearings*.~~

~~(iv) — The Office of Administrative Hearings shall make proposed findings of fact, proposed conclusions of law and recommended decisions to the State Health Officer.~~