



Notice of Intent to Adopt Rules

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

Revised June 2020

1. General Information

a. Agency/Board Name* Administration and Information, Dept of/WY State Board of Pharmacy			
b. Agency/Board Address 1712 Carey Avenue, Suite 200		c. City Cheyenne	d. Zip Code 82002
e. Name of Agency Liaison Matthew R. Martineau		f. Agency Liaison Telephone Number (307) 634-9636	
g. Agency Liaison Email Address matt.martineau@wyo.gov			
h. Date of Public Notice March 24, 2021		i. Comment Period End Date May 8, 2021	
j. Public Comment URL or Email Address: bop@wyo.gov			
k. Program Pharmacy, Board of			
Amended Program Name (if applicable):			

* 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 non-emergency 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 non-emergency regular rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

No. Yes. If the rules are new, please provide the Legislative Chapter Numbers and Years Enacted (e.g. 2015 Session Laws Chapter 154):

3. Rule Type and Information For purposes of this Section 3, "New" means an emergency or regular rule that has never been previously created.

a. Provide the Chapter Number, Title and Proposed Action for Each Chapter. Please use the "Additional Rule Information" form to identify additional rule chapters.

Chapter Number: 16	Chapter Name: Immunization Regulations	<input type="checkbox"/> New	<input checked="" type="checkbox"/> Amended	<input type="checkbox"/> Repealed
Amended Chapter Name (if applicable):				
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 Repealed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 Repealed
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Chapter Number:	Chapter Name:	<input type="checkbox"/> New	<input type="checkbox"/> Amended	<input type="checkbox"/> Repealed
Amended Chapter Name (if applicable):				
Chapter Number:	Chapter Name:	<input type="checkbox"/> New	<input type="checkbox"/> Amended	<input type="checkbox"/> Repealed
Amended Chapter Name (if applicable):				

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:

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/repealed to comply with federal law or regulatory requirements. No. Yes. Please complete the boxes below.

Applicable Federal Law or Regulation Citation:

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. The Agency has completed a takings assessment as required by 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: _____

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)

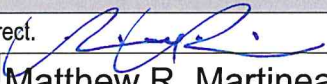
b. Checklist

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.



Printed Name of Authorized Individual

Matthew R. Martineau

Title of Authorized Individual

Executive Director

Date of Authorization

March 18, 2021

WYOMING STATE BOARD OF PHARMACY



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307-634-9636 Telephone
307-634-6335 Fax
bop@wyo.gov electronic mailbox
Matthew R. Martineau, RPh, Executive Director

Keith R. Bennett, RPh, Inspector/Compliance Officer

Governor: Mark Gordon

WYOMING PHARMACY ACT RULES AND REGULATIONS

STATEMENT OF PRINCIPAL REASONS FOR REVISIONS

February 26, 2021

The Board of Pharmacy is proposing to revise Chapter 16 of the Wyoming Pharmacy Act Rules in order to include the COVID-19 vaccines, ease requirements for administering vaccines, and to update the incorporated CDC recommended vaccination schedules.

Chapter 16: Immunization Regulations

-) Vaccines for COVID-19 are being added to the vaccines that are allowed to be prescribed and administered to healthy adults or healthy minors or that may be administered by a prescription of a physician to a high risk adult or high risk minor.
-) The incorporation by reference is being updated to include the current (2021) CDC recommended vaccine schedules.
-) The definition for "Private space" and the requirement for individuals receiving vaccinations while seated in a chair with back support is being removed. This is being done to ease the requirements for pharmacists and interns to administer vaccines, which allows patients to receive vaccines in a less restrictive environment.
-) The basic life support requirement is being amended to basic cardiopulmonary resuscitation (CPR).

As required by Wyoming Statute § 16-3-103(a)(i)(G), these rules meet minimum substantive state statutory requirements.

Chapter 16

Immunization Regulations

Section 1. Authority.

These rules are promulgated as authorized by the Wyoming Pharmacy Act W.S. § 33-24-157.

Section 2. Definitions.

(a) “Healthy Adults” means those individuals who are eighteen (18) years of age or older and have no absolute contraindications to receive immunizations allowed by this Chapter.

(b) “Healthy Minor” means those individuals who are seven (7) years of age or older but have not attained the age of eighteen (18) years old and have no absolute contraindications to receive immunizations allowed by this Chapter.

(c) “High Risk Adults” means for the purpose of this Chapter those adults eighteen (18) years of age or older who may have an absolute or relative contraindication to receive immunizations as allowed by this Chapter for whom a physician has issued a prescription authorizing a pharmacist to dispense and administer an immunization.

(d) “High Risk Minors” means for the purpose of this Chapter those individuals seven (7) years of age or older but who have not attained the age of eighteen (18) who may have an absolute or relative contraindication to receive immunizations as allowed by this Chapter for whom a physician has issued a prescription authorizing a pharmacist to dispense and administer an immunization.

Section 3. Registration.

(a) Prior to prescribing or administering immunizations a pharmacist shall submit an application supplied by the Board and pay a \$10.00 fee.

(i) The Board shall issue a registration to the pharmacist if they meet all of the requirements to prescribe and administer immunizations;

(ii) Registrations shall expire on December 31 of each year;

(iii) Registrations shall be renewed annually;

(iv) Renewal applications will be mailed by the Board annually on or about November 1.

(b) Prior to administering immunizations, a pharmacy intern shall submit an application supplied by the Board and pay a \$10.00 fee.

(i) The Board shall issue a registration to the pharmacy intern if they meet all of the requirements to administer immunizations;

(ii) Registrations shall expire on September 30 of each year;

(iii) Registrations shall be renewed annually;

(iv) Renewal applications will be mailed by the Board annually on or about August 1.

Section 4. Qualifications.

(a) A pharmacist shall meet the following qualifications to prescribe and administer immunizations:

(i) Register with the Board to prescribe and administer immunizations;

(ii) Successfully complete:

(A) The American Pharmacists Association's (APhA) immunization training certification program entitled "*Pharmacy-Based Immunization Delivery*" or;

(B) The Washington State Pharmacy Association's immunization training certification program entitled "*Vaccinating Adults and Adolescents: An Immunization Program Practicum Session*" or;

(C) Other equivalent training certification program approved by the Board.

(iii) Successfully complete training specific to administering vaccines to the pediatric population if they will be administering to minors;

(iv) Hold a current certification in basic cardiopulmonary resuscitation (CPR);
and

(v) Complete a minimum of one (1) contact hour (0.1 CEU) of continuing education related to immunizations annually. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (ACPE).

(b) It is unprofessional conduct for a pharmacist to prescribe or administer an immunization, who is not in compliance with this Chapter.

(c) A pharmacy intern shall meet the following qualifications to administer immunizations:

(i) Register with the Board to administer immunizations;

(ii) Successfully complete:

(A) The American Pharmacists Association's (APhA) immunization training certification program entitled "*Pharmacy-Based Immunization Delivery*" or;

(B) The Washington State Pharmacy Association's immunization training certification program entitled "*Vaccinating Adults and Adolescents: An Immunization Program Practicum Session*" or;

(C) Other equivalent training certification program approved by the Board.

(iii) Successfully complete training specific to administering vaccines to the pediatric population if they will be administering to minors;

(iv) Hold a current certification in basic cardiopulmonary resuscitation (CPR);
and

(d) A pharmacy intern who is registered to administer immunizations shall do so under the direct supervision of the pharmacist who is registered to administer immunizations.

Section 5. Adults and Minors.

(a) Vaccines which may be prescribed and administered to a healthy adult or healthy minor or may be administered by a prescription of a physician for high risk adults or high risk minors shall include all those included in the following documents incorporated by reference:

(i) The CDC Recommended Adult Immunization Schedule incorporated by reference in this Chapter of these rules is the 2021 United States CDC Recommended Adult Immunization Schedule for Ages 19 Years or Older as existing on February 18, 2021. Copies of this document can be obtained from the Board at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming, 82002.

(ii) The CDC Recommended Child and Adolescent Immunization Schedule incorporated by reference in this Chapter of these rules is the 2021 United States CDC Recommended Child and Adolescent Immunization Schedule for Ages 18 and Younger as

existing on February 18, 2021. Copies of this document can be obtained from the Board at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming, 82002.

(iii) For any code, standard, rule or regulation by reference in these rules:

(A) The Board has determined that incorporation of the full text in these rules could be cumbersome or inefficient given the length or nature of the rules;

(B) The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (ii) of this section;

(C) The incorporated codes, standards, rules or regulations are maintained at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming 82002 and are available for public inspection any copying at cost as the same location.

(b) Vaccines which may be prescribed and administered to a healthy adult or healthy minor or may be administered by a prescription of a physician for high risk adults or high risk minors shall also include:

(i) Vaccines for COVID-19 approved by the FDA under an Emergency Use Authorization and any vaccine for COVID-19 completing the FDA approval process.

(c) Parental or legal guardian consent shall be required for all minors receiving a vaccination. The parent or legal guardian shall be present during the administration.

(d) Immunizations authorized by this Chapter shall be prescribed in accordance with the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). Specifically, CDC's "*Recommended Adult Immunization Schedule, by Vaccine and Age Group*" and "*Recommended Adult Immunization Schedule by Vaccine and Medical and Other Indications,*" or "*Recommended Immunization Schedule for Persons Aged 0 Through 18 Years,*" including the footnotes provided for each schedule, shall be utilized by the pharmacist when considering the eligibility of a healthy individual to receive an immunization. The latest notice from CDC may be found at CDC's website (<http://www.cdc.gov>).

(e) Pharmacists shall utilize the manufacturer's package insert for indications, contraindications, adverse reactions, dosing, route of administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this Chapter.

(f) A current *Vaccine Information Statement*, as provided by the CDC, shall be provided to each person receiving an immunization for each immunization administered. The *Vaccine Information Statement* is available from the CDC's website (<http://www.cdc.gov>).

Section 6. Record-keeping.

(a) An Immunization Questionnaire and Consent Form shall be completed for each individual receiving and immunization. The consent form shall include:

(i) Documentation that the pharmacist has discussed the side effects with the patient; and

(ii) A recommendation that the patient stays in the vicinity for fifteen (15) minutes; and if the patient chooses not to stay, the pharmacist has discussed how to seek treatment for side effects should they occur.

(b) The Immunization Questionnaire and Consent Form shall be filed in a manner that will allow timely retrieval and shall be on file for two (2) years. All records shall be maintained in the pharmacy where the pharmacist who administered the immunization is employed.

Section 7. Emergencies.

(a) A pharmacist authorized to prescribe and administer immunizations may administer epinephrine in the management of an acute allergic reaction to an immunization. The pharmacist shall follow guidelines as outlined in the American Pharmacists Association's (APhA) or Washington State Pharmacy Association's immunization training certification program.

(b) A pharmacist shall post a protocol as outline in APhA's or Washington State Pharmacy Association's immunization training certification program in the private space or maintain a handout within the emergency kit. The emergency kit shall be maintained and readily retrievable to manage an acute allergic reaction to a vaccine administered.

Section 8. Immunizations Administered Off-Site.

(a) Vaccines may be administered by a pharmacist at a site away from the pharmacy if proper storage, transportation and disposal of vaccines and supplies are followed.

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~~(e) "Private Space" means a physical area separate from the pharmacy that is no less than 48 square feet and has a partition at least six (6) feet tall to ensure patient safety and confidentiality. The partition cannot be a curtain.~~

Section 3. Registration.

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(C) Other equivalent training certification program approved by the Board.

(iii) Successfully complete training specific to administering vaccines to the pediatric population if they will be administering to minors;

(iv) Hold a current certification in basic life support (BLS) offered by the American Heart Association or the American Red Cross cardiopulmonary resuscitation (CPR); and

(v) Complete a minimum of one (1) contact hour (0.1 CEU) of continuing education related to immunizations annually. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (ACPE).

(b) It is unprofessional conduct for a pharmacist to prescribe or administer an immunization, who is not in compliance with this Chapter.

(c) A pharmacy intern shall meet the following qualifications to administer immunizations:

(i) Register with the Board to administer immunizations;

(ii) Successfully complete:

(A) The American Pharmacists Association's (APhA) immunization training certification program entitled "*Pharmacy-Based Immunization Delivery*" or;

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(iii) Successfully complete training specific to administering vaccines to the pediatric population if they will be administering to minors;

(iv) Hold a current certification in basic life support (BLS) offered by the American Heart Association or the American Red Cross cardiopulmonary resuscitation (CPR); and

(d) A pharmacy intern who is registered to administer immunizations shall do so under the direct supervision of the pharmacist who is registered to administer immunizations.

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(i) The CDC Recommended Adult Immunization Schedule incorporated by reference in this Chapter of these rules is the ~~2019~~2021 United States CDC Recommended Adult Immunization Schedule for Ages 19 Years or Older as existing on ~~September 12, 2019~~February

18, 2021. Copies of this document can be obtained from the Board at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming, 82002.

(ii) The CDC Recommended Child and Adolescent Immunization Schedule incorporated by reference in this Chapter of these rules is the ~~2019~~2021 United States CDC Recommended Child and Adolescent Immunization Schedule for Ages 18 and Younger as existing on ~~September 12, 2019~~February 18, 2021. Copies of this document can be obtained from the Board at 1712 Carey Avenue, Suite 200, Cheyenne, Wyoming, 82002.

(iii) For any code, standard, rule or regulation by reference in these rules:

(A) The Board has determined that incorporation of the full text in these rules could be cumbersome or inefficient given the length or nature of the rules;

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~~(i) Vaccines for COVID-19 approved by the FDA under an Emergency Use Authorization and any vaccine for COVID-19 completing the FDA approval process.~~

~~(c) Immunizations authorized by this Chapter shall be prescribed in accordance with the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). Specifically, CDC's "Recommended Adult Immunization Schedule, by Vaccine and Age Group" and "Recommended Adult Immunization Schedule by Vaccine and Medical and Other Indications," or "Recommended Immunization Schedule for Persons Aged 0 Through 18 Years," including the footnotes provided for each schedule, shall be utilized by the pharmacist when considering the eligibility of a healthy individual to receive an immunization. The latest notice from CDC may be found at CDC's website (<http://www.cdc.gov>). Parental or legal guardian consent shall be required for all minors receiving a vaccination. The parent or legal guardian shall be present during the administration.~~

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~~administration, and storage requirements for each specific immunization authorized by this Chapter.~~ Immunizations authorized by this Chapter shall be prescribed in accordance with the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). Specifically, CDC's "*Recommended Adult Immunization Schedule, by Vaccine and Age Group*" and "*Recommended Adult Immunization Schedule by Vaccine and Medical and Other Indications,*" or "*Recommended Immunization Schedule for Persons Aged 0 Through 18 Years,*" including the footnotes provided for each schedule, shall be utilized by the pharmacist when considering the eligibility of a healthy individual to receive an immunization. The latest notice from CDC may be found at CDC's website (<http://www.cdc.gov>).

(e) ~~All immunizations shall be administered with the individual receiving the vaccine seated in a chair with back support.~~ Pharmacists shall utilize the manufacturer's package insert for indications, contraindications, adverse reactions, dosing, route of administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this Chapter.

(f) A current *Vaccine Information Statement*, as provided by the CDC, shall be provided to each person receiving an immunization for each immunization administered. The *Vaccine Information Statement* is available from the CDC's website (<http://www.cdc.gov>).

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