

SECRETARY OF STATE

2024 FEB -1 PM 3:02

FILED

**AGENCY RECEIPT**

**NOTICE OF FINAL RULEMAKING**

**1. State of Arizona Naturopathic Physicians Medical Board**

**2. TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 18. NATUROPATHIC PHYSICIANS MEDICAL BOARD**

**ARTICLE 9. CERTIFICATE TO DISPENSE**

R4-18-902

R4-18-903

**ARTICLE 10. DISPENSING OF A NATURAL SUBSTANCE, DRUG OR DEVICE**

R4-18-1001

R4-18-1002

R4-18-1003

R4-18-1004

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AGENCY CERTIFICATE

NOTICE OF FINAL RULEMAKING

FILED

- 1. Agency name: State of Arizona Naturopathic Physicians Medical Board
- 2. Chapter heading: Chapter 18. Naturopathic Physicians Medical Board
- 3. Code citation for the Chapter: Code Title 4. A.A.C. Code Chapter 18.
- 4. The Subchapters, if applicable; the Articles; the Parts, if applicable; and the Sections involved in the rulemaking, in numerical order:

R4-18-902

R4-18-903

Article 10.

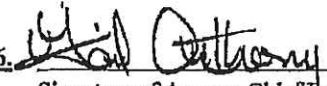
R4-18-1001

R4-18-1002

R4-18-1003

R4-18-1004

- 5. The rules contained in this package are true and correct as made

6.   
 Signature of Agency Chief Executive Officer in ink

2/1/24  
 Date signed

GAIL ANTHONY  
 Printed or typed name of signer

EXECUTIVE DIRECTOR  
 Title of signer



# GOVERNOR'S REGULATORY REVIEW COUNCIL

## CERTIFICATE OF APPROVAL OF FINAL RULES

1. Agency Name: Naturopathic Physicians Medical Board
2. Chapter Heading: NATUROPATHIC PHYSICIANS MEDICAL BOARD
3. Citation for the Chapter: 4 A.A.C. 18

**Action:**        Subchapters, Articles, Parts and Sections

New Section    Article 10, R4-18-1001, R4-18-1002, R4-18-1003, R4-18-1004

Amend         R4-18-902, R4-18-903

4. The rules described above are approved as final rules.
  - approved as submitted (R1-6-205(A))
  - approved in part, returned in part (A.R.S. § 41-1052(C))
  - approved with changes accepted by the agency (R1-6-205(B))

5. Effective date:
  - standard 60-day delayed effective date
  - immediate effective date
  - other [specify date:            ]

Nicole Sornsin  
Council Chair

Nov 7, 2023

Date of Approval

NOTICE OF FINAL RULEMAKING  
TITLE 4. PROFESSIONS AND OCCUPATIONS  
CHAPTER 18. NATUROPATHIC PHYSICIANS MEDICAL BOARD

PREAMBLE

<u>1. Article, Part, or Section Affected (as applicable)</u>	<u>Rulemaking Action</u>
R4-18-902	Amend
R4-18-903	Amend
Article 10	New Section
R4-18-1001	New Section
R4-18-1002	New Section
R4-18-1003	New Section
R4-18-1004	New Section

2. Citations to the agency’s statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 32-1504(A)

Implementing statute: A.R.S. § 32-1581(E)

3. The effective date of the rule:

a. If the agency selected a date earlier than the 60 day effective date as specified in A.R.S. § 41-1032(A), include the earlier date and state the reason or reasons the agency selected the earlier effective date as provided in A.R.S. § 41-1032(A)(1) through (5):

The Agency requests a general effective date.

b. If the agency selected a date later than the 60 day effective date as specified in A.R.S. § 41-1032(A), include the later date and state the reason or reasons the agency selected the later effective date as provided in A.R.S. § 41-1032(B):

The Agency requests a general effective date.

4. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 29 A.A.R. 810, March 31, 2023

Notice of Proposed Rulemaking: 29 A.A.R. 1391, June 23, 2023

**5. The agency's contact person who can answer questions about the rulemaking:**

Name: Gail Anthony, Executive Director  
Address: State of Arizona Naturopathic Physicians Medical Board  
1740 W. Adams, Ste. 3002  
Phoenix, AZ 85007  
Telephone: (602) 542-8242  
E-mail: Gail.anthony@nd.az.gov  
Web site: <https://nd.az.gov>

**6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**

A recent Auditor General report recommended the Board adopt rules relating to the labeling, recordkeeping, storage, and packaging of natural substances, pursuant to A.R.S. § 32-2581(E). The Board found that R4-18-901 defines "dispense" by reference to AR.S. § 32-1581(H)(2), with the statute requiring the labeling, recordkeeping, storage and packaging of natural substances be consistent with the requirements of chapter 18. However, the Auditor General report did make the recommendation to adopt more specific rules regarding this topic, and the Board agreed to the recommendation. The Board chose to create a new Article (Article10), to address the specifics required by A.R.S. § 32-2581(E). A.R.S. § 32-1581(A)(1) allows a naturopathic physician to dispense a natural substance, a drug with the exception of a schedule II controlled substance that is an opioid, or a device, to a patient for a condition that is being diagnosed or treated by the physician if the physician is certified by the board to dispense. These new rules seek to clarify when a certificate to dispense is required, the packaging and inventory requirements of the dispensing physician, the recordkeeping requirements of the dispensing physician, and when a physician is required to cooperate with inspections of dispensing practices. Current statute, A.R.S. §32-1581(E) allows for inspections.

**7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

The Board did not review or rely on any study for this rulemaking

**8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable.

**9. A summary of the economic, small business, and consumer impact:**

Currently the Board regulates approximately 1200 licensed Naturopathic Physicians. Statute requires those physicians to obtain a certificate to dispense under certain conditions. There should be little to no economic, small business, and consumer impact with implementation of the proposed rules.

**10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:**

None

**11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:**

No comments were received.

**12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:**

**a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**

The Board issues certificates to dispense to qualified applicants to conduct identified activities as a naturopathic physician. Use of a general permit allowing for specific activities is not applicable.

**b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:**

Not applicable.

**c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**

The Board did not receive such an analysis from any person.

**13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:**

None.

**14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:**

The rules was not previously made, amended or repealed as an emergency rule.

**15. The full text of the rules follows:**

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 18. NATUROPATHIC PHYSICIANS MEDICAL BOARD**

**ARTICLE 9. CERTIFICATE TO DISPENSE**

R4-18-902. Qualifications for a Certificate to Dispense

R4-18-903. Application for a Certificate to Dispense; Renewal

**ARTICLE 10. DISPENSING OF A NATURAL SUBSTANCE, DRUG OR DEVICE.**

R4-18-1001. Certificate to Dispense Required

R4-18-1002. Packaging and Inventory

R4-18-1003. Recordkeeping and Reporting Shortages

R4-18-1004. Inspections



R4-18-902. Qualifications for a Certificate to Dispense

- A. To qualify for a certificate to dispense, an applicant shall have completed before the submission date of the application, Board approved training in the safe administration of natural substances, drugs, or devices.
- B. The Board approves documentation of the following as evidence of completion of Board approved training in the safe administration of natural substances, drugs, or devices:
  - 1. Graduation from an approved school of naturopathic medicine after January 1, 2005 as referenced in A.R.S. § 32-1525(B)(4); or
  - 2. Completion of a 60 hour or more pharmacological course on natural substances, drugs, or devices that is offered, approved, or recognized by one of the organizations in R4-18-205(B)(1) or R4-18-205(B)(2), or by passing of The North American Board of Naturopathic Examiners (NABNE) add on Parenteral Medicine Examination.
- C. If an applicant intends to administer a natural substance or drug intravenously, the Board approved training completed by the applicant shall include administration of a natural substance or drug by intravenous means.

R4-18-903. Application for a Certificate to Dispense; Renewal

- A. An applicant for a certificate to dispense shall submit:
  - 1. An application to the Board that contains:
    - a. The applicant's:
      - i. Full legal name;
      - ii. Naturopathic license number, if known; and

- iii. Social Security number;
  - b. If a corporation, a statement of whether the corporation holds tax exempt status;
  - c. A statement of whether the applicant holds a drug enforcement number issued by the United States Drug Enforcement Administration, and if so, the drug enforcement number;
  - d. A statement of whether the applicant has ever had the authority to prescribe, dispense, or administer a natural substance, drug, or device limited, restricted, modified, denied, surrendered or revoked by a federal or state agency or court of law, and if so, an explanation that includes:
    - i. The name and address of the federal or state agency or court having jurisdiction over the matter, and
    - ii. The disposition of the matter;
  - e. A statement, signed by the applicant, that the applicant agrees to conform to all federal and state statutes, regulations, and rules; and
  - f. The date the application is submitted; and
2. Unless exempted by A.R.S. § 32-1530, the fee required by the Board.
- B.** ~~An applicant for a naturopathic license may request a certificate to dispense as part of a naturopathic license application. When this request is made, approval of the naturopathic license by the Board includes approval of the certificate to dispense.~~
- C. B.** A certificate holder shall renew a certificate to dispense on or before July 1 of each year by submitting:

1. An application to the Board that contains:
  - a. The applicant's full legal name;
  - b. If a corporation, a statement of whether the corporation holds tax exempt status;
  - c. A statement of whether the applicant has had the authority to prescribe, dispense, or administer a natural substance, drug, device limited, restricted, modified, denied, surrendered or revoked by a federal or state agency or court of law, during the one year period immediately preceding the renewal date and if so, an explanation that includes:
    - i. The name and address of the federal or state agency or court having jurisdiction over the matter; and
    - ii. The disposition of the matter; and
  - d. A statement, signed and dated by the applicant, verifying the information on the application is true and correct and the applicant is the licensee named on the application; and
2. Unless exempted by A.R.S. § 32-1530, the fee required by the Board.

**D. C.** The Board shall grant or deny the certificate to dispense or renewal of certificate to dispense according to the time-frames in 4 A.A.C. 18, Article 7, Table 1.

## **ARTICLE 10. DISPENSING OF A NATURAL SUBSTANCE, DRUG OR DEVICE**

### **R4-18-1001. Certificate to Dispense Required**

**A.** A doctor of naturopathic medicine may dispense a natural substance, a drug,

except a schedule II controlled substance that is an opioid, or a device to a patient for a condition that is being diagnosed or treated by the doctor. A doctor who holds a current medical license with the board shall obtain a certificate to dispense annually if the doctor:

1. Maintains a supply of Natural Substances as defined in A.R.S. 32-1501(23), controlled substances as defined in A.R.S. 32-1501(12), prescription-only drugs as defined in A.R.S. 321501(17), or prescription-only devises as defined in A.R.S. 32-1581(H)(i), excluding manufacturer's samples;
2. Prescribes the items listed in subsection (A)(1) to a patient of the doctor for use outside the office;
3. Obtains payment for the items listed in subsection (A)(1), including payment from a fulfillment center; or
4. Administers substances approved for intravenous administration pursuant to A.R.S. 32-1501(15)(a)(i)(ii)(iii).

**B. To obtain a certificate to dispense, a doctor shall:**

1. Submit the application form referenced in R4-18-903;
2. Submit a copy of the doctor's current Drug Enforcement Administration certificate of registration, for each location from which the doctor will dispense a controlled substance; and
3. Submit the fee required under R4-18-107, unless the doctor is exempt from paying the fee pursuant to A.R.S. 32-1530. A doctor applying for exemption is required to submit proof of exempt status with the application.

**C. A doctor shall renew the certificate to dispense by July 1 of each year. If a doctor**

makes a timely and complete application to renew the certificate, the doctor may continue to dispense until the Board approves or denies the renewal application.

- D.** If a doctor fails to submit a timely and complete application to renew the certificate to dispense, the doctor shall immediately cease dispensing.
- E.** If a doctor fails to comply with subsection (C), the doctor shall not dispense any natural substance, controlled substance, prescription-only drug, or prescription-only device, including substances approved for intravenous administration, until the doctor complies fully with subsection (B) and receives notice the Board approves the application.

#### R4-18-1002. Packaging and Inventory

- A.** A doctor shall dispense all controlled substances and prescription-only drugs in appropriate containers that are in compliance with state and federal laws.
- B.** A doctor shall ensure the natural substance, drug or device dispensed is in compliance with labeling requirements outlined in A.R.S. 32-1581(2). For the purpose of compliance with A.R.S. 32-1581(2), if the natural substance or device dispensed does not require a prescription, the information required may be incorporated into an accompanying instruction sheet. For a natural substance that contain multiple ingredients, the strength of each ingredient is not required to be documented, only the brand name of the supplement is required for documentation. All ingredients and amounts administered by intravenous or intramuscular administration are required to be fully documented in the patient chart.
- C.** A doctor shall:

1. Secure all controlled substances in a locked cabinet or room;
2. Control access to the locked cabinet or room by a written procedure that include, at a minimum:
  - a. Designation of the persons who have access to the locked room, and
  - b. Procedures for recording requests for access to the locked cabinet or room;
3. Make a written procedure required under subsection (C)(2) available on demand by the Board or its authorized represented for inspection and copying;
4. Store prescription-only drugs so they are not accessible to patients; and
5. Store controlled substances and prescription-only drugs not requiring refrigeration in an area where the temperature does not exceed 85 degrees Fahrenheit.

**D.** A doctor shall maintain an ongoing dispensing log for all controlled substances and prescription-only drugs dispensed by the physician. The dispensing log shall Include the following:

1. A separate inventory sheet for each controlled substance and prescription-only drug;
2. The date the drug is dispensed;
3. The patient's name;
4. The name of the controlled substance or prescription-only drug, strength, dosage, form, and name of manufacturer;
5. The number of dosage units dispensed;
6. A running total of each controlled substance or prescription-only drug

dispensed; and

7. The written signature of the doctor next to each entry.

E. A doctor may use a computer to maintain the dispensing log required under subsection (D) if the dispensing log is password protected and quickly accessible through either on-screen viewing or printing a copy.

F. This Section does not apply to a prepackaged manufacturer sample of a controlled substance or prescription-only drug unless otherwise provided by federal law.

G. The doctor must report the dispensing of controlled substances in compliance with the Arizona Controlled Substance Prescription Monitoring Program.

#### R4-18-1003. Recordkeeping and Reporting Shortages

A. A doctor who dispenses a controlled substance or prescription-only drug shall ensure an original prescription order for the controlled substance or prescription-only device is dated, consecutively number in the order in which it is originally dispensed, and filed separately from patient medical records. The doctor shall ensure original prescription orders are maintained in three separate files, as follows:

1. Schedule II controlled substances;
2. Schedule III, IV and V controlled substances; and
3. Prescription-only drugs.

B. A doctor shall ensure purchase orders and invoices are maintained for all controlled substances and prescription-only drugs dispensed, whether for profit or not for profit, for three years from the date of the purchase order or invoice. Purchase

orders and invoices shall be maintained in three separate files as follows:

1. Schedule II controlled substances only;
2. Schedule III, IV and V controlled substances; and
3. All other prescription-only drugs.

C. A doctor who discovers a theft or loss of a prescription only drug from the doctors office shall:

1. Immediately notify the local law enforcement agency,
2. Provide the local law enforcement agency with a written report, and
3. Send a copy of the report provided under subsection (C)(2) to the Drug Enforcement Administration and Board within seven days of the discovery.

R4-18-1004. Inspections

- A. A doctor shall cooperate with and allow access to the doctor's office and records for inspection of dispensing practices by the Board or its authorized representative.
- B. The Board shall revoke a doctor's certificate to dispense if the doctor's license is suspended, revoked or surrendered.
- C. The certificate automatically expires if:
  1. The doctor fails to renew the medical license in a timely manner; or
  2. The doctor fails to renew the certificate in a timely manner.
- D. A doctor who holds a certificate and is not currently under investigation, may request the certificate be cancelled.



STATE OF ARIZONA  
NATUROPATHIC PHYSICIANS MEDICAL BOARD  
ECONOMIC, SMALL BUSINESS AND CONSUMER IMPACT STATEMENT

FILED

TITLE 4., PROFESSIONS AND OCCUPUCANTION  
CHAPTER 18, ARTICLE 9. AND NEW ARTICLE 10.

1. **An identification of the proposed rulemaking.**

A recent Auditor General report recommended the Board adopt rules relating to the labeling, recordkeeping, storage, and packaging of natural substances, pursuant to A.R.S. § 32-2581(E). The Board found that R4-18-901 defines “dispense” by reference to AR.S. § 32-1581(H)(2), with the statute requiring the labeling, recordkeeping, storage and packaging of natural substances be consistent with the requirements of chapter 18. However, the Auditor General report did make the recommendation to adopt more specific rules regarding this topic, and the Board agreed to the recommendation. The Board chose to create a new Article (Article10), to address the specifics required by A.R.S. § 32-2581(E). A.R.S. § 32-1581(A)(1) allows a naturopathic physician to dispense a natural substance, a drug with the exception of a schedule II controlled substance that is an opioid, or a device, to a patient for a condition that is being diagnosed or treated by the physician if the physician is certified by the board to dispense. These new rules seek to clarify when a certificate to dispense is required, the packaging and inventory requirements of the dispensing physician, the recordkeeping requirements of the dispensing physician, and when a physician is required to cooperate with inspections of dispensing practices. Current statute, A.R.S. §32-1581(E) allows for inspections.

2. **An identification of the persons who will be directly affected by, bear the costs of or directly benefit from the proposed rule making.**

**Persons affected:**

The rulemaking affects Naturopathic Medical Doctors licensed by this Board.

**Cost Bearer:**

Naturopathic Medical Doctors seeking to obtain a certificate to dispense.

**Beneficiaries:**

Naturopathic Medical Doctors licensed by this Board.

3. **A cost benefit analysis of the following:**

**(a.) The probable costs and benefits to the implementing agency and other agencies directly affected by the implementation and enforcement of the proposed rule making. The probable costs to the implementing agency shall include the number of new full-time employees necessary**

**to implement and enforce the proposed rule. The preparer of the EIS shall notify the joint legislative budget committee of the number of new full-time employees necessary to implement and enforce the rule before the rule is approved by the Council.**

There should be no economic impact to the agency. No new FTE's are required to implement the proposed rule changes.

**(b.) The probable costs and benefits to a political subdivision of this state directly affected by the implementation and enforcement of the proposed rulemaking.**

None apparent.

**(c.) The probable costs and benefits to businesses directly affected by the proposed rule making, including any anticipated effect on the revenues or payroll expenditure of employers who are subject to the proposed rulemaking.**

None apparent.

4. **A general description of the probable impact on private and public employment in business, agencies and political subdivisions of this state directly affected by the proposed rulemaking.**

None apparent.

5. **A statement of the probable impact of the rulemaking on small business.**

**(a.) An identification of the small business subject to the rulemaking.**

None apparent.

**(b.)Administrative/other costs required for compliance with the rulemaking.**

The Board already issues certificates to dispense to qualified physicians. There should be no additional costs associated with compliance of the rule.

**(c.) A description of the methods prescribed in section 41-1035 that the agency may use to reduce the impact on small businesses with reasons for the agency's decision to use or not to use each method.**

None identified.

**(d.)The probable cost and benefit to private persons and consumers who are directly affected by the proposed rulemaking.**

None identified.

6. **A statement of the probable effect on the state revenues.**

There should be no significant change to revenue.

7. A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rulemaking, including the monetizing of the costs and benefits for each option and providing the rationale for not using nonselected alternatives.

None identified.

8. A description of any data on which a rule is based with a detailed explanation of how the data was obtained and why the data is acceptable data. An agency advocating that any data is acceptable ata has the burden of proving that the data is acceptable. For the purposes of this paragraph, "acceptable data" means empirical, replicable and testable data as evidenced in supporting documentation, statistics, reports, studies or research.

The rule is being updated based upon a recommendation reflected in the recent Auditor General's Report.