



NOTICES OF EMERGENCY RULEMAKING

This section of the Arizona Administrative Register contains Notices of Emergency Rulemaking.

The Office of the Secretary of State is the filing office and publisher of these rules.

Questions about the interpretation of the emergency rules should be addressed to the agency proposing them. Refer to Item #5 to contact the person charged with the rulemaking.

NOTICE OF EMERGENCY RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 18. NATUROPATHIC PHYSICIANS MEDICALBOARD

[R15-54]

PREAMBLE

- 1. Article, Part, or Section Affected (as applicable) Rulemaking Action
2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statutes (specific):
3. The effective date of the rule:
4. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the of the final rulemaking package:
5. The agency's contact person who can answer questions about the rulemaking:
6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:



Administration or compounded by a pharmacy licensed in Arizona, another state, or United States territory. The rule however goes further by establishing a list of four (4) excluded nutrients in A.A.C. R4-18-904(B)(2); Silver protein, or any substance that contains silver, Cesium chloride, Hydrazine sulfate, and Lipid replacement as used in total parenteral nutrition. A.R.S. § 32-1501(15)(iii) defines nutrients as a substance that provides nourishment for growth or metabolism and that is manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug Administration or compounded by a pharmacy licensed by the state board of pharmacy. Statute does not require rule to list specific nutrients because both statute and rule already define substances considered not suitable for intravenous administration.

It has come to the attention of the Board that some of our licensees have used one or more of the substances listed in A.A.C. R4-18-904(B)(2), and state they have had positive results with their use. The American Naturopathic Research Institute/Naturopathic Oncology Research Institute report, they are currently conducting an IRB (ID # IORG0007953), in which one or more of the excluded nutrients had been used. The current rules have an impact on the data supplied for the IRB. According to the website [www.cancer.gov](http://www.cancer.gov); The Food and Drug Administration (FDA) has approved the study of hydrazine sulfate in clinical trials. According to [www.researchednutritionals.com](http://www.researchednutritionals.com); Lipid Replacement is not just the dietary substitution of certain lipids with proposed health benefits; it is the actual replacement of damaged cellular lipids with undamaged lipids to ensure proper structure and function of cellular structures, mainly cellular and organelle membranes. Removing the use any of the 4 excluded substances, may impact the health and safety of the public. The Board is requesting an emergency rule change under A.R.S. § 41-1032(A)(1).

The Emergency rules package was submitted to the Attorney General for approval on November 18, 2014. The Attorney General approved the rules package and filed with the Secretary of State on December 18, 2014. The Emergency rules are part of a general rules package the Board is in the process of submitting to GRRC for approval. The Board hopes to submit the general rules package to GRRC by May 15, 2015. The general rules package Notice of Rulemaking Docket Opening is published in the Register: 22 A.A.R. 61, January 9, 2015. Because the general rules package may not be approved before the original one hundred eighty day time period has expired, the Board is seeking approval for one (1) renewal of one hundred eighty days. The Board is seeking approval of the renewal Pursuant to A.R.S. § 41-1026 (5) and has determined the following apply; 1. The agency has determine that the emergency situation still exists. If the emergency rule expires prior to the rules package being approved by GRRC, the rules will again exclude the 4 substances and may impact the health and safety of the public, 2. By filing this renewal, the Board is following procedure as prescribed in statute, 3. The Board is requesting approval by the Attorney General, 4. The Board has issued the rule as part of a regular rules package.

**7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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.

**8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rules 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:**

When used in the economic impact statement summary, annual cost/revenue are designated as minimal when less than \$5,000, moderate when between \$5,000 and \$10,000, and substantial when greater than \$10,000.

The Board will incur minimal expense to write the rules and enforce their requirements.

The elimination of R4-18-904(B)(2) should not result in any costs to a naturopathic physician, medical student, or medical assistant, as the removal should not cause extra burden on any licensee or certificate holder.

**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:**

The Board received written notice from the State of Arizona Naturopathic Association (AzNMA) requesting review of the current rule. The Board received a letter from Attorney Steven C. Mahaffy in his capacity as Council representing licensee Dr. Colleen Huber, has also requested removal of the current rule. The Board heard comments from Licensees and members of the public at the meeting of July 10, 2014 and September 11, 2014. All correspondence and comments are in favor of removing the rule. The Board has not received additional public comment.



**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 a license or certificate, which fall within the definition of general permit.

**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:**

Federal law is applicable to the subject of the rule. A.A.C. R4-18-904(B)(1) requires that nutrients for intravenous administration must be manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug administration. This provision is consistent with the requirements for registration in 21 U.S.C. § 360(b) (U.S. operations) and (i) (foreign establishments).

**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 rules:**

There is no incorporation by reference document.

**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 package:**

The rule was previously made as an emergency rule. The Board is seeking renewal.

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

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 18. NATUROPATHIC PHYSICIANS BOARD OF MEDICAL EXAMINERS**

**ARTICLE 9. CERTIFICATE TO DISPENSE**

Section  
R4-18-904.     Dispensing; Intravenous Nutrients

**ARTICLE 9. CERTIFICATE TO DISPENSE**

**R4-18-904.     Dispensing; Intravenous Nutrients**

- A.** To prevent toxicity due to the excessive intake of a natural substance, drug, or device, before dispensing the natural substance, drug, or device to an individual, a certified physician shall:
  - 1. Conduct a physical examination of the individual,
  - 2. Conduct laboratory tests as necessary that determine the potential for toxicity of the individual, and
  - 3. Document the results of the physical examination and laboratory tests in the individual’s medical record.
- B.** For the purposes of A.R.S. § 32-1504(A)(8), a substance is considered a nutrient ~~not~~ suitable for intravenous administration if it is:
  - 1. ~~Not manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug Administration or compounded by a pharmacy licensed in Arizona, another state, or United States territory; or Complies with A.R.S. § 32-1501(15)(iii).~~
  - 2. One of the following:
    - a. ~~Silver protein, or any substance that contains silver;~~
    - b. ~~Cesium chloride;~~
    - c. ~~Hydrazine sulfate; or~~
    - d. ~~Lipid replacement as used in total parenteral nutrition.~~