

# NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

## NOTICE OF FINAL RULEMAKING

### TITLE 4. PROFESSIONS AND OCCUPATIONS

#### CHAPTER 23. BOARD OF PHARMACY

*Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 730.)*

[R13-54]

#### PREAMBLE

- 1. Articles, Parts, and Sections Affected (as applicable)**      **Rulemaking Action**  
R4-23-604      Amend  
R4-23-605      Amend
- 2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):**  
Authorizing statute: A.R.S. §§ 32-1904(A)(1) and (B)(3), 32-1929, 32-1930, 32-1931, and 32-1933  
Implementing statute: A.R.S. §§ 32-1981, 32-1982, 32-1983, 32-1984, and 32-1985
- 3. The effective date of the rule:**  
June 1, 2013
- 4. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed rule:**  
Notice of Rulemaking Docket Opening: 18 A.A.R. 2260, September 14, 2012  
Notice of Proposed Rulemaking: 18 A.A.R. 3036, November 23, 2012
- 5. The agency's contact person who can answer questions about the rulemaking:**  
Name:      Dean Wright, Compliance Officer  
Address:      Board of Pharmacy  
                    1616 W. Adams  
                    Phoenix, AZ 85007  
Telephone:      (602) 771-2727  
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- 6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**  
In 2008 the 48th Legislature passed HB 2020. HB 2020 removed the requirement that only a pharmacist could manufacture a drug and specifically allowed a person who is not a pharmacist to manufacture a drug if that person possessed a permit to manufacture drugs from the Board of Pharmacy. The Board has a rule (R4-23-604 Resident Drug Manufacturer) that implements the statutory requirements for drug manufacturing. Before the Board could move to make changes to R4-23-604 necessitated by HB 2020, the Governor imposed a rulemaking moratorium. The Board is now ready to make the necessary changes to R4-23-604 to bring the rule into compliance with the statutory changes made in HB 2020. The Board has also determined that R4-23-605 Resident Drug Wholesaler Permit needs to be amended to remove the requirement that a pharmacy or licensee who is returning a drug to a drug wholesaler must provide the lot number and expiration date of the drug being returned on the return paperwork. Since a drug wholesaler does not have to provide a lot number and expiration date of a drug on the invoice when the wholesaler delivers

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the drug to the pharmacy, the pharmacies do not see why a pharmacy should be required to provide a lot number and expiration date of a drug when the drug is returned to the wholesaler. The Board agrees with the pharmacies, and intends to remove the lot number and expiration date requirement.

The rulemaking will amend R4-23-604 Resident Drug Manufacturer by removing all references that require a pharmacist-in-charge, including references to nuclear pharmacists, in a drug manufacturing operation. Those references are in R4-23-604 (B)(9) and (12), (C)(2), (D), (H)(1)(d), (I), (J), and (O). The rulemaking will amend R4-23-605 Resident Drug Wholesaler Permit by removing the requirement for a lot number and expiration date in subsection (H)(3)(a). The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that approval of the rules benefits the public, pharmacies, resident drug manufacturers, and resident drug wholesalers by establishing standards for the manufacturing and distribution of drugs.

**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 agency did not review or rely on any study relevant to the rule.

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

The amended rule will impact the Board, pharmacies, resident drug manufacturers, and resident drug wholesalers. The amended rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the amended rules will have no economic impact on pharmacies, resident drug manufacturers, and resident drug wholesalers. In 2008 the 48th Legislature passed HB 2020. HB 2020 removed the requirement that only a pharmacist could manufacture a drug and specifically allowed a person who is not a pharmacist to manufacture a drug if that person possessed a permit to manufacture drugs from the Board of Pharmacy. The Board has a rule (R4-23-604 Resident Drug Manufacturer) that implements the statutory requirements for drug manufacturing. Before the Board could move to make changes to R4-23-604 necessitated by HB 2020, the Governor imposed a rulemaking moratorium. The Board is now ready to make the necessary changes to R4-23-604 to bring the rule into compliance with the statutory changes made in HB 2020. The Board has also determined that R4-23-605 Resident Drug Wholesaler Permit needs to be amended to remove the requirement that a pharmacy or licensee who is returning a drug to a drug wholesaler must provide the lot number and expiration date of the drug being returned on the return paperwork. Since a drug wholesaler does not have to provide a lot number and expiration date of a drug on the invoice when the wholesaler delivers the drug to the pharmacy, the pharmacies do not see why a pharmacy should be required to provide a lot number and expiration date of a drug when the drug is returned to the wholesaler. The Board agrees with the pharmacies, and intends to remove the lot number and expiration date requirement. The rulemaking will have no economic impact on pharmacies, drug manufacturers, or drug wholesalers.

The Board believes that approval of the rules benefits the public, pharmacies, resident drug manufacturers, and resident drug wholesalers by establishing standards for the manufacturing and distribution of drugs.

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

There are no substantial changes in the final rules from the proposed rules. There are nonsubstantive changes including replacing "and" with "or" in R4-23-604(H)(1)(a) to allow a drug manufacturer permittee to choose whether to distribute to a pharmacy, drug manufacturer, or a full-service or nonprescription drug wholesaler, rather than requiring distribution to all three. The Board indicates that drug manufacturer permittees have always been able to make this choice; however, the rule will now be in conformity with current practice. In addition, the Board changed "in no less than" to "within" to account for receipt of documents before two days had elapsed. In addition, the Board corrected a citation in R4-23-604(I) that was changed by the legislature in 2008. The citation should have referred to A.R.S. § 32-1927.02. A citation to A.R.S. § 32-1901(4) found in R4-23-604(K)(3) was changed to A.R.S. § 32-1901(5) to correctly refer to the subsection related to compliance or other authorized officers as stated in the rule. Finally, the Board corrected an internal reference to subsection (H) in R4-23-605(K). The citation should have referred to subsection (J). There are minor changes to style, format, grammar, and punctuation requested by GRRC staff.

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

A public hearing was held December 28, 2012. No one attended the hearing and 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 per-**

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**mit is not used:**

The rules require a permit. The Board does not issue a general permit, but issues the specific permit required under A.R.S. §§ 32-1929, 32-1930, and 32-1931.

**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:**

Yes, federal law is incorporated by reference to ensure that the rules are not more stringent.

**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:**

No

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

21 CFR 210 through 211, April 1, 2011 in R4-23-604(J)

**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:**

No

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

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 23. BOARD OF PHARMACY**

**ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS**

Section

- R4-23-604. Resident Drug Manufacturer
- R4-23-605. Resident Drug Wholesaler Permit

**R4-23-604. Resident Drug Manufacturer**

- A.** Permit. A person shall not manufacture, package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical without a current Board-issued drug manufacturer permit.
- B.** Application. To obtain a permit to operate a drug manufacturing firm in Arizona, a person shall submit a completed application, on a form furnished by the Board, that includes:
  - 1. Business name, address, mailing address, if different, telephone number, and facsimile number;
  - 2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
  - 3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
  - 4. Whether the owner, any officer, or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
  - 5. Whether the owner, any officer, or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
  - 6. A copy of the drug list required by the FDA;
  - 7. Plans or construction drawings showing facility size and security for the proposed business;
  - 8. Applicant's and manager's name, address, emergency telephone number, and resumé indicating educational or experiential qualifications related to drug manufacturer operation;
  - 9. ~~Pharmacist in charge's name, address, emergency telephone number, Arizona pharmacist license number, and expiration date;~~
  - ~~10.~~ The applicant's current FDA drug manufacturer or repackager registration number and expiration date;
  - ~~11.~~ Documentation of compliance with local zoning laws;
  - ~~12.~~ ~~11.~~ For an application submitted because of ownership change, the former owner's name and business name, if different;
  - ~~13.~~ ~~12.~~ Date signed, and applicant's, corporate officer's, partner's, or manager's, or pharmacist in charge's verified signature and title; and
  - ~~14.~~ ~~13.~~ Fee specified in R4-23-205.
- C.** Before issuing a drug manufacturer permit, the Board shall:

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1. Receive and approve a completed permit application;
  2. Interview the applicant and manager, if different from the applicant, ~~and the pharmacist in charge~~ at a Board meeting; and
  3. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.
- D.** Notification. A resident drug manufacturer permittee shall notify the Board of changes involving the drug list, ownership, address, telephone number, name of business, ~~or manager, or pharmacist in charge,~~ including manager's ~~or pharmacist in charge's~~ telephone number. The resident drug manufacturer permittee shall submit a written notice via mail, fax, or e-mail to the Executive Director within 24 hours of the change, except any change of ownership requires that the resident drug manufacturer permittee comply with subsection (E).
- E.** Change of ownership. Before a change of ownership occurs that involves changes of stock ownership of more than 30% of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit the application packet described under subsection R4-23-604(B).
- F.** Before an existing resident drug manufacturer permittee relocates, the drug manufacturer permittee shall submit the application packet described in subsection R4-23-604(B), excluding the fee. The facility at the new location shall pass a final inspection by a Board compliance officer before operations begin.
- G.** A resident drug manufacturer permittee shall submit the application packet described under subsection R4-23-604(B) for any change of officers in a corporation, excluding the fee and final inspection.
- H.** Manufacturing and distribution.
1. A drug manufacturer permittee shall manufacture and distribute a drug only:
    - a. To a pharmacy, drug manufacturer, ~~and~~ or full-service or nonprescription drug wholesaler currently permitted by the Board;
    - b. To a medical practitioner currently licensed as a medical practitioner as defined in A.R.S. § 32-1901; or
    - c. To a properly permitted, registered, licensed, or certified person or firm of another jurisdiction; ~~and~~
    - d. ~~Under the supervision of an Arizona Board licensed pharmacist as required in A.R.S. § 32-1961. Manufacturing processes that require the supervision of a pharmacist include weighing, mixing, compounding, tableting, packaging, and labeling.~~
  2. Before manufacturing and distributing a drug that is not listed on a drug manufacturer's permit application, the drug manufacturer permittee shall send to the Board office a written request to amend the permit application, including documentation of FDA approval to manufacture the drug not listed on the original permit application. If a request to amend a permit application includes the documentation required in this subsection, the Board or its designee shall approve the request to amend within 30 days of receipt.
- I.** A drug manufacturer permit is subject to denial, suspension, probation, or revocation under A.R.S. § ~~32-1932~~ 32-1927.02.
- J.** ~~A drug manufacturer permittee shall:~~
1. ~~Designate an Arizona Board licensed pharmacist as the pharmacist in charge. The pharmacist in charge shall:~~
    - a. ~~Communicate Board directives to the management, other pharmacists, interns, and other personnel of the drug manufacturer; and~~
    - b. ~~Ensure compliance with all federal and state drug laws and rules by the drug manufacturer; and~~
  2. ~~Ensure that an Arizona Board licensed pharmacist is present at the facility whenever a drug is manufactured, packaged, repackaged, labeled, or relabeled.~~
- ~~K.~~** Current Good Manufacturing Practice. A drug manufacturer permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210 through 211, ~~published April 1, 2000 (Revised April 1, 2011, and no future amendments or editions,~~ incorporated by reference and on file with the Board and available at [www.gpo.gov](http://www.gpo.gov) and the Office of the Secretary of State. This incorporated material includes no future editions or amendments.
- ~~L.~~** **K.** Records. A drug manufacturer permittee shall:
1. Establish and implement written procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law;
  2. Retain the records required by this Article and 21 CFR 210 through 211 as incorporated in subsection ~~(H)~~ (J) for at least two years after distribution of a drug or one year after the expiration date of a drug, whichever is longer; and
  3. Make the records required by this Article and 21 CFR 210 through 211 as incorporated in subsection ~~(H)~~ (J) available within 48 hours for review by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § ~~32-1901(4)~~ 32-1901(5).
- ~~M.~~** **L.** Inspections. A drug manufacturer permittee shall make the drug manufacturer's facility available for inspection by the Board or its compliance officer under A.R.S. § 32-1904.
- ~~N.~~** **M.** Nonresident drug manufacturer. A nonresident drug manufacturer shall comply with the requirements of R4-23-607.
- ~~O.~~** **N.** Manufacturing radiopharmaceuticals. Before manufacturing a radiopharmaceutical, a drug manufacturer permittee shall:
1. Comply with the regulatory requirements of the Arizona Radiation Regulatory Agency, the U.S. Nuclear Regulatory Commission, the FDA, and this Section; and
  2. ~~Be or employ an Arizona Board licensed authorized nuclear pharmacist as specified in R4-23-681(A);~~

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- ~~3. Comply with the requirements specified in R4-23-682(F)(1), (2), (3), and (5);~~
4. Hold a current Arizona Radiation Regulatory Agency Radioactive Materials License. If a drug manufacturer permittee who manufactures radiopharmaceuticals fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License, the permittee's drug manufacturer permit shall be immediately suspended pending a hearing by the Board;
5. ~~Designate an authorized nuclear pharmacist as the pharmacist in charge. The pharmacist in charge shall:~~
  - ~~a. Communicate Board directives to the management, other pharmacists, interns, and other personnel of the drug manufacturer; and~~
  - ~~b. Ensure compliance with all federal and state drug laws and rules by the drug manufacturer;~~
6. Ensure that an authorized nuclear pharmacist:
  - a. Directly supervises all personnel who perform tasks in the manufacture and distribution of radiopharmaceuticals; and
  - b. Is present at the facility whenever a radiopharmaceutical is manufactured, packaged, repackaged, labeled, relabeled, or distributed.

**R4-23-605. Resident Drug Wholesaler Permit**

- A. Permit. A person shall not operate a business or firm for the wholesale distribution of any drug, device, precursor chemical, or regulated chemical without a current Board-issued full-service or nonprescription drug wholesale permit.
- B. Application.
  1. To obtain a permit to operate a full-service or nonprescription drug wholesale firm in Arizona, a person shall submit a completed application on a form furnished by the Board that includes:
    - a. Whether the application is for a full-service or nonprescription drug wholesale permit;
    - b. Business name, address, mailing address, if different, telephone number, and facsimile number;
    - c. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
    - d. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
    - e. Whether the owner, any officer or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
    - f. Whether the owner or any officer or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
    - g. For a full-service drug wholesale firm:
      - i. The designated representative's name, address, and emergency telephone number;
      - ii. Documentation that the designated representative meets the requirements of A.R.S. § 32-1982(B) and the following as specified in A.R.S. § 32-1982(C):
        - (1) A full set of fingerprints from the designated representative; and
        - (2) The state and federal criminal history record check fee specified by and made payable to the Arizona State Department of Public Safety by money order, certified check, or bank draft; and
      - iii. A \$100,000 bond as specified in A.R.S. § 32-1982(D) submitted on a form supplied by the Board;
    - h. The type of drugs, whether nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
    - i. Plans or construction drawings showing facility size and security for the proposed business;
    - j. Documentation of compliance with local zoning laws;
    - k. For a nonprescription drug wholesale firm, the manager's or designated representative's name, address, emergency telephone number, and resumé indicating educational or experiential qualifications related to drug wholesale operation;
    - l. For an application submitted because of ownership change, the former owner's name and business name, if different;
    - m. Date signed, and applicant's, corporate officer's, partner's, manager's, or designated representative's verified signature and title; and
    - n. Fee specified in R4-23-205.
  2. Before issuing a full-service or nonprescription drug wholesale permit, the Board shall:
    - a. Receive and approve a completed permit application;
    - b. Interview the applicant and the designated representative, if different from the applicant, at a Board meeting;
    - c. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer; and
    - d. For a full-service drug wholesale permit, issue a fingerprint clearance to a qualified designated representative, as specified in subsection (L). If the fingerprint clearance of a designated representative for a full-service drug wholesale permit applicant is denied, the full-service drug wholesale permit applicant shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii).

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- C. Notification.** A resident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the type of drugs sold or distributed, ownership, address, telephone number, name of business, or manager or designated representative, including the manager's or designated representative's telephone number.
1. The resident full-service or nonprescription drug wholesale permittee shall submit a written notice via mail, fax, or e-mail to the Executive Director within 10 days of the change, except any change of ownership requires that the resident full-service or nonprescription drug wholesale permittee comply with subsection (D).
  2. For a change of designated representative, a resident full-service drug wholesale permittee shall submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii). If the fingerprint clearance of a designated representative for a full-service drug wholesale permit applicant is denied, the full-service drug wholesale permit applicant shall appoint another designated representative and submit the documentation, fingerprints, and fee required in subsection (B)(1)(g)(ii).
- D. Change of ownership.** Before a change of ownership occurs that involves changes of stock ownership of more than 30% of the voting stock of a corporation or an existing and continuing corporation that is not actively traded on any securities market or over-the-counter market, the prospective owner shall submit the application packet described under subsection (B).
- E.** Before an existing resident full-service or nonprescription drug wholesaler permittee relocates, the resident full-service or nonprescription drug wholesale permittee shall submit the application packet described under subsection (B), excluding the fee. The facility at the new location shall pass a final inspection by a Board compliance officer before operations begin.
- F.** A resident full-service or nonprescription drug wholesale permittee shall submit the application packet described under subsection (B) for any change of officers in a corporation, excluding the fee and final inspection.
- G. Distribution restrictions.** In addition to the requirements of this subsection, a resident full-service wholesale permittee shall comply with the distribution restrictions specified in A.R.S. § 32-1983.
1. Records.
    - a. A full-service drug wholesale permittee shall:
      - i. Maintain records to ensure full accountability of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;
      - ii. File the records required in subsection (G)(1)(a)(i) in a readily retrievable manner for a minimum of three years;
      - iii. Make the records required in subsection (G)(1)(a)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days; and
      - iv. In addition to the records requirements of subsection (G)(1)(a)(i), provide a pedigree as specified in A.R.S. § 32-1984(E) for all prescription-only drugs that leave the normal distribution channel as defined in A.R.S. § 32-1981.
    - b. A nonprescription drug wholesale permittee shall:
      - i. Maintain records to ensure full accountability of any nonprescription drug, precursor chemical, or regulated chemical including dates of receipt and sales, names, addresses, and DEA registration numbers, if required, of suppliers or sources of merchandise, and customer names, addresses, and DEA registration numbers, if required;
      - ii. File the records required in subsection (G)(1)(b)(i) in a readily retrievable manner for a minimum of three years; and
      - iii. Make the records required in subsection (G)(1)(b)(i) available upon request during regular business hours for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5). Records kept at a central location apart from the business location and not electronically retrievable shall be made available within two business days.
  2. Drug sales.
    - a. A full-service drug wholesale permittee shall:
      - i. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;
      - ii. Not package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical;
      - iii. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, or prescription-only drug or device, to anyone except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;

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- iv. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
  - v. Provide pedigree records upon request, if immediately available, or ~~in no less than~~ within two business days from the date of a request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5);
  - vi. Maintain a copy of the current permit or license of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
  - vii. Provide permit and license records upon request, if immediately available, or ~~in no less than~~ within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).
- b. A nonprescription drug wholesale permittee shall:
- i. Not sell, distribute, give away, or dispose of any nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;
  - ii. Not package, repack, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical;
  - iii. Not sell or distribute any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32;
  - iv. Maintain a record of the current permit or license of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
  - v. Provide permit and license records upon request, if immediately available, or ~~in no less than~~ within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5).
- c. Nothing in this subsection shall be construed to prevent the return of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to the original source of supply.
3. Out-of-state drug sales.
- a. A full-service drug wholesale permittee shall:
- i. Not sell, distribute, give away, or dispose of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;
  - ii. Not package, repack, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical;
  - iii. Not sell, distribute, give away, or dispose of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, to anyone except a person or firm that is properly permitted, registered, licensed, or certified in another jurisdiction;
  - iv. Provide pedigree records upon request, if immediately available, or ~~in no less than~~ within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5);
  - v. Maintain a copy of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and
  - vi. Provide permit, registration, license, and certificate records upon request, if immediately available, or ~~in no less than~~ within two business days from the date of the request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5); and
- b. A nonprescription drug wholesale permittee shall:
- i. Not sell, distribute, give away, or dispose of any nonprescription drug, precursor chemical, or regulated chemical, except in the original container packaged and labeled by the manufacturer or repackager;
  - ii. Not package, repack, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical;
  - iii. Not sell or distribute any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a person or firm that is properly permitted, registered, licensed, or certified in another jurisdiction;
  - iv. Maintain a record of the current permit, registration, license, or certificate of each person or firm who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
  - v. Provide permit, registration, license, or certificate records upon request, if immediately available, or ~~in no less than~~ within two business days from the date of the request of a Board compliance officer or other autho-

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- rized officer of the law as defined in A.R.S. § 32-1901(5).
4. Cash-and-carry sales.
    - a. A full-service drug wholesale permittee shall complete a cash-and-carry sale or distribution of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, only after:
      - i. Verifying the validity of the order;
      - ii. Verifying the identity of the pick-up person for each transaction by confirming that the person or firm represented placed the cash-and-carry order; and
      - iii. For a prescription-only drug order, verifying that the cash-and-carry sale or distribution is used only to meet the immediate needs of a particular patient of the person or firm who placed the cash-and-carry order; and
    - b. A nonprescription drug wholesale permittee shall complete a cash-and-carry sale or distribution of any nonprescription drug, precursor chemical, or regulated chemical, only after:
      - i. Verifying the validity of the order; and
      - ii. Verifying the identity of the pick-up person for each transaction by confirming that the person or firm represented placed the cash-and-carry order.
  - H. Prescription-only drug returns or exchanges. A full-service drug wholesale permittee shall ensure that any prescription-only drug returned or exchanged by a pharmacy or chain pharmacy warehouse under A.R.S. § 32-1983(A) meets the following criteria:
    1. The prescription-only drug is not adulterated or counterfeited, except an adulterated or counterfeited prescription-only drug that is the subject of an FDA or manufacturer recall may be returned for destruction or subsequent return to the manufacturer;
    2. The quantity of prescription-only drug returned or exchanged does not exceed the quantity of prescription-only drug that the full-service drug wholesale permittee or a full-service drug wholesale permittee under common ownership sold to the pharmacy or chain pharmacy warehouse; and
    3. The pharmacy or chain pharmacy warehouse provides documentation that:
      - a. Lists the name, strength, and manufacturer, ~~lot number, and expiration date~~ of the prescription-only drug being returned or exchanged; and
      - b. States that the prescription-only drug was maintained in compliance with storage conditions prescribed on the drug label or manufacturer's package insert.
  - I. Returned, outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, and contraband drugs.
    1. Except as specified in subsection (H)(1) for a prescription-only drug, a full-service drug wholesale permittee shall ensure that the return of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical meets the following criteria.
      - a. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, or otherwise deemed unfit for human or animal consumption shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.
      - b. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical whose immediate or sealed outer or secondary containers or product labeling are misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA. When the immediate or sealed outer or secondary containers or product labeling are determined to be misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, the full-service drug wholesale permittee shall provide notice of the misbranding, counterfeiting, or contrabandage or suspected misbranding, counterfeiting, or contrabandage within three business days of the determination to the Board, FDA, and manufacturer or wholesale distributor from which the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical was acquired.
      - c. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that has been opened or used, but is not adulterated, misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, shall be identified as opened or used, or both, and quarantined and physically separated from other narcotics or other controlled substances, pre-

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- scription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.
- d. If the conditions under which a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the narcotic's or other controlled substance's, prescription-only drug's or device's, nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical shall be quarantined and physically separated from other narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals until the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA, except as provided in subsection (I)(1)(d)(i).
    - i. If examination, testing, or other investigation proves that the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical meets appropriate standards of safety, identity, strength, quality, and purity, it does not have to be destroyed or returned to the manufacturer or wholesale distributor.
    - ii. In determining whether the conditions under which a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the narcotic's or other controlled substance's, prescription-only drug's or device's, nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the full-service drug wholesale permittee shall consider, among other things, the conditions under which the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical has been held, stored, or shipped before or during its return and the condition of the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical and the condition of its container, carton, or product labeling as a result of storage or shipping.
  - e. For any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical identified under subsections (I)(1)(a) or (b), the full-service drug wholesale permittee shall ensure that the identified item or items and other evidence of criminal activity, and accompanying documentation is retained and not destroyed until its disposition is authorized by the Board and the FDA.
2. A nonprescription drug wholesale permittee shall ensure that the return of any nonprescription drug, precursor chemical, or regulated chemical meets the following criteria.
- a. Any nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, or otherwise deemed unfit for human or animal consumption shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.
  - b. Any nonprescription drug, precursor chemical, or regulated chemical whose immediate or sealed outer or secondary containers or product labeling are misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA. When the immediate or sealed outer or secondary containers or product labeling are determined to be misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, the nonprescription drug wholesale permittee shall provide notice of the misbranding, counterfeiting, or contrabandage or suspected misbranding, counterfeiting, or contrabandage within three business days of the determination to the Board, FDA, and manufacturer or wholesale distributor from which the nonprescription drug, precursor chemical, or regulated chemical was acquired.
  - c. Any nonprescription drug, precursor chemical, or regulated chemical that has been opened or used, but is not adulterated, misbranded, counterfeited, or contraband or suspected of being misbranded, counterfeited, or contraband, shall be identified as opened or used, or both, and quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA.
  - d. If the conditions under which a nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity,

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strength, quality, or purity, the nonprescription drug, precursor chemical, or regulated chemical shall be quarantined and physically separated from other nonprescription drugs, precursor chemicals, or regulated chemicals until the nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired as authorized by the Board and the FDA, except as provided in subsection (I)(2)(d)(i).

i. If examination, testing, or other investigation proves that the nonprescription drug, precursor chemical, or regulated chemical meets appropriate standards of safety, identity, strength, quality, and purity, it does not need to be destroyed or returned to the manufacturer or wholesale distributor.

ii. In determining whether the conditions under which a nonprescription drug, precursor chemical, or regulated chemical has been returned cast doubt on the nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, strength, quality, or purity, the nonprescription drug wholesale permittee shall consider, among other things, the conditions under which the nonprescription drug, precursor chemical, or regulated chemical has been held, stored, or shipped before or during its return and the condition of the nonprescription drug, precursor chemical, or regulated chemical and the condition of its container, carton, or product labeling as a result of storage or shipping.

e. For any nonprescription drug, precursor chemical, or regulated chemical identified under subsections (I)(2)(a) or (b), the nonprescription drug wholesale permittee shall ensure that the identified item or items and other evidence of criminal activity, and accompanying documentation is retained and not destroyed until its disposition is authorized by the Board and the FDA.

3. A full-service drug wholesale permittee and nonprescription drug wholesale permittee shall comply with the record-keeping requirements of subsection (G) for all outdated, damaged, deteriorated, adulterated, misbranded, counterfeited and contraband narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.

**J.** Facility. A full-service or nonprescription drug wholesale permittee shall:

1. Ensure that the facility occupied by the full-service or nonprescription drug wholesale permittee is of adequate size and construction, well-lighted inside and outside, adequately ventilated, and kept clean, uncluttered, and sanitary;

2. Ensure that the permittee's warehouse facility:

a. Is secure from unauthorized entry; and

b. Has an operational security system designed to provide protection against theft;

3. In a full-service drug wholesale facility, ensure that only authorized personnel may enter areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is kept;

4. In a nonprescription drug wholesale facility, ensure that only authorized personnel may enter areas where any nonprescription drug, precursor chemical, or regulated chemical is kept;

5. In a full-service drug wholesale facility, ensure that any thermolabile narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;

6. In a nonprescription drug wholesale facility, ensure that any thermolabile nonprescription drug, precursor chemical, or regulated chemical is stored in an area where room temperature is maintained in compliance with storage conditions prescribed on the product label;

7. Make the facility available for inspection by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(5) during regular business hours;

8. In a full-service drug wholesale facility, provide a quarantine area for storage of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, otherwise deemed unfit for human or animal consumption, or that is in an open container; and

9. In a nonprescription drug wholesale facility, provide a quarantine area for storage of any nonprescription drug, precursor chemical, or regulated chemical that is outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, or contraband or suspected of being adulterated, misbranded, counterfeited, or contraband, otherwise deemed unfit for human or animal consumption, or that is in an open container.

**K.** Quality controls.

1. A full-service drug wholesale permittee shall:

a. Ensure that any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that meets the criteria specified in subsection (I)(1) is not sold, distributed, or delivered to any person for human or animal consumption;

b. Ensure that a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;

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- c. Ensure that any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:
    - i. Kept clean,
    - ii. Protected from contamination and other deteriorating environmental factors, and
    - iii. Stored in a manner that complies with applicable federal and state law and official compendium storage requirements;
  - d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is stored; and
  - e. Develop and implement a program to ensure that:
    - i. Any expiration-dated narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;
    - ii. Any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical that has less than 120 days remaining on the expiration date, or is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
    - iii. Any quarantined narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired.
2. A nonprescription drug wholesale permittee shall:
- a. Ensure that any nonprescription drug, precursor chemical, or regulated chemical that meets the criteria specified in subsection (1)(2) is not sold, distributed, or delivered to any person for human or animal consumption;
  - b. Ensure that a nonprescription drug, precursor chemical, or regulated chemical is not manufactured, packaged, repackaged, labeled, or relabeled by any of its employees;
  - c. Ensure that any nonprescription drug, precursor chemical, or regulated chemical stocked, sold, offered for sale, or delivered is:
    - i. Kept clean,
    - ii. Protected from contamination and other deteriorating environmental factors, and
    - iii. Stored in a manner that complies with applicable federal and state law and official compendium storage requirements;
  - d. Maintain manual or automatic temperature and humidity recording devices or logs to document conditions in areas where any nonprescription drug, precursor chemical, or regulated chemical is stored; and
  - e. Develop and implement a program to ensure that:
    - i. Any expiration-dated nonprescription drug, precursor chemical, or regulated chemical is reviewed regularly;
    - ii. Any nonprescription drug, precursor chemical, or regulated chemical that has less than 120 days remaining on the expiration date, or is deteriorated, damaged, or does not comply with federal law, is moved to a quarantine area and not sold or distributed; and
    - iii. Any quarantined nonprescription drug, precursor chemical, or regulated chemical is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired.
- L. Fingerprint clearance.
- 1. After receiving the state and federal criminal history record of a designated representative, the Board shall compare the record with the list of criminal offenses that preclude a designated representative from receiving a fingerprint clearance. If the designated representative's criminal history record does not contain any of the offenses listed in subsection (L)(2), the Board shall issue the designated representative a fingerprint clearance.
  - 2. The Board shall not issue a fingerprint clearance to a designated representative who is awaiting trial for or who has been convicted of committing or attempting or conspiring to commit one or more of the following offenses in this state or the same or similar offenses in another state or jurisdiction:
    - a. Unlawfully administering intoxicating liquors, controlled substances, dangerous drugs, or prescription-only drugs;
    - b. Sale of peyote;
    - c. Possession, use, or sale of marijuana, dangerous drugs, prescription-only drugs, or controlled substances;
    - d. Manufacture or distribution of an imitation controlled substance;
    - e. Manufacture or distribution of an imitation prescription-only drug;
    - f. Possession or possession with intent to use an imitation controlled substance;
    - g. Possession or possession with intent to use an imitation prescription-only drug; or
    - h. A felony offense involving sale, distribution, or transportation of, offer to sell, transport, or distribute, or conspiracy to sell, transport, or distribute marijuana, dangerous drugs, prescription-only drugs, or controlled substances.
  - 3. If after conducting a state and federal criminal history record check the Board determines that it is not authorized to issue a fingerprint clearance, the Board shall notify the full-service drug wholesale applicant or permittee that



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**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:**

None

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

The Board expects that updating R4-30-247 will benefit all parties involved in its regulatory processes. This proposed rulemaking will incorporate legislatively authorized inspections of Swimming Pools and Spas into the Board's rule defining what constitutes a home inspection in Arizona.

The proposed rule change will not impose any additional costs for small home inspection businesses in Arizona. It proposes to exempt those home inspectors who have been certified prior to February 28, 2012, from any additional or testing requirements related to swimming pools and spas. The proposed rule change does not require home inspectors to include inspections of swimming pools and spas in their inspection reports. But, it will require those who choose to conduct these inspections to comply with the Board's adopted Standards of Practice in order to protect the public's health, safety and welfare.

The proposed rulemaking is not expected to have a significant impact on the following sectors of the economy: 1) the competitiveness of professionals in Arizona compared to their counterparts from other states; 2) the prices of goods and services in the state; 3) state revenues. Any additional administrative costs to state agencies, such as to the Board, the Secretary of State's Office, and the Governor's Regulatory Review Council, are not expected to be significant.

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

The Board changed the language used in subsection (B) to reflect the Board's original intent of incorporating the "Standards of Professional Practice for the Inspection of Swimming Pools & Spas for Arizona Home Inspectors" by changing the date listed to the version of the adopted standards rather than the date the standards were adopted by the Board in conformity with A.R.S. § 41-1028(B) (requiring the incorporated material to be fully identified by date). In addition, the Board added the location at which a person may obtain a copy of the standards from the organization originally issuing the incorporated matter, in conformity with the requirements of A.R.S. § 41-1028(D).

The Board also modified the language of subsection (F) from exempting registrants certified prior to February 28, 2012, from "any additional education or testing requirements" to more accurately reflect the Board's original intent of only exempting such registrants from "additional education or testing requirements relating to pools and spas." The Board also made minor clerical and grammatical corrections to this Notice of Final Rulemaking at the suggestion of GRRC staff.

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

BTR received no comments about the rulemaking and issued no responses.

**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:**

Not applicable

**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:**

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:**

Not applicable

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

In R4-30-247(B), the Board incorporated, without any later amendments or editions, "The Standards of Professional Practice for the Inspection of Swimming Pools and Spas for Arizona Home Inspectors," adopted on March 11, 2011, and published by the Arizona Chapter of the American Society of Home Inspectors.

**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:**

Not applicable

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

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 30. BOARD OF TECHNICAL REGISTRATION**

**ARTICLE 2. REGISTRATION PROVISIONS**

Section

R4-30-247. Home Inspector Certification

**ARTICLE 2. REGISTRATION PROVISIONS**

**R4-30-247. Home Inspector Certification**

- A.** An applicant for certification as a home inspector shall submit an original and one copy of a completed application package that contains the following:
1. Evidence of successful completion, within two years before the date of application, of the National Home Inspector Examination as administered by the Examination Board of Professional Home Inspectors;
  2. The information in subsections (B)(1) through (10);
  3. A completed fingerprint card;
  4. Applicable fees;
  5. Evidence of successful completion of ~~80~~ 84 hours of classroom training or an equivalent course conducted by an educational facility that is licensed by the applicable post-secondary education regulatory agency in the home state of the facility, or accredited by the Accrediting Commission of the Distance Education and Training Council, or by an accrediting agency approved by the United States Department of Education. The course of study shall encompass all of following major content areas:
    - a. Structural Components,
    - b. Exterior,
    - c. Roofing,
    - d. Plumbing,
    - e. Heating,
    - f. Cooling,
    - g. Electrical,
    - h. Insulation and Ventilation,
    - i. Interiors,
    - j. Fireplaces and Solid Fuel-Burning Devices, ~~and~~
    - k. ~~Professional Practice; and Swimming Pools & Spas, and~~
    - l. Professional Practice;
  6. An applicant who has lawfully conducted home inspections as part of a business shall provide evidence of successful completion of 100 home inspections that meet the standards referenced in R4-30-301.01 on a form provided by the Board. An applicant under this subsection shall meet all other requirements for certification in this Section, and;
  7. To complete a home inspector in-training program, an applicant who otherwise qualifies for certification as a home inspector except for meeting the qualification in subsection (A)(6), shall present evidence of completion of 30 parallel inspections. The 30 parallel inspections and home inspection report shall meet the standards in R4-30-301.01 and be retained by the applicant for at least two years from the date of application. The applicant shall conduct these inspections on separate residential dwelling units and shall list them on a log provided by the Board. The log shall include, with respect to each inspection, the address of the property, the date of the inspection, and the name and certification number of the supervising home inspector. The Board may hold the applicant's package for a period of one year based solely on the need for time to permit the applicant to complete the required parallel inspections. All time-frames promulgated under A.R.S. Title 41, Chapter 6, Article 7.1 are suspended during this period.
- B.** A certified home inspector is not required to inspect a pool and/or spa as part of a home inspection. If a certified home inspector conducts a pool and/or spa inspection, it shall be conducted in accordance with the "Standards of Professional Practice for the Inspection of Swimming Pools & Spas for Arizona Home Inspectors," ("Standards") adopted and published by Arizona Chapter of the American Society of Home Inspectors on March 11, 2011, and incorporated by reference, without any later amendments or editions, by the Board on February 28, 2012. Copies of the Standards are available at the Board's office and at the Arizona Chapter of the American Society of Home Inspectors' web site, [www.azashi.org](http://www.azashi.org).
- B.C.** The application package shall contain the following:
1. Name, residence address, mailing address if different from residence address, and telephone number;
  2. Date of birth and ~~social security~~ Social Security number of the applicant;
  3. Citizenship or legal residence;

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4. A detailed explanatory statement regarding:
    - a. Any disciplinary action, including suspension and revocation, taken by any state or jurisdiction on any professional or occupational registration, license, or certification held by the applicant in any state or jurisdiction;
    - b. Refusal of any professional or occupational registration, license, or certification by any state or jurisdiction;
    - c. Any pending disciplinary action in any state or jurisdiction on any professional or occupational registration, license, or certification held by the applicant;
    - d. Any alias or other name used by the applicant;
    - e. Any conviction for a felony or misdemeanor, other than a minor traffic violation.
  5. Documentation of absolute discharge from sentence at least five years before the date of application if an applicant has been convicted of one or more felonies;
  6. State or jurisdiction in which any professional or occupational registration, license or certification is held; type of registration, license, or certification; number; year granted, and how registration, license, or certification was granted (that is, by examination, education, experience, or reciprocity);
  7. The current status of any application for any type of professional or occupational registration, license, or certification pending in another state or jurisdiction;
  8. A release authorizing the Board to investigate the applicant's education, experience, and moral character and repute;
  9. Certification that the information provided to the Board is accurate, true, and complete;
  10. Copy of one report that meets the standards in R4-30-301.01; and
  11. Sworn statement or statements by the supervising certified home inspector or inspectors that the parallel inspections conducted by the applicant meet the standards in R4-30-301.01.
- C.D.** The Board staff shall review all applications and, if necessary, refer completed applications to the Home Inspector Rules and Standards Committee for evaluation. If the application is complete and in the proper form, the Board staff or committee is satisfied that all statements on the application are true, and the applicant is eligible in all other aspects to be certified as a home inspector, the Board staff or committee shall recommend that the Board certify the applicant. If the evidence is not clear and convincing of qualification for certification, the matter shall be reviewed by the committee and the committee may request additional information regarding any issue upon which the applicant has not established qualification by clear and convincing evidence.
- D.E.** A certified home inspector shall notify the Board in writing within five business days of any loss of, or change in, financial assurance. The Board shall suspend the certificate holder's certification immediately and prohibit further home inspections until current proof of financial assurance is provided to the Board. The Board shall revoke a certificate if the certificate holder fails to provide proof of financial assurance within 90 days of loss of financial assurance or lapse of policy. All certified home inspectors shall provide proof of financial assurance at the time of each annual certification renewal. The Board shall not renew a home inspector certification unless the financial assurance is in full force and effect.
- E.** A registrant who has been certified by the Board to conduct home inspections prior to February 28, 2012, will be exempt from any additional education or testing requirements relating to pools and spas.