

## NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

### NOTICE OF PROPOSED RULEMAKING

#### TITLE 4. PROFESSIONS AND OCCUPATIONS

#### CHAPTER 23. BOARD OF PHARMACY

[R07-52]

#### PREAMBLE

- 1. Sections Affected**

R4-23-110	Amend
R4-23-605	Amend
R4-23-607	Amend
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3)  
Implementing statutes: A.R.S. §§ 32-1981, 32-1982, 32-1983, 32-1984, and 32-1985
- 3. A list of all previous notices appearing in the Register addressing the proposed rules:**

Notice of Rulemaking Docket Opening: 12 A.A.R. 3074, August 25, 2006
- 4. The name and address of agency personnel with whom persons may communicate regarding the rules:**

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Ste. 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@cox.net
- 5. An explanation of the rules, including the agency's reasons for initiating the rules:**

During the 2005 legislative session, the Legislature passed a bill adding Article 3.1 (Regulation of Full Service Wholesale Permittees) to A.R.S. Title 32 (Professions and Occupations) Chapter 18 (Pharmacy). The new Article 3.1 contains five sections: § 32-1981 (Definitions), § 32-1982 (Full service wholesale permittees; bonds; designated representatives; application), § 32-1983 (Restrictions on transactions), § 32-1984 (Pedigrees; electronic files), and § 32-1985 (Injunctive relief). In order to implement the changes made by the 47th Legislature, the Board is amending R4-23-605 (Resident Drug Wholesaler Permit) and R4-23-607 (Nonresident Permits) to incorporate new requirements for designated representatives, bonds, fingerprints, pedigrees, and drug return and exchanges as specified in A.R.S. Article 3.1. A new subsection detailing requirements for returned, outdated, damaged, deteriorated, adulterated, misbranded, counterfeited, and contraband drugs will be added to R4-23-607 to bring the rules up to standards established in the National Association of Boards of Pharmacy (NABP) Model Rules.

The Board staff discovered that many licensees and permittees are not aware that precursor chemical and regulated chemical are defined in A.R.S. Title 13 (Criminal Code) Chapter 34 (Drug Offenses). The rulemaking will add a definition for "precursor chemical" and "regulated chemical" to R4-23-110 (Definitions), so the definitions of those terms will be readily available to the Board's licensees and permittees. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

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The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing the standards for resident and nonresident drug wholesaler permittees.

**6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rules and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:**

The agency did not review or rely on any study relevant to these rules.

**7. A showing of good cause why the rules are 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

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

The proposed rules will impact the Board, drug wholesalers, and the public. The proposed rules' impact on the Board will be the usual rulemaking-related costs which are minimal. The Board estimates the proposed rules will have minimal to moderate economic impact on Board office operations through increased staff time to process drug wholesaler permit applications, including verifying the criminal records history check and issuing fingerprint clearances. The Board estimates the proposed rules will have minimal economic impact on drug wholesalers. The proposed rules will require a full-service drug wholesale permittee to submit a full set of fingerprints from the permittee's designated representative and a criminal history record check fee specified by and made payable to the Arizona Department of Public Safety. A person will pay about \$12 to \$15 to have a fingerprint card prepared by a local police department and the current fee for a federal and state criminal history record check is \$29. The total cost for a criminal history record check will be between \$41 and \$44. The cost of preparing a fingerprint card and the DPS federal and state criminal history record check fee will have a minimal economic impact on full-service drug wholesalers and will help ensure that only people with clean records are allowed to oversee the operations of a full-service drug wholesale firm. The proposed rules have no economic impact on the public.

The public, Board, pharmacies, and pharmacists benefit from rules that are clear, concise, and understandable. The proposed rules benefit the public and the pharmacy community by clearly establishing the standards for resident and nonresident drug wholesaler permittees.

**9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**

Name: Dean Wright, Compliance Officer  
Address: Board of Pharmacy  
4425 W. Olive Ave., Ste. 140  
Glendale, AZ 85302  
Telephone: (623) 463-2727, ext. 131  
Fax: (623) 934-0583  
E-mail: rxcop@cox.net

**10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:**

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, April 23, 2007. An oral proceeding is scheduled for:

Date: April 23, 2007  
Time: 10:00 a.m.  
Location: 4425 W. Olive Ave., Ste. 140  
Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed above.

**11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**

Not applicable

**12. Incorporations by reference and their location in the rules:**

None

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

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

**ARTICLE 1. ADMINISTRATION**

Section  
R4-23-110. Definitions

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

Section  
R4-23-605. Resident Drug Wholesaler Permit  
R4-23-607. Nonresident Permits

**ARTICLE 1. ADMINISTRATION**

**R4-23-110. Definitions**

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to A.A.C. Title 4 Chapter 23:

- “Active ingredient” No change
- “Alternate physician” No change
- “Approved course in pharmacy law” No change
- “Approved Provider” No change
- “Authentication of product history” No change
- “Batch” No change
- “Beyond-use date” No change
- “Biological safety cabinet” No change
- “Care-giver” No change
- “Community pharmacy” No change
- “Component” No change
- “Compounding and dispensing counter” No change
- “Computer system” No change
- “Computer system audit” No change
- “Contact hour” No change
- “Container” No change
- “Continuing education” No change
- “Continuing education activity” No change
- “Continuing education unit” or “CEU” No change
- “Correctional facility” No change
- “CRT” No change
- “Current good compounding practices” No change
- “Current good manufacturing practice” No change
- “Cytotoxic” No change
- “Day” No change
- “DEA” No change
- “Dietary supplement” No change
- “Dispensing pharmacist” No change
- “Drug sample” No change
- “Drug therapy management” No change
- “Drug therapy management agreement” No change
- “Eligible patient” No change
- “Extreme emergency” No change
- “FDA” No change
- “Immediate notice” No change

“Inactive ingredient” No change  
“Internal test assessment” No change  
“ISO Class 5 environment” No change  
“ISO Class 7 environment” No change  
“Limited-service correctional pharmacy” No change  
“Limited-service long-term care pharmacy” No change  
“Limited-service mail-order pharmacy” No change  
“Limited-service nuclear pharmacy” No change  
“Limited-service pharmacy permittee” No change  
“Limited-service sterile pharmaceutical products pharmacy” No change  
“Long-term care consultant pharmacist” No change  
“Long-term care facility” or “LTCF” No change  
“Lot” No change  
“Lot number” or “control number” No change  
“Materials approval unit” No change  
“Mediated instruction” No change  
“MPJE” No change  
“NABP” No change  
“NABPLEX” No change  
“NAPLEX” No change  
“Other designated personnel” No change  
“Outpatient” No change  
“Outpatient setting” No change  
“Patient profile” No change  
“Pharmaceutical patient care services” No change  
“Pharmaceutical product” No change  
“Pharmacist-administered immunizations training program” No change  
“Pharmacy counter working area” No change  
“Pharmacy law continuing education” No change  
“Pharmacy permittee” No change  
“Precursor chemical” means any substance listed in A.R.S. § 13-3401(26) and (27).  
“Prepackaged drug” No change  
“Prep area” No change  
“Proprietor” No change  
“Provider pharmacy” No change  
“Radiopharmaceutical” No change  
“Radiopharmaceutical quality assurance” No change  
“Radiopharmaceutical services” No change  
“Red C stamp” No change  
“Refill” No change  
“Regulated chemical” means any substance listed in A.R.S. § 13-3401(30).  
“Remodel” No change  
“Remote drug storage area” No change  
“Resident” No change  
“Responsible person” No change  
“Score transfer” No change

- “Sight-readable” No change
- “Single-drug audit” No change
- “Single-drug usage report” No change
- “Standard-risk sterile pharmaceutical product” No change
- “Sterile pharmaceutical product” No change
- “Strength” No change
- “Substantial-risk sterile pharmaceutical product” No change
- “Supervision” No change
- “Supervisory physician” No change
- “Supplying” No change
- “Support personnel” No change
- “Transfill” No change
- “Verified signature” or “signature verifying” No change
- “Wholesale distribution” No change
- “Wholesale distributor” No change

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

**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. The type of 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, 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 bond as specified in A.R.S. § 32-1982(D) submitted on a form supplied by the Board;
    - ~~g-h.~~ The type of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
    - ~~h-i.~~ Plans or construction drawings showing facility size and security adequate for the proposed business;
    - ~~i-j.~~ Documentation of compliance with local zoning laws;
    - ~~j-k.~~ Manager’s or responsible person’s For a nonprescription drug wholesale firm, the manager’s or designated representative’s name, address, emergency telephone number, and ~~resume~~ resumé indicating educational or experiential qualifications related to drug wholesale operation;
    - ~~k-l.~~ For an application submitted because of ownership change, the former owner’s name and business name, if different;
    - ~~l-m.~~ Date signed, applicant’s, corporate officer’s, partner’s, manager’s, or ~~responsible person’s~~ designated representative’s verified signature and title; and
    - ~~m-n.~~ Fee specified in R4-23-205.
  - 2. Before issuing a full-service or nonprescription drug wholesale permit, the Board shall:

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- a. Receive and approve a completed permit application;
  - b. Interview the applicant and the ~~responsible person~~ designated representative, if different from the applicant, at a Board meeting; ~~and~~
  - 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 a full-service drug wholesale permit applicant's designated representative's fingerprint clearance 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).
- 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, manager, or ~~responsible person~~ designated representative, including manager's or ~~responsible person's~~ designated representative's telephone number. 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 24 hours of the change, except any change of ownership requires that the resident full-service or nonprescription drug wholesale permittee comply with subsection (D). 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 a full-service drug wholesale permit applicant's designated representative's fingerprint clearance 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 R4-23-605(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 R4-23-605(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 R4-23-605(B) for any change of officers in a corporation, excluding the fee and final inspection.
- G. Distribution restrictions. In addition to 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 ~~(D)(G)~~(1)(a)(i) in a readily retrievable manner for a minimum of ~~two~~ three years; ~~and~~
      - iii. Make the records required in subsection ~~(D)(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(4). 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 ~~(D)(G)~~(1)(b)(i) in a readily retrievable manner for a minimum of ~~two~~ three years; ~~and~~
      - iii. Make the records required in subsection ~~(D)(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(4). 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;
  - 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. Maintain a copy of each pedigree required by A.R.S. § 32-1984;
  - vi. Provide pedigree records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) or in no less than two business days from the date of the request;
  - ~~vii.~~ 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
  - ~~viii.~~ Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) or in no less than two business days from the date of the request.
  - 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, repackage, 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 of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) or in no less than two business days from the date of the request.
  - 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, 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, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, to anyone except a properly permitted, registered, licensed, or certified person or firm of other jurisdictions;
    - iv. Maintain a copy of each pedigree required by A.R.S. § 32-1984;
    - v. Provide pedigree records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) or in no less than two business days from the date of the request;
    - ~~vi.~~ 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
    - ~~vii.~~ Provide permit, registration, license, and certificate records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) or in no less than two business days from the date of the request; 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, repackage, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical;

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- iii. Not sell or distribute, any nonprescription drug, precursor chemical, or regulated chemical, to anyone except a properly permitted, registered, licensed, or certified person or firm of 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 of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) or in no less than two business days from the date of the request.
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; ~~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; 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 sold to the pharmacy or chain pharmacy warehouse; and
  3. The pharmacy or chain pharmacy warehouse provides documentation that:
    - a. Lists the name, strength, 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 R4-23-605(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, 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 either the manufacturer or wholesale distributor from which it was acquired;
    - 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 either the manufacturer or wholesale distributor from which it was acquired. 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 such, and 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 either the manufacturer or wholesale distributor from which it was acquired;
  - 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 either the manufacturer or wholesale distributor from which it was acquired, unless 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. 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 its container, carton, or product labeling as a result of storage or shipping; and
  - 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, 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 either the manufacturer or wholesale distributor from which it was acquired;
  - 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 either the manufacturer or wholesale distributor from which it was acquired. 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 such, and 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 either the manufacturer or wholesale distributor from which it was acquired;
  - d. If the conditions under which a nonprescription drug, precursor chemical, or regulated chemical has been

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returned cast doubt on the nonprescription drug's, precursor chemical's, or regulated chemical's safety, identity, 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 either the manufacturer or wholesale distributor from which it was acquired, unless 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. 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 its container, carton, or product labeling as a result of storage or shipping; and

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; and

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.

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

1. Ensure that the facility occupied by a 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 warehouse facility:
  - a. Is secure from unauthorized entry; and
  - b. Has an operational security system designed to provide protection against theft and diversion;
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(4) 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, ~~misbranded~~, adulterated, ~~misbranded~~, counterfeited, or contraband, 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, ~~misbranded~~, adulterated, ~~misbranded~~, counterfeited, or contraband, suspected of being adulterated, misbranded, counterfeited, or contraband, otherwise deemed unfit for human or animal consumption, or that is in an open container.

**I.K.** Quality controls.

1. A full-service drug wholesale permittee shall:
  - a. Ensure that any ~~fire, flood, or otherwise damaged or deteriorated~~ 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;
  - 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. ~~In compliance~~ Compliant 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, 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 its source of supply.
2. A nonprescription drug wholesale permittee shall:
- a. Ensure that any ~~fire, flood, or otherwise damaged or deteriorated~~ 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. ~~In compliance~~ Compliant 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, 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 its source of supply.

**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 the 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. A designated representative who is awaiting trial 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 is precluded from receiving a fingerprint clearance:
  - 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. Felony offenses 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. The full-service drug wholesale applicant or permittee shall assume the costs of fingerprint checks and may charge these costs to the designated representative.
4. 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 employs the designated representative that the Board is not authorized to issue a fingerprint clearance. This notice shall include the criminal history information on which the denial was based. This criminal history information is subject to dissemination restrictions under A.R.S. § 41-1750 and Public Law 92-544.

5. The Board is not liable for damages resulting from:
  - a. The issuance of a fingerprint clearance to a person who is later found to have been ineligible to receive a fingerprint clearance at the time the clearance was issued; or
  - b. The denial of a fingerprint clearance to a person who is later found to have been eligible to receive a fingerprint clearance at the time the clearance was denied.
6. The issuance of a fingerprint clearance does not entitle a person to employment.

**R4-23-607. Nonresident Permits**

- A. Permit. A person, who is not a resident of Arizona, shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:
  1. ~~A Possessing a~~ Possessing a current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit; ~~and~~
  2. ~~A Possessing a~~ Possessing a current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
  3. Employing a pharmacist, designated as the pharmacist-in-charge, who possesses a current Arizona Board-issued pharmacist license; and
  4. For a nonresident pharmacy permit issued before the effective date of subsection (A)(3), complying with subsection (A)(3) and submitting to the Board the pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number by November 1, 2007.
- B. Application. To obtain a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesale, or nonprescription drug permit, 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. A copy of the applicant's current equivalent license or permit, issued by the licensing authority in the jurisdiction where the person or firm resides and required by subsection (A)(2);
  6. For an application submitted because of ownership change, the former owner's name and business name, if different;
  7. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, pharmacist-in-charge's, or ~~responsible person's~~ designated representative's verified signature and title; and
  8. Fee specified in R4-23-205.
- C. In addition to the requirements of subsection (B), the following information is required:
  1. Nonresident pharmacy.
    - a. The type of pharmacy;
    - b. Whether the owner, any officer, or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
    - c. If applying for a hospital pharmacy permit, the number of beds, manager's or administrator's name, and a copy of the hospital's current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
    - d. Pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number; and
    - e. For an application submitted because of ownership change, the former pharmacy's name, address, and permit number; and
  2. Nonresident manufacturer.
    - a. 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;
    - b. A copy of the drug list required by the FDA;
    - c. Manager's or responsible person's name, address, and emergency telephone number; and
    - d. The firm's current FDA drug manufacturer or repackager registration number and expiration date; and
  3. Nonresident full-service drug wholesaler.

- a. The designated representative's name, address, and emergency telephone number;
- b. 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):
  - i. A full set of fingerprints from the designated representative; and
  - ii. 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
- c. A bond as specified in A.R.S. § 32-1982(D) submitted on a form supplied by the Board; and

**3-4.** Nonresident full-service or nonprescription drug wholesaler.

- a. The type of drug wholesale permit;
- b. Whether the owner, 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;
- c. The types of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
- d. ~~Manager's or responsible person's~~ designated representative's name, address, emergency telephone number, and ~~resume~~ resumé indicating educational or experiential qualifications related to drug wholesale operation; and

**4-5.** Nonresident nonprescription drug retailer.

- a. Whether applying for Category I or Category II permit;
- b. Date business started or planned opening date; and
- c. Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine.

**D.** Before issuing a nonresident full-service drug wholesale permit, the Board shall:

- 1. Receive and approve a completed permit application; and
- 2. Issue a fingerprint clearance to a qualified designated representative, as specified in R4-23-605(L). If a nonresident full-service drug wholesale permit applicant's designated representative's fingerprint clearance is denied, the nonresident full-service drug wholesale permit applicant shall appointment another designated representative and submit the documentation, fingerprints, and fee required in subsection (C)(3)(b).

**~~D.~~E.** Notification. A permittee shall submit any notification of change required in this subsection as 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 nonresident permittee comply with subsection (F).

- 1. Nonresident pharmacy. A nonresident pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, ownership, address, telephone number, name of business, or pharmacist-in-charge.
- 2. Nonresident manufacturer. A nonresident manufacturer permittee shall notify the Board of changes involving listed drugs, ownership, address, telephone number, name of business, or manager, including manager's telephone number.
- 3. Nonresident drug wholesaler. A nonresident full-service or nonprescription drug wholesale permittee shall notify the Board of changes involving the types of drugs sold or distributed, ownership, address, telephone number, name of business, ~~or manager or~~ designated representative, including manager's ~~or designated representative's~~ telephone number. For a change of designated representative, a nonresident full-service drug wholesale permittee shall submit the documentation, fingerprints, and fee required in subsection (C)(3)(b). If a nonresident full-service drug wholesale permit applicant's designated representative's fingerprint clearance is denied, the nonresident full-service drug wholesale permittee shall appointment another designated representative and submit the documentation, fingerprints, and fee required in subsection (C)(3)(b).
- 4. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall notify the Board of changes involving permit category, ownership, address, telephone number, name of business, or manager, including manager's telephone number.

**F.** 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 appropriate application packet described under subsections (B) and (C).

**~~E.~~G.** Drug Sales.

- 1. Nonresident pharmacy. A nonresident pharmacy permittee shall:
  - a. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except:
    - i. A pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board;
    - ii. A medical practitioner currently licensed under A.R.S. Title 32; or
    - iii. An Arizona resident upon receipt of a valid prescription order for the resident;
  - b. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except:
    - i. A pharmacy, drug manufacturer, full-service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board;

- ii. A medical practitioner currently licensed under A.R.S. Title 32; or
  - iii. An Arizona resident either upon receipt of a valid prescription order for the resident or in the original container packaged and labeled by the manufacturer;
  - c. Except for a drug sale that results from the receipt and dispensing of a valid prescription order for an Arizona resident, maintain a copy of the current permit or license of each person or firm in Arizona 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
  - d. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
2. Nonresident manufacturer. A nonresident manufacturer permittee shall:
- a. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona 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;
  - b. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona 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;
  - c. Maintain a copy of the current permit or license of each person or firm in Arizona 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
  - d. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
3. Nonresident full-service drug wholesaler. ~~A~~ In addition to complying with the distributions restrictions specified in A.R.S. § 32-1983, a nonresident full-service drug wholesaler permittee shall:
- a. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona 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;
  - b. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona 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;
  - ~~c.~~ Maintain a copy of each pedigree required by A.R.S. § 32-1984;
  - ~~d.~~ Provide pedigree records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4) or in no less than two business days from the date of the request;
  - ~~e-e.~~ Maintain a copy of the current permit or license of each person or firm in Arizona 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
  - ~~f.~~ Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
4. Nonresident nonprescription drug wholesaler. A nonresident nonprescription drug wholesaler permittee shall:
- a. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona 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;
  - b. Maintain a copy of the current permit or license of each person or firm in Arizona who buys, receives, or disposes of any nonprescription drug, precursor chemical, or regulated chemical; and
  - c. Provide permit and license records upon request of a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).
5. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall not:
- a. Sell, distribute, give away, or dispose of, a nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona except in the original container packaged and labeled by the manufacturer;
  - b. Package, repackage, label, or relabel any drug, precursor chemical, or regulated chemical; or
  - c. Sell, distribute, give away, or dispose of, any drug, precursor chemical, or regulated chemical to anyone in Arizona that exceeds its expiration date, is contaminated or deteriorated from excessive heat, cold, sunlight, moisture, or other factors, or does not comply with federal law.
- F.H.** When selling or distributing any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona, a nonresident pharmacy, nonresident manufacturer, nonresident full-service or nonprescription drug wholesaler, or nonprescription drug permittee shall comply with federal law, the permittee's resident state drug law, and this Section.