

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;
 - ~~11.10.~~ 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:
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 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);~~
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).
- 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;

- 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, 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, 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, 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 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, 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 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 authorized 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, 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.
- 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, 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 recordkeeping 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;
 - 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 (I)(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 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 federal law.
4. The issuance of a fingerprint clearance does not entitle a person to employment.