

This is an amendment to 16.19.8 NMAC, Section 9 effective 8/12/2025

**16.19.8.9 MINIMUM REQUIRED INFORMATION FOR WHOLESALE DRUG DISTRIBUTION LICENSURE:**

**A.** Every wholesale distributor who engages in the wholesale distribution of drugs shall be licensed with the board by submitting an application and providing information required by the board on an application approved by the board including:

(1) applicant's full name; all trade or business names used by the licensee (includes "is doing business as" and "formerly known as") which cannot be identical to the name used by another unrelated wholesale distributor, third-party logistics provider, or repackager licensed by the board; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including:  
(a) if a person, the name, address, social security number or Federal Employer Identification Number (FEIN), and date of birth;

(b) if other than a person, the name, address, social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c) if a corporation, the state of incorporation; and

(d) if a publicly traded corporation, the information in Subparagraph (b) of this paragraph is not required for corporate officers and corporate directors;

(e) any other relevant information that the board requires;

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the wholesale distributor that engages in the distribution of drugs;

(5) evidence of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;

(6) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the wholesale drug distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess and distribute drugs;

(7) a list of all disciplinary actions or any other sanction by state and federal agencies against the wholesale distributor as well as any such actions against principals, owners, directors or officers;

(8) a full description of each facility and warehouse located in New Mexico, including all locations utilized for drug storage or distribution; the description must include the following:

(a) square footage;

(b) security and alarm system descriptions;

(c) terms of lease or ownership;

(d) address and;

(e) temperature and humidity controls;

(9) a description of the wholesale distributor's drug import and export activities;

(10) a copy of the wholesale distributor's written policies and procedures as required in Subsection I of 16.19.8.13 NMAC, (Written policies and procedures);

(11) a facility located outside of New Mexico shall submit a copy of a current satisfactory inspection report issued by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such wholesale distributor, or by the board;

(12) the information collected pursuant to Paragraphs (5), (8) and (10) of this subsection shall be made available only to the board, and to state and federal law enforcement officials; the board shall make provisions for protecting the confidentiality of the information collected under this section.

(13) renewal applications shall be on a form furnished by the board.

**B.** Every wholesale drug distributor who engages in wholesale distribution shall submit a reasonable fee to be determined by the board.

C. Each facility located in New Mexico that engages in wholesale drug distribution must undergo an inspection by the board for the purpose of inspecting the wholesale drug distribution facility and operations prior to initial licensure. Manufacturing facilities located outside of this state are exempt from inspection by the board if the manufacturing facilities are currently registered with the food and drug administration in accordance with Section 510 of the Federal Act.

D. All wholesale distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the board.

E. Changes in any information in this section shall be submitted to the board within 30 days of such change unless otherwise noted.

F. Information submitted by the wholesale drug distributor to the board that is considered trade secret or proprietary information as defined under this states privacy and trade secret or proprietary statutes shall be maintained by the board as private or trade secret proprietary information and be exempt from public disclosure.

G. The board shall have the authority to recognize a third-party to accredit and inspect wholesale distributors.

H. The board may license by reciprocity, a wholesale distributor that is licensed under the laws of another state if:

(1) the applicant submits documentation of a current satisfactory inspection conducted by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such wholesale distributor, or the board; and

(2) the requirements of that state are deemed by the board to be substantially equivalent.

~~I. Every wholesale distributor must furnish a bond or other equivalent means of security, as follows:~~  
~~(1) for the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of \$100,000 or other equivalent means of security acceptable to the board;~~

~~(2) for purposes of Paragraph (1) above, the board may accept a surety bond in the amount of \$25,000 if the annual gross receipts of the previous tax year for the wholesaler is \$10,000,000 or less;~~

~~(3) if a wholesale distributor can provide evidence that it possesses the required bond in a state, the requirement for a bond in New Mexico shall be waived.]~~

[16.19.8.9 NMAC - Rp, 16.19.8.9 NMAC, 11/28/2017; A 10/10/2023; A, 8/12/2025]