# WEST VIRGINIA CODE: §60a-8-7

**§60A-8-7. Wholesale drug distributor licensing requirements.**

(a) Every applicant for a license under this article shall provide the board with the following as part of the application for a license and as part of any renewal of such license:

(1) The name, full business address and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers and the names of contact persons for all facilities used by the licensee for the storage, handling and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation or sole proprietorship);

(5) The name(s) of the owner and operator, or both, of the licensee, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation; and

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) Any other information or documentation that the board may require.

(b) All wholesale distributors and pharmacy distributors shall be subject to the following requirements:

(1) No person or distribution outlet may act as a wholesale drug distributor without first obtaining a license to do so from the Board of Pharmacy and paying any reasonable fee required by the Board of Pharmacy, such fee not to exceed four hundred dollars per year: Provided, That for licenses that are effective on and after July 1, 2012, the annual fee shall be $750 per license until modified by legislative rule. All fees collected pursuant to this section shall be used for the operation and implementation of the West Virginia Controlled Substances Monitoring Program database or in the same manner as those fees governed by article five, chapter thirty of this code.

(2) The Board of Pharmacy may grant a temporary license when a wholesale drug distributor first applies to the board for a wholesale drug distributor's license and the temporary license shall remain valid until the Board of Pharmacy finds that the applicant meets or fails to meet

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the requirements for regular licensure, except that no temporary license shall be valid for more than ninety days from the date of issuance. Any temporary license issued pursuant to this subdivision shall be renewable for a similar period of time not to exceed ninety days pursuant to policies and procedures to be prescribed by the Board of Pharmacy.

(3) No license may be issued or renewed for a wholesale drug distributor to operate unless the distributor operates in a manner prescribed by law and according to the rules promulgated by the Board of Pharmacy with respect thereto.

(4) The Board of Pharmacy may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subsidiaries, or affiliate companies within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) The minimum qualifications for licensure are set forth in this section as follows:

(1) As a condition for receiving and retaining any wholesale drug distributor license issued pursuant to this article, each applicant shall satisfy the Board of Pharmacy that it has and will continuously maintain:

(A) Acceptable storage and handling conditions plus facilities standards;

(B) Minimum liability and other insurance as may be required under any applicable federal or state law;

(C) A security system which includes after hours central alarm or comparable entry detection capability, restricted premises access, adequate outside perimeter lighting, comprehensive employment applicant screening and safeguards against employee theft;

(D) An electronic, manual or any other reasonable system of records describing all wholesale distributor activities governed by this article for the two-year period following disposition of each product and being reasonably accessible as defined by Board of Pharmacy regulations during any inspection authorized by the Board of Pharmacy;

(E) Officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, who must at all times demonstrate and maintain their capability of conducting business according to sound financial practices as well as state and federal law;

(F) Complete, updated information to be provided to the Board of Pharmacy as a condition for obtaining and retaining a license about each wholesale distributor to be licensed under this article including all pertinent licensee ownership and other key personnel and facilities information determined necessary for enforcement of this article;

(G) Written policies and procedures which assure reasonable wholesale distributor preparation for protection against and handling of any facility security or operation

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problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized product control, appropriate disposition of returned goods and product recalls;

(H) Sufficient inspection procedures for all incoming and outgoing product shipments; and

(I) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(2) The board of pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who apply for a wholesale distributor license under this section or for renewal of that license:

(A) Any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(B) Any felony convictions of the applicant or any key person under federal, state or local laws;

(C) The applicant's past experience in the manufacture or distribution of prescription drugs, including, but not limited to, controlled substances;

(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(E) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drug, including, but not limited to, controlled substances;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Whether personnel employed by the applicant in wholesale drug distribution have appropriate education or experience, or both education and experience, to assume responsibility for positions related to compliance with the requirements of this article;

(H) Compliance with requirements to maintain and make available to the Board of Pharmacy or to federal, state or local law-enforcement officials those records required by this article; and

(I) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with the public health and safety, including whether the granting of the license would not be in the public interest.

(3) All requirements set forth in this subsection shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration

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(FDA); and in case of conflict between any wholesale drug distributor licensing requirement imposed by the Board of Pharmacy pursuant to this subsection and any food and drug administration wholesale drug distributor licensing guideline, the latter shall control.

(d) An employee of any licensed wholesale drug distributor need not seek licensure under this section and may lawfully possess pharmaceutical drugs when the employee is acting in the usual course of business or employment.

(e) The issuance of a license pursuant to this article does not change or affect tax liability imposed by this state's Department of Tax and Revenue on any wholesale drug distributor.

(f) An applicant who is awarded a license or renewal of a license shall give the board written notification of any material change in the information previously submitted in, or with the application for the license or for renewal thereof, whichever is the most recent document filed with the board, within thirty days after the material change occurs or the licensee becomes aware of the material change, whichever event occurs last. Material changes include, but are not limited to:

(1) A change of the physical address or mailing address;

(2) A change of the responsible individual, compliance officer or other executive officers or board members;

(3) A change of the licensee's name or trade name;

(4) A change in the location where the records of the licensee are retained;

(5) The felony conviction of a key person of the licensee; and

(6) Any other material change that the board may specify by rule.

(g) Before denial of a license or application for renewal of a license, the applicant shall be entitled to a hearing in accordance with subsection (h), section eight, article one, chapter thirty of this code.

(h) The licensing of any person as a wholesale drug distributor subjects the person and the person's agents and employees to the jurisdiction of the board and to the laws of this state for the purpose of the enforcement of this article, article five, chapter thirty of this code and the rules of the board. However, the filing of an application for a license as a wholesale drug distributor by, or on behalf of, any person or the licensing of any person as a wholesale drug distributor may not, of itself, constitute evidence that the person is doing business within this state.

(i) The Board of Pharmacy may adopt rules pursuant to section nine of this article which permit out-of-state wholesale drug distributors to obtain any license required by this article on the basis of reciprocity to the extent that: (1) An out-of-state wholesale drug distributor

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possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor of this state as prerequisites for obtaining a license under the laws of this state; and (2) such other state would extend reciprocal treatment under its own laws to a wholesale drug distributor of this state.

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