



Ohio Revised Code

Section 4729.53 Registration requirements.

Effective: March 22, 2019

Legislation: Senate Bill 229 - 132nd General Assembly

(A) The state board of pharmacy shall not license any person as a manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs unless the applicant for licensure furnishes satisfactory proof to the board that all of the following conditions are met:

(1) If the applicant has committed acts that the board finds violate any federal, state, or local law, regulation, or rule relating to drug samples, manufacturing, compounding, repackaging, wholesale or retail drug distribution, or distribution of dangerous drugs, including controlled substances, or constitute a felony, or if a federal, state, or local governmental entity has suspended or revoked any current or prior license of the applicant for the manufacture, compounding, repackaging, distribution, or sale of any dangerous drugs, including controlled substances, the applicant, to the satisfaction of the board, assures that the applicant has in place adequate safeguards to prevent the recurrence of any such violations.

(2) The applicant's past experience in the manufacture, compounding, repackaging, or distribution of dangerous drugs, including controlled substances, is acceptable to the board.

(3) The applicant is properly equipped as to land, buildings, equipment, and personnel to properly carry on its business, including providing adequate security for and proper storage conditions and handling for dangerous drugs, and is complying with the requirements under this chapter and the rules adopted pursuant thereto for maintaining and making available records to properly identified board officials and federal, state, and local law enforcement agencies.

(4) Personnel employed by the applicant have the appropriate education or experience, as determined by the board, to assume responsibility for positions related to compliance with this chapter and the rules adopted pursuant thereto.

(5) The applicant has designated the name and address of a person to whom communications from



the board may be directed and upon whom the notices and citations provided for in section 4729.56 of the Revised Code may be served.

(6) Adequate safeguards are assured to prevent the sale of dangerous drugs other than in accordance with section 4729.51 of the Revised Code.

(7) With respect to criminal records checks, the applicant has done both of the following and the board has decided that the results of the criminal records checks do not make the applicant ineligible for a license issued pursuant to section 4729.52 of the Revised Code:

(a) Complied with sections 4776.01 to 4776.04 of the Revised Code;

(b) Required any person who is seeking to serve as the responsible person on the license, who has an ownership interest, or who is a corporate officer, as set forth in rules adopted under division (C) of this section, to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and send the results of the criminal records check directly to the board.

(8) The applicant meets any other requirement or qualification the board, by rule adopted under division (C) of this section, considers relevant to and consistent with the public safety and health.

(B) In addition to the causes described in section 4729.56 of the Revised Code for refusing to grant or renew a license, the board may refuse to grant or renew a license if the board determines that the granting of the license or its renewal is not in the public interest.

(C) The board shall adopt rules in accordance with Chapter 119. of the Revised Code that do all of the following:

(1) For purposes of division (A)(7)(b) of this section, define "responsible person" and specify the persons with ownership interests and the corporate officers who are required to submit to criminal records checks;

(2) For purposes of division (A)(8) of this section, specify other requirements or qualifications, if any, that an applicant must meet to receive a license;



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(3) Address any other matter the board considers appropriate to implement this section.