



GENERAL GUIDANCE FOR SUBMITTING SURETY BOND FOR IN-STATE WHOLESALERS, DISTRIBUTORS, AND VIRTUAL MANUFACTURERS

Act 101 of 2024 amended the Pennsylvania Wholesale Prescription Drug Distributors License Act (WPDDLA), 63 P.S. § 391.1 to § 391.15, to require a person who engages in the wholesale distribution of prescription drugs, including wholesaler prescription drug distributors and virtual drug and/or device manufacturers (Licensees), to submit a Surety Bond to the licensing agency, the Pennsylvania Department of Health (PA DOH). This amendment provides further consistency with the Surety Bond requirements for the wholesale distribution of a drug under the federal Drug Supply Chain and Security Act, 21 U.S.C. § 360eee to §360eee-4.

PA DOH is providing this guidance in response to questions from current and potential Licensees regarding the new licensure requirements, specifically, surety bonds. The guidance provides general industry standards for filing a surety bond with PA DOH. Compliance with this guidance, however, does not constitute automatic acceptance of a surety bond that is filed with PA DOH or fulfillment of the surety bond requirements. This information does not constitute legal advice or opinion and is only meant as a general guide. Parties are encouraged to review federal and state laws and if necessary, seek legal counsel.

General Surety Bond Guidance:

Licensees located in Pennsylvania shall file a surety bond with PA DOH for licensure.

Is a surety company required?

The amendment to the WPDDLA requires a surety bond. As such, the bond must be from an authorized surety company and shall include the surety company's name, street address or post office box number, city, state, and zip code.

What is the amount of the surety bond?

The amendment to the WPDDLA requires that Licensees submit a surety bond of \$100,000. If the Licensee's annual gross receipts for the previous tax year are less than \$10,000,000, the Licensee may request PA DOH to lower the bond amount, however, the bond amount shall never be less than \$25,000. If requesting the lower bond amount, the Licensee must provide documentation of annual gross receipts in the form of the Licensee's previous year tax records or a review of the entity's previous year sales by a Certified Public Accountant.

Who is listed as the principal of the surety bond?

The amendment of the WPDDLA requires Licensees be the principal of the surety bond. The Licensee's name on the surety bond must be consistent with the name listed with the application for licensure.

Who is the beneficiary or obligee of the surety bond?

The amendment to the WPDDLA requires that the beneficiary of the surety bond shall be PA DOH. To confirm the requirements of the WPDDLA, the surety bond must be held and firmly bound upon the "Commonwealth of Pennsylvania" or the "Pennsylvania Department of Health." Under the federal Drug Supply Chain and Security Act, however, a Licensee who is licensed in another state and has filed a surety bond with that state, may provide proof of the filed surety bond in lieu of filing a surety bond with PA DOH. Proof of a surety bond filed in

another state shall include a copy of the surety bond and letter from the state's licensing agency verifying the licensee has filed a surety bond with that state.

How long must the term of the surety bond be?

The surety bond must remain in full force and effect until one year after the license expires or license is placed inactive, after which liability for license administrative fees ceases except as to any liability or indebtedness incurred or accrued before the termination date.

Do Licensees with more than one location in Pennsylvania require more than one surety bond?

A single surety bond in the amount of \$100,000 shall cover all Licensee's licensed sites under common ownership in Pennsylvania.

How does a Licensee change surety companies?

The amendment to the WPDDLA requires the Licensee to have a surety bond. A Licensee that obtains a replacement surety bond from a different surety company to cover the remaining term of a previously obtained surety bond must submit the new surety bond to PA DOH within 30 calendar days prior to the expiration of the previous surety bond. There may be no gap in the coverage of the surety bond periods.

What if a Licensee cancels or lets a surety bond lapse?

The amendment to the WPDDLA requires the Licensee to have a surety bond. A Licensee must immediately notify PA DOH if the surety bond is no longer in place. A lack of a surety bond is grounds for suspension or other measures against the Licensee unless the Licensee provides a new surety bond before the effective date of the bond's cancellation. If a new surety bond is provided before the effective date of the bond's cancellation, the liability of the surety company continues until the cancellation date.