

Maryland Board of Pharmacy

Wholesale Drug Distributor Frequently Asked Questions

1) What is the deadline for submitting a renewal application?

A fully completed renewal application, *to include the results from the criminal history background checks*, must be received by the Board by December 17 in order for the renewal to be issued and mailed before the current wholesale distributor permit expires. Please note that it takes 4-6 weeks for the Central Repository to process fingerprint cards and inform the Board of the results, so waiting until December to submit a renewal application may result in a lapse of licensure, during which time your facility may not distribute drugs within or into Maryland. The Board will not issue a renewal license until the criminal history records check is complete.

2) How long does it take to process my renewal?

Upon receipt of a completed application *and* the results of the criminal history background checks, it will take approximately 30 days to process a renewal application. Again, please note that it may take at least 6 weeks for the Board to receive the results of the criminal history background checks from the Central Repository.

3) Which types of applicants may complete the abbreviated application form?

Only actual manufacturers distributing their own prescription drugs approved by the U.S. Food and Drug Administration are eligible to complete this form. Applicants completing this form must satisfy the definition of “manufacturer” as provided in 21 C.F.R. 205.3(d): “Manufacturer means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.” If your facility is not the site approved by the U.S. F.D.A. for the manufacturer of approved prescription drugs, do not complete this wholesale distributor application.

If the facility address listed on the short application form is not the facility where the drug is physically manufactured, the applicant must complete the long application form.

“Virtual,” “own label,” “sponsor,” “contract,” and “private label” manufacturers must all submit the complete application form. A “manufacturer’s exclusive distributor” is NOT synonymous with a “manufacturer distributing its own product” and must also submit the complete application form.

4) When is a bond required?

A bond is always required unless the applicant is a manufacturer of its own FDA-approved prescription drugs.

5) Which types of distributors does NABP accredit?

NABP accredits distributors of prescription drugs and prescription devices through its VAWD program. NABP does not have an accreditation program for medical gases or DME. Those distributors which distribute only non-prescription DME are not required to be licensed by the Board as wholesale drug distributors.

6) Is there a Board-approved accreditation organization for distributors of medical gases?

The Board is in the process of approving an accreditation organization for this purpose. Please revisit the Board's website after its October 2010 meeting.

7) What should I do if my facility has not yet received VAWD-accreditation?

Renewal applicants must submit an otherwise completed application along with proof of having submitted a VAWD application to NABP. NABP will be notifying the Board of those applicants who are not making diligent efforts to comply with the accreditation process. Those applicants who fail to comply with NABP's accreditation process, to include failing to promptly respond to requests for materials or other correspondence, will be denied.

New applicants should wait until VAWD accreditation is granted before applying to the Board for a permit.

8) What forms of payment are accepted for the application fee?

Applicants may pay the application fee with a check or money order made payable to "The Maryland Board of Pharmacy." Credit cards are NOT accepted. Applicants must submit separate payment for processing of the fingerprint cards made payable to "CJIS – Central Repository."

9) Where should I send the completed fingerprint cards and checks?

Completed criminal background check fingerprint cards and checks should be sent to the Board. **Both** the designated representative and the supervisor of the designated representative must submit **two** complete sets of legible fingerprints taken on forms approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigations. **Both** the designated representative and the supervisor of the designated representative must submit payment to CJIS in the amount of \$37.25.

10) What happens if I submit an incomplete application?

Incomplete applications will be returned in their entirety. The application processing fee will be retained by the Board and will be applied toward the completed application provided a completed application is submitted within one year from the original application date.