Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies and Outsourcing Facilities to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy or nonresident outsourcing facility that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

For a nonresident pharmacy, an application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) or Gates Healthcare Associates, Inc. that satisfy the inspection report requirements of Virginia Code § 54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

An “opening” inspection report for a newly opened pharmacy or a new location for an existing pharmacy indicating compliance with the requirements of statute, including compliance with USP-NF standards for pharmacies performing non-sterile compounding, may satisfy the requirements for obtaining initial registration as a nonresident pharmacy. However, an “operational” inspection report shall be provided during the subsequent renewal of the registration. An “opening” inspection report for a newly opened pharmacy or a new location for an existing pharmacy performing sterile compounding shall not satisfy the requirements for obtaining initial registration or renewal as a nonresident pharmacy. Submission of an “operational” inspection report indicating compliance with USP-NF standards for sterile compounding shall be required for consideration for obtaining initial registration or renewal as a nonresident pharmacy.

For a resident or nonresident outsourcing facility, an application for new registration or renewal must include documentation of an FDA outsourcing facility inspection and any facility related responses to documented observations within the required timeframe as outlined in Virginia Code §§ 54.1-3434.5 and 54.1-3434.05. If the facility has not been inspected by the FDA within the required time frame, outsourcing facility cGMP inspections from the California Board of Pharmacy, Florida Board of Pharmacy or Bestech GMP are acceptable alternatives.

Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

References

Va. Code § 54.1-3434.1
Va. Code § 54.1-3434.5
Va. Code § 54.1-3434.05