

Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. The law (Code of Virginia) provides:

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

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As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

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For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

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) that satisfy the inspection report requirements of §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.

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.

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.