



Florida Department of Health Business Establishment Renewal Application (Active Status)

Expedite your application by applying online at www.flhealthsource.gov

Your license expires at midnight on the expiration date. Renewal notification postcards are mailed to the last known mailing address on record 90 days prior to the expiration date.

General Renewal Requirements:

- Must pay the biennial renewal fee and apply with a complete application, as defined by rule of the board, or the department if there is no board, to renew an active status license before the license expires.
- Must pay \$5.00 unlicensed activity fee as required in s. 456.065(3), Florida Statutes. Active duty members of the Armed Forces whose license is currently in a “military status” are not required to pay an unlicensed activity fee.
- Must submit your renewal application, any applicable fees, and any supplemental documentation to the Department of Health online at www.flhealthsource.gov or by US Mail to P.O. Box 6320, Tallahassee, Florida 32314-6320. Applications mailed must be postmarked by midnight on the license expiration date.

Note: If you are renewing your license after the expiration date, you are required to pay a delinquency fee in addition to your renewal fees. Failure of a delinquent business establishment to renew the license within the 6 months after the expiration date of the license renders the license null without any further action by the board or the department.

Profession Specific Requirements:

Continuing Education: If you are a Dental Laboratory you are required under Section 466.032(5)(d), Florida Statutes, to report the continuing education courses required for your profession. Your continuing education credits must be reported to the Department’s Continuing Education Tracking system on or before the day you submit your renewal application. To view continuing education requirements for your profession, visit www.flhealthsource.gov. To view your course history and report hours please register for a Free Basic Account by visiting <http://www.flhealthsource.gov/AYRR>.

Nonresident Sterile Compounding - Outsourcing Facilities: Along with the renewal application, **Outsourcing Facilities** must submit the following:

1. Proof of registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services (HHS) **if any changes have been made since the facility’s last application;**
2. An active and unencumbered license, permit, or registration issued by the state, territory, or district in which the outsourcing facility is physically located which allows the facility to engage in compounding and to ship, mail, deliver, or dispense a compounded sterile product into this state.
3. A current inspection report compliant with section 465.0158, Florida Statutes, from an inspection conducted by:
 - a. the regulatory or licensing agency of the state, territory, or district in which the applicant is located; (Options b. and c. are acceptable in lieu of the state inspection report only if you meet the exceptions as outlined in Florida Administrative Rule 64B16-28.905(3)(a) through (f).)
 - b. the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act; or
 - c. from an entity approved by the board as set forth in Florida Administrative Rule 64B16-28.905(4)(a) through (k).

A current inspection is an inspection that was conducted within 1 year before the date of submitting the application for a renewal permit.

4. Existing policy and procedures for sterile compounding **if any changes have been made since the facility's last application**;
5. Written attestation by an owner or officer of the applicant and by the applicant's prescription department manager, supervising pharmacist or pharmacist in charge that:
 - a. The attestor has read and understands the laws and rules governing sterile compounding in Florida;
 - b. A compounded sterile product shipped, mailed, delivered, or dispensed into Florida meets or exceeds Florida's standards for sterile compounding;
 - c. A compounded sterile product shipped, mailed, delivered, or dispensed into Florida must not have been, and may not be, compounded in violation of the laws and rules of the state, territory, or district in which the applicant is located;
6. Any and all other documentation requested or mandated within this application.

Nonresident Sterile Compounding - Nonresident Pharmacies: Along with the renewal application, **Nonresident Pharmacies** must submit the following:

1. Verification of an active and unencumbered license, permit, or registration issued by the state, territory, or district in which the pharmacy is physically located which allows the pharmacy to engage in compounding and to ship, mail, deliver, or dispense a compounded sterile product into this state.
2. Verification of an active and unencumbered license, permit, or registration for the pharmacist designated as the prescription department manager or equivalent issued by the state, territory, or district in which the pharmacy is physically located.
3. Written attestation by an owner or officer of the applicant and by the applicant's prescription department manager or pharmacist in charge that:
 - a. The attestor has read and understands the laws and rules governing sterile compounding in Florida;
 - b. A compounded sterile product shipped, mailed, delivered, or dispensed into Florida meets or exceeds Florida's standards for sterile compounding;
 - c. A compounded sterile product shipped, mailed, delivered, or dispensed into Florida must not have been, and may not be, compounded in violation of the laws and rules of the state, territory, or district in which the applicant is located.
4. A current inspection report compliant with section 465.0158, Florida Statutes, from an inspection conducted by:
 - a. the regulatory or licensing agency of the state, territory, or district in which the applicant is located; (Options b. or c. are acceptable in lieu of the state inspection report only if you meet the exceptions as outlined in Florida Administrative Code Rule 64B16-28.905(3)(a) through (f).)
 - b. the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act; or
 - c. from an entity approved by the board as outlined in Florida Administrative Code Rule 64B16-28.905(4)(a) through (k).

A current inspection is an inspection that was conducted within 1 year before the date of submitting the application for a renewal permit.

5. A copy of the applicant's existing policies and procedures for sterile compounding **if any changes have been made since the facility's last application**.
6. Any and all other documentation requested or mandated within this application.