



Florida Department of Health (Department) 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 section 456.065(3), Florida Statutes (F.S.). 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 the appropriate 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), F.S., 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 Florida.
3. A current inspection report compliant with section 465.0158, F.S., 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 Code 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 Florida.
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, F.S., 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.

Criminal History and Medicaid / Medicare Fraud Questions:

As required by section 456.0635(3), F.S., please answer Yes or No to the following questions below. If you answer 'YES' to any of the following questions, please send a written explanation for each such question, including the county and state of each termination, plea, or conviction, the date of each termination, plea, or conviction, and copies of supporting documentation, to the address below. Supporting documentation may include court dispositions or agency orders.

**Department of Health
Division of Medical Quality Assurance
Bureau of Operations
4052 Bald Cypress Way, Bin #C-10
Tallahassee, FL 32399-3260**

1. Yes No Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? **(If you responded "no," skip to question 2.)**
 - a. Yes No If "yes" to 1, did the arrest or felony charge resulting in the conviction or plea occur before July 1, 2009? **(If you responded "yes," skip to question 2.)**
 - b. Yes No If "yes" to 1, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea or conviction, and completion of any sentence or subsequent period of probation?
 - c. Yes No If "yes" to 1, for the felonies of the third degree, has it been more than 10 years from the date of the plea or conviction, and completion of any sentence or subsequent period of probation? (This question does not apply to felonies of the third degree under section 893.13(6)(a), F.S.)
 - d. Yes No If "yes" to 1, for the felonies of the third degree under section 893.13(6)(a), F.S., has it been more than 5 years from the date of the plea or conviction, and completion of any sentence or subsequent period of probation?
 - e. Yes No If "yes" to 1, is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently enrolled in a pretrial diversion or drug court program that allows for the withdrawal of the plea or dismissal of the charges for the felony offense upon successful completion of that program? (If "yes", please provide supporting documentation).

2. Yes No Since July 1, 2009, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? **(If you responded "no," skip to question 3.)**
 - a. Yes No If "yes" to 2, did the sentence and any subsequent period of probation for such conviction or plea end more than 15 years before the date of this application?

3. Yes No Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to section 409.913, F.S.? **(If you responded "no," skip to question 4.)**
 - a. Yes No If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated but reinstated, has that person been in good standing with the Florida Medicaid Program for the most recent 5 years?

4. Yes No Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program? (If you responded "no," skip to question 5.)
- a. Yes No Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program for the most recent five years?
- b. Yes No Did the termination occur at least 20 years before the date of this application?
5. Yes No Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Profession Specific Questions:

For Outsourcing Facilities only:

1. Have you had a change to your HHS registration that has not been provided to the department since the facility's last application? Yes No
 - a. If YES, is your new proof of registration enclosed with this application? Yes No
2. Have you submitted to the department a current inspection report conducted within 1 year before the date of submitting this application? Yes No
 - a. If NO, Is the inspection report included with this renewal packet? Yes No Department Conducted
3. Have any changes been made to your existing policy and procedures for sterile compounding since the initial application that you have not already reported to the department? Yes No
 - a. If YES, is a copy of your new existing policy and procedures for sterile compounding enclosed with this application? Yes No

For Nonresident Pharmacies only:

1. Has there been a change to the facility ownership, pharmacy manager, pharmacy supervisor or the pharmacist in charge since initial application that has not been reported to the department? Yes No
 - a. If YES, is/are licensure verification(s) enclosed with this application? Yes No
2. Have you submitted a current inspection report that was conducted within 1 year before the date of submitting this application to the department for review? Yes No
 - a. If NO, Is the inspection report included with this renewal packet? Yes No Department Conducted
3. Have any changes been made to your policies and procedures for sterile compounding since the facility's last application that you have not already provided to the department? Yes No
 - a. If YES, is a copy of the amendment(s) to the policies and procedures for sterile compounding enclosed with this application? Yes No

Statement of Applicant:

I have carefully read the questions in the foregoing application and have answered them completely. These statements are true and correct. I recognize that providing false information may result in disciplinary action against my business establishment, or criminal penalties. If there are any changes to my status or any change that would affect any of my answers to this application I must notify the department within 30 days.

Signature

Date

Profession Specific Attestation:

For Outsourcing Facilities only:

I declare that I have read the foregoing application and that the facts stated in this application are true, complete, and correct and I agree that said statements shall form the basis of this application. I authorize the Florida Board of Pharmacy and the Department to make any investigations that they deem appropriate and to secure any additional information concerning the applicant or me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units. I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be denied, revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit.

I, the undersigned, hereby acknowledge that providing false information in relation to this application, may result in denial of licensure, discipline, and/ or criminal penalties pursuant to sections 456.067, 465.015 (5), 775.082, 775.083, and 775.084, F.S.

SIGNATURE _____ TITLE _____ DATE _____
Owner/Officer

Nonresident Sterile Compounding Attestation required by section 465.0158(3)(c), F.S.:

Section 465.0158(3)(c), F.S., requires that an applicant submit attestation by an owner or officer of the applicant and by the applicant's Prescription Department Manager (PDM), pharmacy supervisor or Pharmacist In Charge (PIC).

I hereby attest that I have read and understand the laws and rules governing sterile compounding in the State of Florida, and that any sterile compounded product shipped, mailed, delivered, or dispensed into the State of Florida from this facility meets or exceeds the standards for sterile compounding set by the State of Florida and has not been compounded in violation of the laws and rules of the state, territory, or district in which this facility is located.

I declare that I have read the foregoing Attestation and that the facts stated in it are true.

SIGNATURE _____ TITLE _____ DATE _____
Owner/Officer

SIGNATURE _____ TITLE _____ DATE _____
PDM/PIC

If the owner or officer who executed this attestation is no longer an owner or officer, another or new owner or officer shall execute a new attestation within 10 days of the change.

If there is a change in the PDM or PIC who executed this attestation, the new supervising pharmacist shall execute a new attestation within 10 days of the change.