Florida Biomedical Waste Regulations

Home health agency reference | November 2026

Who regulates what

Florida Department of Health (DOH): Regulates packaging, transportation, storage, and treatment and establishes treatment effectiveness standards under section 381.0098, Florida Statutes. Contact the county health department for permits, exemptions, and local implementation.

Florida Department of Environmental Protection (DEP): Regulates onsite and offsite incineration and disposal. DEP establishes statewide environmental impact standards for treatment and disposal, including water discharges and air emissions.

Agency for Health Care Administration (AHCA): Reviews applicable agency practices through its licensing surveys. AHCA's home health survey set identifies Rule 59A-8.0095(2)(b), F.A.C., at tag H1201. The rule directs designated agency leadership to establish biomedical waste policies and procedures for home health agencies providing nursing and physical therapy services.

Open the complete official regulations

Section 381.0098, Florida Statutes - Biomedical waste

Chapter 64E-16, F.A.C. - Complete DOH rule text (PDF)

Florida Administrative Code - Chapter 64E-16 rule index

Rule 59A-8.0095, F.A.C. - Home health personnel requirements

AHCA Home Health Agency Survey Regulation Set (PDF)

DOH biomedical waste applications, forms and operating plan

DOH biomedical waste program and residential sharps information

This reference summarizes agency responsibilities. The linked publications provide the full official text.

From the home visit to disposal

In the patient’s home - Rules 64E-16.001 and .002

Give clients both verbal and written instructions on handling home-generated biomedical waste. Keep a record of the education. For waste generated while staff provide in-home medical services, the provider must remove it or arrange removal by a registered biomedical waste transporter.

Distinguish agency-generated waste from waste a patient creates independently (for example, self-injection needles). Direct the patient or caregiver to county-approved residential sharps options. Keep this instruction separate from the agency’s procedure for removing its own waste.

Apply the rule’s definition when classifying waste. Ordinary household waste and biomedical waste require separate handling. Used disposable sharps are biomedical waste.

Segregate, contain, label and store - Rules .004 and .005

Segregate biomedical waste at the point of origin. Place sharps in a compliant sharps container at the point of use and use compliant red bags for applicable non-sharps waste. Close and label containers as required and maintain a designated, secure storage area when applicable.

For storage at the generating facility, the 30-day period starts when the first non-sharps biomedical waste enters a red bag or sharps container, or when a sharps-only container is sealed. Offsite storage is measured from collection from the generator and may not exceed 30 days.

Transport, treatment and final disposal - Rules .006 through .009

Arrange collection with a registered transporter or confirm allowable agency transport procedures with the county. A generator carrying less than 25 pounds of its own waste in its own transport vehicle on one occasion is exempt from transporter registration, fees and placarding under Rule .009(1). Review remaining applicable handling and transportation requirements before using agency transport.

Treatment must take place within 30 days of collection from the generator. The rule provides for steam, incineration, or a DOH-approved alternative. DEP regulates incineration and disposal under section 381.0098. Retain the applicable pickup or delivery records.

Prepare for inspection and survey

Operating plan, training and records - Rule 64E-16.003

Maintain an accessible written biomedical waste operating plan. Address staff training, segregation, labeling, packaging, transport, storage, treatment procedures, spill decontamination and emergency contingencies as applicable. Train personnel before they begin handling biomedical waste and annually thereafter. Retain biomedical waste management records for three years.

Permits, exemptions and fees - Rules .010 through .012

A generator producing or treating less than 25 pounds in each 30-day period can qualify for the permit and fee exemption under Rule .011. Confirm the documentation and application requirements with the local county health department. Use DOH Form DH 4089 for the generator permit or exemption process. The monthly generator exemption and the per-trip transporter exemption are separate provisions. Continue applicable waste-handling practices regardless of permit status.

Home health agency checklist

[ ] Confirm DOH generator permit or documented exemption with the county.

[ ] Keep the written operating plan and any transporter registration on file.

[ ] Review staff training dates and confirm field staff have compliant supplies.

[ ] Verify patients received verbal and written disposal education.

[ ] Verify agency-generated waste is removed or collected as required.

[ ] Confirm labeling, storage start dates, and timely collection.

[ ] Retain logs, receipts, training records and corrective actions.

[ ] Check AHCA survey tag H1201 and confirm applicable policy requirements.

Administrator or designee: _____ Date: _____