

# OFFICE USE COMPOUNDING FLORIDA'S INSPECTION CRITERIA

*Ensuring Product Quality & Standards*

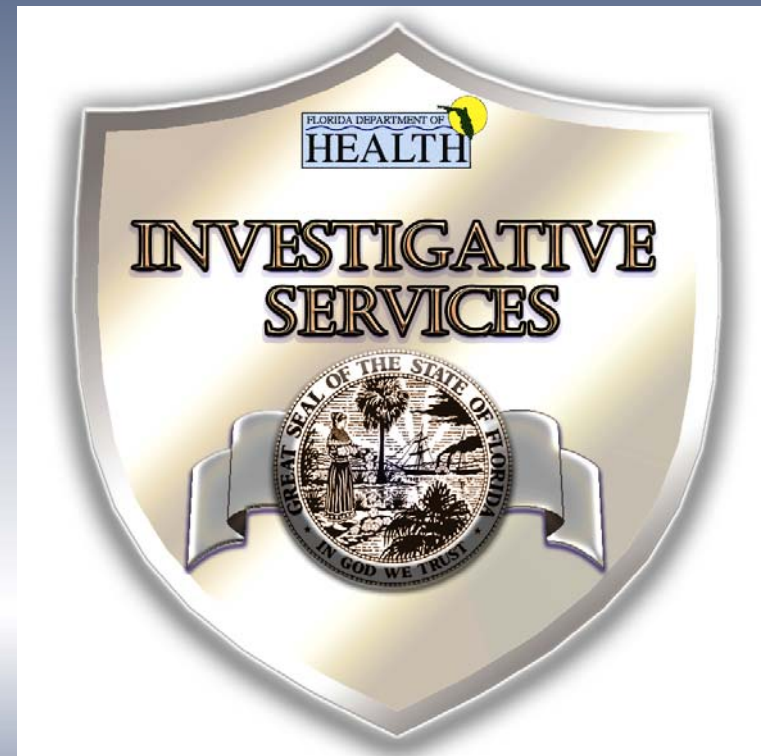


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Statewide Pharmaceutical Program Manager



# Mission:

Promote, protect, and improve the health of all people in Florida.



# 64B16-27.700 Definition of Compounding:

- “Compounding” is the professional act by a pharmacist or other practitioner authorized by law, employing the science
- or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing
- to a patient or for administration by a practitioner or his agent; and shall specifically include the professional act of
- preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S.

# (1) Compounding includes:

- (a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
- (b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.
- (c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

# BUT THE DEFINITION GOES ON TO SAY...

*(2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding.*

Except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.

# CHAPTER 893 F.S.

## *“Manufacture”*

*(b) "means and includes every person who prepares, derives, produces, compounds, or repackages any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to manufacturers of patent or proprietary preparations as defined in the Florida Pharmacy Act.*

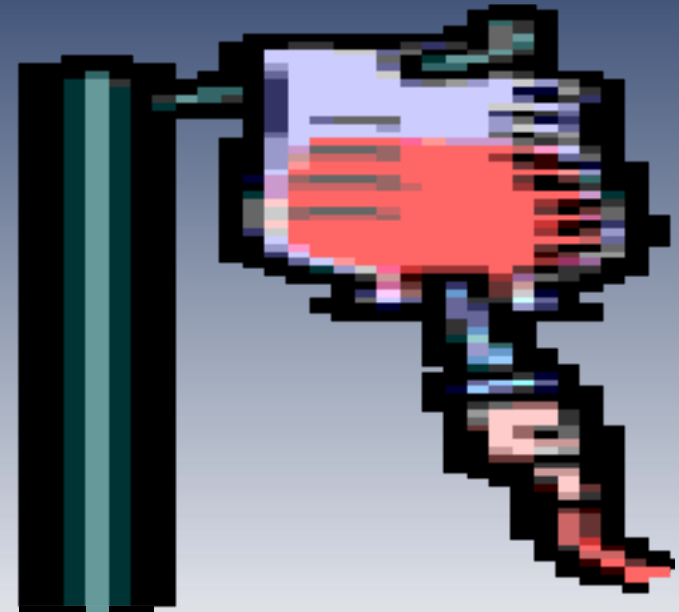
*Pharmacies, and pharmacists employed thereby, are specifically excluded from this definition.*

# CHAPTER 893 cont.

*"Manufacture" does not include the preparation, compounding, packaging, or labeling of a controlled substance by:*

- 1. A practitioner or pharmacist as an incident to his or her administering or delivering of a controlled substance in the course of his or her professional practice.*

# STERILE PRODUCTS & SPECIAL P&E COMPOUNDING PHARMACY:



**Requires a Pharmacy Manager of record. This permit allows compounding of Sterile Products as well as compounding and mixing for IV Therapy. Can be “bundled” with an existing community permit.**

## 64B16-28.860 Special Pharmacy - Parenteral/Enteral Extended Scope Permit.

(1)(a) A Special Parenteral/Enteral Extended Scope permit, as authorized by Section 465.0196, F.S., is required for pharmacies to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits.

# “797” NEW RULE

## 64B16-27.797 Standards of Practice for Compounding Sterile Preparations (CSPs).

1. *Anteroom present Y/N/NA, Certification for ISO Class 8 within previous 12 months and available for inspection.*
2. *All CSP’s properly labeled with “Beyond-use-date.”*
3. *Semiannual test results available for inspection.*

# WHOLESALE PRODUCTS

- Cannot Wholesale COMPOUNDED Prescription Drugs
- Only FDA Approved Prescription Drugs
  - 499.023, 499.013(2)(a) and 64B-16.27.700



# Questions





# STATEWIDE PHARMACEUTICAL PROGRAM MANAGER

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