#### Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Vision: To be the Healthiest State in the Nation

Rick Scott Governor

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State Surgeon General & Secretary

# FAQ for Dispensing / Issuing / Receiving Medication at County Health Departments (CHDs)

#### 1. What is administration?

Section 465.003, Florida Statutes (F.S.), Definitions.--As used in this part: (3)(a)2. The administration of medications and treatments as prescribed or authorized by a duly licensed practitioner authorized by the laws of this state to prescribe such medications and treatments.

Section 465.003, F.S., Definitions.--As used in this chapter, the term:

(1) "Administration" means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.

#### 2. What is dispensing?

Section 465.003, F.S., Definitions.--As used in this chapter, the term:

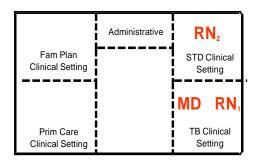
(6) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. ... [The] delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

#### 3. What is Nurse Issuance?

Section 154.04, F.S., Personnel of county health departments; duties; compensation. — (1)(c)

- A registered nurse or licensed physician assistant working in a county health department is authorized to assess a patient and order medications, provided that:
  - No licensed physician is on the premises;What is meant by premises?

### **PREMISES**



Physician in the same clinical setting -

#### Nurse Issuance does not apply to RN1 but does to RN2

- ii. The patient is assessed and medication ordered in accordance with rules promulgated by the department and pursuant to a protocol approved by a physician who supervises the patient care activities of the registered nurse or licensed physician assistant;
- iii. The patient is being assessed by the registered nurse or licensed physician assistant as a part of a program approved by the department; and,
- iv. The medication ordered appears on a formulary approved by the department and is prepackaged and labeled with dosage instructions and distributed from a source authorized under Chapter 499 F.S., to repackage and distribute drugs, which source is under the supervision of a consultant pharmacist employed by the department.
- b. Each county health department shall adopt written protocols which provide for supervision of the registered nurse or licensed physician assistant by a physician licensed pursuant to Chapter 458 or Chapter 459, F.S., and for the procedures by which patients may be assessed, and medications ordered and delivered, by the registered nurse or licensed physician assistant. Such protocols shall be signed by the supervising physician, the director of the CHD, and the registered nurse or licensed physician assistant.
- Each CHD shall maintain and have available for inspection by representatives of the DOH all medical records and patient care protocols, including records of medications delivered to patients, in accordance with rules of the department.
- d. The DOH shall adopt rules, which establish the conditions under which a registered nurse or licensed physician assistant may assess patients and order and deliver medications, based upon written protocols of supervision by a physician licensed pursuant to Chapter 458 or Chapter 459, F.S., and which establish the formulary from which medications may be ordered.

- e. The department shall require that a consultant pharmacist conduct a periodic inspection of each county health department in meeting the requirements of this paragraph.
- 4. How should the medication be packaged for medication being issued?

For prescriptions dispensed from Central Pharmacy, packaging should be according to all labeling requirements as described in Rule, 64F-12.006, Florida Administrative Code (F.A.C.) to include:

- a. The label on the immediate container of each unit dose repackaged drug product or multiple unit prepackaged drug product must contain the following:
  - i. Brand or generic name, or both;
  - ii. Strength of drug;
  - iii. Dosage form;
  - iv. Manufacturer's name and lot number or a control number if a log is maintained which cross references the control number with the manufacturer's name and lot number; and
  - v. Expiration date.
- b. An authorized practitioner dispensing complimentary prescription drugs to his own patients may dispense them in the manufacturer's package which shall also include the practitioner's name, the patient's name and the date dispensed. If complimentary prescription drugs are not dispensed in the manufacturer's labeled package, they shall be dispensed in a container which bears a label containing the following:
  - Practitioner's name and address;
  - ii. Patient's name;
  - iii. Date dispensed;
  - iv. Name and strength of drug;
  - v. Directions for use; and
  - vi. Expiration date.
- 5. What permits and or licenses are needed for a CHD to accept and store pharmaceuticals from the Prime Vendor or Central Pharmacy?

For CHDs with Pharmacies: Community pharmacy permits as described in Chapter 465.018, F.S.

For CHDs without Pharmacies: No permit is required for the CHD; but, all prescription drugs transferred to the CHD from Central Pharmacy (not including patient specific prescription drugs dispensed by the Central Pharmacy) can only be transferred to a CHD through a licensed "responsible physician" who practices at the facility, on behalf of Department of Health (DOH). The responsible physician is responsible for ensuring that any prescription drug inventory transferred to the CHD through use of the physician's license number is properly stored and accounted for pursuant to the DOH policies and procedures manual, Sections 499.0121; 499.003 (54) (a) 4., F.S. (2008) and rules 64F-12.013 and 64F-12.023 (5), F.A.C.

## 6. What permits and or licenses are needed for a CHD to ship pharmaceuticals to another location (satellite clinic etc...)?

A Restricted Prescription Drug Distributor permit is required for any person that engages in the distribution of a legend drug, which distribution is not considered "wholesale distribution" under s. 499.012(1)(a)1., F.S.

A CHD, with or without a community pharmacy permit, should obtain a Restricted Prescription Drug Distributor, Government Programs permit from the DOH Drugs Devices and Cosmetics Program prior to providing a prescription drug to an off-site DOH clinic or to a DOH contract pharmacy. The clinic must have a "responsible physician"/ contract provider practicing at the satellite clinic. The preferred way to accomplish this is to allow the Central Pharmacy, which has this permit, to transfer the prescription drugs directly to the satellite clinic or to the contract pharmacy. No CHD, in the absence of an emergency that meets the requirements of Rule 64F-12.011 (1), F.A.C., should be transferring DOH prescription drugs to any establishment that is not the place of practice of a DOH employed or contracted prescribing practitioner, or the location of a contract pharmacy or DOH pharmacy licensed under Chapter 465, F.S.

## 7. What permits and or licenses are needed for the satellite clinic to accept, administer and issue pharmaceutical products?

A satellite clinic may issue pre-package, pre-labeled medication sent from Central Pharmacy under nurse issuance protocol or through the Central Pharmacy physician issuance program/ protocol. Additionally, any one time dose which is given on-site would be considered "administration." No pharmacy permit is required. Each practitioner would be administering under his/her own individual license. A DOH employee, independently licensed to prescribe prescription drugs, as well as a non-prescribing DOH employee authorized by licensure and protocol to administer a prescription drug (e.g. RN), may carry a prescription drug to a satellite clinic to administer the prescription drug.

DOH employees at a DOH satellite clinic may accept and store a prescription drug at a satellite clinic on behalf of DOH and the responsible physician who practices at the clinic.