

**Mission:**

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



**Rick Scott**  
Governor

**John H. Armstrong, MD, FACS**  
State Surgeon General & Secretary

**Vision:** To be the **Healthiest State** in the Nation

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**Rule Title: Wholesale Distribution of Prescription Drugs - Exceptions and Specific Distributions Authorized (Transferred)**

**Department:** [DEPARTMENT OF HEALTH](#)

**Division:** [Division of Family Health Services](#)

**Chapter:** [REGULATIONS FOR DRUGS, DEVICES AND COSMETICS](#)

**[64F-12.011](#) Wholesale Distribution of Prescription Drugs - Exceptions and Specific Distributions Authorized.**

- (1) The exemption from the definition of wholesale distribution in Section 499.012(1)(a)2.b., F.S., for “emergency medical reasons” includes:
- (a) Transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules, and should not occur between the parties so as to amount to the health care entity regularly and systematically supplying that drug;
  - (b) Transfers of prescription drugs by a health care entity to an emergency transport vehicle which is under the direction of a medical director of an emergency medical service provider licensed under Chapter 401, F.S., for use in the treatment of persons transported to that health care entity to immediately restock a licensed vehicle or an emergency medical kit for prescription drugs used on that person or to immediately restock prescription drugs on the vehicle which have become unsuitable for use. This exception does not extend to the stocking of supply inventory or for warehousing of prescription drugs used by emergency medical service providers;
  - (c) Emergency transfers of prescription drugs as authorized in Rule 59A-4.112, F.A.C., for nursing homes or Rule 64B16-28.6021, F.A.C., of the Florida Board of Pharmacy; or
  - (d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy or to a health care entity to alleviate a temporary shortage, but not for the regular and systematic supplying of that prescription drug;
  - (e) Transfers of prescription drugs in an emergency declared pursuant to Section 252.36, F.S., until the state of emergency is lifted, under the following conditions:
    - 1. The manufacturer, wholesaler, or other person supplying the prescription drugs is authorized by Florida law to distribute prescription drugs in or into Florida; and
    - 2. The prescription drugs are delivered to a temporary emergency medical station, officially designated by the state emergency operation center as a Disaster Medical Assistance Team or State Medical Response Team site;
    - 3. The prescription drugs are delivered to a Pharmacy licensed under Chapter 465, F.S.;
  - (f) Transfers of prescription drugs from a health care entity to a pharmacy or other end-user practitioner for a named patient to treat or prevent a serious medical

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- condition when a shortage of the product is documented by the manufacturer; but does not include regular and systematic sales of prescription drugs to licensed practitioners that will be used for routine office procedures.**
- (g) Transfers of prescription drugs by or on behalf of the Department of Health to the medical director of an advanced life support service provider, licensed under Chapter 401, Part III, F.S., and for further distribution to an emergency transport vehicle operated by the advanced life support services provider, for use in the treatment of persons in need of emergency medical services;
  - (h) **Transfers of prescription drugs by or on behalf of the Department of Health to a health care entity authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health;**
  - (i) **Transfers of prescription drugs by or on behalf of the Department of Health to the licensed medical director of a government agency health care entity, authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health.**
- (2) The revocation of a sale or the return of a prescription drug purchased by a hospital or other health care entity, or acquired at a reduced price by or donated to a charitable institution to the manufacturer or the wholesale distributor that sold, donated, or supplied the prescription drug, is not a wholesale distribution prohibited by Section 499.005(21), F.S., provided:
- (a) The hospital, health care entity or charitable institution forwards a copy of the documentation for the return to the manufacturer of the product. This documentation must at a minimum comply with the requirements of Rule 64F-12.012, F.A.C.; and
  - (b) The value of any credit, refund, or exchange for the returned product does not exceed the purchase price or, if a donation, the fair market price of the returned product.
  - (c) Prescription drugs returned or to be returned to a manufacturer or wholesale distributor must be kept under proper conditions for storage, handling, and shipping as set forth in Section 499.0121, F.S.; and written documentation showing that these conditions were or were not maintained must be provided to the manufacturer or wholesale distributor to which the prescription drugs are returned.
- (3) A person authorized to possess non-dispensed prescription drugs can donate prescription drugs that are not misbranded or adulterated to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs provided the transfer is not for sale or trade and the donor receives no financial benefit (except for tax benefits related to charitable contributions) either directly or indirectly. Records to document the transfer must comply with Section 499.0121(6), F.S., and paragraph 64F-12.008(2)(c), F.A.C.
- (4) A person who uses prescription drugs for lawful research, teaching, or testing may obtain a registration number from the department to authorize acquisition of the requisite prescription drugs for this activity. The person must submit correspondence to the department explaining the conditions of the lawful research, teaching, or testing, along with a statement signed by the individual who will be responsible for the prescription drugs that

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the drugs will be secured, access will be restricted to authorized individuals, and that the prescription drugs are not for resale. If applicable, this correspondence should also identify the name in which purchases will be made, the specific prescription drug(s) required for the activity, the quantity which will ordinarily be purchased, the frequency of the purchases, and the name and state permit or license or permit number of suppliers of the prescription drugs. A letter and registration number will be assigned to the person which authorizes the purchase or other acquisition and possession of prescription drugs. This registration number must be included on invoices as required by Section 499.0121(6)(a), F.S.

*Specific Authority 499.012, 499.014, 499.03, 499.05 FS. Law Implemented 499.012, 499.014, 499.03 FS. History—New 7-1-96, Formerly 10D-45.0525, Amended 1-26-99, 4-17-01, 1-1-04, 10-4-07.*