

Section IV Emergency Rules

BOARD OF TRUSTEES OF THE INTERNAL IMPROVEMENT TRUST FUND

Notices for the Board of Trustees of the Internal Improvement Trust Fund between December 28, 2001 and June 30, 2006, go to <http://www.dep.state.fl.us/> under the link or button titled "Official Notices."

DEPARTMENT OF ENVIRONMENTAL PROTECTION

Notices for the Department of Environmental Protection between December 28, 2001 and June 30, 2006, go to <http://www.dep.state.fl.us/> under the link or button titled "Official Notices."

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE NO.:	RULE TITLE:
64FER09-1	Wholesale Distribution of Prescription Drugs – Exceptions and Specific Distributions Authorized

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: Influenza, commonly called "the flu" is an infection of the respiratory tract caused by the influenza virus. On June 11, 2009, the WHO Director-General Dr Margaret Chan issued a statement raising the level of pandemic influenza alert to Phase 6, beginning the 2009 Influenza Pandemic, stating: "This particular H1N1 strain has not circulated previously in humans. The virus is entirely new. The virus is contagious, spreading easily from one person to another, and from one country to another. . . Spread in several countries can no longer be traced to clearly-defined chains of human-to-human transmission. Further spread is considered inevitable."

On April 26, 2009, Acting HHS Secretary Charles Johnson determined that a nationwide Public Health Emergency existed, with potential to affect national security. On June 19, 2009 the HHS Secretary further issued a federal PREP Act declaration identifying the pharmaceuticals Tamiflu and Relenza as "covered countermeasures" to address the threat of or actual human influenza that results from the infection of humans with highly pathogenic avian influenza A viruses including the swine H1N1 virus. On June 25, 2009 the HHS Secretary issued a PREP Act declaration similarly identifying the 2009 H1N1 vaccines as a "covered countermeasure" for that same purpose, and, on July 14, 2009 the FDA issued an Emergency Use Authorization letter expanding uses of Tamiflu for treatment and prophylaxis of influenza. Finally, following

her confirmation by the Senate as Secretary of HHS, on July 24, 2009 Secretary Kathleen Sebelius renewed that Public Health Emergency declaration.

On May 6, 2009 CDC released guidance for antiviral treatment of influenza in certain high-risk groups, stating, "A person who is at high-risk for complications of novel influenza (H1N1) virus infection is defined as the same for seasonal influenza at this time."

- Children younger than 5 years old. The risk for severe complications from seasonal influenza is highest among children younger than 2 years old.
- Adults 65 years of age and older.
- Persons with the following conditions:
 - Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus);
 - Immunosuppression, including that caused by medications or by HIV;
 - Pregnant women;
 - Persons younger than 19 years of age who are receiving long-term aspirin therapy;
 - Residents of nursing homes and other chronic-care facilities.
- On the same date, CDC stated that no person should be denied treatment with antivirals due to inability to pay. The identical position was announced the preceding day, May 5, 2009, by the Florida Department of Health regarding access to treatment.

In May 2009 the Department of Health received 25% of Florida's allocation of Strategic National Stockpile antivirals to treat persons ill with influenza, and another 25% is arriving this week. Dispensing by retail pharmacies is the most expeditious way to get antivirals to ill persons who need them, particularly since the influenza is impacting schoolchildren – many of whom participate in the School Lunch Program, a need-based program.

REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The normal distribution channel for antiviral prescription drugs is from the manufacturer to a wholesaler to the dispensing retail pharmacy. Current law and rule do not allow the Department of Health to transfer antivirals (received from the Strategic National Stockpile, or, "public health antivirals") from the Department to retail pharmacies, unless there is a shortage of antivirals or a distribution delay. There is no shortage or delay, but at the present time only a barrier arising from the high cost of antivirals (approximately \$100 for a 5-day treatment course). Several major pharmacy chains have agreed to dispense antivirals, without cost, to persons bearing a valid prescription but lacking ability to pay for these antivirals (an effective "shortage" if antivirals are unaffordable).

One exception to the prohibition against the wholesale distribution of prescription drugs is for “emergency medical reasons.” The Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, contains a provision in Section 499.003(53)(b)2., F.S., for the “emergency medical reasons” exemption to the prohibition against the wholesale distribution of prescription drugs by health care entities if the distribution is conducted in accordance with the rules established by the department. Rule authority is found in Section 499.05(1)(i), F.S., to implement an emergency medical reason exemption. The emergency rule provides the mechanism to allow the Department of Health to transfer public health antivirals to licensed Florida retail pharmacies willing to dispense those antivirals without cost to ill persons with a prescription for the same, so that Florida residents and visitors have access to treatment for the novel influenza regardless of inability to pay. County Health Departments are authorized under current rule to accept a patient’s oral representation of inability to pay. Subsection 64F-16.003(3), F.A.C. Department of Health will suggest that licensed retail pharmacies may choose to apply this standard regarding ability to pay.

SUMMARY: This emergency rule authorizes the transfer of public health antivirals from the Department of Health to licensed retail pharmacies, for dispensing to persons unable to pay for antivirals.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Rebecca Poston, R.Ph., Director, Drugs, Devices & Cosmetics Program, Department of Health, 4052 Bald Cypress Way, Bin #C-04, Tallahassee, Florida 32399-1703

THE FULL TEXT OF THE EMERGENCY RULE IS:

64FER09-1 (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 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.

(j) Transfers of prescription drugs, during the pendency of a declared emergency, by or on behalf of the Department of Health to a community pharmacy authorized to purchase prescription drugs, for dispensing to 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, provided that the community pharmacy transfers such un-dispensed prescription drugs back to the Department of Health Central Pharmacy as described in a written agreement.

(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 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.

Rulemaking 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, 9-11-09.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.

EFFECTIVE DATE: September 11, 2009

Section V Petitions and Dispositions Regarding Rule Variance or Waiver

DEPARTMENT OF LAW ENFORCEMENT

NOTICE IS HEREBY GIVEN THAT on September 8, 2009, the Criminal Justice Standards and Training Commission, received a petition for a waiver of portions of subsections 11B-27.002(4) and 11B-35.002(2), (7), F.A.C., by Joseph Gagliardi. The Petitioner wishes to waive those portions of the rules requiring candidates attending cross-over training to be Commission certified before beginning cross-over training or to have passed basic recruit training and have passed the State Officer Certification Examination prior to entry into the cross-over training program. Copies of the petition may be obtained from: Grace A. Jaye, Assistant General Counsel, Florida Department of Law Enforcement, P. O. Box 1489, Tallahassee, FL 32302, (850)410-7676.

A copy of the Petition for Variance or Waiver may be obtained by contacting: Grace A. Jaye, Assistant General Counsel, Florida Department of Law Enforcement, P. O. Box 1489, Tallahassee, FL 32302, (850)410-7676.

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