

Sandra.DuPont@fldfs.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
 THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Sandra DuPont, Specialty Product Administration, Office of Insurance Regulation, E-mail: Sandra.DuPont@fldfs.com

THE FULL TEXT OF THE PROPOSED RULE IS:

69O-136.019 Insurance Administrator Annual Report and Licensure Application.

(1) The forms adopted in subsections (2) and (3) below, are forms that Insurance Administrators must submit to the Office of Insurance Regulation to apply to do business in Florida and to report financial information. The forms may be viewed at the Office's website: <http://www.floir.com/pdf/OIR-C1-1075.pdf> and <http://www.floir.com/pdf/OIR-A3-975.pdf>.

(2) Form OIR-C1-1075, "Application for Certificate of Authority – Insurance Administrator" (REV 02/07), is hereby incorporated by reference and is to be submitted to the Office of Insurance Regulation when applying to do business in Florida.

(3) Form OIR-A3-975, "Insurance Administrator Annual Report" (REV 02/07), is hereby incorporated by reference and is to be submitted to the Office of Insurance Regulation to report financial information.

(4) All forms submitted for review or approval shall be submitted electronically to <http://portal.fldfs.com>.

Specific Authority 626.8991 FS. Law Implemented 626.8805, 626.89 FS. History–New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE:
 Sandra DuPont, Specialty Product Administration, Office of Insurance Regulation

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Rich Robleto, Deputy Commissioner, Office of Insurance Regulation

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 16, 2006

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 23, 2005

Section III Notices of Changes, Corrections and Withdrawals

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 ENVIRONMENTAL PROTECTION

RULE NO.:	RULE TITLE:
62-730.186	Universal Pharmaceutical Waste
	NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 33, No. 3, January 19, 2007 issue of the Florida Administrative Weekly.

62-730.186 Universal Pharmaceutical Waste

(1) through (2) No change.

(3) Hazardous waste pharmaceuticals are considered to be universal waste in Florida when managed in accordance with this section. Hazardous waste pharmaceuticals not managed as universal waste in accordance with this section shall be managed in accordance with Chapter 62-730, F.A.C., and shall be disposed of at a permitted hazardous waste treatment, storage or disposal facility.

(4)(a) through (j) No change.

(k) "Reverse distributor" means a person engaged in the reverse distribution of prescription drugs who:

1. Operates a warehouse licensed by the Department of Health Bureau of Statewide Pharmaceutical Services under Chapter 499, F.S., as a reverse distributor; and

2. Has management systems in place to ensure compliance with applicable requirements of 40 CFR Parts 260 through 273 [as adopted in sections 62-730.021 and 62-730.183, and subsections 62-730.020(1), 62-730.030(1), 62-730.160(1), 62-730.170(1), 62-730.180(1) and & (2), 62-730.181(1), 62-730.185(1), and 62-730.220(1), F.A.C.] and Chapter 62-730, F.A.C.

NOTE: The Federal Drug Enforcement Administration has registration requirements for persons engaged in the reverse distribution of prescription drugs who handle controlled substances in Schedules II through V promulgated under United States Code, Title 21, Section 812.

(l) through (7)(a) No change.

(b) A handler shall clearly label those containers and tanks accumulating waste pharmaceuticals with the phrase “universal pharmaceutical waste” or “universal waste pharmaceuticals,” and with specific hazardous waste codes applicable to the universal pharmaceutical waste that is or may be placed in the container or tank.

(c) A handler may conduct the following activities as long as the innermost container of each individual pharmaceutical remains intact and closed, or if the innermost container is placed into another individual sealed container and marked with the applicable hazardous waste code:

1. Sorting or mixing individual pharmaceuticals in one outer container, as long as the pharmaceuticals are compatible;
2. Disassembling packages containing several pharmaceuticals into individual pharmaceuticals; and
3. Removing pharmaceuticals from consumer packaging.

(7)(d) No change.

(e)1. A reverse distributor or wholesaler who meets the definition of “universal waste handler” in 40 CFR 273.9 [as adopted in subsection 62-730.185(1), F.A.C.] shall meet the requirements for “handlers” in subsections 62-730.186(6) through (12), F.A.C., of this section.

2. A reverse distributor or wholesaler that makes determinations as to whether pharmaceuticals are viable shall:

~~2. A reverse distributor or wholesaler that makes determinations as to whether pharmaceuticals are viable shall:~~

~~(e) 1. A reverse distributor or wholesaler who meets the definition of “universal waste handler” in 40 CFR 273.9 [as adopted in subsection 62-730.185(1), F.A.C.] shall meet the requirements for “handlers” in subsections 62-730.186(6) through (12), F.A.C., of this section.~~

a. Begin the process of distinguishing viable pharmaceuticals from universal pharmaceutical waste or hazardous waste within 14 days of receipt of a complete shipment of returns from a handler, and in no event more than 21 days from the receipt of the first installment of a partial shipment;

b. Complete the universal pharmaceutical waste or hazardous waste identification process within 21 days of receipt of the complete shipment, and in no event more than 30 days from receipt of the first installment of a partial shipment; and

c. Keep a record of each shipment of returns by any method that clearly demonstrates the date on which the shipment was received and the date on which the reverse

distributor or wholesaler determined the universal pharmaceutical waste or hazardous waste status of all items in the shipment.

(7)(f) through (9) No change.

(10) A handler shall immediately contain all releases of universal pharmaceutical waste (including spills that occur indoors). A handler shall determine whether any material resulting from a release is hazardous waste. A handler shall manage any such hazardous waste in compliance with the requirements of 40 CFR Parts 260 through 272 [as adopted in sections 62-730.021, and 62-730.183, and subsections 62-730.020(1), 62-730.030(1), 62-730.160(1), 62-730.170(1), 62-730.180(1) ~~and~~ & (2), 62-730.181(1), and 62-730.220(1), F.A.C.] The handler is considered the generator of the material resulting from the release and shall manage the material in compliance with 40 CFR Part 262 [as adopted in subsection 62-730.160(1), F.A.C.] Material resulting from the release of universal pharmaceutical waste may not be managed as universal pharmaceutical waste.

(11)(a) through (e) No change.

(f) A handler that transports a universal pharmaceutical waste to a reverse distributor or another handler must provide the reverse distributor or handler with written information sufficient to allow the reverse distributor or other handler to make knowledgeable decisions about the safe handling and proper disposal of the universal pharmaceutical waste.

(g) through (13) No change.

Specific Authority 403.061, 403.151, 403.704, 403.72, 403.721 FS. Law Implemented 120.52, 120.54, 403.061, 403.151, 403.704, 403.72, and 403.721 FS. History—New _____.

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.:
64B16-28.605

RULE TITLE:
Class II Institutional Pharmacies –
Automated Distribution and
Packaging

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 31 No. 4, January 28, 2005 issue of the Florida Administrative Weekly.

The change is in response to written comments submitted by the staff of the Joint Administrative Procedures Committee. The changes are as follows:

(1) Subsection (1)(f) shall now read as follows:

(f) “Override medication” means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, Chapter 459, or Chapter 466, Florida Statutes, has determined that the clinical status of the patient would be significantly compromised by delay.

(2) Subsection (1)(g) shall now read as follows:

(g) "Low risk override medication" is a medication determined by a practitioner licensed pursuant to Chapter 458, Chapter 459, or Chapter 466, Florida Statutes, to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.

(3) Subsection (2)(a)3.a. shall now read as follows:

a. Operation of the automated medication system;

(4) Subsection (3)(b)4. shall now read as follows:

4. Have its decisions reviewed and approved by the consultant pharmacist of record.

(5) Subsection (9) shall now read as follows:

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.

(6) Section 465.0235, F.S. will be added to the Law Implemented.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE NO.: 64F-12.026 RULE TITLE: Cancer Drug Donation Program

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 33, No. 3, January 19, 2007 issue of the Florida Administrative Weekly has been withdrawn.

FINANCIAL SERVICES COMMISSION

OIR – Insurance Regulation

RULE NO.: 69O-149.005 RULE TITLE: Reasonableness of Benefits in Relation to Premiums

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 32, No. 51, December 22, 2006 issue of the Florida Administrative Weekly.

These changes are being made to address concerns expressed at the public hearing.

Rule 69O-149.005 is changed to read as follows:

69O-149.005 Reasonableness of Benefits in Relation to Premiums.

(1) through (13) No change.

(14) An insurer may issue multiple year rate guarantee or rating cap provisions subject to the following:

(a) The coverage is for annually rated group health insurance policies for which filing of rates is exempted by Section 627.410(6), F.S., and excluding disability income policies;

(b) The provision may not apply for greater than 24 months;

(c) The rate for the entire rating period reflects the increased risk of a rate guarantee with an increased premium or other consideration, is actuarially sound, includes claim costs projected at trend levels at least as high as those applicable to other groups with similar benefit structures in the rating area covered under the form(s) and is reasonably anticipated to meet the target loss ratio for the group;

(d) The provision is available to groups on a nondiscriminatory basis as determined by the insurer's underwriting standards; and

(e) The insurer uses experience rating in determining the group's rate consistently based on its rating and underwriting practices without regard to whether the rate is issued with or without a rate guarantee.

Specific Authority 624.308(1), 627.410(6)(b), (d), (e) FS. Law Implemented 626.9541(1), 627.410(6)(d), (e), 627.410(7), 627.411(1)(a), (e), 627.9175 FS. History--New 7-1-85, Formerly 4-58.05, 4-58.005, Amended 4-18-94, 11-20-02, Formerly 4-149.005, Amended 5-18-04,_____.

FINANCIAL SERVICES COMMISSION

OIR – Insurance Regulation

RULE NO.: 69O-171.003 RULE TITLE: Reports by Insurers of Professional Liability Claims and Actions Required

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 32, No. 8, February 24, 2006 issue of the Florida Administrative Weekly.

These changes are being made to address concerns expressed at the public hearing.

Rule 69O-171.003 is changed to read as follows:

69O-171.003 Reports by Insurers of Professional Liability Claims and Actions Required.

(1)(a) Each entity self insurer identified in Section 627.912(1)(a), or 627.912(5), F.S., authorized under Section 627.357, F.S., and each insurer or joint underwriting association providing professional liability insurance to a practitioner of medicine licensed pursuant to the provisions of Chapter 458, F.S., to a practitioner of osteopathic medicine licensed pursuant to the provisions of Chapter 459, F.S., to a podiatric physician licensed pursuant to the provisions of Chapter 461, F.S., to a dentist licensed pursuant to the

provisions of Chapter 466, F.S., to a hospital licensed pursuant to the provisions of Chapter 395, F.S., to crisis stabilization units licensed under Part IV of Chapter 394, F.S., to a health maintenance organization certified under Part I of Chapter 641, F.S., to clinics included in Chapter 390, F.S., to an ambulatory surgical center as defined in Section 395.002, F.S., or to a member of the Florida Bar, shall report to the Office of Insurance Regulation (Office) any claim or action for damages for personal injuries claimed to have been caused by error, omission, or negligence in the performance of such insured's professional services or based on a claimed performance of professional services without consent. In any calendar year in which no claim or action for damages has been closed, the entity shall file a "No Claim Submission Report". Each such entity insurer or self insurer required to report under this rule shall submit such information to the Office using the "Professional Liability Claims Reporting ("PLCR") located at <https://apps.fldfs.com/plcr>, Form OIR-A1-1672 (1-06). The PLCR is incorporated and adopted by reference, electronically by using computer software provided by the Office. A copy of the judgment or settlement must be provided along with any other information required by the Office that is not included in the computer software. The following forms have been converted into the software provided by the Office are hereby incorporated by reference, and shall take effect on the effective date of this rule amendment: Form OIR-303 (5/99) "Florida Medical Professional Liability Insurance Claims Report" and OIR-304 (5/99) "Lawyers Professional Liability Closed Claim Reporting Form." Professional liability closed claim reports must be filed by the insurer if the claim resulted in:

(a) A final judgment in any amount; or

(b) In addition to the requirements set forth in Section 627.912(2), F.S., reports shall contain: A settlement in any amount.

1. The type of entity insured to include but not limited to hospitals, individuals or other facilities;

2. The field of medicine in which a physician practices;

3. The facility license or registration number, if available;

4. The amount the insurance company has set aside to pay the claim as of the closing date of the claim;

5. The names of all known defendants;

6. Whether or not the claim was closed due to a jury verdict or settlement;

7. The county in which the injury occurred; and

8. The date on which payment was made.

(c) In order to determine the cost of medical malpractice claims, the commissioner may require additional information, through filings, special data calls, informational hearings or by any other means consistent with statute or the Florida Administrative Code, that the commissioner believes will help in the determination of ultimate cost of medical malpractice claims.

(2) Each authorized insurer, risk retention group, joint underwriting association and surplus lines insurer shall annually report to the Office on or before April 1 of each calendar year a reconciliation of all paid claims and loss adjustment expenses reported pursuant to Section 627.912, F.S., and direct loss and loss adjustment expenses paid in the state of Florida and reported in their NAIC annual statement. Such reconciliation shall be reported using the method as described in paragraph (1)(a) and include by are not limited to the following:

(a) Payments on claims not closed in current calendar year;

(b) Payments made prior to January 1 on claims closed during the current calendar year;

(c) Losses paid on claims not settled under Florida law but which are reported in the NAIC annual statement;

(d) Payments on claims reported on policies written in another state;

(e) Reimbursements received;

(f) Rounding and statistical adjustments (explaining documentation must be provided);

(g) Un-reconciled amounts (explaining documentation must be provided);

(h) Closed claim subtractions; and

(i) Closed claim additions.

(3)(2) Any self-insurance program established under Section 240.213, F.S., shall report, using such method as described in paragraph (1)(a), in duplicate to the Office of Insurance Regulation any claim or action for damages for personal injuries claimed to have been caused by error, omission, or negligence in the performance of professional services provided by the Board of Regents through an employee or agent of the Board of Regents, including practitioners of medicine licensed under Chapter 458, F.S., practitioners of osteopathic medicine licensed under Chapter 459, F.S., podiatric physicians licensed under Chapter 461, F.S., and dentists licensed under Chapter 466, F.S., or based on a claimed performance of professional services without consent if the claim resulted in a final judgment in any amount, or a settlement in any amount.

(4)(3) Reports are due no later than 30 days after the claim has been closed, following the occurrence of one of the events listed in paragraph (a) or (b) above. "No Claim Submission Reports" are due no later than March 1st of each year. Entities not filing a closed claim or a "No Claim Submission Report" will be subject to fines and penalties as listed in Section 627.912, F.S. A closed claim report which is inaccurate, incomplete, or not properly formatted will be returned unprocessed and will be considered late until an accurate, complete and properly formatted report is received.

~~(4) The Office shall impose a fine of \$250 per day per case, but not to exceed a total of \$1,000 per case against an insurer or self-insurer that violates the professional liability closed claim reporting requirements. This applies to claims closed on or after October 1, 1997.~~

~~(5) Copies of the Professional Liability Closed Claim Software are available from the Office of Insurance Regulation, Bureau of Property and Casualty Forms and Rates, Room 238.14, Larson Building, Tallahassee, Florida 32399-0300, (850) 413-5346.~~

Specific Authority 624.308(1) FS. Law Implemented 624.307(1), 627.912, 627.918 FS. History–New 1-16-83, Amended 6-14-83, 7-1-85, 12-31-85, Formerly 4-59.03, Amended 11-9-86, 6-15-88, Formerly 4-59.003, Amended 4-28-92, 6-13-99, Formerly 4-171.003, Amended.

FINANCIAL SERVICES COMMISSION

OIR – Insurance Regulation

RULE NO.: RULE TITLE:
69O-191.054 Rates

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 32, No. 51, December 22, 2006 issue of the Florida Administrative Weekly.

These changes are being made to address concerns expressed at the public hearing.

Rule 69O-191.054 is changed to read as follows:

69O-191.054 Rates.

(1) through (10) No change.

(11) An HMO may issue multiple year rate guarantee or rating cap provisions subject to the following:

(a) The coverage is for annually rated group health insurance contracts for which filing of rates is exempted by Section 641.31(3)(d), F.S.:

(b) The provision may not apply for greater than 24 months;

(c) The rate for the entire rating period reflects the increased risk of a rate guarantee with an increased premium or other consideration, is actuarially sound, includes claim costs projected at trend levels at least as high as those applicable to other groups with similar benefit structures in the rating area covered under the form(s) and is reasonably anticipated to meet the target loss ratio for the group;

(d) The provision is available to groups on a nondiscriminatory basis as determined by the insurer’s underwriting standards; and

(e) The HMO uses experience rating in determining the group’s rate consistently based on its rating and underwriting practices without regard to whether the rate is issued with or without a rate guarantee.

Specific Authority 641.31, 641.36 FS. Law Implemented 641.21(1)(e), 641.22(2), (4), (6), 641.31(2), (3), 641.31074, 641.3922(3) FS. History–New 2-22-88, Amended 10-25-89, Formerly 4-31.054, Amended 10-8-96, 8-15-02, 1-19-03, Formerly 4-191.054, Amended.

**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.”

**Section V
Petitions and Dispositions Regarding Rule
Variance or Waiver**

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.”

WATER MANAGEMENT DISTRICTS

NOTICE IS HEREBY GIVEN that on January 30, 2007, the Suwannee River Water Management District, received a petition for Mr. Kenneth Roesch, 15411 N. W. 46th Lane, Chiefland, FL 32626, for demonstration of hardship for ERP06-0508, Treasure Camp Work-of-the-District Project with regard to subsection 40B-4.3030(9) and paragraph (11)(b), Fla. Admin. Code. Property is located in Township 12 South, Range 13 East, Section 32, Levy County.

A copy of the Petition for Variance or Waiver may be obtained by contacting: Robin Lamm, Administrative Assistant, Suwannee River Water Management District, 9225 C.R. 49, Live Oak, Florida 32060, (386)362-1001 or 1(800)226-1066 (FL only).
