Section I
Notices of Development of Proposed Rules and Negotiated Rulemaking

DEPARTMENT OF INSURANCE

Division of Risk Management

RULE CHAPTER TITLE:	RULE CHAPTER NO.:
Florida Fire Insurance Trust Fund	4H-1
RULE TITLES:	RULE NOS.:
Purpose	4H-1.001
Certificate and Other Forms	4H-1.003
Settlement of Losses	4H-1.007

PURPOSE AND EFFECT: To adopt and incorporate by reference the Risk Management forms which have been revised or created to accommodate the needs of program areas.

SUBJECT AREA TO BE ADDRESSED: These forms are utilized by the State Property Claims Unit in the Division of Risk Management. This unit processes property damage claims to state owned buildings and property damaged by fire, wind, lightning and other covered perils.

SPECIFIC AUTHORITY: 284.17 FS.

LAW IMPLEMENTED: 284.01 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 2:00 p.m., September 20, 2000

PLACE: Room 116, Larson Building, 200 East Gaines Street, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Ray Williams, Senior Management Analyst II, Risk Management, Department of Insurance, 200 E. Gaines Street, Tallahassee, Florida, (850)413-4754

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this program, please advise the Department at least 5 calendar days before the program by contacting Yvonne White, (850)413-4214.

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS AVAILABLE AT NO CHARGE FROM THE CONTACT PERSON LISTED ABOVE.

DEPARTMENT OF INSURANCE

Division of Risk Management

RULE CHAPTER TITLE:	RULE CHAPTER NO.:
State Risk Management Trust Fund, State Casualty Claims	4H-2
RULE TITLES:	RULE NOS.:
Purpose	4H-2.001
Premium Assessment	4H-2.003
Certificate of Coverage	4H-2.004
Fleet Automobile Liability Coverage for Coordinated Community Transportation Providers	4H-2.005
Loss Prevention Program	4H-2.007
Other Forms Adopted	4H-2.008

PURPOSE AND EFFECT: To amend the rule and adopt and incorporate by reference the Risk Management forms which have been revised or created to accommodate the needs of program areas.

SUBJECT AREA TO BE ADDRESSED: These forms are utilized by the Bureau of State Liability Claims and Bureau of State Employees' Workers' Compensation Claims in the Division of Risk Management. These units process liability and workers' compensation claims filed against state agencies.

SPECIFIC AUTHORITY: 284.39, 284.17 FS.

LAW IMPLEMENTED: 284.39, 284.01 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 2:00 p.m., September 20, 2000

PLACE: Room 116, Larson Building, 200 East Gaines Street, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Ray Williams, Senior Management Analyst II, Risk Management, Department of Insurance, 200 E. Gaines Street, Tallahassee, Florida, (850)413-4754

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this program, please advise the Department at least 5 calendar days before the program by contacting Yvonne White, (850)413-4214.

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS AVAILABLE AT NO CHARGE FROM THE CONTACT PERSON LISTED ABOVE.

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Division of Aquaculture

RULE CHAPTER TITLE:	RULE CHAPTER NO.:
Comprehensive Shellfish Control Code	5L-1
RULE TITLES:	RULE NOS.:
Shellfish Harvesting Area Standards	5L-1.003
Container Identification, Terminal Sale Date; Prohibitions	5L-1.007

PURPOSE AND EFFECT: This amendment proposes to reclassify the Alligator Harbor shellfish harvesting area, Franklin County. A sanitary survey has been conducted that evaluates current information on pollution sources and bacteriological water quality, and recommends reclassification of the Alligator Harbor shellfish harvesting area. Additionally, the four-digit area codes used on shellfish tags will be updated to identify the locations of the Alligator Harbor shellfish harvesting area.

SUBJECT AREA TO BE ADDRESSED: The proposed reclassification and management of the Alligator Harbor shellfish harvesting area for shellfish harvesting is in accordance with 5L-1.003 to protect the health of shellfish consumers and to provide access to renewable and natural shellfish resources. If illness outbreaks, the updated four-digit harvest area codes will provide for tracing of shellfish to where the shellfish were harvested.

SPECIFIC AUTHORITY: 570.07(23) FS.

LAW IMPLEMENTED: 370.071 FS.

A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 7:00 p.m. – 9:00 p.m., Monday, September 18, 2000

PLACE: Volunteer Fire Department, 1348 Alligator Drive, Alligator Point, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: John McDowell, Division of Aquaculture, 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301, Phone (850)488-5471

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF EDUCATION

State Board of Education

RULE TITLE:	RULE NO.:
General Requirements	6F-1.001

PURPOSE AND EFFECT: The purpose of this rule development is to make this rule consistent with Section 246.203, Florida Statutes, and to clarify existing requirements.

SUBJECT AREA TO BE ADDRESSED: General requirements of the State Board of Nonpublic Career Education.

SPECIFIC AUTHORITY: 246.205(1), 246.207(1)(e), 246.213 FS.

LAW IMPLEMENTED: 120.53(1)(b), 246.207(1)(e), 246.213(1), 246.215(1), 246.217(3), 246.226, 246.2265, 246.228 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE TO BE ADVERTISED IN A FUTURE EDITION OF THE FLORIDA ADMINISTRATIVE WEEKLY.

Requests for the rule development workshop should be addressed to Wayne V. Pierson, Agency Clerk, Department of Education, Room 1702, The Capitol, Tallahassee, Florida 32399-0400.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Samuel L. Ferguson, Executive Director, State Board of Nonpublic Career Education, Department of Education, 325 West Gaines Street, Tallahassee, Florida 32399-0400, (850)488-9504

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF EDUCATION

State Board of Independent Postsecondary Vocational, Technical, Trade and Business Schools

RULE TITLES:	RULE NOS.:
Certificate of Licensure for Schools	6F-2.001
Change in Ownership	6F-2.0015
Change in Control	6F-2.0016
Student Protection Fund	6F-2.0017
Minimum Standards for Licensure of Schools	6F-2.002
Fair Consumer Practices	6F-2.0024
Fee Schedule	6F-2.0026
School Descriptive Inventory	6F-2.003
Advertising	6F-2.004

PURPOSE AND EFFECT: The purpose of these rule developments is to eliminate duplicate language, provide consistency between the rule and their implementing law, and to clarify requirements specific to each rule.

SUBJECT AREA TO BE ADDRESSED: Subject areas to be addressed include: certificate of license for schools, changes in ownership and control; student protection funds; minimum standards for licensure of schools; fair consumer practices; fee schedules; school inventories; and advertising of nonpublic career institutions.

SPECIFIC AUTHORITY: 246.205(1), 246.207(1)(e), 246.213, 246.219 FS.

LAW IMPLEMENTED: 120.53(1)(b), 120.60, 246.207(1)(e), 246.213, 246.215, 246.217, 246.219, 246.226, 246.2265, 246.228 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE TO BE ADVERTISED IN A FUTURE EDITION OF THE FLORIDA ADMINISTRATIVE WEEKLY.

Requests for the rule development workshop should be addressed to Wayne V. Pierson, Agency Clerk, Department of Education, Room 1702, The Capitol, Tallahassee, Florida 32399-0400.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Samuel L. Ferguson, Executive Director, State Board of Nonpublic Career Education, Department of Education, 325 West Gaines Street, Tallahassee, Florida 32399-0400, (850)488-9504

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF EDUCATION

State Board of Independent Postsecondary Vocational, Technical, Trade and Business Schools

RULE TITLES:	RULE NOS.:
Agents; License Required	6F-3.001
Agents; Qualifications, Training Limitation of Authority, Responsibilities of Schools, Agents, and Applicants	6F-3.002

PURPOSE AND EFFECT: The purpose of these rule developments is to clarify the procedures for submitting fees for an agent license and the fee for the cost of obtaining criminal justice information and to delete obsolete language. The effect will be rules that are clear and concise for the affected institutions and the agents representing them.

SUBJECT AREA TO BE ADDRESSED: The procedures and requirements for the licensure of agents representing nonpublic career education schools and the responsibilities of the agent and the school represented will be the subject matter.

SPECIFIC AUTHORITY: 246.207(1)(e), 246.213 FS.

LAW IMPLEMENTED: 246.207(1)(e), 246.213(1), 246.215(2), 246.219 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE TO BE ADVERTISED IN A FUTURE EDITION OF THE FLORIDA ADMINISTRATIVE WEEKLY.

Requests for the rule development workshop should be addressed to Wayne V. Pierson, Agency Clerk, Department of Education, Room 1702, The Capitol, Tallahassee, Florida 32399-0400.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Samuel L. Ferguson, Executive Director, State Board of Nonpublic Career Education, Department of Education, 325 West Gaines Street, Tallahassee, Florida 32399-0400, (850)488-9504

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF EDUCATION

State Board of Independent Postsecondary Vocational, Technical, Trade and Business Schools

RULE TITLE:	RULE NO.:
License Application Package	6F-4.001

PURPOSE AND EFFECT: The purpose of this rule development is to provide an application package for schools seeking licensure and to inform the public where to obtain this package. The effect is to provide a standardized application package for interested parties.

SUBJECT AREA TO BE ADDRESSED: The required forms for licensure in the state of Florida will be the subject matter to be addressed.

SPECIFIC AUTHORITY: 246.207(1)(e), 246.213 FS.

LAW IMPLEMENTED: 120.53(1)(b), 246.207(1)(e), 246.213(1), 246.215, 246.217, 246.219 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE TO BE ADVERTISED IN A FUTURE EDITION OF THE FLORIDA ADMINISTRATIVE WEEKLY.

Requests for the rule development workshop should be addressed to Wayne V. Pierson, Agency Clerk, Department of Education, Room 1702, The Capitol, Tallahassee, Florida 32399-0400.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Samuel L. Ferguson, Executive Director, State Board of Nonpublic Career Education, Department of Education, 325 West Gaines Street, Tallahassee, Florida 32399-0400, (850)488-9504

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF CORRECTIONS

RULE TITLE:	RULE NO.:
Probation and Restitution Centers	33-504.101

PURPOSE AND EFFECT: The purpose of the proposed rule is to correct technical errors and clarify procedures relating to probation and restitution centers. The effect is to correct grammatical errors; correct titles; clarify procedures relating to revocation and removal; and increase room and board fees.

SUBJECT AREA TO BE ADDRESSED: Probation and Restitution Centers.

SPECIFIC AUTHORITY: 944.026, 921.187, 948.03, 958.04 FS.

LAW IMPLEMENTED: 944.026, 921.187, 948.03, 958.04 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE WEEKLY:

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Giselle Lylen Rivera, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

33-504.101 Probation and Restitution Centers.

(1) General Policy.

(a) Probation and restitution centers are short-term ~~short term~~ residential facilities which provide the courts with an alternative to committing offenders to more secure correctional institutions and provide assistance in the supervision of probationers and community controllees. The centers provide a controlled setting designed to prepare offenders for advancement or return to community supervision and for eventual release from supervision.

(b) Probation and restitution centers house felony probationers and community controlees who have violated their terms or conditions of supervision and felony offenders assigned to pretrial intervention programs. These offenders reside in the centers while working, receiving treatment or attending school. Probation and restitution centers also provide outpatient ~~out-patient~~ substance abuse counseling for persons on felony probation or community control.

(c) The ~~Probation and Parole Program~~ Office of Program Services shall be responsible for the operation and contract management of ~~program development and monitoring of the centers, and for providing technical assistance to the~~ centers.

(d) ~~The regional administrator for each region shall be responsible for the operation of the region's centers and shall maintain close coordination with the Probation and Parole Program Office and correctional probation administrators of probation and parole services.~~ Each probation and restitution center major ~~chief~~ shall be responsible for the management and supervision of the center, for supervising the probation and restitution center officers, and for ensuring the proper supervision, care and control of the center's offenders. The primary duty and responsibility of probation and restitution center officers is the care, supervision and control of the offenders at the center.

(2) through (3) No change.

(4) Referral Responsibilities.

(a) The correctional probation officers are responsible for assuring the probation and restitution center is included in the pre-sentence investigation as a possible alternative recommendation to imprisonment when more structured ~~structural~~ control is needed than what regular probation can provide.

(b) through (6)(b) No change.

~~(c) A copy of the Affidavit of Violation of Probation, warrant, order of revocation, or any other court order shall be provided to the originating circuit office.~~

(7) Termination or Transfer From Program. Recommendations for termination, transfers or other types of removal from the program shall be a decision of center staff. Offenders shall be considered for removal ~~removed~~ from the program for violation of the conditions of probation or community control, violation of a ~~any~~ center regulation, inability to complete program requirements, or where such removal is deemed to be in the best interest of the offender, the department, or the community.

(8) Room and Board Fees.

(a) All offenders shall be charged room and board fees at the rate of $8.00 ~~$6.00~~ per day beginning ~~on~~ the ~~first~~ day they enter ~~upon entering~~ the program.

(b) through (12)(f) No change.

(g) Recommendations for graduation based on the above outlined criteria shall be made by the offenders treatment team and approved by the major ~~correctional officer chief~~.

(13) No change.

Specific Authority 944.026, 921.187, 948.03, 958.04 FS. Law Implemented 944.026, 921.187, 948.03, 958.04 FS. History–New 10-26-92, Amended 9-4-95, Formerly 33-24.020, Amended _____.

DEPARTMENT OF CORRECTIONS

RULE TITLE: RULE NO.:
Use of Force 33-602.210

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to provide for the use of specialty impact munitions, to clarify the process for review of use of force reports, to clarify staff supervision required for the use of chemical agents, and to specifically prohibit discharging firearms at departing aircraft involved in escape attempts.

SUBJECT AREA TO BE ADDRESSED: Use of force.

SPECIFIC AUTHORITY: 944.09 FS.

LAW IMPLEMENTED: 20.315, 944.09, 944.35 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Perri King Dale, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

33-602.210 Use of Force.

(1) through (7) No change.

(8) The warden or assistant warden shall immediately conduct a preliminary review of the video tape(s) and all associated reports for signs of excessive force or procedural deviation. The Warden shall then appoint a staff member of equal or higher rank than those involved in the use of force to collect all pertinent information. This information will include statements from all involved staff, inmates and staff and inmate witnesses. This process will be completed within 5 working days (Monday through Friday). The warden shall review the information and note any inappropriate actions. The warden shall complete the Use of Force File Checklist, Form DC1-813, and shall forward the videotape(s) and associated reports on the use of force and the warden's summary to the institutional inspector. Form DC1-813 is hereby incorporated by reference. Copies of this form are available from the Forms Control Administrator, Office of the General Counsel, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500. The effective date of this form is _____. The institutional inspector will review the videotape(s) and associated documentation to ensure that all documentation is complete and will forward all materials to the Use of Force Unit within the Office of the Inspector General (OIG) within 5 working days. The OIG, following its review, will either approve the use of force action or disapprove it and refer it for investigation. Copies of the employee's report, the warden's summary and the inspector general's review and determination shall be kept in the inmate's file. A Use of Force Log, Form DC2-802, shall be placed in every employees personnel file. This form will be maintained by the servicing personnel office and shall contain a record of every report of use of force and staff supplement completed by the employee. The institutional inspector shall be responsible for submitting accurate information to the personnel office in order to maintain the DC2-802. Any use of force reports completed prior to April 15, 1998 shall also remain in the file. Form DC2-802, Use of Force Log, is hereby incorporated by reference. Copies of this form can be obtained from the Forms Control Administrator, Office of the General Counsel, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500. Requests for copies to be mailed must be accompanied by a self-addressed stamped envelope. The effective date of this form is February 7, 2000.

(9) through (10) No change.

(11) The use of electronic restraining devices, batons, ~~or~~ chemical agents, or specialty impact munitions within institutions shall be authorized only by the warden, or duty warden if the warden is not available. For purposes of this rule, the duty warden shall be of a rank of correctional officer colonel or higher. The correctional officer major at the main unit can serve as duty warden at those institutions that do not have a correctional officer colonel. Batons shall be used only by trained baton squad members to disarm an inmate or during situations in which the squad has been activated to quell a disturbance. The decision to use chemical agents, specialty impact munitions, or authorized electronic restraining devices shall be based on which level of force is most likely to resolve the situation with the least amount of injury to all parties involved. Hands-on physical force shall be avoided if injury is less likely to occur by using chemical agents, specialty impact munitions, or electronic restraining devices.

(12) through (13)(l) No change.

(m) Procedure for the use of chemical agents on disruptive inmates under controlled conditions:

1. If an inmate becomes disorderly, disruptive, unruly, and attempts by officers at counseling and ordering the cessation of disruptive behavior fails, the confinement/close management lieutenant or shift supervisor or higher shall be contacted for further instructions.

2. If the confinement/close management lieutenant or shift supervisor's efforts to control the disorderly inmate have failed and the use of chemical agents is the least level of force that can be expected to successfully gain control of the disruptive inmate while minimizing the risk of injuries to all involved, the shift supervisor shall:

a. Ensure that medical staff are contacted when time and circumstances permit, to determine if the inmate has a medical condition that would prevent the use of chemical agents; and

b. Contact the warden or duty warden and request authorization to utilize chemical agents.

3. Prior to using chemical agents, the inmate again shall be ordered by staff to cease his actions.

a. If these efforts fail, the confinement/close management lieutenant or shift supervisor shall order the disorderly inmate to cease his actions and inform him that chemical agents will be administered if he continues his disruptive behavior.

b. Any uninvolved inmates in the cell or immediate area shall be given an opportunity to leave the potentially affected area, if it will not jeopardize the safety of staff or other inmates.

c. Except in cases of emergency, the confinement/close management lieutenant or shift supervisor shall be present during the time of the final counseling period and the administering of chemical agents.

n. through o. No change.

(14) Specialty Impact Munitions. Specialty impact munitions shall be used primarily by the department's rapid response teams and correctional emergency response teams during riots and disturbances. They are intended as a less lethal alternative to the use of deadly force.

(a) Definitions:

1. Specialty Impact Munitions – Munitions designed to incapacitate, distract, and control a subject with less likelihood of life-threatening injury.

2. Rubber Ball Rounds – Multiple pellets fired from cartridges at the lower extremities of rioters, designed to inflict pain compliance.

3. Wooden Baton Rounds – Multiple wooden baton pellets fired from a 37-MM weapon, designed to be skip fired into the lower extremities of rioters to inflict pain compliance.

4. Skip Firing – The practice of firing specialty impact munitions 5-7 feet in front of rioters, thereby deflecting the munitions into the legs of the rioters.

5. Direct Firing – The practice of firing specialty munitions directly into a group of rioters, from a distance of greater than 20 feet with a target area of center body mass or below.

(b) The following specialty impact munitions have been approved for use by the department:

1. 37-MM rubber ball pellet rounds,

2. 12 gauge rubber ball pellet rounds,

3. 37-MM wooden baton rounds.

(c) Selection and deployment of specialty impact munitions during a riot or disturbance shall be authorized by the ultimate commander and supervised by the rapid response or correctional emergency response team leader. For the purposes of this rule, the ultimate commander is the secretary or his designee at the central office level, the regional director or his designee at the regional level, or the warden or his designee at the institution level.

(d) Specialty impact munitions shall only be employed by officers trained in their use and effects.

(e) Specialty impact munitions shall only be used after all other reasonable alternatives to regain control have been exhausted. They are intended to be used as an interim force response between the use of chemical agents and lethal force.

(f) Specialty impact munitions shall not be deployed in the direction of any individual at a distance of less than 10 feet, unless the threat justifies the escalation to deadly force.

(g) Storage of Specialty Impact Munitions.

1. Specialty impact munitions shall be stored and maintained in the main arsenal.

2. Specialty impact munitions shall not be mixed with lethal munitions. Weapons designated to deploy specialty impact munitions shall be marked in a manner to alert staff of their intended use.

3. All specialty impact munitions will be accounted for in the same manner as firearms and ammunition.

(h) As soon as possible after each use of specialty impact munitions, exposed inmates shall be examined by medical personnel.

(i) In any case where specialty impact munitions are deployed, a use of force report shall be filed in accordance with use of force procedures set forth in this rule.

(j) As soon as practical after deployment of specialty impact munitions the discharging officer shall file an incident report, Form DC6-210. Form DC6-210 is incorporated by reference in (9) of this rule. Every effort shall be made to collect and secure the empty munitions cartridges for accountability and investigative purposes.

(15)~~(14)~~ Use of Firearms. In order for all concerned to be aware of their responsibilities, the statewide procedures set forth in this rule shall be included in the appropriate Department of Corrections procedures, post orders and escape emergency plans at each institution.

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

8. If attempts to prevent inmates from boarding the aircraft described in 7. above fail and the aircraft leaves, the aircraft is not to be fired upon. I~~i~~mmediate notification should be made to law enforcement personnel and the Federal Aviation Administration giving departing flight directions and any other information necessary to identify the aircraft. Additional information on the escaped inmates, possible damage to the aircraft, and weapons used by persons in the aircraft should also be reported.

(h)9. through (17) No change.

Specific Authority 944.09 FS. Law Implemented 20.315, 944.09, 944.35 FS. History–New 4-8-81, Amended 10-10-83, 9-28-85, Formerly 33-3.066, Amended 3-26-86, 11-21-86, 4-21-93, 7-26-93, 11-2-94, 2-12-97, 11-8-98, Formerly 33-3.0066, Amended 10-6-99, 2-7-00, _____.

AGENCY FOR HEALTH CARE ADMINISTRATION

Medicaid

RULE TITLE: RULE NO.:

County Health Department Clinic Services 59G-4.055

PURPOSE AND EFFECT: The purpose of this rule amendment is to incorporate by reference the revised Florida Medicaid County Health Department Clinic Services Coverage and Limitations Handbook, October 2000. The effect will be to incorporate by reference in the rule the updated Florida Medicaid County Health Department Clinic Services Coverage and Limitations Handbook.

SUBJECT AREA TO BE ADDRESSED: Medicaid County Health Department Clinic Services Program.

SPECIFIC AUTHORITY: 409.919 FS.

LAW IMPLEMENTED: 409.905, 409.908 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW.

TIME AND DATE: 9:00 a.m., September 19, 2000

PLACE: 2728 Ft. Knox Blvd., Building 3, Conference Room C, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Kay Aloi, Medicaid Program Development, P. O. Box 12600, Tallahassee, Florida 32317-2600, (850)922-7330

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

59G-4.055 County Health Department Clinic Services.

(1) This rule applies to all county health department clinic services providers enrolled in the Medicaid program.

(2) All county health department clinic services providers enrolled in the Medicaid program must comply with the Florida Medicaid County ~~Public~~ Health Department ~~Unit~~ Clinic Services Coverage and Limitations Handbook, September 2000 ~~December 1996~~, incorporated by reference, and the Florida Medicaid Provider Reimbursement Handbook, HCFA 1500 and Child Health Check-Up ~~EPSDT~~ 221, incorporated by reference in 59G-5.020. Both handbooks are available from the Medicaid fiscal agent.

Specific Authority 409.919 FS. Law Implemented 409.905, 409.908 FS. History–New 6-27-93, Formerly 10P-4.350, Amended 4-16-95, 6-4-96, 6-24-98, _____.

AGENCY FOR HEALTH CARE ADMINISTRATION

Medicaid

RULE TITLE: RULE NO.:
Prescribed Drug Services 59G-4.250

PURPOSE AND EFFECT: The purpose of this rule amendment is to incorporate by reference the revised Florida Medicaid Prescribed Drug Services, Coverage, Limitations and Reimbursement Handbook, November 2000. The revised handbook contains the requirements for assignment of certain recipients to specified providers. The effect will be to incorporate by reference in the rule the current Florida Medicaid Prescribed Drug Coverage, Limitations, and Reimbursement Handbook.

SUBJECT AREA TO BE ADDRESSED: Prescribed Drug Services.

SPECIFIC AUTHORITY: 409.919 FS.

LAW IMPLEMENTED: 409.906(20), 409.908 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 9:00 a.m., September 18, 2000

PLACE: Conf. Room E, Bldg 3, 2727 Mahan Drive, Tallahassee, FL 32308

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Jerry F. Wells, Medicaid Bureau of Pharmacy Services, P. O. Box 12600, Tallahassee, Florida 32317-2600, (850)487-4441

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

59G-4.250 Prescribed Drug Services.

(1) No change.

(2) All participating prescribed drug services providers enrolled in the Medicaid program must be in compliance with the Florida Medicaid Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook, November 2000 ~~July 1999~~, which is incorporated by reference, and available from the Medicaid fiscal agent.

Specific Authority 409.919 FS. Law Implemented 409.906(20), 409.908 FS. History–New 1-1-77, Amended 6-30-77, 10-1-77, 2-1-78, 4-1-78, 9-28-78, 6-1-79, 2-28-80, 11-11-81, 7-3-84, Formerly 10C-7.42, Amended 3-11-86, 12-5-88, 6-4-90, 10-29-90, 5-20-92, 4-11-93, Formerly 10C-7.042, Amended 12-28-95, 8-3-97, 2-11-98, 9-13-99, 7-14-00, _____.

AGENCY FOR HEALTH CARE ADMINISTRATION

Medicaid

RULE TITLE: RULE NO.:
Provider Requirements 59G-5.020

PURPOSE AND EFFECT: The purpose of this rule is to incorporate by reference the revised Florida Medicaid Provider Reimbursement Handbook, HCFA-1500 and Child Health Check-Up 221, November 2000. The effect will be to incorporate by reference in the rule the revised Florida Medicaid Provider Handbook, HCFA-1500 and Child Health Check-Up 221.

SUBJECT AREA TO BE ADDRESSED: Medicaid provider requirements.

SPECIFIC AUTHORITY: 409.919 FS.

LAW IMPLEMENTED: 409.902, 409.906, 409.907, 409.908 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 10:30 a.m., Monday, September 18, 2000

PLACE: 2308 Killearn Center Blvd, Suite 200, Conference Room, Tallahassee, Florida, 32308

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS. Karen Girard, Medicaid Contract Management, 2308 Killearn Center Blvd, Suite 200, (850)922-7342

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

59G-5.020 Provider Requirements.

All advanced registered nurse practitioners; ambulatory surgery centers; audiologists; birthing centers; child health check-up providers; chiropractors; community mental health services providers; county health departments; county health department certified match providers; dentists (when submitting claims on the HFCA-1500 claim form); durable

medical equipment and medical supply providers; early intervention service providers; federally qualified health centers; freestanding dialysis centers; hearing aid specialists; home health agencies; independent laboratories; licensed midwives; Medicaid certified school match providers; medical foster care providers; opticians; optometrists; physicians; physician assistants; podiatrists; portable x-ray providers; prescribed pediatric extended care centers; registered nurse first assistants; rural health clinics; therapists; and visual services providers enrolled in the Medicaid program and their billing agents must comply with the provisions of the Florida Medicaid Provider Reimbursement Handbook, HCFA-1500 and Child Health Check-Up 221, updated November 2000 ~~July 1999~~, which is incorporated by reference and available from the fiscal agent.

Specific Authority 409.919 FS. Law Implemented 409.902, 409.906, 409.907, 409.908 FS. History–New 9-22-93, Formerly 10P-5.020, Amended 7-8-97, 1-9-00, _____.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Architecture and Interior Design

RULE TITLE: RULE NO.:
Grounds for Disciplinary Proceedings 61G1-12.001

PURPOSE AND EFFECT: The purpose of the rule amendments is to update the rule text with regard to grounds for disciplinary proceedings.

SUBJECT AREA TO BE ADDRESSED: Grounds for disciplinary proceedings.

SPECIFIC AUTHORITY: 455.304, 481.2055 FS.

LAW IMPLEMENTED: 455.303, 455.304, 481.225, 481.2251 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Sherry Landrum, Executive Director, Board of Architecture and Interior Design, 1940 North Monroe Street, Northwood Centre, Tallahassee, Florida 32399-0750

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

61G1-12.001 Grounds for Disciplinary Proceedings.

(1) No change.

(2) As provided in Sections 481.225(1)(h) and 481.2251(1)(d), F.S., an architect or interior designer, ~~or~~ firm, or business holding a certificate of authorization shall not "advertise goods or services in a manner which is fraudulent, false, deceptive, or misleading in form or content." A false, fraudulent, misleading, or deceptive statement or claim shall include without limitation:

(a) through (f) No change.

(3) No change.

(4) An architect, ~~or~~ firm, or business holding a certificate of authorization may not be negligent in the practice of architecture. The term negligence is defined as the failure, by an architect, to exercise due care to conform to acceptable standards of architectural practice in such a manner as to be detrimental to a client or to the public at large.

(a) No change.

(b) An architect shall be required to coordinate his activities with other professionals involved in those projects wherein the architect is engaged to provide plans, drawings and specifications which result in the production of working documents which are used or intended to be used for the construction of a structure. If so contracted, the architect shall administer the construction project to protect the client's financial interests.

(c) An architect qualifying a firm shall be responsible for supervison of the financial aspects of the firm in providing architectural services.

(5) No change.

(6) An architect, ~~or~~ firm or business holding a certificate of authorization shall not commit misconduct in the practice of architecture. Misconduct in the practice of architecture shall include but not be limited to:

(a) through (c) No change.

1. through 3. No change.

(d) through (k) No change.

Specific Authority 455.304, 481.2055 FS. Law Implemented 455.303, 455.304, 481.225, 481.2251 FS. History–New 12-23-79, Amended 12-19-82, Formerly 21B-12.01, Amended 9-23-86, 11-8-88, Formerly 21B-12.001, Amended 2-25-98, _____.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Funeral Directors and Embalmers

RULE TITLE: RULE NO.:
Continuing Education for License Renewal 61G8-17.0034

PURPOSE AND EFFECT: The Board proposes to add language to this rule to elucidate and improve the interpretation of text.

SUBJECT AREA TO BE ADDRESSED: Continuing education for license renewal.

SPECIFIC AUTHORITY: 470.005(1), 470.015(1), 470.018 FS.

LAW IMPLEMENTED: 455.273, 470.015, 470.018 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE SCHEDULED AND ANNOUNCED IN THE NEXT AVAILABLE ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Juanita Chastain, Program Administrator, Board of Funeral Directors and Embalmers, Northwood Centre, 1940 N. Monroe Street, Tallahassee, Florida 32399-0750

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

61G8-17.0034 Continuing Education for License Renewal.

(1) through (2)(a) No change.

(b) Registered Direct Disposers shall complete three (3) contact hours of continuing education, which shall include courses in the areas of health, safety, and laws and rules.

(c) through (d) No change.

(3) through (6) No change.

Specific Authority 470.005(1), 470.015(1), 470.018 FS. Law Implemented 455.273, 470.015, 470.018 FS. History–New 4-10-94, Amended 3-14-95, 7-25-95, 9-25-95, 9-25-97, 11-11-99, _____.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Funeral Directors and Embalmers

RULE TITLE: RULE NO.:
Direct Disposal Establishments 61G8-23.004

PURPOSE AND EFFECT: The Board proposes to add language to this rule to improve clarity of the rule and facilitate its correct interpretation.

SUBJECT AREA TO BE ADDRESSED: Direct disposal establishments.

SPECIFIC AUTHORITY: 470.005, 470.021 FS.

LAW IMPLEMENTED: 455.219(6), 470.021 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE SCHEDULED AND ANNOUNCED IN THE NEXT AVAILABLE ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Juanita Chastain, Program Administrator, Board of Funeral Directors and Embalmers, Northwood Centre, 1940 N. Monroe Street, Tallahassee, Florida 32399-0750

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

61G8-23.004 Direct Disposal Establishments.

(1) No change.

(2) Prior to the issuance and renewal of its license a direct disposal establishment shall be approved by the Department if upon inspection by the Department it is shown that:

(a) through (c) No change.

(d) The establishment shall be at a fixed, non-residential location in a building owned or leased by the direct disposer.

(e) The establishment shall be at least 625 square feet in size.

(f) If the establishment does not itself provide removal services, refrigeration facilities or cinerator facilities at or from its physical location address (profile location), upon application for registration, the establishment shall provide copies of its contracts with a removal service, refrigeration facility, retort or any appropriate combination thereof, located within 75 miles of the establishment's profile location.

(3) through (9) No change.

Specific Authority 470.005, 470.021 FS. Law Implemented 455.219(6), 470.021 FS. History–New 2-13-80, Amended 11-8-82, 8-16-83, Formerly 21J-23.04, Amended 6-5-90, Formerly 21J-23.004, Amended 4-10-94, 9-17-97, 1-4-98, 2-16-98, 5-17-98, 2-17-00, 6-14-00, _____.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Funeral Directors and Embalmers

RULE TITLE: RULE NO.:
Supervision of Pre-need agents 61G8-28.001

PURPOSE AND EFFECT: The Board proposes to amend this rule to remove inconsistencies.

SUBJECT AREA TO BE ADDRESSED: Supervision of pre-need agents.

SPECIFIC AUTHORITY: 470.005 FS.

LAW IMPLEMENTED: 470.005, 470.028 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE SCHEDULED AND ANNOUNCED IN THE NEXT AVAILABLE ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Juanita Chastain, Program Administrator, Board of Funeral Directors and Embalmers, Northwood Centre, 1940 N. Monroe Street, Tallahassee, Florida 32399-0750

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

61G8-28.001 Supervision of Pre-need Agents.

A pre-need agent shall be required to work under the supervision of a ~~the~~ funeral director to whom he is responsible, pursuant to Section 470.028, Florida Statutes.

Specific Authority 470.005 FS. Law Implemented 470.005, 470.028 FS. History–New 10-13-82, Formerly 21J-28.01, 21J-28.001, Amended _____.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Florida Real Estate Commission

RULE TITLES:	RULE NOS.:
Citation Authority	61J2-24.002
Notice of Noncompliance	61J2-24.003

PURPOSE AND EFFECT: The Commission will consider reducing penalties for certain violations from citations, which include fines, to notices of noncompliance, which do not.

SUBJECT AREA TO BE ADDRESSED: To consider reducing penalties imposed upon licensees, permitholders and registrants for certain violations.

SPECIFIC AUTHORITY: 475.05 FS.

LAW IMPLEMENTED: 455.224, 455.225(3), 120.695 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 8:30 a.m., September 20, 2000

PLACE: Office of Florida Real Estate Commission, 400 West Robinson Street, Suite 301, North Tower, Orlando, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Herbert S. Fecker, Jr., Director, Division of Real Estate, 400 West Robinson Street, Suite 308, North Tower, Orlando, Florida 32801

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF HEALTH

Board of Acupuncture

RULE TITLE:	RULE NO.:
English Proficiency Requirement for Licensure	64B1-4.0012

PURPOSE AND EFFECT: The proposed rule will set forth the procedures for applicants for licensure as an acupuncturist to demonstrate their ability to communicate in English.

SUBJECT AREA TO BE ADDRESSED: English Proficiency Requirement for Licensure

SPECIFIC AUTHORITY: 457.104 FS., Section 62, Chapter 2000-318, Laws of Florida.

LAW IMPLEMENTED: Section 62, Chapter 2000-318, Laws of Florida.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: William Buckhalt, Executive Director, Board of Acupuncture, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF HEALTH

Board of Medicine

RULE TITLE:	RULE NO.:
Standard of Care for Office Surgery	64B8-9.009

PURPOSE AND EFFECT: The Board proposes the developments of rule amendments to address surgery performed in physicians offices.

SUBJECT AREA TO BE ADDRESSED: Office surgery.

SPECIFIC AUTHORITY: 458.309(1),(3), 458.331(1)(v) FS.

LAW IMPLEMENTED: 458.331(1)(g),(t),(v),(w) FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Tanya Williams, Executive Director, Board of Medicine/MQA, 4052 Bald Cypress Way, Bin #C03, Tallahassee, Florida 32399-1753

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE TITLES:	RULE NOS.:
Fees and License Renewal Application	64B16-26.101
Inactive License Renewal	64B16-26.102
Consultant Pharmacists Initial Registration Fee and Renewal Fee	64B16-26.105
Nuclear Pharmacists Initial Registration Fee and Renewal Fee	64B16-26.106
Inactive Nuclear Pharmacist License Renewal	64B16-26.107

PURPOSE AND EFFECT: The Board proposes to discuss the rules referenced above to determine if the fees should be increased.

SUBJECT AREA TO BE ADDRESSED: Proposed increase in fees.

SPECIFIC AUTHORITY: 465.005, 465.008, 465.012, 465.0125, 465.0126, 465.022(8) FS.

LAW IMPLEMENTED: 455.641, 455.711, 465.008, 465.012, 465.0126, 465.022(8), 468.0125 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 10:00 a.m., October 12, 2000

PLACE: The Radisson Hotel, 415 N. Monroe Street, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: John Taylor, Executive Director, Board of Pharmacy/MQA, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE TITLE: RULE NO.:

Requirements for an Internship Program Sufficient to Qualify and Applicant for Licensure by Examination 64B16-26.401

PURPOSE AND EFFECT: The Board proposes to amend this rule to update the rule text with regard to the requirements for an internship program sufficient to qualify an applicant for licensure by examination.

SUBJECT AREA TO BE ADDRESSED: Requirements.

SPECIFIC AUTHORITY: 465.005 FS.

LAW IMPLEMENTED: 465.007 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 10:00 a.m., October 12, 2000

PLACE: The Radisson Hotel, 415 N. Monroe Street, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: John Taylor, Executive Director, Board of Pharmacy/MQA, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

64B16-26.401 Requirements for an Internship Program Sufficient to Qualify an Applicant for Licensure by Examination.

(1) through (6) No change.

(7) Applicants graduating after January 1, 2001, with the doctor of pharmacy degree from an institution meeting the requirements of 465.007(1)(b)1. shall be deemed to have met the requirements of this section with documentation of graduation.

(8)~~(7)~~ The Board may conduct periodic review of programs to assure compliance with these rules.

Specific Authority 465.005 FS. Law Implemented 465.007 FS. History–New 8-20-83, Amended 5-19-72, 8-18-73, 12-18-74, 11-10-80, 10-25-84, Formerly 21S-1.22, 21S-1.022, Amended 7-31-91, Formerly 21S-26.401, Amended 12-27-93, Formerly 61F10-26.401, 59X-26.401, Amended _____.

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE TITLE: RULE NO.:

Transfer of Prescriptions 64B16-27.105

PURPOSE AND EFFECT: The Board proposes to amend this rule to update the rule text.

SUBJECT AREA TO BE ADDRESSED: Transfer of prescriptions.

SPECIFIC AUTHORITY: 465.005, 465.0155 FS.

LAW IMPLEMENTED: 465.026 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 10:00 a.m., October 12, 2000

PLACE: The Radisson Hotel, 415 N. Monroe Street, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: John Taylor, Executive Director, Board of Pharmacy/MQA, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

64B16-27.105 Transfer of Prescriptions.

(1) A pharmacist or registered pharmacy intern acting under the direct personal supervision of a Florida registered pharmacist may transfer a valid prescription which is on file in another pharmacy in this state or any other jurisdiction ~~state~~ if such transfer is consistent with the conditions set forth in Section 465.026, Florida Statutes. Prior to dispensing, the pharmacist or pharmacy where the prescription is on file shall be notified verbally, or by any electronic means that the former prescription must be voided.

(2) No change.

Specific Authority 465.005, 465.0155 FS. Law Implemented 465.026 FS. History–New 1-3-79, Formerly 21S-1.33, 21S-1.033, Amended 7-30-91, Formerly 21S-27.105, 61F10-27.105, Amended 9-19-94, Formerly 59X-27.105, Amended 6-15-98, _____.

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE TITLES: RULE NOS.:
Nuclear Pharmacy – General Requirements 64B16-28.901
Nuclear Pharmacy – Minimum Requirements 64B16-28.902

PURPOSE AND EFFECT: The Board proposes to discuss the rules referenced above for possible amendments which would require the use of containers to prevent contamination.

SUBJECT AREA TO BE ADDRESSED: Increase in fees.

SPECIFIC AUTHORITY: 465.005, 465.022 FS.

LAW IMPLEMENTED: 465.003(14), 465.0193, 465.022(1) FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 10:00 a.m., October 12, 2000

PLACE: The Radisson Hotel, 415 N. Monroe Street, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: John Taylor, Executive Director, Board of Pharmacy/MQA, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF HEALTH

Division of Disease Control

RULE TITLE: RULE NO.:
Control of Communicable Diseases, Public and Nonpublic Schools, Grades Preschool, and Kindergarten Through 12; Forms and Guidelines 64D-3.011

PURPOSE AND EFFECT: The Bureau proposes an amendment to provide a department form under which a parent or guardian may elect not to participate in the immunization registry; to provide a department form for application and approval to obtain access to the immunization registry by health care practitioners licensed under chapters 458, 459 or 464, F.S., and departmental form for application and approval to obtain access to the immunization registry by public and nonpublic schools and licensed or registered child care facilities.

SUBJECT AREA TO BE ADDRESSED: The subject to be addressed is Florida SHOTS (State Health Online Tracking System) Opt Out Provision, Florida SHOTS Private Provider Participation, and Florida SHOTS School and Licensed or Registered Child Care Facility Participation, and the required procedure for forms completion and application.

SPECIFIC AUTHORITY: 381.003(1)(e)2.,4. FS.

LAW IMPLEMENTED: 381.003 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND PLACE: 1:00 p.m. (EST), September 18, 2000

PLACE: Room 320P, 2585 Merchants Row Blvd., Tallahassee, FL 32399-1719

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Susan Lincicome, Senior Management Analyst II, Department of Health, Bureau of Immunization, Room 210N, 2585 Merchants Row Blvd., Tallahassee, FL 32399-1719, (850)245-4342; Mailing address: 4052 Bald Cypress Way, Bin #A-11, Tallahassee, FL 32399-1719

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

64D-3.011 Control of Communicable Diseases, Public and Nonpublic Schools, Grades Preschool, and Kindergarten Through 12; Forms and Guidelines.

(1) through (6) No change.

(7) Florida SHOTS (State Health Online Tracking System) Opt Out Provision – Parents or guardians may elect to decline participation in the Florida immunization registry, Florida SHOTS, by completing a DH Form 1478, Florida SHOTS Notification and Opt Out Form, as incorporated by reference in 64D-3.011(10), and returning the form to the Department of Health. The immunization records of children whose parents choose to opt-out will not be shared with other entities that are allowed by law to have access to the child's immunization record via authorized access to Florida SHOTS.

(8) Florida SHOTS Private Provider Participation – Any health care practitioner licensed in Florida under Chapters 458, 459 or 464, Florida Statutes may request authorization to access Florida SHOTS by filling out a DOH Form 1479, Authorized Private Provider User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking System), as incorporated by reference in 64D-3.011(10). The DOH Form 1479 will be returned to the Department of Health for processing and authorization to access Florida SHOTS. Notification of access approval and instructions for accessing Florida SHOTS will be provided by the Department of Health. The authorized user and the applicable licensing authority or agency shall notify the Department of Health Bureau of Immunization Florida SHOTS personnel when an authorized user's license or registration has expired or has been suspended or revoked.

(9) Florida SHOTS School and Licensed or Registered Child Care Facility Participation – Any public or nonpublic school, or licensed or registered child care facility may request authorization to access Florida SHOTS by completing a DOH Form 2115, Authorized School, and Licensed or Registered Child Care Facility User Agreement for Access to Florida

SHOTS, as incorporated by reference in 64D-3.011(10). The DOH Form 2115 will be returned to the Department of Health for processing and authorization to access Florida SHOTS. Notification of access approval and instructions for accessing Florida SHOTS will be provided by the Department of Health. The authorized user and the applicable licensing authority or agency shall notify the Department of Health Bureau of Immunization Florida SHOTS when an authorized user's license or registration has expired or has been suspended or revoked.

(10) Forms and Guidelines – Forms used to document compliance with section 381.003, F.S., and guidelines for completion of the forms, are hereby incorporated by reference:

FORM #	EFFECTIVE DATE	TITLE AVAILABILITY	FORMS AND GUIDELINES
DH 1478	Nov. 2000	Florida SHOTS Notification and Opt Out Form	DOH Bureau of Immunization 4052 Bald Cypress Way Bin # A-11 Tallahassee, FL 32399-1719
DH 1479	Nov. 2000	Authorized Private Provider User Agreement for Access to Florida SHOTS (State Health Online Tracking System)	DOH Bureau of Immunization 4052 Bald Cypress Way Bin #A-11 Tallahassee, FL 32399-1719
DH 2115	Nov. 2000	Authorized School And Licensed or Registered Child Care Facility User Agreement For Access to Florida SHOTS (State Health Online Tracking System)	DOH Bureau of Immunization 4052 Bald Cypress Way Bin # A-11 Tallahassee, FL 32399-1719

Specific Authority 232.032(1), 381.0011(13), 381.003(1), 381.003(2), 381.005(2) FS. Law Implemented 232.032(1), 381.0011(4), 381.003(1), 381.005(1)(i), 458, 459, 460 FS. History–New 12-29-77, Amended 6-7-82, 11-6-85, Formerly 10D-3.88, Amended 2-26-92, 9-20-94, 9-21-95, 4-7-96, Formerly 10D-3.088, Amended 7-14-99, _____.

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE TITLES:	RULE NOS.:
General Regulations; Definitions	64F-12.001
False and Misleading Labeling or Advertising	64F-12.002
Guaranty or Undertaking	64F-12.003
Prohibited Acts	64F-12.004
Requirements for Intrastate Investigational Drug Program; Suspension and Revocation	64F-12.005
Drugs and Devices; Labeling Requirements	64F-12.006
Complimentary Human Prescription Drug Samples: Distribution and Disposal	64F-12.008
Cosmetic Labeling Requirements	64F-12.009
Wholesale Distribution of Prescription Drugs – Exceptions and Specific Distributions Authorized	64F-12.011
Records of Drugs, Cosmetics and Devices	64F-12.012
Prescription Drugs; Receipt, Storage and Security	64F-12.013
Licensing, Application, Permitting	64F-12.015
Product Registration	64F-12.016
Certificates of Free Sale	64F-12.017
Fees	64F-12.018
Inspections, Investigations, Monitoring	64F-12.019
Restricted Prescription Drug Distributor Permits; Special Provisions	64F-12.023
Administrative Enforcement	64F-12.024

PURPOSE AND EFFECT: The purpose and effect of the proposed rule revisions are to repeal redundant rules which were incorporated into the Florida Statutes during recent legislative sessions, repeal rules associated with the legislatively repealed Investigational Drug Program, update federal references incorporated by reference, provide for more consistency with federal regulations, update application forms and requirements, clarify terms and concepts, establish a new permit and procedures for the transfer of prescription drugs by certain entities to university researchers, articulate inspection and investigation authority under the Florida Drug and Cosmetic Act, and reduce permit fees for certain restricted prescription drug distributor permits.

SUBJECT AREA TO BE ADDRESSED: The subject areas addressed include authorized recipients, brokers, retail pharmacy wholesalers, emergency transfers of prescription drugs, recordkeeping, order forms for certain controlled substances, written notification requirements for changes in address, clearance letters for prescription drug wholesalers and brokers, inspections and investigations, restricted drug distributor permits including transfers for university researchers, fees, and labeling requirements for drugs, devices, and cosmetics.

SPECIFIC AUTHORITY: 499.003, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.018, 499.028, 499.04, 499.041, 499.05, 499.052, 499.06, 499.701 FS.

LAW IMPLEMENTED: Chapter 499, Parts I and II, FS.

A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 10:00 a.m., Wednesday, August 20, 2000

PLACE: Bureau of Pharmacy Services, Conference Room, 2818-A Mahan Drive, Tallahassee, Florida 32308

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Sandra Stovall, Compliance Officer, 2818-A Mahan Drive, Tallahassee, Florida 32308, (850)487-1257, Ext. 210; sandra_stovall@doh.state.fl.us.fl. The draft is also available on our web site at doh.state.fl.us/pharm

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

64F-12.001 General Regulations; Definitions.

(1) A word or phrase defined in 21 U.S.C. ss. 301 et seq. or federal regulations promulgated thereunder in Title 21 Code of Federal Regulations(CFR), (as of _____ ~~12/1/98~~) which

are incorporated by reference, shall have the same meaning as in those provisions unless specifically defined otherwise in Chapter 499, F.S., or rule chapter 64F-12, F.A.C.

(2) In addition to definitions contained in sections 499.003, 499.012(1), 499.0122(1), 499.028(1), and 499.61, F.S., the following definitions apply to rule chapter 64F-12:

(a) No change.

(b) "Authorized recipient" – means a person permitted by or otherwise authorized by Chapter 499, F.S., to purchase, receive or possess prescription drugs; a pharmacy licensed by Chapter 465, F.S. except a Class I institutional pharmacy since it is only authorized to possess dispensed prescription drugs and medical oxygen for administration to its patients; a practitioner licensed by Florida law to purchase and receive prescription drugs; or a person who is authorized by the law where the delivery occurs to purchase, receive or possess prescription drugs. A licensed ship captain or first officer for a vessel engaged in international trade or in trade between ports of the United States and any merchant vessel belonging to the U.S. Government is an authorized recipient for prescription drugs intended solely for emergency medical purposes, provided the prescription drugs are delivered by the wholesaler directly to the ship.

(c) "Broker" – means a person participating in the wholesale distribution of a prescription drug that buys and sells the drug but does not take physical possession such that the drug is "sold to" the broker and "shipped to" a third party.

(d) "Change in Ownership" – means a majority (50% or more) of the ownership or controlling interest changes. A change in ownership occurs when there has been any change in a partnership amounting to 50% or more of the ownership or controlling interest. For a publicly traded corporation, the changing of officers or directors is not a change in ownership nor is the change in ownership of a parent company provided that such change does not result in a 50% change in the ownership or controlling interest of any permitted establishment.

(e)~~(d)~~ "Charitable institution or charitable organization" – means a health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.

(f)~~(e)~~ "Chief Executive Officer" – means the owner or the highest ranking official of a corporation, company, or business.

~~(f) "Distribute" means to sell, offer to sell, give away, deliver, or offer to deliver other than to administer or dispense.~~

(g) through (h) No change.

~~(i) "Group purchasing organization" means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by a written contract with the entity.~~

(i)~~(j)~~ "Legend Device or Restricted Device" – is any device which can be dispensed only by the prescription or order of a licensed practitioner and which device on its label bears either the words: "Caution: Federal Law restricts this device to sale by or on the order of a _____," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any practitioner licensed by law to use or prescribe the device; or "Caution: Federal Law prohibits dispensing without prescription," or "Caution: Florida Law prohibits dispensing without prescription."

(j)~~(k)~~ "Ongoing relationship" means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute ~~sell~~ the manufacturer's product(s) for a period of time or for a number of shipments, at least one sale is made under that agreement, and the name of the authorized distributor of record is entered on the manufacturer's list of authorized distributors of record or equivalent list. An ongoing relationship may also be documented by at least three purchases of a manufacturer's product(s) directly from that manufacturer within a six month period from the date for which the authorized distributor of record relationship is claimed and the distributor's name is entered on the manufacturer's list of authorized distributors of record or equivalent list.

(k) "Practitioner" means a persons who is duly licensed and authorized by laws of the state to administer, prescribe, or dispense, as appropriate, a particular product for medical purposes.

(l) "Provides prescription services to the public" – means holding the pharmacy out to the public through advertising, prominently displayed pharmacy signs on the exterior of the building, and adequate inventory on hand to fill a variety of prescriptions for a variety of medical conditions that would be required by the public generally.

(l) through (s) renumbered (m) through (t) No change.

(u)~~(t)~~ "State Current Good Manufacturing Practices" means current good manufacturing practices and quality system regulations as prescribed as of ~~12/1/98~~ in Title 21 Code of Federal Regulations, Parts 210, 211, 600-610, and 820, and the federal guidelines which are incorporated by reference herein and made a part of this rule, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the guidelines for manufacturing cosmetics as set forth in rule in 64F-12.010.

(u) through (v) renumbered (v) through (w) No change.

Specific Authority 499.003, 499.05, 499.61, 499.701 FS. Law Implemented Chapter 499, Parts I and II FS. History–New 1-1-77. Amended 12-12-82, 1-30-85, Formerly 10D-45.31, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.031, Amended 1-26-99, _____.

64F-12.002 False and Misleading Labeling or Advertising.

Specific Authority 499.05 FS. Law Implemented 499.007, 499.009, 499.018, 499.023, 499.054, 499.055, 499.057 FS. History–New 1-1-77, Amended 12-12-82, Formerly 10D-45.32, Amended 11-26-86, 7-1-96, Formerly 10D-45.032, Amended 1-26-99, Repealed _____.

64F-12.003 Guaranty or Undertaking.

(1) No change.

(2) A guaranty or undertaking may be limited or general and continuing as set forth in Title 21 CFR Sections 7.12 and 7.13, (as of _____ ~~12/1/98~~) which are incorporated by reference.

Specific Authority 499.05 FS. Law Implemented 499.069 FS. History–New 1-1-77, Amended 12-12-82, Formerly 10D-45.33, Amended 7-1-96, Formerly 10D-45.033, Amended 1-26-99, _____.

64F-12.004 Prohibited Acts.

Specific Authority 499.05, 499.701 FS. Law Implemented 499.005, 499.012, 499.0121, 499.028, 499.03 FS. History–New 11-26-86, Amended 11-25-92, 7-1-96 Formerly 10D-45.0365, Amended 1-26-99, Repealed _____.

64F-12.005 Requirements for Intrastate Investigational Drug Program; Suspension and Revocation.

Specific Authority 499.05 FS. Law Implemented 499.018, 499.019 FS. History–New 12-12-82, Amended 1-30-85, Formerly 10D-45.375, Amended 11-26-86, Amended 7-1-96 Formerly 10D-45.0375, Amended 1-26-99, Repealed _____.

64F-12.006 Drugs and Devices; Labeling Requirements.

(1) The department adopts and incorporates by reference the labeling requirements for prescription drugs and over-the-counter drugs as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 1-1299 (as of _____ ~~12/1/98~~).

(a) through (c) No change.

(2) The department adopts and incorporates by reference the labeling requirements for medical devices as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 800-895 (as of _____ ~~12/1/98~~).

~~(a) the label of a kit which has been classified as a device by approval of a premarket notice submitted under 21 U.S.C. s. 510(k), which contains prescription drugs, shall also contain the following elements on the kit packaging unless the packaging allows full visibility of the prescription drug contents for the required information:~~

~~1. an accurate list of the prescription drug components, listed by common or usual or proprietary name, including the quantity and strength of each component;~~

~~2. the lot or control number for each component; and~~

~~3. an expiration date identical to the expiration date appearing on any component which will first expire. Under no circumstances can the expiration date of the kit be extended beyond any component's expiration date.~~

~~(b) in addition to the label requirements of paragraph (a) above, the label of a kit which contains a prescription drug shall bear the phrase:~~

~~CAUTION: Federal Law Prohibits Dispensing Without a Prescription" or "CAUTION" State Law Prohibits Dispensing Without a Prescription."~~

~~(c) the label of a kit which contains any legend device as a component shall bear the phrase: "CAUTION: This Device is Restricted to Use By or On the Order of a Practitioner" or "CAUTION: Federal Law Restricts this Device to Sale By or On the Order of a _____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by law to use or order the use of the device.~~

Specific Authority 499.05, 499.0122 FS. Law Implemented 499.007, 499.0122, 499.013 FS. History–New 1-1-77, Amended 12-12-82, 7-8-84, Formerly 10D-45.39, Amended 11-26-86, 7-1-96, Formerly 10D-45.039, Amended 1-26-99, _____.

64F-12.008 Complimentary Human Prescription Drug Samples: Distribution and Disposal.

~~(1) Distributions of complimentary or sample packages of prescription drugs listed within the provisions of s. 893.03, F.S., must also comply with provisions in Rule Chapter 64B16-28, F.A.C., Chapter 465, F.S., and Title 21 CFR 1301, (as of _____ 12/1/98) which is incorporated by reference herein.~~

(1)~~(2)~~ Charitable Donations of Prescription Drug Samples. A physician or other authorized recipient of prescription drug samples may donate samples received according to s. 499.028, F.S., to a Restricted Prescription (Rx) Drug Distributor – Charitable Organizations permittee; to a charitable institution~~s~~ in this state for administration or dispensing by the charitable institution provided the charitable institution ~~is enrolled with the FDA, if enrollment is required by the FDA, and~~ is otherwise licensed to administer or dispense prescription drugs; or to a charitable organization~~s~~ outside of this state that is ~~are enrolled with the FDA, if so required by the FDA and~~ licensed by that state, if so required. The donation and transfer however, must be made in accordance with these provisions and the laws or regulations of other applicable jurisdictions.

(a) through (b) No change.

(c) A complete and accurate donation record must be prepared and maintained by the donor and recipient. The donation record shall include:

1. the donor's name, address, telephone number, the practitioner's state license number and the D.E.A. number, if applicable;

2. the manufacturer, brand name, strength, and dosage form of the product; the quantity donated by lot number; and the expiration date of the product;

3. the date of the donation;

4. the name, address, ~~FDA central file number~~ and state license number of the charitable organization, if applicable;

5. the signature of the donor; and

6. a signature of the authorized agent or employee of the recipient charitable institution. If delivery is made by mail or common carrier, the recipient charitable institution must countersign the record, keeping a copy, and return it to the donor within 48 hours, excluding holidays and weekends.

(d) No change.

(3) through (5) renumbered (2) through (4) No change.

Specific Authority 499.01, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.05 FS. Law Implemented 499.014, 499.028 FS., Part I Ch 499 FS. History–New 12-12-82, Amended 7-8-84, Formerly 10D-45.445, Amended 11-26-86, 2-7-93, 7-1-96, Formerly 10D-45.0445, Amended 1-26-99, _____.

64F-12.009 Cosmetic Labeling Requirements.

The department adopts and incorporates by reference the labeling requirements for cosmetics as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 700-799 (as of _____ ~~12/1/98~~).

Specific Authority 499.013, 499.05 FS. Law Implemented 499.009, 499.013 FS. History–New 1-1-77, Amended 12-12-82, Formerly 10D-45.48, Amended 7-1-96 , Formerly 10D-45.048, Amended 1-26-99, _____.

64F-12.011 Wholesale Distribution of Prescription Drugs – Exceptions and Specific Distributions Authorized.

(1) The exemption from the definition of wholesale distribution in s. 499.012(1)(a)2.b. ~~499.012(1)(a)5.~~, F.S., for "emergency medical reasons" includes:

(a) through (e) No change.

(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.

(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 s. 499.005(21), F.S., provided:

(a) through (b) No change.

(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; and written ~~otherwise~~ documentation showing that proper conditions were ~~not~~ maintained is ~~must be~~ provided to the manufacturer or wholesale distributor to which the prescription drugs are returned.

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, _____.

64F-12.012 Records of Drugs, Cosmetics and Devices.

(1) through (3) No change.

(4) Retailers of veterinary legend drugs or medical oxygen must also maintain a prescription or other order of an authorized practitioner evidencing the authority of the purchaser or recipient to receive the veterinary legend drug or medical oxygen. A veterinary legend drug retailer must have the prescription prior to delivery of the drug to the customer. In the case of a medical oxygen retailer, the prescription or order ~~Prescriptions or orders~~ for medical oxygen must be in writing~~, signed by the practitioner~~ and ~~must be~~ in the possession of the retailer within 30 days of ~~prior to~~ delivery of the drug to the patient. An order or prescription for veterinary legend drugs or medical oxygen does not constitute authority for the retailer to sell to the purchase beyond 12 months from the date of the original sale.

(5) A person distributing a controlled substance scheduled as a I or II under chapter 893, F.S., that is scheduled as a III, IV, or V under federal law must receive and maintain an order form prepared by the purchaser prior to the distribution to the purchaser. The order form may be written or electronic, provided it is prepared by the purchaser. The order form must at a minimum include the name of the substance, strength, quantity, date, purchaser's name, applicable DEA number and the address to which the controlled substance will be sent. ~~Any person who manufactures devices, over-the-counter drugs, or cosmetics must maintain records which include the following information on one document: the name and principal address of the seller or transferor, the address of the location from which the products were shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person purchasing the product.~~

(6) through (15) No change.

(16) A copy of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, and Rule 64F-12, Florida Administrative Code, Regulation for Drugs, Devices and Cosmetics, must be at the permitted establishment.

(17) Charitable Donations of Prescription Drug. A physician or other authorized recipient donating prescription drug samples pursuant to s. 499.012(1)(2)(e), F.S., must prepare and maintain a donation record that includes at a minimum:

(a) The donor's name, address, telephone number, the practitioner's state license number and the D.E.A. number, if applicable;

(b) The manufacturer, brand name, strength, and dosage form of the product; the quantity donated by lot number; and the expiration date of the product;

(c) The date of the donation;

(d) The name, address, and state license number of the charitable organization, if applicable;

(e) The signature of the donor; and

(f) A signature of the authorized agent or employee of the recipient charitable institution. If delivery is made by mail or common carrier, the recipient charitable institution must countersign the record, keeping a copy, and return it to the donor within 48 hours, excluding holidays and weekends.

Specific Authority 499.05, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.052 FS. Law Implemented 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.05, 499.051, 499.052 FS. History–New 1-1-77, Amended 12-12-82, 7-8-84, 1-30-85, Formerly 10D-45.53, Amended 11-26-86, 2-7-93, 7-1-96, Formerly 10D-45.053, Amended 1-26-99, _____.

64F-12.013 Prescription Drugs; Receipt, Storage and Security.

(1) No change.

~~(2)(a) Vehicles used for transporting prescription drugs which contain prescription drugs shall be secured at all times from unauthorized access to the prescription drugs. During deliveries, the vehicle must be securely locked while unattended.~~

(2)(a)~~(b)~~ While not being used to make deliveries, a vehicle of a permittee containing prescription medical oxygen must be parked at the permitted establishment and either locked inside a fenced compound or secured by a vehicle alarm system. A vehicle containing prescription medical oxygen may only be parked at a residence temporarily while the vehicle is making deliveries or while "on call" for emergency deliveries.

(b)~~(c)~~ When a vehicle used for prescription drug wholesale distributions or for distributions subject to a restricted prescription drug distributor's permit contains prescription drugs and is not being used to make deliveries, it must be parked inside a building secured by an alarm system.

(c)~~(d)~~ A residence cannot be used to store any prescription drug which has not been dispensed, unless a natural person residing at that residence is licensed or otherwise authorized to possess prescription drugs.

(3) through (5) No change.

Specific Authority 499.0121(1), 499.05 FS. Law Implemented 499.004, 499.006, 499.007, 499.0121, 499.052 FS. History–New 7-8-84, Amended 1-30-85, Formerly 10D-45.535, Amended 11-26-86, 7-1-96, Formerly 10D-45.0535, Amended 1-26-99, _____.

64F-12.015 Licensing, Application, Permitting.

This section addresses the application and permitting requirements of persons regulated under Part I of Chapter 499, F.S.

(1) No change.

(2) A permit is valid only for the name and address to which it is issued. The name in which a permit is issued will be changed, at no cost, upon notification to the department.

(a) No change.

(b) A permit that authorizes the purchase of prescription drugs will not be issued in a name identical to the name used by any other establishment or licensed permit holder at that address authorized to purchase prescription drugs pursuant to Chapter 465, F.S., or the statutes regulating a practitioner authorized to purchase prescription drugs except:

~~1. a Retail Pharmacy Drug Wholesaler permit will be issued in the name of the retail pharmacy unless that name is identical to a health care entity at that address, in which case no retail pharmacy drug wholesaler permit will be issued,~~

~~2. a Restricted Rx Drug Distributor – Health Care Entity permit will be issued in the name of the health care entity,~~

1.~~3.~~ a Restricted Rx Drug Distributor – Charitable Organization permit will be issued in the name of the charitable organization or health care entity, and

2.~~4.~~ a Medical Oxygen Retailer permit may be issued in the name of a nursing home's Class I Institutional Pharmacy permit.

(c) No change.

(3) ON-SITE INSPECTIONS. Passing an on-site inspection is a prerequisite to issuance of a new permit for the following permit types: Prescription Drug Manufacturer, Device Manufacturer, Compressed Medical Gases Manufacturer, Over-the-Counter Drug Manufacturer, Cosmetic Manufacturer, Prescription Drug Wholesaler, Compressed Medical Gases Wholesaler, Veterinary Legend Drug Retailer, Medical Oxygen Retailer, and ~~all~~ Restricted Rx ~~Prescription~~ Drug Distributor permits for the Health Care Entity, Reverse Distributor, and Destruction facilities. However, the department may elect to perform an inspection of the Restricted Rx Drug Distributor – Charitable Organization, Government Program, or Institutional Research as a condition of permitting but an on-site inspection fee will not be assessed.

(a) through (c) No change.

(d) The department will request from the applicant written documentation to evidence compliance with the requirements of Chapter 499, F.S., when an on-site inspection cannot be completed within 30 days of receipt of a completed ~~an~~ application for a permit requiring an on-site inspection.

(4) No change.

(5) Notification to the department regarding the change of address of a permitted establishment must be in writing. Notification regarding the closing of a permitted establishment shall also include the name and~~,~~ address~~, and telephone number~~ of a person to contact for up to two years after the closing of the business for ~~regarding~~ access to required records.

(6) MANUFACTURER PERMITS.

(a) No change.

~~(b) A device manufacturer's permit is not required for a company manufacturing custom devices.~~

(b)~~(c)~~ A device manufacturer's permit is required for an establishment that refurbishes medical devices for subsequent sale but is not required when the refurbishing is performed as a service for the owner of the medical device and the device is returned to the owner for further use.

(c)~~(d)~~ Application requirements for manufacturers include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. through 5. No change.

(7) WHOLESALER PERMITS.

(a) through (c) No change.

(d) Application requirements for Prescription Drug Wholesalers and Compressed Medical Gases Wholesalers include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. Pay the appropriate fee(s) as required by Rule 64F-12.018.

4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

5. Submission of a "Clearance Letter" issued by a local law enforcement agency that discloses the presence or absence of past felony convictions of the owners, officers, and managers-in-charge for sole proprietorships, partnerships, and closely held corporations for persons applying for a permit as a Prescription Drug Wholesaler and Prescription Drug Wholesaler – Broker Only.

(e) Application requirements for Out-of-State Prescription Drug Wholesalers include:

1. No change

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S." effective JUN 00 ~~Jan. 1999~~, which is incorporated by reference herein.

3. through 5. No change.

(f) Application requirements for Retail Pharmacy Wholesalers include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. through 5. No change.

(8) OTHER DISTRIBUTORS. Persons conducting certain distributions of prescription drugs which are not considered wholesale distributions in the state of Florida must obtain a permit from the department prior to initiating that activity. These permits include Complimentary Drug Distributors, all of the designated Restricted Rx Drug Distributor permits as further discussed in rule 64F-12.023, Medical Oxygen Retailers, and Veterinary Legend Drug Retailers.

(a) Application requirements for Complimentary Drug Distributors include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. through 5. No change.

(b) Application requirements for Restricted Rx Drug Distributor – Health Care Entity include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. through 5. No change.

(c) Application requirements for Restricted Rx Drug Distributor – Charitable Organization include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. through 6. No change.

(d) Application requirements for Restricted Rx Drug Distributor – Reverse Distributor or Restricted Rx Drug Distributor – Destruction include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. through 4. No change.

(e) Application requirements for Restricted Rx Drug Distributor – Government Programs include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. No change.

4. Submit a list of the intended contractors and subcontractors that will receive the entity's prescription drugs under this permit and the permit numbers that authorize them to administer or dispense. Also submit a copy of the provisions of the contract that address the requirements in s. 499.012(1)(a)1.d., F.S.

5. through 6. No change.

(f) Application requirements for a Restricted Rx Drug Distributor – Institutional Research include:

1. Contact the department's Bureau of Pharmacy Services to request an application or download the application from the bureau's web site.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00, which is incorporated by reference herein.

3. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

4. Pay the appropriate fee(s) as required by Rule 64F-12.018.

(g) Application requirements for a Veterinary Legend Drug Retailer include:

1. Contact the department's Bureau of Pharmacy Services to request an application or download the application from the bureau's web site.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference herein.

3. Pay the appropriate fee(s) as required by Rule 64F-12.018.

4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(h)~~(g)~~ Application requirements for a Medical Oxygen Retailer include:

1. Contact the department's Bureau of Pharmacy Services to request an application or download the application from the bureau's web site.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN 00 ~~January 1999~~, which is incorporated by reference to this rule.

3. Pay the appropriate fee(s) as required by Rule 64F-12.018.

4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and these rules.

5. Have an FDA establishment registration number if the establishment will be transfilling medical oxygen.

(9) PERMIT RENEWALS. Submission of a renewal application represents to the department that conditions have not changed with the permitted person which would make the permitted person ineligible to renew the permit.

(a) No change.

(b) An applicant applying to renew a permit which has not expired, been revoked, suspended or otherwise terminated must:

1. file with the department a completed application for a permit using an "Application for Permit Renewal Under Chapter 499, F.S.," DOH Form 1034, effective _____ ~~January 1999~~, which is incorporated by reference herein. The permittee should contact the department if the renewal application has not been received at least 30 days prior to the permit's expiration date.

2. through 5. No change.

(c) No change.

Specific Authority 499.01, 499.012, 499.0122, 499.013, 499.014, 499.018, 499.028, 499.04, 499.041, 499.05, 499.06, 499.62, 499.63, 499.64, 499.66, 499.67, 499.701 FS. Law Implemented 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.018, 499.028,499.04, 499.041, 499.05, 499.06, 499.062, 499.063, 499.064, 499.066, 499.067 FS. History–New 12-12-82, Amended 7-8-84, 1-30-85, Formerly 10D-45.54, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.054, Amended 1-26-99, _____.

64F-12.016 Product Registration.

~~(1)(a) The department will not register products that are not in compliance with the provisions of the federal Food, Drug, and Cosmetic Act, as amended, and Title 21 Code of Federal Regulations, (as of _____ 12/1/98) which are incorporated by reference herein, or which are not approved investigational drugs as provided for in s. 499.018, F.S. However, registration of a product by the department does not mean that the product does in fact comply with all provisions of the federal Food, Drug, and Cosmetic Act, as amended.~~

(1)(a)~~(b)~~ Each product that is registered shall be registered either as a drug~~, device,~~ or cosmetic, but shall not have duplicate registrations. Products that are both a cosmetic and a drug must be registered as a drug.

(b)~~(c)~~ A formula marketed under different brand names, sizes, quantities, or distributors is not considered a separate and distinct product for registration purposes. Furthermore, the adding of color, flavor, or scents to a formula does not make a separate and distinct product for registration purposes, even for fragrance preparations where the scent is the primary product. However, the different variations must be listed on the Identical Product Certification form.

~~(d) Devices having variations in physical characteristics such as size, package, shape, or color may be considered as one device for registration purposes provided the variation does not change the function or intended use of the device. Products having different 510K approvals or different premarket approvals from the FDA must be registered separately.~~

~~(e) Kits that have variable components may be registered as a separate and distinct product according to the particular procedure and intended use of the kit, i.e., surgical kit, obstetric kit, tonsillectomy kit, etc. The listing of individual components from which a customer could choose must be attached to the registration application.~~

(c)~~(f)~~ The separate and distinct drug~~, device,~~ or cosmetic product for a person who performs limited manufacturing operations at an establishment such as only encapsulating, sterilizing or other processing or manipulation of the product,

but not labeling, may be the product resulting from such processing and not each separate and distinct product to which the limited manufacturing operation is performed.

(2)(a) Applicants applying for an initial product registration of a product must:

1. file with the department a completed application for the appropriate product registration using DOH Form 1035, "Application for Product Registration – Drugs," effective Jan 99~~; DOH Form 1036, "Application for Product Registration – Devices," effective Jan 99;~~ or DOH Form 1037, Application for Product Registration – Cosmetics," effective Jan 99; and if applicable the Identical Product Certification, DOH Form 1039, effective January 1993; all of which are incorporated by reference herein;

2. submit a product label or copy thereof for every product registered on the Application and listed on the Identical Product Certification form. (An English translation is required for a product manufactured for export only which has labeling in a foreign language.);

3. submit documentation that supports the product is legal in interstate commerce (such as approval of a drug through a new drug application – NDA, ANDA, IND, NADA, etc., or the monograph category to which the drug belongs, ~~a premarket approval or approved 510K for a device,~~ or a product category identifier if the product is a cosmetic); and

4. pay the appropriate fee pursuant to Rule 64F-12.018.

(b) No change.

(3) No change.

Specific Authority 499.01, 499.015, 499.04, 499.05 FS. Law Implemented 499.01, 499.015, 499.04 FS. Formerly 10D-45.054, History–New 7-1-96, Formerly 10D-45.0542, Amended 1-26-99, _____.

64F-12.017 Certificates of Free Sale.

(1) A written request for a certificate of free sale must be submitted to the department by the Florida permitted manufacturer of the product indicating the name and address of the company to be designated on the free sale certificate as the distributor or manufacturer or both; the name, address, and product registration number of the company who has registered the product; the specific name of the product(s) to be included in the certificate; the product label if a current label is not on file with the department; and the appropriate fee as provided in Rule 64F-12.018.

(2) No change.

Specific Authority 499.05, 499.015 FS. Law Implemented 499.015, 499.04, 499.05 FS. History–New 7-1-96, Formerly 10D-45.0543, Amended _____.

64F-12.018 Fees.

(1) through (2) No change.

(3) Biennial fees for other distribution permits are as follows:

Permit	Biennial Fee
Complimentary Drug Distributor	$500
Veterinary Legend Drug Retail Establishment	$500
Medical Oxygen Retail Establishment	$500
Restricted Rx Drug Distributors – Health Care Entity	$500
Restricted Rx Drug Distributor – Charitable Organization	$400
Restricted Rx Drug Distributor – Reverse Distributor	$500
Restricted Rx Drug Distributor – Destruction	$500
Restricted Rx Drug Distributor – Government Program	$400
Restricted Rx Drug Distributor – Institutional Research	$400

(4) Miscellaneous other fees are as follows:

Description of other service fees	Fee
Initial Application/On-site Inspection ~~(initial application)~~	$150
Prescription Drug Wholesaler Bond (refundable)	$200

Change of Address Fee:

A relocation fee of $100 must be paid for each permitted person relocating for which an on-site inspection is required. If no on-site inspection is required, the relocation fee is $25 per permit. If a permitted person has multiple permits under the same permitted name and address and relocates any or all permitted activities concurrently to the new location, then only one $100 fee is required plus $25 for all other permits.

Product Registration (per product registered)	$ 20*

* The registration fee for a product being amended to an existing product registration that has 12 months or less until it expires is $10.

Listed Identical Products	$ -0-
Free Sale Certificate	$ 25
Signature copy (requested concurrently)	$ 2
Delinquent Establishment Permit Renewal (per permit)	$100
~~Approval of Investigational Drug~~	~~$1,000~~

(5) No change

Specific Authority 499.01, 499.012, 499.015, 499.04, 499.041, 499.05 FS. Law Implemented 499.01, 499.012, 499.015, 499.04, 499.041 FS. History–New 7-1-96, Formerly 10D-45.0544, Amended _____.

(Substantial rewording of Rule 64F-12.019 follows. See Florida Administrative Code for present text.)

64F-12.019 Inspections, Investigations, Monitoring.

(1) An inspection or investigation is a review or examination of an establishment permitted under the provisions of chapter 499 or any rule adopted thereunder, or of a non-permitted establishment for the purpose of protecting public health from misbranded or adulterated drugs, devices, or

cosmetics or from any other violation of chapter 499 and chapter 893 or any rules adopted thereunder. An inspection may also take place in a non-permitted establishment to assess whether the establishment complies with the requirements for a chapter 499 permit.

(2) The department may inspect, monitor, and investigate all drug, device and cosmetic manufacturers, wholesalers, repackagers, distributors, or other establishments where drugs, devices or cosmetics are made, stored, sold, offered for sale, exposed for sale, or kept for sale or use, for the purpose of determining compliance with the provisions of chapter 499 and chapter 893 or any rules adopted thereunder and to secure evidence of any non-compliance.

(3) Inspections and investigations may be announced or unannounced, at the discretion of the department. The owner, officer, or employee of the establishment shall make the premises and all records and other information required by chapter 499 and chapter 893 or any rules adopted thereunder available to the department inspector.

(4) Inspections and investigations under this rule may include:

(a) Review and copying of all records pertaining to the manufacture, advertisement, storage, holding, and distribution of any prescription, over-the-counter or investigational drug, device or cosmetic. These records include, but are not limited to receiving documents, shipping documents, purchase orders, purchase requisitions, invoices, paid receipts, contracts, checks, deposits, and credits or debits in any form whatsoever;

(b) Entry to any establishment, vehicle or space therein in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, held or transported;

(c) Entry to any establishment, vehicle, or space therein in which records related to drugs, devices, or cosmetics are held;

(d) Surveillance of procedures related to drugs, devices or cosmetics;

(e) Collection of facts and information related to drugs, devices or cosmetics;

(f) Questioning of persons who may have information relating to the inspection or investigation and taking sworn statements from these persons, all related to drugs, devices or cosmetics;

(g) Sampling any drug, device or cosmetic, including any related product (whether or not in finished form), material, component, document, literature, label, labeling or other evidence;

(h) Photographing any drug, device or cosmetic including any related component, materials, physical plant, storage condition, article or product;

(i) Observations and identification of:

1. any drug, device or cosmetic consisting wholly or in part of filthy, putrid or decomposed substances;

2. any undesirable conditions or practices bearing on filth, contamination, or decomposition which may result in a drug, device or cosmetic becoming adulterated or misbranded;

3. any unsanitary conditions or practices which may render a drug, device or cosmetic injurious to health;

4. any faulty manufacturing, processing, packaging, or holding of drugs, devices or cosmetics as related to current good manufacturing practices (CGMP) including recordkeeping;

5. any deviation from recommended processing, storage or temperature requirements for any drug, device or cosmetic as specified by federal or state law;

6. any deviation from FDA requirements for the label and labeling of any drug, device or cosmetic;

7. any other action to determine compliance with chapters 499 and 893, F.S., and this rule chapter.

(j) taking of evidence related to a drug, device or cosmetic; and

(k) securing the removal of any potentially misbranded or adulterated drug, device, or cosmetic from commerce or public access.

(5) The department shall take reasonable steps to assure that a sampled product is not reintroduced into commerce if it is or has become adulterated or misbranded.

Specific Authority 499.05 FS. Law Implemented Chapter 499, Parts I and II, FS. History–New 7-8-84, Formerly 10D-45.545, Amended 11-26-86, 7-1-96, Formerly 10D-45.0545, Amended _____.

64F-12.023 Restricted Prescription Drug Distributor Permits; Special Provisions.

The following Restricted Prescription Rx Drug Distributor permits will be issued by the department:

(1) No change.

(2) Restricted Rx Drug Distributor – Health Care Entity. This permit is required for a hospital or health care entity as defined in section 499.003(14), F.S., for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are (1) under common control as provided in s. 499.012(1)(a)3., F.S.; or (2) members of a group purchasing organization as provided for in s. 499.012(1)(a)1., F.S. For the purpose of this permit and transfers thereunder, an independent contractor cannot be under "common control" as defined in s. 499.012(1)(a)3., F.S. Transfers are limited to a facility under common control or member of the group purchasing organization, either of which must be licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs. This permit also authorizes a warehouse or purchasing depot of a university to transfer prescription drugs to practitioner or non-practitioner researchers for university sponsored research conducted in accordance with s. 240.241, F.S. All requirements of paragraph (6) of this rule related to the Restricted Rx Drug Distributor – Institutional Research permit must be complied with for transfers under this provision.

(3) through (4) No change.

(5) Restricted Rx Drug Distributor – Government Programs. This permit is required for a state or local government agency, or any entity eligible to purchase prescription drugs at public health services prices pursuant to s. 602, PL 102-585, hereafter "the entity," to distribute its prescription drugs to a contract provider or its subcontractor for administering or dispensing to eligible patients of the entity under the eligible program. A prescription drug distributed under this permit may not be sold or transferred for reimbursement or payment of any kind.

(a) No change.

~~(b) The contract provider or subcontractor that receives the prescription drugs under this paragraph must be authorized by law to administer or dispense prescription drugs.~~

~~(c) In the case of a subcontractor, the entity must be a part of and execute the subcontract for services involving a prescription drug distributed under this permit.~~

~~(d) A contract provider or subcontractor must maintain separate and apart any prescription drugs of the entity in its possession from other prescription drug inventory.~~

~~(e) The contract provider and subcontractor shall maintain and produce immediately for inspection by the bureau all records of movement or transfer of all the prescription drugs belonging to the entity including but not limited to the records of receipt and disposition of these prescription drugs. Each contractor and subcontractor dispensing or administering these drugs shall maintain and produce records to the bureau documenting the dispensing or administration. Records required to be maintained include, but are not limited to, a perpetual inventory itemizing prescription drugs received and prescription drugs dispensed by prescription number or administered by patient identifier, which shall be submitted to the entity quarterly.~~

~~(f) The contract provider or subcontractor shall either administer or dispense a prescription drug of the entity only to an eligible patient of the entity or shall return the prescription drug for or to the entity. Any other transfer constitutes a violation of s. 499.005. The contract provider or subcontractor shall require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the entity and shall, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required by subparagraph (5)(e).~~

~~(g) The establishment of the contract provider and subcontractor and all records pertaining to prescription drugs distributed under this subsection must by contract be subject to inspection by the entity.~~

(b)~~(h)~~ The entity must monitor the prescription drugs transferred under this permit. Discrepancies must be investigated and reported by the entity to the bureau.

(6) Restricted Rx Drug Distributor – Institutional Research. This permit is required for a licensed pharmacy of a university to transfer prescription drugs to practitioner or non-practitioner researchers for university sponsored research conducted in accordance with s. 240.241, F.S.

(a) A non-practitioner recipient researcher is not required to obtain an exemption letter pursuant to rule 64F-12.011(4) if the researcher and research activities are located on the university campus. However, if the researcher is not located on the university campus and the drug is not stored on the university campus, then an exemption letter is required prior to the transfer of any prescription drugs to the researcher.

(b) The Restricted Rx Drug Distributor – Institutional Research permit holder must maintain records that include at a minimum, the researcher; specific research project / grant number; location in which the research is done and/or storage location of the prescription drug and the researcher's exemption number if applicable; and the name, strength, dosage form, and quantity of the drug transferred to the researcher. The researcher's DEA number is also required if a controlled substance has been transferred to the researcher. The researcher must sign for the prescription drug with an acknowledgement that the drug cannot be sold, traded or transferred to anyone not directly involved in the specific research project for which the drug was obtained. If the permit holder is a pharmacy, these records must be maintained separate from the pharmacy dispensing records.

(c) The recipient researcher must maintain security over any prescription drugs and adequate recordkeeping to account for disposition of all prescription drugs received.

(d) The university must designate an individual responsible for periodic monitoring of the distributions under this permit. Such monitoring must include, but is not limited to, unannounced inspections and reconciliation of the inventory of prescription drugs in the researcher's possession and records of prescription drugs used by university researchers. Discrepancies must be investigated and corrective action implemented as indicated.

Specific Authority 499.014, 499.05 FS. Law Implemented 499.01, 499.012, 499.0121, 499.014 FS. History–New 7-1-96, Formerly 10D-45.059, Amended 1-26-99, _____.

64F-12.024 Administrative Enforcement.

(1) through (3) No change.

(4) The following codes outline department policy under s. 499.066(3)(a), F.S., and are used to designate the general severity in terms of the threat to the public health for violation and the range of action which the department will initiate.

3 = Warning Letter,
Letter of Violation with no fine or
Notice of Violation or Administrative Complaint with a fine ranging from $250* to $1,000 per violation per day.
(*) If medical oxygen is the prescription drug involved, the range of the fine is $50 to $1,000.

2 = Notice of Violation or Administrative Complaint with a fine ranging from $500 to $2,500 per violation per day.

1 = Notice of Violation or Administrative Complaint with a fine ranging from $1,000 to $5,000 per violation per day;
Suspension of the permit with a fine; or
Revocation of the permit with a fine.

CITE	VIOLATION	GENERAL SEVERITY
499 refers to Chapter 499, F.S.		
12 refers to Rule 64F-12		
FACILITY, STORAGE:		
No change		
MISCELLANEOUS:		
No change		
OPERATING:		
499.005(6) & 499.67(5)	Refusing entry, inspection, taking evidence	2-1
499.005(6)	Inaccessible during business hours	3
12.015(2)(c) ~~12.004(3)~~ 499.005(22); 499.62 & 12.015	Failure to obtain proper permit; (cost of permit plus fine)	3
499.015 & 12.012	Failure to register products ($50 per product per year)	3
499.01(4)(a) & 12.012(4)	Failure to notify dept. of address change	3
RECORDKEEPING:		
No change		
SAMPLES:		
499.005(17)	Sample drug distribution – activity with	1
~~12.004(1)~~	~~Repackaging sample drugs~~	~~1~~
499.005(25) ~~12.004(5)~~	Charging a dispensing fee for a prescription sample	2-1
ADULTERATED & MISBRANDED:		
499.005(1)	Activity with adulterated or misbranded product	3-1
499.005(2)	Adulterating or misbranding a product	3-1
499.005(3)	Receiving adulterated/ misbranded product	3
499.005(9)	Making a product misbranded	3-1
12.007(3)	Improper labeling on medical oxygen	3
499.013(2)(a)	Prescription Drug Manufacturer not following GMP	3-1
499.013(2)(b)	OTC Drug Manufacturer not following GMP	3-1
499.013(2)(c) & 12.007(1)	Compr. Med. Gas Manufacturer not following GMP	3-1
499.013(2)(d)	Device Manufacturer not following GMP	3-1
12.010	Cosmetic Manufacturer not following GMP/guidelines	3-1
499.005(1) ~~12.004(2)~~	Activity with drug which left regulatory control, GMP	3-1
COUNTERFEIT:		
No change		
FALSE & MISLEADING:		
499.005(5) & 12.002	Disseminating false/misleading ad	3
499.005(7)	Giving a false guaranty or undertaking	2
499.005(10)	Forging, counterfeiting, falsely representing a product	2-1
499.005(11) & ~~12.002~~ 499.005(19); 499.005(23);	Labeling or advertisement of effectiveness when not	3
499.66 & 499.67	Making false or fraudulent statements	2-1
499.005(19), 499.64(4), 499.67	Providing department with false/fraudulent records/ statements	2-1
499.0054	Advertising Violations	3
~~499.005(19) &~~ 499.005(23)	Obtaining/attempting to obtain by fraud, deceit, misrepresentation, subterfuge	2-1
499.005(13)	Activity w/self-testing HIV/AIDS products	2
UNAUTHORIZED SOURCE OR RECIPIENT:		
499.005(14) & ~~12.004(6)~~	Purchase or receipt of prescription drug from unauthorized source	3*
499.005(16)	Purchase/receipt of Comp Med Gas from unauthorized source	3*
499.005(15) ~~&~~ ~~12.004(4)~~	Sale or transfer of prescription drug to unauthorized person	3*
499.005(24)	Sale or transfer of legend device to unauthorized person	3
~~12.004(7)~~	~~Distributing investigational drug to unauthorized person~~	~~3~~
499.0122(1)(d) & 12.012(4)	Improper sale of veterinary prescription drug	3
12.012(4)	Distribution of medical oxygen by a medical oxygen retailer without a prescription (order)	3
499.66	Sale or transfer of ether to unauthorized person	3 - 2

POSSESSION:
No change
(5) No change.

Specific Authority 499.05 FS. Law Implemented 499.066 FS. History–New 7-1-96, Formerly 10D-45.0595, Amended 1-26-99, _____.

DEPARTMENT OF CHILDREN AND FAMILY SERVICES

Economic Self-Sufficiency Program

RULE TITLES:	RULE NOS.:
Administrative Definitions and Acronyms Applicable to RAP	65A-1.802
General Eligibility	65A-1.803
Citizenship	65A-1.804
Employment Registration and Participation in Employment and Language Training Programs	65A-1.805
Need Requirement	65A-1.806
Assets	65A-1.807
Income	65A-1.808
Budgeting	65A-1.809

PURPOSE AND EFFECT: These rule amendments will remove rule text that repeats federal regulation requirements for the Refugee Assistance Program (RAP). The department plans to repeal all rules indicated above except one rule that will provide a source statement for federal program requirements.

SUBJECT AREA TO BE ADDRESSED: The department is removing detailed statements about eligibility requirements from rule text. Current rule text repeats statements made in federal law or federal regulation. Applicable federal law and regulation will be cited for refugee program administration and eligibility requirements.

SPECIFIC AUTHORITY: 409.953 FS.

LAW IMPLEMENTED: Specific Appropriation 435, 2000 General Appropriations Act, Ch. 2000-166, Laws of Florida.

IF REQUESTED AND DEEMED NECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 11:00 a.m., September 15, 2000

PLACE: 1317 Winewood Boulevard, Building 3, Room 455, Tallahassee, Florida 32399-0700

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Audrey Mitchell, Program Administrator, 1317 Winewood Boulevard, Building 3, Room 421, Tallahassee, Florida 32399-0700, Telephone (850)488-3090

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

DEPARTMENT OF CHILDREN AND FAMILY SERVICES

Economic Self-Sufficiency Program

RULE TITLES:	RULE NOS.:
Rights and Responsibilities of Applicants and Recipients	65A-2.022
Application and Determination of Eligibility	65A-2.023
Determination of Continued Eligibility	65A-2.024
Advance Notice: Written Ten Day Advance Notice	65A-2.031
General Eligibility Criteria	65A-2.032
Eligibility Factors Other Than Need	65A-2.033
Definitions of Special Living Arrangement	65A-2.034
Eligibility Factors of Need	65A-2.035
Amount of Optional State Supplementation Payments	65A-2.036

PURPOSE AND EFFECT: These rules will be amended to implement a Medicaid coverage program for assistive care services for individuals enrolled in or eligible for Optional State Supplementation (OSS). Medicaid coverage for assistive care services will enable increased benefit levels to those enrolled in or eligible for OSS and, thereby, increased payments to care providers.

SUBJECT AREA TO BE ADDRESSED: The department will implement changes in cost of care, rates of payment, personal needs allowances and any related changes necessary to implement Medicaid coverage for assistive care services. Additionally, the department will clarify language and revise out-dated citations of statutes, federal regulations and other administrative rules.

SPECIFIC AUTHORITY: 409.212(6) FS.

LAW IMPLEMENTED: 409.212 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATE: 10:00 a.m., September 18, 2000

PLACE: 1317 Winewood Boulevard, Building 3, Room 455, Tallahassee, Florida 32399-0700

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Audrey Mitchell, Program Administrator, 1317 Winewood Boulevard, Building 3, Room 421, Tallahassee, Florida 32399-0700, Telephone (850)488-3090

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

Section II
Proposed Rules

DEPARTMENT OF INSURANCE

RULE TITLES:	RULE NOS.:
Purpose	4-228.010
Scope	4-228.020
Definitions	4-228.030
Course Providers	4-228.040
School Officials and Administrative Supervising Instructors	4-228.050
Supervising Instructors	4-228.055
Instructors and Supervising Instructors	4-228.060
Speakers	4-228.070
Course Approval; Requirements; Guidelines	4-228.080
Course Offerings and Attendance Records	4-228.090
Certification of Students	4-228.100
Textbooks	4-228.110
Course Fees	4-228.120
Facilities	4-228.130
Examinations	4-228.140
Advertising	4-228.150
Prohibited Practices	4-228.160
Falsification of Reports	4-228.170
Forms	4-228.180
Transition Time in the Event of Rule Changes	4-228.190
Penalties for Course Providers, School Officials, Administrative Supervising Instructors, Supervising Instructors, Instructors, and Monitors	4-228.210
Licensee Compliance; Requirements; Penalties for Non-Compliance	4-228.220
Extensions	4-228.230
Applicability of Continuing Education Requirement for New Licensees	4-228.240
Exempted Licensees	4-228.250

PURPOSE AND EFFECT: The proposed amendments are intended to conform the rule chapter to the statutes as they now exist. The rule chapter establishes standards for continuing education courses for insurance agents. In 1998 s. 626.2816, F.S. (1998 Supp.) was created. It provides the department with rulemaking authority for the specific purpose of "establishing standards for the approval, regulation, and operation of the continuing education program and for the discipline of licensees, course providers, instructors, school officials, and monitor groups." The standards are to be "designed to ensure that such course providers, instructors, school officials, and monitor groups have the knowledge, competence, and integrity to fulfill the educational objectives of §§ 626.2815, 626.869(5), 648.385, and 648.386." The rules address procedures and standards for electronic courses.

SUMMARY: The rules establish requirements and standards for continuing education courses and records for limited surety or bailbond agents, licensed worker's compensation adjusters, and others authorized to offer or teach related coursework.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: None.

Any person who wishes to provide information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative, must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 624.308, 626.9611, 648.26 FS.

LAW IMPLEMENTED: 624.307(1), 624.4211, 624.501, 624.501(20), 624.501(20)(c), 626.2815, 626.2816, 626.611, 626.621, 626.681, 626.691, 626.869(5), 626.9541(1)(b), 648.26, 648.36, 648.38, 648.385, 648.386, 648.396, 648.396(4) FS.

IF REQUESTED IN WRITING WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

TIME AND DATE: 9:30 a.m., September 26, 2000

PLACE: Room 116, Larson Building, 200 East Gaines Street, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Shirley Kerns, Bureau Chief, Bureau of Licensing, Division of Agent and Agency Services, Department of Insurance, 200 East Gaines Street, Tallahassee, Florida 32399-0319, phone (850)413-5405

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this program, please advise the Department at least 5 calendar days before the program by contacting Yvonne White, (850)413-4214.

THE FULL TEXT OF THE PROPOSED RULES IS:

(Substantial rewording of Rule 4-228.010 follows. See Florida Administrative Code for present text.)

4-228.010 Purpose.

The purpose of this rule chapter is to establish requirements and standards for continuing education courses and records for persons:

(1) Licensed to solicit or sell insurance or act as limited surety or bail bond agents in this state;

(2) Licensed to adjust workers' compensation claims in this state; and

(3) Authorized to offer or teach related coursework in this state.

Specific Authority 624.308 FS. Law Implemented 624.307(1), 626.2815, 626.2816, 626.869(5) FS. History–New 8-17-93, Amended _____.