application shall be filed with the Office of Financial Regulation through the Central Registration Depository ("CRD") of the NASD in accordance with Rule 69W-600.0092, F.A.C. For investment adviser applicants and registrants who file via the IARD, such application shall be filed with the Office of Financial Regulation through the CRD of the NASD in accordance with Rule 69W-600.0093, F.A.C.

- (b) A complete initial application must include the following exhibits or forms that are appropriate for the type of registration requested:
 - 1. No change.
- 2. Statutory fee in the amount of \$30, for each registration sought, in the amount as required by Section 517.12(10), F.S.
 - 3. through 5. No change.
 - (c) No change.
 - (2) No change.

Specific Authority 517.03(1), 517.12(6) FS. Law Implemented 517.12(6), (7), (10), 517.1205 FS. History-New 9-20-82, Formerly 3E-301.02, Amended 10-15-86, 10-4-88, 6-24-90, 7-29-90, 10-14-90, 8-1-91, 6-16-92, 6-28-93, 11-14-93, 3-13-94, 4-30-96, 12-29-96, 6-22-98, 5-10-00, 9-19-00, 7-31-02, 12-11-03, Formerly 3E-600.002, Amended 3-16-06, 5-15-07.

Section II **Proposed Rules**

DEPARTMENT OF AGRICULTURE AND CONSUMER **SERVICES**

Division of Agricultural Environmental Services

RULE TITLE: RULE NO.:

5E-1.023 Procedures for Landowners and

> Leaseholders to Submit a Notice of Intent to Implement Nitrogen Best Management Practices (BMPs)

PURPOSE AND EFFECT: This amendment is proposed to provide for the adoption of an interim best management practice for fertilization for urban landscape maintenance.

SUMMARY: Addresses a request to adopt interim measure for nitrogen management per paragraph 5E-1.023(3)(a), F.A.C., by representatives of the landscape maintenance industry.

STATEMENT SUMMARY OF OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 576.045(3)(b) FS.

LAW IMPLEMENTED: 576.045(3)(b) FS.

A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: September 11, 2007, 9:00 a.m.

PLACE: Alachua Regional Service Center, 14101 Northwest Highway 441, Box 200, Alachua, Florida 32615; (386)418-5500

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Mr. Steve Dwinell, Assistant Director. Division of Agricultural Environmental Services, 3125 Conner Boulevard, Tallahassee, Florida 32399-1650; (850)488-7447

THE FULL TEXT OF THE PROPOSED RULE IS:

5E-1.023 Procedures for Landowners and Leaseholders to Submit a Notice of Intent to Implement Nitrogen Best Management Practices (BMPs).

- (1) through (5)(c) No change.
- (d) Urban turf or lawns The document titled "Best Management Practices for Protection of Water Resources in Florida, June 2002, Florida Green Industries" published by the Florida Department of Environmental Protection is hereby adopted and incorporated by reference.

Specific Authority 403.067(7)(c)2., 576.045(6) FS. Law Implemented 403.067, 576.045 FS. History-New 10-16-96, Amended 5-1-01, 10-17-02, 2-4-03<u>.</u>

NAME OF PERSON ORIGINATING PROPOSED RULE: Mr. Steve Dwinell

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Mr. Anderson H "Andy" Rackley DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 16, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: March 23, 2007

DEPARTMENT OF TRANSPORTATION

RULE NO.: RULE TITLE:

14-1.0081 Special Service Charge for Public

Records Request

PURPOSE AND EFFECT: Rule 14-1.0081, F.A.C., is being repealed. Repeal of this rule is part of the Department's overall goal to review existing rules and to repeal any rules that are considered to be obsolete or unnecessary. Repeal of this rule will remove the only rule in Part I as a recent repeal of Rule 14-1.013, F.A.C., removed one of the then three parts, the net result will be the elimination of the Part I and Part II subdivision of the rule chapter.

SUMMARY: Rule 14-1.0081, F.A.C., is being repealed.

OF **STATEMENT** OF SUMMARY **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 334.044(2) FS.

LAW IMPLEMENTED: 119.07, 334.044(29) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE. A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: James C. Myers, Clerk of Agency Proceedings, Florida Department of Transportation, Office of the General Counsel, 605 Suwannee Street, Mail Station 58, Tallahassee, Florida 32399-0458

THE FULL TEXT OF THE PROPOSED RULE IS:

RULES OF PROCEDURE – PUBLIC RECORDS, FINAL ORDERS PART I PUBLIC RECORDS

14-1.0081 Special Service Charge for Public Records Request.

Specific Authority 334.044(2) FS. Law Implemented 119.07, 334.044(29) FS. History-New 3-24-98. Repealed

NAME OF PERSON ORIGINATING PROPOSED RULE: Alexis M. Yarbrough, General Counsel

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Stephanie C. Kopelousos, Secretary DATE PROPOSED RULES APPROVED BY AGENCY HEAD: July 24, 2007

DEPARTMENT OF TRANSPORTATION

RULE NO.: RULE TITLE:

14-10.007 Maintenance of Nonconforming

Signs

PURPOSE AND EFFECT: Rule 14-10.007, F.A.C., is being amended.

SUMMARY: Rule 14-10.007, F.A.C., is being amended to clarify what are permissible modifications and redefine when a nonconforming sign is destroyed or discontinued. Proposed amendments published in the January 5, 2007, Florida Administrative Weekly contained substantial rewording. After rule development workshops were conducted on January 23, 2007, and February 23, 2007, the amendment was revised to include fewer changes to the current rule.

SUMMARY OF **STATEMENT** OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 334.044(2), 479.02(7) FS.

LAW IMPLEMENTED: 339.05, 479.02, 479.07(9) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: August 28, 2007, 10:00 a.m.

PLACE: Haydon Burns Building Auditorium, 605 Suwannee Street, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: James C. Myers, Clerk of Agency Proceedings, Florida Department of Transportation, Office of the General Counsel, 605 Suwannee Street, Mail Station 58, Tallahassee, Florida 32399-0458

THE FULL TEXT OF THE PROPOSED RULE IS:

- 14-10.007 Maintenance of Nonconforming Signs.
- (1) A nonconforming sign must remain substantially the same as it was as of the date it became nonconforming.
- (2) Reasonable repair and maintenance of nonconforming signs, including change of advertising message, is permitted and is not a change which would terminate the nonconforming status. Reasonable repair and maintenance means the work necessary to keep the sign structure in a state of good repair, including the replacement in kind of materials in the sign structure. Where the replacement of materials is involved, such replacement may not exceed 50% of the structural materials in the sign within any 24 month period. "Structural materials" are all those materials incorporated into the sign as load-bearing parts, including vertical supports, horizontal stringers, braces, bracing wires, brackets, and catwalks. Structural materials do not include the sign face, any skirt, any electrical service, or electric lighting, except in cases where such items have been incorporated into the sign as load-bearing parts defined in Section (6)(a)2.a. below. The following are examples of modifications which do not constitute reasonable repair or maintenance, and which constitute substantial changes to a nonconforming sign that will result in the loss of nonconforming status:
- (a) Modification that changes the structure of, or the type of structure of, the sign, such as conversion of a back-to-back sign to a V-type, or conversion of a wooden sign structure to a metal structure;
- 1. The Department will authorize structural alterations to a nonconforming sign in instances where the Occupational Safety and Health Administration (OSHA) requirements or other safety related requirements necessitate alterations, provided that the reconstruction shall not be authorized primarily for the purpose of replacement of deteriorated materials. The Department will accept a notice or other writing from OSHA or other regulatory body to the permittee requiring intended alteration as documentation of safety requirements. If the structural alterations are intended to be made to comply with OSHA regulations, the permittee must submit to the Department a statement in writing citing the OSHA regulation with which it is intending to comply and explaining how the intended alteration is required by the cited OSHA regulation. If the structural alterations are intended to be made to comply with building codes, the permittee must submit to the Department a statement in writing citing the

specific requirement of the building code which the alterations are intended to meet. Structural alterations are allowed only if no alternatives are available which address safety requirements. Documentation of the requirements must be submitted to, and approved by, the Department prior to making any structural alterations. The location, configuration, number of faces, size of the sign faces, sign structure height, and the materials used in the sign structure and sign faces must be the same type as those used in the sign prior to approval of the alterations. Structural configuration means the physical arrangement of a sign whether arranged as a single-faced, V-type, back-to-back, side-to-side, or stacked sign. During the period of temporary removal for those approved structural alterations, the permittee must permanently display the permit tag at the sign location.

- 2. The addition of a catwalk or other fall protection device for safety reasons, where the device does not increase the structural integrity of the sign or prolong the life of the sign, is allowed without obtaining prior approval from the Department;
- (b) Modification that changes the area of the sign facing or the HAGL of the sign, however:
- 1. Reduction in the area of the sign facing or the HAGL of the sign, which reduction is required by an ordinance adopted by a local governmental entity with jurisdiction over the sign, is not a change which would terminate the nonconforming status of the sign, provided like materials are used and no enhancements are made to the visibility of the sign.
- 2. Embellishments may be added to nonconforming signs subject to the limitations regarding size of sign facing, and provided they do not exceed 10% of the area of the sign facing prior to the addition of the embellishment;
- (c) Modification that enhances the visibility of the sign's message, or the period of time that the sign's message is visible;
 - (d) Modification that adds automatic changeable faces; or
- (e) Modification that adds artificial lighting, or changes the existing lighting such that the illumination to the sign facing is substantially increased.
- (3) Prohibited modifications need not be physically part of the sign if they have the effect of enhancing the sign's message, the visibility of the message, or the period of time that the message is visible. However, in such cases, the modifications will not be considered a modification to the sign if:
- (a) The modification is the result of removal, cutting, or trimming of vegetation in front of the sign pursuant to a permit for such removal, cutting, or trimming from the Department; or
- (b) The modification only incidentally affects the visibility of the sign's message, and the bona fide purpose of the modification is unrelated to the sign.
- (4) A nonconforming sign may not be disassembled and re-erected at the same location except as provided in paragraph (6)(a), below.

- (5) A nonconforming sign may not be relocated, except to a conforming location.
- (6) A nonconforming sign may continue to exist so long as it is not destroyed, abandoned, or discontinued. "Destroyed," "abandoned." and "discontinued" have the following meanings:
- (a) "Destroyed" means more than 60% 50% of the upright supports of a sign structure are physically damaged such that normal repair practices of the industry would call for, in the case of wooden sign structures, replacement of the broken supports and, in the case of a metal sign structure, replacement of at least 25% of the length above ground of each broken, bent, or twisted support. A sign will not be considered "destroyed" within the meaning of this section where the under the following conditions:
- 1. The destruction of a sign is caused by vandalism or other criminal or tortious act.
- 2. If the permittee demonstrates that the replacement materials cost to re erect the sign would not exceed 50% of the value of the structural materials in the sign, immediately prior to destruction. The following shall be applicable in determining whether the replacement materials cost to re erect the sign would not exceed 50% of the value of the structural materials in the sign:
- a. Structural materials are all those materials incorporated into the sign as load-bearing parts, including vertical supports, horizontal stringers, braces, bracing wires, brackets, and catwalks. Structural materials do not include the sign face, any skirt, any electrical service, or electric lighting, except in cases where such items have been incorporated into the sign as load-bearing parts.
- b. The value of the structural materials in the sign immediately prior to destruction shall be based on the cost of all structural materials contained in the sign as it was configured just prior to damage, and the cost of such materials shall be based on normal market cost as if purchased new on or about the date of destruction, without regard to any labor costs or special market conditions.
- c. The materials to be included in the replacement materials costs to re erect the sign shall be all materials that would be used to return the sign to its configuration immediately prior to destruction, and shall include any material obtained from a source other than the sign itself, whether used, recycled, or repaired, but shall not include any material from the sign itself that is repaired on site. The repairs to the sign shall be with like materials, both in type and size, and shall be those reasonably necessary to permanently repair the sign in a manner normally accomplished by the industry in that area. The cost of such materials shall be as described in paragraph (6)(a)2.b.
- (b) A nonconforming sign is "abandoned" "discontinued" when the sign owner fails to operate and maintain the sign for a period of 12 months or longer. Signs

displaying bona fide public interest messages are not "abandoned" or "discontinued" within the meaning of this section. The following conditions shall be considered failure to operate and maintain the sign:

- 1. Signs displaying only an "available for lease" or similar message,
- 2. Signs displaying advertising for a product or service which is no longer available,
- 3. Signs which are blank or do not identify a particular product, service, or facility.
- (c) A nonconforming sign is "discontinued" when a sign structure no longer exists at the permitted location.

Specific Authority 334.044(2), 479.02(7) FS. Law Implemented 339.05, 479.02, 479.07(9) FS. History–New 3-28-77, Amended 12-10-77, 1-1-86, Formerly 14-10.07, Amended 6-28-98, 8-10-99, 8-19-01, _______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Kenneth Towcimak, Director, Office of Right of Way

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Stephanie C. Kopelousos, Secretary DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 24, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: January 5, 2007

DEPARTMENT OF TRANSPORTATION

RULE NOS.: RULE TITLES:

14-25.022 Contracts Administration Office

14-25.023 District Offices

14-25.024 Protests

14-25.026 Resolution of Protest

PURPOSE AND EFFECT: Rule Chapter 14-25, F.A.C., is being repealed as the subject of this rule chapter is covered in Rule Chapter 28-110, F.A.C. Further, matters addressed in the rule chapter are covered in bid solicitations and other notices. Repeal of this rule chapter is part of the Department's overall goal to review existing rules and to repeal any rules that are considered to be obsolete or unnecessary.

SUMMARY: Chapter 14-25, F.A.C., is being repealed as the subject of this rule chapter is covered in Rule Chapter 28-110, F.A.C.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 120.57(3), 334.044(2) FS.

LAW IMPLEMENTED: 120.57(3)(a), 120.57(3)(e), 337.11(5) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: James C. Myers, Clerk of Agency Proceedings, Florida Department of Transportation, Office of the General Counsel, 605 Suwannee Street, Mail Station 58, Tallahassee, Florida 32399-0458

THE FULL TEXT OF THE PROPOSED RULE IS:

14-25.022 Contracts Administration Office.

Specific Authority 120.53(5), 334.044(2) FS. Law Implemented 120.53(5)(a)3., 337.11 FS. History—New 11-12-85, Formerly 14-25.22, Amended 10-18-89, 4-17-91, 1-15-92, 2-10-92, 9-20-94, Repealed

14-25.023 District Offices.

Specific Authority 120.53(5), 334.044(2) FS. Law Implemented 120.53(5), 337.11 FS. History—New 11-12-85, Formerly 14-25.23, Amended 10-18-89, 4-17-91, 9-20-94, Repealed ______.

14-25.024 Protests.

Specific Authority 120.57(3), 334.044(2) FS. Law Implemented 120.57(3), 337.11(5) FS. History–New 11-12-85, Formerly 14-25.24, Amended 10-18-89, 4-17-91, 6-24-91, 8-11-92, 9-20-94, 5-23-95, 8-29-95, 1-17-99, Repealed

14-25.026 Resolution of Protest.

Specific Authority 120.57(3), 334.044(2) FS. Law Implemented 120.57(3)(e) FS. History–New 11-12-85, Formerly 14-25.26, Amended 10-18-89, 1-17-99. Repealed ...

NAME OF PERSON ORIGINATING PROPOSED RULE: Juanita Moore, Manager, Contracts Administration Office NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Stephanie C. Kopelousos, Secretary DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 24, 2007

BOARD OF TRUSTEES OF THE INTERNAL IMPROVEMENT TRUST FUND

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

DEPARTMENT OF CORRECTIONS

RULE NO.: RULE TITLE:

33-103.001 Inmate Grievances – General Policy PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to revise the inmate grievance and appeal process to provide access to necessary information for

reviewing staff, ensure the security of grievances and appeals during the review process, ensure inmate access to the process, and clarify consequences of staff obstruction.

SUMMARY: The proposed rule amendments revise the inmate grievance and appeal process to provide access to necessary information for reviewing staff, ensure the security of grievances and appeals during the review process, ensure inmate access to the process, and clarify consequences of staff obstruction.

OF **STATEMENT** OF **ESTIMATED** SUMMARY REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 944.09 FS.

LAW IMPLEMENTED: 944.09 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Perri King Dale, Office of the General Counsel, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE FULL TEXT OF THE PROPOSED RULE IS:

- 33-103.001 Inmate Grievances General Policy.
- (1) through (4) No change.
- (5) Staff in the Bureau of Inmate Grievance Appeals shall have unlimited access to information required to respond to inmate grievances and appeals. All department employees are required to cooperate with staff in the inmate grievance office by providing accurate and timely information.

Specific Authority 944.09 FS. Law Implemented 944.09 FS. History-New 10-12-89, Amended 1-15-92, 12-22-92, 4-10-95, 12-7-97, Formerly 33-29.001, Amended 10-11-00.

NAME OF PERSON ORIGINATING PROPOSED RULE: Celeste Kemp, Chief, Bureau of Inmate Grievance Appeals NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Laura E. Bedard, Ph.D., Deputy Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 12, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 22, 2007

DEPARTMENT OF CORRECTIONS

RULE NO.: RULE TITLE:

33-103.006 Formal Grievance – Institution or

Facility Level

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to revise the inmate grievance and appeal process to provide access to necessary information for reviewing staff, ensure the security of grievances and appeals during the review process, ensure inmate access to the process, and clarify consequences of staff obstruction.

SUMMARY: The proposed rule amendments revise the inmate grievance and appeal process to provide access to necessary information for reviewing staff, ensure the security of grievances and appeals during the review process, ensure inmate access to the process, and clarify consequences of staff obstruction.

STATEMENT OF SUMMARY OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 944.09 FS.

LAW IMPLEMENTED: 944.09 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Perri King Dale, Office of the General Counsel, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE FULL TEXT OF THE PROPOSED RULE IS:

- 33-103.006 Formal Grievance Institution or Facility Level.
 - (1) No change.
 - (2) Procedural Requirements.
 - (a) through (h) No change.
- (i) The inmate shall then submit the grievance or appeal all copies of the complete form, with attachments, to the person designated staff by personally placing the grievance or appeal in a locked grievance box. Locked boxes shall be available to inmates in open population and special housing units. A staff person from classification, the grievance coordinator's office, or the assistant warden's office shall be responsible for the key. If the staff member collecting the grievances is from classification or the assistant warden's office, he or she shall retrieve the grievances and appeals and deliver them to the institutional grievance coordinator. The institutional grievance coordinator shall log all formal grievances and provide the inmates with receipts. The appeals will be forwarded to the

Bureau of Inmate Grievance Appeals after being processed for mailing in accordance with paragraphs 33-103.006(8)(b) and (c), F.A.C. The Bureau of Inmate Grievance Appeals shall log all appeals and forward receipts to the inmates. Grievances and appeals shall be picked up and forwarded by the institutions daily Monday through Friday. Failure to submit all copies as required shall result in one copy being returned to the inmate instead of two.

(j) through (10) No change.

Specific Authority 944.09 FS. Law Implemented 944.09 FS. History—New 10-12-89, Amended 1-15-92, 12-22-92, 4-10-95, 8-10-97, 12-7-97, 5-10-98, 2-17-99, Formerly 33-29.006, Amended 8-1-00, 10-11-00, 2-9-05, ...

NAME OF PERSON ORIGINATING PROPOSED RULE: Celeste Kemp, Chief, Bureau of Inmate Grievance Appeals NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Laura E. Bedard, Ph.D., Deputy Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 12, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 22, 2007

DEPARTMENT OF CORRECTIONS

RULE NO.: RULE TITLE:

33-103.015 Inmate Grievances – Miscellaneous

Provisions

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to revise the inmate grievance and appeal process to provide access to necessary information for reviewing staff, ensure the security of grievances and appeals during the review process, ensure inmate access to the process, and clarify consequences of staff obstruction.

SUMMARY: The proposed rule amendments revise the inmate grievance and appeal process to provide access to necessary information for reviewing staff, ensure the security of grievances and appeals during the review process, ensure inmate access to the process, and clarify consequences of staff obstruction.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 944.09 FS.

LAW IMPLEMENTED: 944.09 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Perri King Dale, Office of the General Counsel, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE FULL TEXT OF THE PROPOSED RULE IS:

33-103.015 Inmate Grievances – Miscellaneous Provisions.

- (1) through (11) No change.
- (12) Staff shall respond to inquiries made by the Bureau of Inmate Grievance Appeals by the close of business on the seventh day after the request.

Specific Authority 944.09 FS. Law Implemented 944.09 FS. History—New 10-12-89, Amended 1-15-92, 1-29-92, 9-3-92, 12-22-92, 07-11-93, 5-3-94, 4-10-95, 9-23-96, 8-10-97, 12-7-97, 5-10-98, 2-17-99, Formerly 33-29.015, Amended 8-1-00, 10-11-00, 2-7-01, Amended 5-27-02, 1-2-03, 2-9-05, 9-4-05.________.

NAME OF PERSON ORIGINATING PROPOSED RULE: Celeste Kemp, Chief, Bureau of Inmate Grievance Appeals NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Laura E. Bedard, Ph.D., Deputy Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 12, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 22, 2007

DEPARTMENT OF CORRECTIONS

RULE NO.: RULE TITLE:

33-103.017 Inmate Grievances – Reprisal

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to revise the inmate grievance and appeal process to provide access to necessary information for reviewing staff, ensure the security of grievances and appeals during the review process, ensure inmate access to the process, and clarify consequences of staff obstruction.

SUMMARY: The proposed rule amendments revise the inmate grievance and appeal process to provide access to necessary information for reviewing staff, ensure the security of grievances and appeals during the review process, ensure inmate access to the process, and clarify consequences of staff obstruction.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 944.09 FS. LAW IMPLEMENTED: 944.09 FS. IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE. A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Perri King Dale, Office of the General Counsel, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE FULL TEXT OF THE PROPOSED RULE IS:

- 33-103.017 Inmate Grievances Reprisal.
- (1) Inmates shall be allowed access to the grievance process without hindrance. Staff found to be obstructing an inmate's access to the grievance process shall be subject to disciplinary action ranging from oral reprimand up to dismissal in accordance with Rules 33-208.001-.003, F.A.C. Good faith use of or good faith participation in the grievance process shall not result in reprisal against the inmate.
- (2) An inmate shall be subject to disciplinary action if the inmate knowingly includes false, threatening, obscene, or profane statements in the grievance or any of its attachments. In this instance the inmate shall be subject to administrative action in accordance with the provisions of Rules 33-601.301-601.314, F.A.C., or criminal prosecution. Notwithstanding administrative or criminal proceedings, the grievance shall be responded to on its merits.

Specific Authority 944.09 FS. Law Implemented 944.09 FS. History-New 10-12-89, Amended 12-22-92, 4-10-95, Formerly 33-29.016, Amended 10-11-00, 2-9-05,

NAME OF PERSON ORIGINATING PROPOSED RULE: Celeste Kemp, Chief, Bureau of Inmate Grievance Appeals NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Laura E. Bedard, Ph.D., Deputy Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 12, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 22, 2007

DEPARTMENT OF CORRECTIONS

RULE NO.: **RULE TITLE:** 33-601.603 **Furloughs**

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to correct an incorrect reference and remove references to exceptions for time frame criteria that no longer

SUMMARY: The proposed rule correct a reference and remove references to exceptions for time frame criteria that no longer exist.

OF **SUMMARY** OF **STATEMENT ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 945.091 FS.

LAW IMPLEMENTED: 945.091 FS.

IF REOUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Perri King Dale, Office of the General Counsel, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE FULL TEXT OF THE PROPOSED RULE IS:

33-601.603 Furloughs.

- (1) through (2) No change.
- (3) Policy Statement.
- (a) through (c) No change.
- (d) The decision as to which inmates shall be allowed to leave the principal places of their confinement shall be based upon criteria set forth in subsection 33-601.603(6) 33-601.602(6), F.A.C. Exceptions for the time frame requirements specified in paragraphs 33-601.602(6)(b) and (c), F.A.C., shall be considered on a case by case basis when extenuating circumstances as defined in paragraph 33-601.602(1)(1), F.A.C., exist.
 - (e) through (f) No change.
 - (4) through (11) No change.

Specific Authority 945.091 FS. Law Implemented 945.091 FS. History-New 12-8-97, Amended 4-13-98, 10-20-98, Formerly 33-9.024, Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: David Pridgen, Deputy Assistant Secretary of Institutions NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Laura E. Bedard, Ph.D., Deputy Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 15, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 6, 2007

DEPARTMENT OF CORRECTIONS

RULE NO.: **RULE TITLE:**

Administrative Confinement 33-602.220

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to amend form DC4-650, Observation Checklist, to include Self Harm Observation Status and amend the descriptive names of the items allowed or issued to inmates in an observation status.

SUMMARY: Form DC4-650, Observation Checklist, is revised to include Self Harm Observation Status and amend the descriptive names of the items allowed or issued to inmates in an observation status.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 944.09 FS.

LAW IMPLEMENTED: 944.09, 945.04 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Perri King Dale, Office of the General Counsel, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE FULL TEXT OF THE PROPOSED RULE IS:

- 33-602.220 Administrative Confinement.
- (1) through (10) No change.
- (11) Forms. The following forms referenced in this rule are hereby incorporated by reference. A copy of any of these forms may be obtained from the Forms Control Administrator, Office of Research, Planning and Support Services, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500.
 - (a) Form DC4-650, Observation Checklist, effective date 3-5-06.
 - (b) through (i) No change.

Specific Authority 944.09 FS. Law Implemented 20.315, 944.09, 945.04 FS. History–New 4-7-81, Amended 6-23-83, 3-12-84, Formerly 33-3.081, Amended 4-22-87, 8-27-87, 7-10-90, 12-4-90, 3-24-97, 4-26-98, 10-5-98, Formerly 33-3.0081, Amended 2-12-01, 2-5-02, 1-19-03, 4-1-04, 3-5-06, 10-31-06, _______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Dean Aufderheide, Ph.D., Mental Health Services Director NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Laura E. Bedard, Ph.D., Deputy Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 15, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 6, 2007

DEPARTMENT OF ELDER AFFAIRS

Federal Aging Programs

RULE NOS.:	RULE TITLES:
58A-2.002	Definitions
58A-2.003	License Requirements
58A-2.005	Administration of the Hospice
58A-2.010	Quality Assurance and Utilization
	Review (QAUR) Committee and
	Plan
58A-2.012	Program Reporting Requirements
58A-2.014	Medical Direction
58A-2 0232	Advance Directives

PURPOSE AND EFFECT: The purpose of the proposed rule amendments is to incorporate additional definitions; changes in licensure requirements; specific definitions regarding reporting requirements; changes to the reporting requirements pursuant to Chapter 2006-155, Section 7, Laws of Florida, including a reporting form incorporated by reference in Rule 58A-2.012, F.A.C; changes in accordance with Chapter 2006-155, Section 7, Laws of Florida, requiring development of outcome measures and adoption of national initiatives such as those developed by the National Hospice and Palliative Care Organization; and additional language, clarification of terms and update of the Health Care Advance Directives form incorporated by reference in Rule 58A-2.0232, F.A.C.

SUMMARY: The proposed rule amendments add definitions; change licensure requirements; specific definitions regarding reporting requirements; changes in reporting requirements including a new reporting form incorporated by reference; development of outcome measures; adoption of national initiatives developed by the National Hospice and Palliative Care Organization; and additional language, clarification of terms, and updating the Health Care Advance Directives form incorporated by reference.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 400.605, 400.60501, 765.110 FS. LAW IMPLEMENTED: 400.602, 400.605, 400.60501, Ch. 765 FS.

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

DATE AND TIME: August 28, 2007, 9:30 a.m. – 12:00 Noon EST.

PLACE: Department of Elder Affairs, 4040 Esplanade Way, Conference 225F, Tallahassee, FL 32399-7000

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 72 hours before the workshop/meeting by contacting: Jim Crochet, Department of Elder Affairs, 4040 Esplanade Way, Tallahassee, FL 32399-7000; telephone number (850)414-2000, SunCom 994-2000; Email address: crochethj@elderaffairs.org. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice). THE PERSON TO BE CONTACTED REGARDING THE

PROPOSED RULES IS: Jim Crochet, Department of Elder Affairs, 4040 Esplanade Way, Tallahassee, FL 32399-7000; telephone number (850)414-2000, SunCom 994-2000; Email address: crochethj@elderaffairs.org

THE FULL TEXT OF THE PROPOSED RULES IS:

58A-2.002 Definitions.

In addition to definitions contained in Chapter 400, Part IV VI, F.S., the following terms shall apply:

- (1) Advertising: The delivery, distribution, publication or display of an item, document, or medium initiated by the hospice that is intended to offer, describe, or advertise hospice or hospice-like services to the general public. A type of listing, which is formatted to only include a licensed hospice provider's name, address, and telephone number in the telephone directory, shall not be considered advertising.
 - (2) Agency: Agency for Health Care Administration.
 - (3) AHCA: Agency for Health Care Administration.
- (4)(1) Autonomous: A means a separate and distinct operational entity, which functions under its own administration and bylaws, either within or independently of a parent organization.
- (5)(2) Branch office: means Aan office or other physical location serving as a contact point for patients, which is remote from the provider's principal office of the provider, but is not separately licensed, and which shares administration with the principal office which serves as a contact point for patients.
 - (6) Department: Department of Elder Affairs.
- (7)(3) Employ: means Tto engage the services of an individual, on either a salary or volunteer basis.
- (8)(4) Home: means Tthe patient's current primary place of residence, including a private residence, assisted living facility, nursing home, hospice residential unit, or other place of permanent or temporary residence.
- (9)(5) Home Health Aide: means Aan individual who provides personal health care services for a patient in the patient's home or place of residence under the supervision of a registered nurse.
- (10)(6) Licensed Practical Nurse: means Aan individual licensed pursuant to Chapter 464, F.S., to practice practical nursing.

- (11)(7) Patient Care Staff: means those Ppersons involved in direct care of the patient, including registered nurses, practical nurses and home health aides, social workers and other mental health professionals, and clergy or pastoral counselors.
- (12)(8) Patient's Family: The means that person or those persons designated by the patient as having primary responsibility for care, or persons who are closely linked with the patient and are involved in the health and supportive care of
- (13)(9) Patient and Family Unit: means Tthe patient and the patient's family.
- (14)(10) Registered Nurse: means Aan individual who is licensed pursuant to Chapter 464, F.S., to practice professional nursing.

Specific Authority 400.605 FS. Law Implemented 400.602, 400.605 Ch. 400, Part VI FS. History-New 5-6-82, Formerly 10A-12.02, 10A-12.002, Amended 4-27-94, Formerly 59A-2.002, Amended

58A-2.003 License Requirements Required.

- (1) The face of the license must shall contain the following information:
- (a) The name and address of the provider, including the principal office and all branch offices;
- (b) All freestanding hospice inpatient facilities and residential units;
 - (c) All counties served by the hospice;
 - (d) The name of the owner; and
 - (e) The effective and expiration dates of the license.
- (2) The hospice must notify the department and the agency in writing at least sixty (60) days before making a change in name or address of the provider's principal or branch offices. the name and address of the provider, including the principal office and all branch offices, all hospice residences and inpatient facilities, all counties served by the hospice, the name of the owner, and the effective and expiration dates of the license. The hospice shall notify AHCA and the Department in writing at least sixty (60) days before making a change in name or address of the provider.
- (3)(2) If a change of ownership as defined in Section 408.803(5), F.S., is contemplated, the new owner must shall submit, or cause to be submitted, a an license application for license and must receive a license prior to commencement of operation of the hospice. The following materials must accompany the license application:
- (a) A signed agreement to correct any existing licensure deficiencies;
- (b) Documented evidence that the change of ownership has taken place or will take place upon approval of the license; and

- (c) A statement that records pertaining to the administrative operation of the provider must be retained and made available for official inspection by the agency.
- A signed agreement to correct any existing licensure deficiencies shall accompany the license application, together with documentation to evidence that the ownership change has taken place, and a statement that records pertaining to the administrative operation of the provider will be retained and available for official inspection by the AHCA.
- (4)(3) If a merger of two or more hospice providers is contemplated, the legal and incorporated entity that will be responsible for the operational function of the hospice after the merger must shall notify the agency AHCA prior to the merger. Notification must will include the anticipated date for the merger and the reason for the merger. The agency AHCA shall require the legal entity to submit a license an application for license, including a revised plan for the delivery of hospice care to terminally ill patients and their families who will be affected by the merger.

Specific Authority 400.605 FS. Law Implemented 400.602, 400.605 Ch. 400, Part VI FS. History—New 5-6-82, Formerly 10A-12.03, 10A-12.003, Amended 4-27-94, Formerly 59A-2.003, Amended 6-5-97.______.

58A-2.005 Administration of the Hospice.

- (1) Governing Body. The hospice must establish written bylaws for There shall be a governing body established by written bylaws of the hospice with autonomous authority for the conduct of the hospice program. The governing body must and which shall satisfy the following requirements:
- (a) Members of the governing body must shall reside or work in the hospice's service area as defined in paragraph 59C-1.0355(2)(k), F.A.C.
 - (b) No change.
 - (c) Duties of the governing body <u>must</u> shall-include:
- 1. Adoption in writing, with updates as necessary, of the following documents which <u>must shall</u> be in compliance with provisions of Chapter 400, Part <u>IV</u> VI, F.S., and these rules, with updates as necessary:
 - a. through c. No change.
- d. A comprehensive emergency management plan for all administrative, residential, free-standing inpatient facilities, and hospice services designed to protect the safety of patients and their families and hospice staff; and
 - e. No change.
- 2. Promulgation of rules and bylaws which include at least the following:
 - a. through c. No change.
- d. The qualifications, method of selection and terms of office of members and chairpersons of the governing body and committees; and

- e. A mechanism for <u>the administrator's</u> appointment by the administrator of the medical director and other professional and ancillary personnel.
- (2) Administrative Officer. The hospice <u>must shall</u> employ an administrator whose duties <u>must shall</u> be <u>outlined enumerated</u> in a <u>written</u> job description, including job qualifications. The administrator <u>must which shall</u> be approved by the governing body. and The job description <u>must be</u> kept in an administrative file.
 - (a) No change.
- (b) The administrator <u>must</u> shall be responsible for maintaining an <u>administrative</u> office facility for the <u>purpose of the operations of the hospice</u>.
 - (3) Administrative Policies and Practices.
- (a) The administrator <u>must</u> shall be responsible for developing, documenting and implementing administrative policies and practices which are consistent with these rules, and the <u>bylaws</u> by-laws, and the plans and decisions adopted by the governing body. These policies and practices must and which ensure the most efficient operation of the hospice program and the safe and adequate care of the patient and family units. At a minimum, these policies and practices must shall include:
 - 1. through 2. No change.
- 3. A plan for orientation and training of all staff, including volunteers, which <u>must shall</u> ensure that all staff receive this training prior to the delivery of their delivering services of any kind to patients and their families. This plan <u>must shall</u> describe the method of assessing training needs and designing training to meet those needs, and <u>must shall</u> include a curriculum outline with specific objectives.
 - 4. No change.
- 5. Policies for administering drugs and biologicals in the home which must shall include:
 - a. through b. No change.
- c. All verbal orders for medication or treatments, or changes in medication or treatment <u>must orders shall</u> be taken by a licensed health professional and <u>recorded in the patient's record reduced to writing.</u> <u>Verbal orders must be and signed by the physician within thirty (30) calendar days from the date of the order.</u>
- d. The use of experimental drugs or any FDA or Chapter 500, F.S., approved drug in a non-approved manner shall not be given without the <u>written</u> consent of the patient or the patient's <u>legal representative</u>, surrogate or proxy. The program administering such drugs <u>must shall be</u> fully informed the patient or the patient's <u>legal representative</u>, surrogate or proxy of any risks, and <u>be</u> prepared to invoke remedial action should an adverse reaction occur. A copy of the signed consent must be kept in the patient's record.
 - 6. No change.

- 7. Policies and procedures approved by the medical director and governing body pertaining to the drug control system in the hospice including which shall include specific policies and procedures for disposal of Class II drugs upon the death of a patient.
 - 8. No change.
- 9. Policies and procedures for mMaintenance, confidentiality, and retention of clinical records for a minimum five-year period following the patient's death.
 - 10. through 11. No change.
- 12. Notice to the public that the hospice provides services regardless of ability to pay.
 - 13. through 14. No change.
- 15. Policies and procedures for cCompletion, retention, and submission of reports and records as required by the dDepartment, the agency, AHCA and other authorized agencies.
 - 16. No change.
- (b) Equipment and personnel, under medical supervision, must shall be provided for diagnostic procedures to meet the needs of the hospice inpatient, residential and home-care programs. This must shall include the services of a clinical laboratory and radiological services, which must shall meet all standards of the State of Florida. There must be written agreements or contracts for such services uUnless provided on the premises of the hospice, there shall be written agreements or contracts for such services. The hospice program must shall ensure that the sum of services are available under contract and services provided directly by the hospice shall assure twenty-four (24) hours a day, seven (7) days a week, either through contractual agreement, written agreement, or direct service provision by the hospice availability.
 - (c) No change.
 - (4) Outcome Measures.

Effective 2009, hospices must report the outcome measures outlined in this subsection on DOEA Form H-002, State of Florida Department of Elder Affairs Hospice Annual Report, July 2007, incorporated by reference in Rule 58A-2.012, F.A.C. The reporting time frame is prescribed in paragraph 58A-2.012(2)(a), F.A.C. In addition to the outcome measure regarding pain management pursuant to Section 400.60501, F.S., each hospice must conduct the National Hospice and Palliative Care Organization (NHPCO) Patient/Family Satisfaction Survey, or a similar survey, with its patients and families.

- (a) Each hospice must report results from survey questions that inquire about the following areas of concern:
- 1. Did the patient receive the right amount of medicine for his or her pain?
- 2. Based on the care the patient received, would the patient and/or family member/caregiver/legal representative/ surrogate/proxy recommend hospice services to others?

- (b) The acceptable standard for this measure must be an affirmative response on at least fifty (50) percent of the survey responses received by the hospice.
 - (5) National Initiatives.
- (a) In accordance with Section 400.60501, F.S., and as referenced in subsection 58A-2.005(4), F.A.C., the department adopts the national initiative of utilizing patient/family surveys as a tool to set benchmarks for measuring quality of hospice care in the State of Florida.
- (b) The department has also considered the national initiatives that are under evaluation and development by the Centers for Medicare and Medicaid Services (CMS) in consultation with the NHPCO. These initiatives include patient-centered outcome measures, quality assessment and performance improvement (QAPI), and infection control. Upon adoption of these initiatives by CMS in final regulation, all hospices shall be required to implement the initiatives consistent with this regulation.
- (c) Hospices must maintain documentary evidence of their compliance with these national initiatives and demonstrate their operations to the department or the agency during the survey process:

Specific Authority 400.605, 400.60501 FS. Law Implemented 400.605(1)(c). 400.60501 FS. History–New 5-6-82, Formerly 10A-12.05, 10A-12.005, Amended 4-27-94, Formerly 59A-2.005, Amended 6-5-97, 8-6-02, 8-10-03,

58A-2.010 Quality Assurance and Utilization Review (QAUR) Committee and Plan.

Each hospice must shall appoint a committee which must shall develop, document and implement a comprehensive quality assurance and utilization review plan pursuant to Section 400.610(2), F.S. The QAUR plan must shall include goals and objectives, provisions for identifying and resolving problems, methods for evaluating the quality and appropriateness of care, and the effectiveness of actions taken to resolve identified problems. The QAUR plan must shall establish a process for revising policies, procedures and practices when reviews have identified problems. The QAUR committee must shall review the QAUR plan and report findings and recommendations to the governing body annually. Dated and signed minutes of those meetings of the governing body at which QAUR findings and recommendations are presented must shall be kept in an administrative file.

- (1) through (2) No change.
- (3) The QAUR committee must shall audit patient records, including interdisciplinary care records, on a regular and periodic basis. All records <u>must</u> shall be stored in secured areas to protect patient confidentiality.
 - (a) No change.

- (b) After the patient's death and the end of the bereavement period, Tthe master record may be moved to storage shall be stored in a secure and accessible location after termination of bereavement services or a minimum of one year after the patient's death.
 - (4) No change.
- (5) Activities undertaken in the QUAR process must shall demonstrate a systematic collection, review, and evaluation of information and must shall result in proposed actions to correct any identified problems. The information used by the QUAR committee must shall include:
 - (a) through (e) No change.
- (f) High-risk, high-volume and problem-prone activities that would have a significant impact on patients, staff or the organization, even if adverse incidents occur infrequently, if at all. For example, high-risk activities may include review and evaluation of protocols for containment of communicable diseases, emergency evacuations and continuity of operations; high-volume activites might include collection of information regarding timely patient intake assessments, administration of medications; lastly, identifying problem-prone activities might be deterioration or malfunction of equipment, including security of informations systems, disposal of contaminated materials or other bio-medical waste; and
- (g) Appropriateness of team services and levels of care measured by whether:
- 1. If Tthe plan of care was directly related to the identified physical and psychosocial needs of the patient and the patient's family;
- 2. If the Sservices, medications and treatments prescribed were in accordance with the current hospice plan of care; and
- 3. If Tthe hospice program of care was primarily a home-care program that utilized inpatient hospice care on a short-term or respite basis only.
 - (6) through (7) No change.

Specific Authority 400.605 FS. Law Implemented 400.605 FS. History-New 5-6-82, Formerly 10A-12.10, 10A-12.010, Amended 4-27-94, Formerly 59A-2.010, Amended 6-5-97,______.

(Substantial rewording of Rule 58A-2.012 follows. See Florida Administrative Code for the present text.)

58A-2.012 Program Reporting Requirements.

(1) Definitions.

The following definitions pertain specifically to program reporting for DOEA Form H-002, State of Florida Department of Elder Affairs Hospice Annual Report, incorporated by reference in this rule:

- (a) Accreditation: Name of the specific accrediting organization.
- (b) Agency Type: Hospice type based on Medicare filing status. Valid options are: Free standing, hospital based, home health based (private residence) or nursing home based.

- (c) Discharge Disposition: The patient's condition upon discharge. Options are death or non-death.
- (d) Facility License Number: The facility's license number provided by the Agency for Health Care Administration.
- (e) Hospice operated inpatient facility: An inpatient facility consisting of one or more beds that is owned or leased by the hospice, is staffed by hospice personnel, and has policies and procedures set by the hospice. This includes beds in hospitals or nursing homes that comply with the conditions set forth in this paragraph.
- (f) Ownership Type: The type of ownership of the hospice. It can be for profit, not for profit or government operated.
- (g) Patient Days: The number of days elapsed during which hospice services were provided for the period of time comprising from start of services until final discharge.
- (h) Payor Source: Options are Medicare, Medicaid, third party, self-pay, uncompensated, and other.
- (i) Race/ethnicity A classification based on the patient's race or self -declared ethnic identity. Options are Asian, Black, Caucasian, Hispanic, and Other.
 - (2) Reporting Criteria.
- (a) Each hospice must complete an annual report for the period January 1 through December 31 of each year and must submit the report to the department no later than February 28 of the following year.
- (b) The report must be submitted electronically to the following Web site address: hospicereport@elderaffairs.org. The report may alternately be submitted to the following address: Department of Elder Affairs, Planning and Evaluation Unit, 4040 Esplanade Way, Tallahassee, FL 32399-7000.
- (c) Effective with the report due in 2009, the information must be recorded on DOEA Form H-002, State of Florida Department of Elder Affairs Hospice Annual Report, July 2007.
- 1. The form is hereby incorporated by reference and may be obtained from the following address: Department of Elder Affairs, Planning and Evaluation Unit, 4040 Esplanade Way, Tallahassee, Florida 32399-7000. The form may be also obtained from the department's Web site at http://elderaffairs.state.fl.us/english/forms/DOEAformH002.pdf.
 - 2. The form must be completed in its entirety.
- (d) A copy of the report must be available to the public during all hours of operation of the hospice principal office and the department.

Specific Authority 400.605, 400.60501 FS. Law Implemented 400.605, 400.60501 Ch. 400, Part VI FS. History-New 5-6-82, Formerly 10A-12.12, 10A-12.012, Amended 4-27-94, Formerly 59A-2.012, Amended 6-5-97,

58A-2.014 Medical Direction.

(1) No change.

- (2)(a) The medical director or his or her designee, a physician licensed under Chapter 458 or 459, F.S., must shall be a member of the hospice care team and must shall be responsible for the direction and quality of the medical component of the care rendered to the patient by the hospice care team. The patient's attending physician(s) may remain the primary physician(s) to the patient, depending upon the preferences of the patient and the patient's family. The patient and the patient's family may elect to have the hospice medical director assume all or part of the primary medical care functions, or act as a consultant to the patient's attending physician(s). In either case, the hospice care team must shall maintain liaison and a reporting relationship with the patient's attending physician(s).
 - (b) No change.
 - (3) through (4) No change.

Specific Authority 400.605 FS. Law Implemented 400.605 FS. History-New 5-6-82, Formerly 10A-12.14, 10A-12.014, Amended 4-27-94, Formerly 59A-2.014, Amended 6-5-97,

58A-2.0232 Advance Directives.

- (1) The administrator must shall ensure the development, documentation and implementation of policies and procedures which delineate the hospice's compliance with the state law and rules relative to advance directives. The hospice must shall not base condition treatment or admission upon whether or not the patient has executed or waived an advance directive. In the event of a conflict between the hospice's policies and procedures and the patient's advance directive, resolution must provision shall be made in accordance with Chapter 765, F.S.
- (2) The hospice's policies and procedures must shall include:
- (a) At the time of admission to a hospice program, providing each patient, or the patient's surrogate or proxy, with a copy of Form SCHS-4-2006, "Health Care Advance Directives – The Patient's Right to Decide," as prepared by the Agency for Health Care Administration, 2727 Mahan Drive, Tallahassee, FL 32308, effective 4-2006 (April 2006) 1-11-93, which is hereby incorporated by reference, or with a copy of some other substantially similar document which incorporates information regarding advance directives included in is a written description of Chapter 765, F.S., regarding advance directives. The form is hereby incorporated by reference and is available from the Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop 34, Tallahassee, FL 32308, or the agency's Web site at: http://ahca.myflorida.com/MCHQ/ Health Facility Regulation/HC Advance Directives/docs/ adv_dir.pdf.
 - (b) through (c) No change.

Specific Authority 765.110, 400.605 FS. Law Implemented 400.605, Ch. 765 FS. History-New 1-11-93, Formerly 59A-2.025, Amended 4-27-94, Formerly 58A-2.0232, Amended 6-5-97,

NAME OF PERSON ORIGINATING PROPOSED RULE: Jim Crochet

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: E. Douglas Beach, Ph.D., Secretary DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 18, 2007

DATE NOTICES OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 22, 2006 and May 11, 2007

AGENCY FOR HEALTH CARE ADMINISTRATION Medicaid

RULE NO.: **RULE TITLE:**

59G-4.070 Durable Medical Equipment and

Medical Supplies

PURPOSE AND EFFECT: The purpose of the rule amendment to Rule 59G-4.070, F.A.C., is to incorporate by reference the Florida Medicaid Durable Medical Equipment and Medical Supply Services Coverage and Limitations Handbook, July 2007. The revised handbook includes the policy and procedure code changes mandated by the federal Health Insurance Portability and Accountability Act (HIPAA) and revised provider enrollment and service requirement policies. The handbook also includes coverage of diabetic testing strips and insulin syringes, which are products that were transferred from the Medicaid Prescribed Drug Program to the Medicaid Durable Medical Equipment and Medical Supplies Program.

The effect of the amendment to Rule 59G-4.070, F.A.C., will be to incorporate by reference in the rule the revised Florida Medicaid Durable Medical Equipment and Medical Supply Services Coverage and Limitations Handbook, July 2007.

In the Notice of Rule Development that was published in Vol. 32, No. 47, November 22, 2006 issue of the Florida Administrative Weekly, we stated the handbook was dated January 2007. We changed this date to July 2007.

SUMMARY: The rule amendment to Rule 59G-4.070, F.A.C., will incorporate by reference the revised Florida Medicaid Durable Medical Equipment and Medical Supply Services Coverage and Limitations Handbook, July 2007.

OF **STATEMENT** SUMMARY OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 409.919 FS.

LAW IMPLEMENTED: 409.906, 409.907, 409.908, 409.913

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

DATE AND TIME: Monday, August 27, 2007, 2:00 p.m.

PLACE: Agency for Health Care Administration, 2727 Mahan Drive, Building 3, Conference Room B, Tallahassee, Florida THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Dan Gabric, Medicaid Services Office, 2727 Mahan Drive, MS #20, Tallahassee, Florida 32308-5403, (850)922-73069, gabricd@ahca.myflorida.com

THE FULL TEXT OF THE PROPOSED RULE IS:

59G-4.070 Durable Medical Equipment and <u>Medical</u> Supplies.

- (1) This rule applies to all durable medical equipment and medical supply providers enrolled in the Medicaid program.
- (2) All durable medical equipment and <u>medical</u> supply providers enrolled in the Medicaid program must <u>be in compliance eomply</u> with the Florida Medicaid Durable Medical Equipment and <u>Medical</u> Supply Services Coverage and Limitations Handbook, <u>July 2007 April 1998</u>, incorporated by reference, and the Florida Medicaid Provider Reimbursement Handbook, <u>CMS HCFA-1500 and EPSDT 221</u>, <u>which</u> is incorporated by reference in Rule 59G-<u>4.001 5.020</u>, F.A.C. Both handbooks are available from the Medicaid fiscal <u>agent's website at http://floridamedicaid.acs-inc.com agent. Click on Provider Support, and then on Handbooks. Paper copies of the handbooks may be obtained by calling the Medicaid fiscal agent at (800)377-8216.</u>
- (3) Medicaid durable medical equipment and medical supply providers are required to use the following form, which is incorporated by reference: the Custom Wheelchair Evaluation form, AHCA Med Serv Form, 015, July 2007, five pages. This form is available from the Medicaid fiscal agent's website at http://floridamedicaid.acs-inc.com. Click on Provider Support, and then on Medicaid Forms. The form may also be photocopied from Appendix A in the Florida Medicaid Durable Medical Equipment and Medical Supply Services Coverage and Limitations Handbook.

Specific Authority 409.919 FS. Law Implemented 409.906, 409.907(7), 409.908. 409.913 FS. History–New 8-26-92, Formerly 10C-7.070, Amended 5-23-94, 1-7-96, 3-4-99, 10-18-00, 4-30-01.

NAME OF PERSON ORIGINATING PROPOSED RULE: Dan Gabric

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Andrew Agwunobi, M.D.

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 25, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 22, 2006

AGENCY FOR HEALTH CARE ADMINISTRATION

Medicaid

RULE NO.: RULE TITLE:

59G-13.081 Developmental Disabilities Waiver

Provider Rate Table

PURPOSE AND EFFECT: The purpose of this rule amendment is to incorporate by reference the Developmental Disabilities Home and Community-Based Services Waiver Provider Rate Table, January 1, 2007. The effect will be to incorporate the Developmental Disabilities Home and Community-Based Services Waiver Provider Rate Table, January 1, 2007, into rule. The proposed rate table is available from Pam Kyllonen at kyllonep@ahca.myflorida.com.

SUMMARY: The purpose of this rule amendment is to incorporate by reference the Developmental Disabilities Home and Community-Based Services Waiver Provider Rate Table, January 1, 2007. The effect will be to incorporate the Developmental Disabilities Home and Community-Based Services Waiver Provider Rate Table, January 1, 2007, into rule.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 409.919 FS.

LAW IMPLEMENTED: 409.906, 409.908 FS.

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

DATE AND TIME: Wednesday, September 5, 2007, 1:30 p.m. PLACE: Agency for Health Care Administration, 2727 Mahan Drive, Building 3, Conference Room C, Tallahassee, Florida 32308

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Pam Kyllonen, Bureau of Medicaid Services, 2727 Mahan Drive, Mail Stop 20, Tallahassee, Florida 32308, (850)414-9756, kyllonep@ahca.myflorida.com

THE FULL TEXT OF THE PROPOSED RULE IS:

59G-13.081 Developmental Disabilities Waiver Provider Rate Table.

- (1) No change.
- (2) All developmental disabilities waiver services providers enrolled in the Medicaid program must be in compliance with the Developmental Disabilities <u>Home and Community-Based Services</u> Waiver Provider Rate Table, <u>January 1, 2007</u> November 2003, which is incorporated by reference. The rate table is available from the Medicaid fiscal

agent's website at http://floridamedicaid.acs-inc.com. Click on Provider Support, and then on Fees and. Paper copies of the rate table may be obtained from the Agency for Health Care Administration, Bureau of Medicaid Services, 2727 Mahan Drive, M.S. 20, Tallahassee, Florida 32308.

Specific Authority 409.919 FS. Law Implemented 409.906, 409.908 FS. History-New 5-29-06, Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: Pam Kyllonen

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Andrew Agwunobi, M.D.

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 14, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 13, 2006

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Accountancy

RULE NO.: RULE TITLE:

61H1-31.001 Fees

PURPOSE AND EFFECT: The Board proposes the rule amendment to include a fee for approval of a continuing education course in ethics.

SUMMARY: The fee for approval of a continuing education course in ethics will be \$250.00.

OF **STATEMENT** OF SUMMARY **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 455.213(2), 455.219(4), 455.271, 473.305, 473.312 FS.

LAW IMPLEMENTED: 119.07, 455.219(4), 455.271, 473.305, 473.312, 473.313 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Veloria Kelly, Division Director, Board of Accountancy, 240 N. W. 76th Dr., Suite A, Gainesville, Florida 32607

THE FULL TEXT OF THE PROPOSED RULE IS:

61H1-31.001 Fees.

(1) through (14) No change.

(15) For approval of a continuing education course in ethics, meeting the requirements of Section 473.312(1)(c), F.S., two hundred fifty dollars (\$250.00).

Specific Authority 455.213(2), 455.219(4), 455.271, 473.305, 473.312 FS. Law Implemented 119.07, 455.219(4), 455.271, 473.305, 473.312, 473.313 FS. History-New 12-4-79, Amended 2-3-81, 3-4-82, 11-6-83, 3-29-84, Formerly 21A-31.01, Amended 6-4-86, 9-16-87, 2-1-88, 8-30-88, 2-6-89, 12-18-89, 12-28-89, 8-16-90, 4-8-92, 12-2-92, Formerly 21A-31.001, Amended 11-4-93, 2-14-95, 11-3-97, 6-22-98, 10-28-98, 7-15-99, 4-3-02, 1-27-04, 1-31-05, 7-14-05, 4-9-06, 12-3-06, 4-29-07,

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Accountancy

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Accountancy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 20, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: May 18, 2007

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Accountancy

RULE NO.: RULE TITLE:

Board Approval of CPA Ethics 61H1-33.0032

Continuing Education by Providers

PURPOSE AND EFFECT: The Board proposes the rule amendment to change the fee for the Board and Department's review of each course for compliance to the one established in subsection 61H1-31.001(15), F.A.C.

SUMMARY: The fee for the Board's and Department's review of each course for compliance will be changed to the fee established in subsection 61H1-31.001(15), F.A.C.

SUMMARY OF STATEMENT OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 120.55(1)(a)4., 455.213(6), 455.2178, 455.2179, 473.304, 473.312 FS.

LAW IMPLEMENTED: 455.213(6), 455.2178, 455.2179, 473.312(1)(a), (c) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Veloria Kelly, Division Director, Board of Accountancy, 240 N. W. 76th Dr., Suite A, Gainesville, Florida 32607

THE FULL TEXT OF THE PROPOSED RULE IS:

- 61H1-33.0032 Board Approval of CPA Ethics Continuing Education by Providers.
 - (1) through (2) No change.
- (3) To allow the Board to evaluate an application for continuing education provider status, the applicant must submit the following:
 - (a) through (h) No change.
- (i) A fee in the amount of \$250.00 to reimburse the Board and Department for the review of each course for compliance with these rules and Section 473.312(1)(c), F.S. The fee as established in subsection 61H1-31.001(15), F.A.C.
 - (4) through (6) No change.

Specific Authority 120.55(1)(a)4., 455.213(6), 455.2178, 455.2179, 473.304, 473.312 FS. Law Implemented 455.213(6), 455.2178, 455.2179, 473.312(1)(a), (c) FS. History–New 6-30-05, Amended ______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Accountancy

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Accountancy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 20, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: May 18, 2007

DEPARTMENT OF ENVIRONMENTAL PROTECTION

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

DEPARTMENT OF JUVENILE JUSTICE

Staff Training

RULE NO.: RULE TITLE:

63H-2.003 Contracted Residential Staff

PURPOSE AND EFFECT: Amending the timing for annual in-service training for contracted residential staff, so that it corresponds with similar provisions elsewhere in the rule chapter.

SUMMARY: The annual in-service training period will no longer commence on the anniversary of hire, but is amended to begin the calendar year after the staff has completed pre-service training.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 20.316(1), 985.601(8) FS. LAW IMPLEMENTED: 985.02(3)(c), 985.601(8) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: Tuesday, August 28, 2007, 10:00 a.m.

PLACE: DJJ Headquarters, 2737 Centerview Dr., General Counsel's Conference Room 312, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Lydia Monroe, 2737 Centerview Dr., Ste. 312, Tallahassee, FL 32399-3100, e-mail: lydia.monroe@djj.state.fl.us

THE FULL TEXT OF THE PROPOSED RULE IS:

63H-2.003 Contracted Residential Staff.

- (1) through (4) No change.
- (5) <u>During each year, beginning on the first anniversary of hire, Ceontracted residential staff must complete 24 hours of annual in-service training beginning the calendar year after the staff has completed pre-service training.</u>
 - (6) through (12) No change.

Specific Authority 20.316(1), 985.601(8) FS. Law Implemented 985.02(3)(c), 985.601(8) FS. History–New 6-11-07. Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: Duane Pace, DJJ Bureau of Staff Development

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Michael McCaffrey, Director of Staff Development

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 20, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 6, 2007

DEPARTMENT OF HEALTH

Division of Disease Control

RULE NO.: RULE TITLE: 64D-4.002 Definitions

PURPOSE, EFFECT AND SUMMARY: This rule chapter is amended to update the effective date of the federal poverty level (FPL) from February 2006 to February 2007, and to comply with the most current federal poverty level standards. The Department of Health and Human Services updates the federal poverty level annually to better serve low-income persons living with HIV disease. This amended rule updates the effective date of the federal poverty level (FPL) from the year 2006 to 2007. The U.S. Department of Health and Human Services publishes the federal poverty level annually, and is used for eligibility purpose for the HIV/AIDS Patient Care Programs.

SPECIFIC AUTHORITY: 381.0011(13) FS.

LAW IMPLEMENTED: 381.001(1), 381.003(1)(c), 381.0011(5) FS.

THIS RULEMAKING IS UNDERTAKEN PURSUANT TO SECTION 120.54(6), F.S.

WRITTEN COMMENTS MAY BE SUBMITTED WITHIN 14 DAYS OF THE DATE OF THIS NOTICE TO: Joseph P. May, Program Administrator, Department of Health, Division of Disease Control, Bureau of HIV/AIDS, Patient Care, 2585 Merchants Row Boulevard, 3rd Floor, Room 345, Tallahassee, Florida 32399-1715.

SUBSTANTIALLY AFFECTED PERSONS MAY WITHIN 14 DAYS OF THE DATE OF THIS NOTICE, FILE AN OBJECTION TO THIS RULEMAKING WITH THE AGENCY. THE OBJECTION SHALL SPECIFY THE PORTIONS OF THE PROPOSED RULE TO WHICH THE PERSON OBJECTS AND THE SPECIFIC REASONS FOR THE OBJECTION.

THE FULL TEXT OF THE PROPOSED RULE IS:

64D-4.002 Definitions.

For the purpose of this rule chapter, the words and phrases listed below are defined in the following manner:

- (1) through (9) No change.
- (10) "Federal Poverty Level" (FPL) means the poverty income levels (effective February 2007 2006) as published by the U.S. Department of Health and Human Services (HHS), Federal Office of Management and Budget (OMB), which is incorporated by reference. The federal poverty guidelines are located on the Department of Health, Bureau of HIV/AIDS website or can be obtained at any Florida county health department.
 - (11) through (16) No change.

Specific Authority 381.0011(13) FS. Law Implemented 381.001(1), 381.0011(5) History-New 381.003(1)(c), FS. 1-23-07, Amended

DEPARTMENT OF HEALTH

Division of Environmental Health

RULE NO.: RULE TITLE:

64E-6.030 Fees

PURPOSE AND EFFECT: The proposed changes to Chapter 64E-6, Florida Administrative Code, address shortfall in fee revenues for services provided in the Onsite Sewage Program. Review of fee revenue versus expenditures for the 2006/2007 fiscal year found that on average revenue covers only 62% of expenditures. These rule amendments reflect a previous agreement and should produce a 25% increase in revenue overall for services in the program.

SUMMARY: Areas addressed include fees for services in the Onsite Sewage Program.

SUMMARY OF **STATEMENT** OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 154.06(1), 381.0066, 489.557(1)

LAW IMPLEMENTED: 381.0065, 381.066, 489.557 FS.

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

DATE AND TIME: August 27, 2007, 1:00 p.m.

PLACE: Bureau of Onsite Sewage Programs, Conference Room 240P, Capital Circle Office Center, 4042 Bald Cypress Way, Tallahassee, Florida

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 hours before the workshop/meeting by contacting: Shirley Kugler, Bureau of Onsite Sewage Programs, 4052 Bald Cypress Way, Bin #A08, Tallahassee, Florida 32399-1713. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Gerald Briggs, Chief, Bureau of Onsite Sewage Programs, 4052 Bald Cypress Way, Bin #A08, Tallahassee, Florida 32399-1713

THE FULL TEXT OF THE PROPOSED RULE IS:

64E-6.030 Fees.

(1) The following fees are required for to accompany applications for site evaluations, construction, modifications to existing systems or repair permits, and other services provided by the department.

•	
(a) Application and plan review for construction	<u> </u>
permit for new system permitting of an onsite	
sewage treatment and disposal system, which	
includes application and plan review	\$ <u>100</u> 50
(b) Application and approval for existing	
system, if system inspection is not required	
does not include system inspection.	\$35
(c) Application and Existing System Evaluation	<u>\$50</u>
(d)(e) Application for permitting	
of a new performance-based treatment system	\$125
(e)(d) Site evaluation for a new system	
which includes an evaluation of criteria	
specified in subsection 64E 6.004(3)	\$115
•	

(e) Site evaluation for a system repair which includes an evaluation of criteria specified in subsection 64E-6.015(1), or modification of a system \$75

(0.0)			
(f) Site re-evaluation , new or repair, or	¢50.75	(s)(u) Septage stabilization facility inspection	
modification of a system	\$ <u>50</u> 75	fee per annum per facility \$150	
(g) Permit or permit amendment for new	0.5.5	(t)(v) Septage disposal site evaluation fee per	
system, or modification <u>or repair</u> to system	\$55	annum \$200	
(h) New system or modification of a system	400	(u)(w) Aerobic treatment unit maintenance	
installation inspection	\$80	entity permit per annum \$25	
The following research fee is to be collected		(v)(x) Variance Application for a single	
in addition to, and concurrent with the permit for		family residence per each lot or building site $$200 \ 150$	
a new system installation fee	\$5	(w)(y) Variance Application for a	
(h)(i) Research / Training surcharge, new		multi-family or commercial building per each	
and repair permits Repair permit issuance,		building site \$ <u>300</u> 200	
which includes inspection	\$ <u>5</u> 50	$\underline{(x)}(z)$ Application for innovative product	
(j) Inspection of existing system, does		approval \$ <u>2500</u> 500	
not include modifications to system	\$50	(2) Except for the research fee which is to be placed in a	ì
(i) Initial system inspection	<u>\$75</u>	designated account, all fees collected pursuant to paragraphs	3
(j)(k) System reinspection (stabilization,		64E-6.030(1)(a) through (w), F.A.C., shall be deposited in an	ì
non-compliance or other inspection after the		individual county health department trust fund to be used to)
initial inspection) Reinspection fee per visit for		meet the cost of administering the onsite sewage treatment and	1
site inspections after system construction approval	\$50	disposal program.	
(k)(1) Application for system Installation		(2)(3) No change.	
reinspection for non-compliant system per		Specific Authority 154.06(1), 381.0066, 489.557(1) FS. Law	17
each site visit	\$50	Implemented 381.0065, 381.0066, 489.557 FS. History–New 2-3-98.	
(m) System abandonment permit, includes		Amended 3-22-00, 4-21-02, 5-24-04, 11-26-06,	,
permit issuance and inspection	\$ <u>50</u> 40		
(LAN) Annual operating permit fee for	· <u>—</u>	NAME OF PERSON ORIGINATING PROPOSED RULES	
systems in industrial/, manufacturing zoning or,		Dale Holcomb, Environmental Administrator, Bureau of	f
and equivalent areas, and for systems receiving		Onsite Sewage Programs	
commercial sewage waste	\$150	NAME OF SUPERVISOR OR PERSON WHO APPROVED)
(m) Amendments or changes to the operating	·	THE PROPOSED RULE: Gerald Briggs, Chief, Bureau of	f
permit during the permit period per change or		Onsite Sewage Programs	
amendment	\$50	DATE PROPOSED RULE APPROVED BY AGENCY	r
(o) Biennial operating permit for aerobic	723	HEAD: July 25, 2007	
Aerobie treatment unit or performance-based		DATE NOTICE OF PROPOSED RULE DEVELOPMENT	Ī
treatment system biennial operating permit	\$100	PUBLISHED IN FAW: March 30, 2007	
(p) Biennial operating permit fee for	Ψ100		
performance based treatment system. A		DEPARTMENT OF HEALTH	
prorated fee is to be charged beginning with		Division of Family Health Services	
second year of operation.	\$100	RULE NO.: RULE TITLE:	
(n) Amendment to operating permit	Ψ100	64F-12.001 General Regulations; Definitions	
(q) Review of application due to proposed		PURPOSE AND EFFECT: The 2006 Florida legislature	•
amendments or changes after initial operating		enacted session law 2006-310, amending Chapter 499, Part I	,
permit issuance for a performance-based		F.S., which changed requirements for prescription drug	3
_	\$ <u>50</u> 75	pedigrees in some instances; added a statutory provision	ì
treatment system.	ψ <u>30</u> 73	authorizing drop shipment of prescription drugs in certain	1
(o)(r) Tank Manufacturer's Inspection	\$100	situations to allow an end user to obtain prescription drugs	š
per annum (n)(s) Sente de Dianocal Service marmit	φ100	directly from the manufacturer without first obtaining a	ì
(p)(s) Septage Disposal Service permit	Ф 7 5	pedigree paper; authorized a cancer drug donation program. It	t
per annum	\$75	is the purpose of this rule to clarify what is meant by specific	3
Additional charge per pumpout vehicle	\$35	terms used to address the changes, address other definitions,	,
(q)(t) Portable or Temporary Toilet Service	Φ=-	including but not limited to defining terminology related to)
permit per annum	\$75	common carriers.	
<u>(r)</u> Additional charge per pumpout vehicle,			
septage disposal service or portable toilet service	\$35		

SUMMARY: The proposed amendments will provide a definition for statutory and rule terms and define the terms "directly from the manufacturer", "intracompany transfer", "pedigree", "point of origin" "specific unit of a prescription drug", "usual course of business as carriers" and "affiliated group". The changes will make the definitions set forth in this rule section applicable to both Chapter 64F-12, Florida Administrative Code and to Chapter 499, Florida Statutes.

SUMMARY OF **STATEMENT** OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 499.05, 499.024, 499.025(5), 499.003(31), 499.01(6), 499.03(4), 499.0121(6), 499.0122(2), 499.014(5), 499.013(3), 499.012(12) FS.

IMPLEMENTED: 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75, 499.081 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, R.Ph., Executive Director, Board of Pharmacy-Drugs Devices and Cosmetics, 4052 Bald Cypress Way, Mail Bin C-04, Tallahassee, Florida 32399

THE FULL TEXT OF THE PROPOSED RULE 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 (C.F.R.), (as of 10/1/03) which are incorporated by reference herein, 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), 499.0121(6), 499.0122(1), 499.028(1), 499.029(3), and 499.61, F.S., the following definitions apply, to Chapter 499, F.S., and to Rule Chapter 64F-12, F.A.C.:
- (a) "Administer" means the obtaining and giving of a single dose of drugs by a legally authorized person to a patient for his consumption.

- (b) "Affiliated group" means the definition set forth in Section 1504 of the Internal Revenue Code, (as of April 24, 2003) which is incorporated by reference herein, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group, if the affiliated group:
- i. Discloses to the department the names of all its members; and
- ii. Agrees in writing to provide records on prescription drug purchases by members of the affiliated group not later than 48 hours after the department requests such records, regardless of the location where the records are stored.
- For an affiliated group to qualify under Section 499.0121(6)(f)1., F.S., such affiliated group must also meet all the conditions specified by Section 499.0121(6)(f)., F.S.
- (c) "Authorized absence"; means, for purposes of Section 499.012(11)(d), F.S., means the management or owner of a permitted wholesale establishment has approved in writing in a document that is available for inspection under Section 499.051, F.S., at the time of the inspection, the absence of the designated representative for a period not to exceed 60 calendar days for situations such as: the birth of the employee's child and to care for the newborn child; the placement of a child with the employee for adoption or foster care; the employee is needed to care for a family member (child, spouse or parent) with a serious health condition; or the employee's own serious health condition makes the employee unable to perform the functions of the designated representative.
- (d) "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 <u>Iinstitutional Ppharmacy</u> 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.
- (e) "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.
- (f) "Change in Ownership" means a majority (more than 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 more than 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 <u>more than</u> a 50% change in the ownership or controlling interest of any permitted establishment.

- (g) "Chief Executive Officer" means the owner or the highest ranking official of a corporation, company, or business.

 (h)(g) "Directly from the manufacturer" means:
- 1. For the purposes of pedigree as defined by Section 499.003(31)(b), F.S., the manufacturer of the specific unit of the prescription drug invoiced and sent that specific unit of the prescription drug directly to the purchasing wholesale distributor, or
- 2. For the purposes of Section 499.0121(6)(d)5., F.S. the manufacturer of the prescription drug ships the specific unit of the prescription drug directly to the person authorized by Section 499.0121(6)(d)5., F.S. to receive the specific unit of the prescription drug. for purposes of Sections 499.0121(6)(d) and (e), F.S., the manufacturer sold the prescription drug to the establishment, or member of the establishment's affiliated group if applicable, as reflected on a true and accurate invoice of sale from the manufacturer to the establishment or affiliated group member. The prescription drug may be shipped directly to another establishment.
- (h) "Chief Executive Officer" means the owner or the highest ranking official of a corporation, company, or business.
- (i) "Electronic signature" means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message.
- (j) "Established safe and effective indication" means any indication that has been approved as safe and effective by the FDA, which is generally recognized as safe and effective under conditions established by the FDA, or which is otherwise in compliance with FDA's regulations.
- (k) "FDA" means the United States Food and Drug Administration.
- (1) "Intracompany transfer" means, pursuant to Section 499.003(31)(b), F.S., a distribution of a specific unit of a prescription drug between two establishments wholly owned and operated by the same business entity.

(m)(1) "Legend Device or Restricted Device" – means 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; "Caution: Federal Law prohibits dispensing without prescription; "Rx Only;" or "Caution: Florida Law prohibits dispensing without prescription."

- (n) "Pedigree" means a document that satisfies the requirements of Section 499.003(31)(a) or (b), F.S. as applicable, and the applicable rule requirements of subsection 64F-12.012(3), F.A.C., and any forms adopted therein.
- (o) "Point of origin" means the location from which the manufacturer transfers title, and the location from which the manufacturer transfers possession, if different, of the specific unit of the prescription drug being transferred or sold.
- (m) "Propagation" of a drug, as used under the definition of "manufacture" at Section 499.003(27), F.S., includes for purposes of permitting under Section 499.013, F.S., the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologies License Application (BLA) or a New Animal Drug Application (NADA), provided that such application has become effective or is otherwise approved consistent with Section 499.023, F.S.; a private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distribution point for the manufacturer, contract manufacturer or private label distributor whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site.
- (n) "Ongoing relationship" means: For a prescription drug other than a specified drug:
- 1. An association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's product(s) for a period of time or for a number of shipments and at least one sale is made under that agreement; or
- 2. The name of the authorized distributor of record is entered on the manufacturer's list of authorized distributors of record or equivalent list; or
- 3. At least three purchases of a manufacturer's product(s) are made directly from that manufacturer within a six month period from the date for which the authorized distributor of record relationship is claimed.
- (p)(o) "Practitioner" means a person who is duly licensed and authorized by laws of the state to administer, prescribe, or dispense, as appropriate, a drug or device for medical purposes.
- (q) "Product" anything produced or made either naturally or artificially.
- (r) "Propagation" of a drug means, as used under the definition of "manufacture" at Section 499.003(27), F.S., for purposes of permitting under Section 499.013, F.S., the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA) or a New Animal Drug Application (NADA), provided that such application has become effective or is otherwise approved consistent with Section 499.023, F.S.; a private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged;

or the distribution point for the manufacturer, contract manufacturer or private label distributor whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site.

(s)(p) "Provides prescription services to the public" – means, for the purposes of the retail pharmacy wholesaler permit, holding the pharmacy out to the public through 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.

(g) "Product" - anything produced or made either naturally or artifically.

(t)(r) "Readily available" and "readily retrievable" – mean that records, either hard copy or computerized, are organized in such a manner that they can be quickly and easily retrieved during an inspection; individual records can be produced within minutes of the request (unless the permitted address is not within the state in which case a 48 hour timeframe is available for producing records). Required records that are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems are kept in such a manner so that they can be separated out from all other records in a reasonable time.

(u)(s) "Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution" means:

- 1. Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1000 to bottles of 100.
- 2. Altering a manufacturer's package for sale under a label different from the manufacturer. For example, a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D packaged together and marketed as an immunization kit under a label of manufacturer Z.
- 3. Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product. This does not include:
- a. Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in multiple units, or
- b. Selling or transferring a fully labeled individual unit, by adding the package insert, by a person authorized to distribute prescription drugs to an institutional pharmacy permit, health care practitioner or emergency medical service provider for the purpose of administration and not for dispensing or further distribution.

(v)(t) "Rx" – means prescription.

(w)(u) "Sale" – includes any transfer whether by barter, exchange or gift.

(x)(v) "Separate and distinct cosmetic product" – means a cosmetic product for that establishment which is, or will be sold, distributed, or given away. The adding of color, flavor, or scents does not make a separate and distinct cosmetic product for each variation.

(y)(w) "Separate and distinct device product" – means a device product in its finished form for that manufacturer which is, or will be sold, distributed, or given away. The function or use of the device determines whether a device is separate and distinct.

(z)(x) "Separate and distinct drug product" – means a drug product in the finished form and strength for that manufacturer which is, or will be sold, distributed or given away.

(aa) "Specific unit of a prescription drug" - means the individual saleable unit of a specific prescription drug being transferred or sold, which is capable of being serialized to contain its own serial number, which drug is identified by name, strength, dosage form, container size, and lot number.

 $(\underline{bb})(\underline{y})$ "Specified drug" $\underline{}$ means all dosage forms, strengths and container sizes of the following prescription drugs:

- 1. Bextra (valdecoxib);
- 2. Celebrex (celecoxib);
- 3. Combivir (lamivudine/zidovudine);
- 4. Crixivan (indinavir sulfate);
- 5. Diflucan (fluconazole);
- 6. Epivir (lamivudine);
- 7. Epogen (epoetin alfa);
- 8. Gamimune (globulin, immune);
- 9. Gammagard (globulin, immune);
- 10. Immune globulin;
- 11. Lamisil (terbinafine);
- 12. Lipitor (atorvastatin calcium);
- 13. Lupron (leuprolide acetate);
- 14. Neupogen (filgrastim);
- 15. Nutropin AQ (somatropin, e-coli derived);
- 16. Panglobulin (globulin, immune);
- 17. Procrit (epoetin alfa);
- 18. Retrovir (zidovudine);
- 19. Risperdal (risperidone);
- 20. Rocephin (ceftriaxone sodium);
- 21. Serostim (somatropin, mannalian derived);
- 22. Sustiva (efavirenz);
- 23. Trizivir (abacavir sulfate/lamivudine/zidovudine);
- 24. Venoglobulin (globulin, immune);
- 25. Viagra (sildenafil citrate);
- 26. Videx (didanosine);
- 27. Viracept (nelfinavir mesylate);
- 28. Viramune (nevirapine);
- 29. Zerit (stavudine);
- 30. Ziagen (abacavir sulfate);

- 31. Zocor (simvastatin);
- 32. Zofran (ondansetron);
- 33. Zoladex (goserelin acetate); and
- 34. Zyprexa (olanzapine).

(cc)(z) "State Current Good Manufacturing Practices" means current good manufacturing practices and quality system regulations as prescribed as of 1/1/01 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 64F-12.010, F.A.C.

(dd)(aa) "Unapproved new drug" - means any drug which has not been approved or otherwise authorized for use under the federal act, 21 U.S.C. ss. 301 et seq., and the regulations promulgated thereunder or which does not have a Notice of Claimed Investigational Exemption on file with the United States Food and Drug Administration.

- (ee) "Usual course of business as carriers" means for purposes of commercial airlines, the purchase, receipt, distribution and storage of prescription drugs for emergency medical reasons, which includes:
- 1. The transportation of a prescription drug aboard a commercial aircraft where the drug is required by 14 CFR s. 121.803 (and appendix A to 14 CFR part 121), to be on board the aircraft as part of an approved emergency medical kit; and,
- 2. The purchase of the prescription drug by the commercial airline, and receipt of the prescription drug by the commercial airline at an establishment operated by the airline, provided that, the prescription drug is sold and provided to the commercial airline by a person and establishment that is licensed to engage in wholesale distribution of prescription drugs. The recordkeeping requirements of subsections 64F-12.012(1), (2), F.A.C. apply to all distributions of prescription drugs under this sub-sub paragraph. In all such distributions to commercial airlines, the recipient's license number shall be the registration number assigned to the carrier by the-Federal Aviation Administration.

(ff)(bb) "Valid client-veterinarian relationship" – means one in which (1) a veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client (the owner or other caretaker of the animal or animals) has agreed to follow the instructions of the veterinarian; (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue

of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

(gg)(ce) "Verifiable account" - means a number issued by the manufacturer to a wholesaler when the wholesaler sets up an account with the manufacturer for the purchase of a prescription drug from that manufacturer that uniquely identifies the wholesaler and that is to be used on a recurring basis.

(hh)(dd) "Wholesale distribution" – means distribution of prescription drugs to persons other than a consumer or patient as set forth in Section 499.012(1)(a), F.S.

(ii)(ee) "Wholesaler" means a person who engages in the wholesale distribution of a prescription drug.

(ii)(ff) "Written agreement" means any type of written correspondence or documentation to establish an account for ongoing sales of prescription drugs by the manufacturer to that wholesaler.

Specific Authority 499.05, 499.024, 499.025(5), 499.003(31), 499.01(6), 499.03(4), 499.0121(6), 499.0122(2), 499.014(5), 499.013(3), 499.012(12) FS. Law Implemented 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 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, 4-17-01, 6-30-03, 10-7-03, 1-1-04, 1-29-04, 5-29-05, 1-19-06, 2-14-06, 8-6-06,

NAME OF PERSON ORIGINATING PROPOSED RULE: Rebecca Poston, R.Ph.

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Rebecca Poston, R.Ph.

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 24, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 4, 2006

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE NO .: RULE TITLE:

64F-12.012 Records of Drugs, Cosmetics and

Devices

PURPOSE AND EFFECT: The Department intends to enact rules that implement the pedigree provisions of Florida Session Law 2006-310 concerning implementing the direct purchase statement pedigree related provisions of that session law. The Department intends to provide clarification as to when wholesale distributions of prescription drugs are eligible for the direct purchase pedigree, as well as conditions on content of the direct purchase pedigree. The Department intends to revise the rule chapter to delete outdated pedigree language for pedigree requirements that were deleted from Chapter 499, Florida Statutes, effective July 1, 2006. The Department intends to make changes regarding when the operating systems of businesses licensed under Chapter 499, Florida Statutes, are required to be maintained separately for each type of business. The Department also intends to make changes to the emergency distributions paragraph within this rule, changing the documentation requirements for use of this provision. The Department intends to make changes to the requirements for permitting for contract distributors of prescription drugs on behalf of manufacturers, who do not have to pass pedigrees. The Department proposes to provide additional language regarding the requirements for returns of prescription drugs to wholesalers.

SUMMARY: The rule implements the direct purchase pedigree provisions of Florida Session Law 2006-310; the rule provides for clarification on use of the pedigree and the content thereof, including but not limited to, the number of intracompany transfers allowed by use of the direct purchase pedigree. The rule deletes language related to deleted statutory pedigree requirements, found in subsection 16 of the rule. The rule allows Restricted Drug Distributor-Health Care Entity permitted prescription drug distributors to commingle drugs used for in house administration and for wholesale distribution. The rule adds restrictions to the documentation required for use of the "Emergency Distributions" distribution of prescription drugs without the passing of a pedigree. The rule clarifies the permitting requirements for third party logistics providers and the manufacturers they are contract distributors for, in order for the third party contract distributors to be exempt from licensure as wholesale distributors who would be required to pass pedigrees. The rule will require the contract distributor to be permitted at the distribution point as well as the manufacturer. In addition, the manufacturer will be required to be permitted at the location from which it is passing title to the prescription drugs. The rule provides the conditions under which a specified prescription drug can be can be returned and re-distributed.

SUMMARY OF **STATEMENT** OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 499.003, 499.05, 499.0121. 499.0122, 499.013, 499.014, 499.052 FS.

LAW IMPLEMENTED: 499.01, 499.003, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066,

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, R.Ph., C.Ph., Executive Director, Board of Pharmacy-Drugs Devices and Cosmetics, 4052 Bald Cypress Way, Mail Bin C-04, Tallahassee, Florida 32399-3254

THE FULL TEXT OF THE PROPOSED RULE IS:

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

- (1)(a) Records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component. A complete audit trail includes records, which document each transaction or step in the receipt, manufacture, shipping, transfer, or other steps in the channel of trade of that person, whether or not physical possession or handling of the product or component occurs. At a minimum, records shall consist of invoices from the supplier or source, which documents acquisition of each product by the person, and invoices of sale or other transfer by the person to the recipient. Retail sales transactions to the consumer of over-the-counter drugs, non-restricted devices, or cosmetics are exempt from the requirements of this rule. Additional recordkeeping is required for persons permitted by the department as further stated in this rule.
- (b) A person engaged in the distribution of drugs, devices, or cosmetics is not required to maintain documentation from a common carrier that the designated recipient received the product shipped; however, the person must obtain such documentation from the common carrier and make it available to the department upon specific request of the department.
- (2) Any person engaged in the manufacture of prescription drugs, the wholesale distribution of prescription drugs, or otherwise receiving or distributing prescription drugs must maintain records as follows:
- (a) For each step in the channel of trade, records containing the information required by Section 499.0121(6)(a), F.S., and the Florida permit or license number, which authorizes the source to possess and transfer prescription drugs in or into Florida, must appear on one document. If delivery of prescription drugs is made to a person other than the purchaser, the name, address or location where the prescription drugs are delivered, and the state license, permit or registration number for that location must be included also.
- (b) The state permit or registration number of the purchaser may be omitted if the prescription drugs are exported; but a validated airway bill, bill of lading or other appropriate documentation must be maintained to evidence the exportation of the product.
- (c) Invoices must reflect the amount billed per prescription drug product.
- (d) Records to document the distribution of prescription drugs required by Section 499.0121(6), F.S., and this rule are to be created during the transaction (i.e., at the time of order,

receipt, processing, picking or shipping) and not retroactively created. A pharmacy or other person authorized to possess prescription drugs that transfers prescription drugs to an establishment performing reverse distribution services or destruction activities must prepare or have prepared an inventory or other record of the prescription drugs so transferred prior to the prescription drugs leaving the premises. In addition to the name, address, and license number of the sender and the name, address, and license number of the receiving establishment, the record must include the elements set forth in paragraph 64F-12.023(3)(a), F.A.C.

- (e) Inventory. A complete and accurate record of all stock of prescription drugs on hand must be made annually by establishments permitted under Chapter 499, F.S. A physical inventory must be conducted at least annually unless perpetual inventory records are maintained, in which case the physical inventory may be conducted on a biennial basis. Significant inventory discrepancies must be investigated and handled in accordance with written policies and procedures of the establishment. In addition, no later than July 17, 2006, each wholesale distributor shall submit to the department an inventory of drugs it has on hand as of June 30, 2006.
- (f) Inventory existing as of June 30, 2006. A wholesale distributor permitted under Section 499.012, F.S., that has purchased a prescription drug on or before close of business June 30, 2006, without the pedigree required by Section 499.0121(6)(d)(f), F.S., may distribute such drug provided the wholesale distributor submits to the department an inventory of such drugs no later than July 17, 2006, conforming to paragraph (2)(e) above and provided further that such drugs are otherwise in compliance with the provisions of Sections 499.001 through 499.081, F.S. Inventories shall be submitted to the department in written form, email, facsimile, or electronic media excluding a web page. The department will consider the submittal to be a trade secret as defined by Section 812.081(1)(c), F.S., provided that the sending wholesale distributor complies with the requirements of subsections 64F-12.021(1) and (2), F.A.C.
- (3) Pedigree<u>s; Direct Purchase Pedigree; Alternative Pedigree</u> Papers.

In order to satisfy the pedigree requirements in Section 499.0121(6)(d)1., F.S., one of the two pedigree documents defined in Section 499.003(31), F.S., must be used. They are the "Direct Purchase Pedigree" document, which is defined at Section 499.003(31)(b), F.S., and the "Alternative Pedigree" document, which is defined at Section 499.003(31)(a), F.S., and contains the elements in the forms approved by the department in this rule section.

(a) Direct Purchase Pedigree.

1. The direct purchase pedigree is the pedigree document defined in Section 499.003(31)(b), F.S. It is a signed statement, under oath, in written or electronic form, accurately confirming that the wholesale distributor who purchased and received the

- specific unit of the prescription drug being distributed, purchased and received the specific unit of the prescription drug directly from the manufacturer of the drug. The direct purchase pedigree document can be used to satisfy the requirements of Section 499.0121(6)(d), F.S., only if the wholesale distributor distributes that specific unit of the prescription drug that it purchased and received directly from the manufacturer, to a chain pharmacy warehouse as described at Section 499.003(31)(b), F.S., or to a person authorized to purchase a prescription drug for the purpose of administering or dispensing such drug ("purchaser") in one of two ways:
- a. The subject wholesale distributor distributes the prescription drug directly to the purchaser; or,
- b. The subject wholesale distributor distributes the prescription drug indirectly to the purchaser through the use of one intracompany transfer between two establishments wholly owned and operated by the same business entity.
- 2. In order to qualify for use of the direct purchase pedigree the wholesale distributor who purchases and receives the specific unit of prescription drug directly from the manufacturer must: accurately provide the statement and information required by Section 499.003(31)(b)1., F.S., on the pedigree document and maintain and make available the documentation required by Section 499.003(31)(b)1., F.S., as well as the documentation required by Section 499.0121(6), F.S., and this rule chapter.
- 3. The direct purchase pedigree shall be provided to every recipient of the prescription drug, except for a patient or consumer, who receives the specific unit of the prescription drug directly or indirectly, from the wholesale distributor who purchases and receives the specific unit of the prescription drug directly from the manufacturer. In a wholesale distribution, of a prescription drug, the direct purchase pedigree document shall not contain any reference to a prescription drug that is not eligible for use of the direct purchase pedigree to satisfy the requirements of Section 499.0121(6)(d)1., F.S., unless the prescription drug not qualifying for the direct purchase pedigree is clearly identified on the pedigree document as not having been purchased and received directly from the manufacturer of the drug. For any distribution of prescription drugs in or into this state, the direct purchase pedigree shall not be used unless all distributions, including transfer of title and transfer of possession of a prescription drug, from the manufacturer to the end user, are eligible for use of the direct purchase pedigree to satisfy the requirements of Section 499.0121(6)(d)1., F.S.
 - (b) Alternative Pedigree.

The alternative pedigree is the pedigree defined in Section 499.003(31)(b), F.S. For all wholesale distributions that require a pedigree pursuant to Section 499.0121(6)(d), F.S., the alternative pedigree must be used for all distributions of

prescription drugs that are not eligible for use of the direct purchase pedigree. The forms approved by the department for this pedigree are:

- 1. Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)," Form DH 2135, effective July 2006, which is incorporated by reference herein, or an electronic record that contains all of the elements of Form DH 2129, for the wholesale distribution of a prescription drug; or
- 2. Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)," Form DH 2135, effective July 2006, which is incorporated by reference herein, or an electronic record that contains all of the elements of Form DH 2135.
- 3. A repackager must use either Form DH 2135 or an electronic record that contains all of the elements of Form DH 2135. A wholesaler that further distributes a repackaged prescription drug must include in the pedigree the information related to the repackaged drug contained in Form DH 2135 or the electronic record that contains all of the elements of Form DH 2135.
- 4. The alternative pedigree must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree; the name and address of each location from which it was shipped if different from the owner's; and the transaction dates. The pedigree must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.
- (c) A copy of the pedigree must be maintained by each wholesaler required to prepare or furnish a pedigree and by each recipient. This copy may be maintained in an electronic medium that is readily available and easily accessible to the wholesaler required to prepare or furnish the pedigree; each recipient; and authorized federal, state, and local regulators or law enforcement. If a wholesaler serves as the repository of its customer's pedigree, the wholesaler must specify on the customer's invoice or other distribution document the method for immediately accessing all pedigrees associated with each prescription drug distributed and must enable access by the persons listed above for the duration of the applicable records retention period.
- (d) Each alternative pedigree must contain a signature that meets the requirements of Form DH 2129 or DH 2135 as applicable. Each direct purchase pedigree must contain the signature, under oath, attesting to the accuracy of the direct purchase statement provided on the pedigree as required by Section 499.003(31)(b)1.a., F.S. An electronic signature may be used on a pedigree.

- (e) An electronic record must be easily readable or easily rendered in a readable format, and capable of being produced in a paper medium. Data on an electronic pedigree may be transmitted via the internet, data communications, a portable medium such as a CD-Rom or smart card or similar devices. Additional information to the information required by these rules and Section 499.003(31)(a) or (b), F.S., as applicable, may be provided on a pedigree so long as the additional information does not detract or confuse the history of the distribution of the drug.
- (f) A copy of the pedigree paper must be maintained by each recipient. A copy of the pedigree paper provided to the wholesale distributor must be maintained by the wholesaler providing the pedigree paper.

(g) Returns.

- 1. When a distribution of a prescription drug by a wholesaler to an authorized recipient is the result of a mistake in ordering or shipment, the return of that shipment by the authorized recipient to the wholesaler need no be reflected in the pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within seven calendar days after the date of receipt of the original shipment:
- a. The authorized recipient ships the specific unit of the prescription drug back to the wholesaler from which that specific unit was purchased; or
- b. The authorized recipient transmits a documented communication to the wholesaler from which the prescription drug was purchased stating the authorized recipient's intent to return the shipment in accordance with the wholesaler's prescribed written policies and procedures and the wholesaler communicates authorization for return of the product.
- 2. Any returns to the wholesaler by an authorized recipient that are not within the scope of subparagraph 1. shall be reflected in the pedigree paper trail for any further distributions of the returned drug product to the extent required by Section 499.0121(6)(d), F.S.
- 3. An authorized recipient that returns a shipment to the wholesaler in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the returned product.
- a. That specific unit (exact unit) being returned was purchased from the receiving wholesaler (including the corresponding sales invoice number and the date of the sale from that wholesaler to the authorized recipient); and
- b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted hereunder while in the purchaser's custody and control.
- c. The written declaration shall be printed or typed at the end of or immediately below the statements in sub-subparagraphs 3.a. and 3.b. and shall state "Under

penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true," followed by the signature of the person making the declaration.

- 4. The redistribution of a prescription drug that is not a specified prescription drug as defined in subsection 64F-12.001(2), F.A.C., which was purchased before July 1, 2006 and returned by the purchaser after July 1, 2006, may be distributed under the following conditions:
- a. The redistribution occurs prior to the effective date of this rule or December 21, 2007, whichever is later, and
- b. The wholesale distributor discloses in writing to the purchaser and to the recipient, if different from the purchaser, all prior sales and returns of the prescription drug, including the name of the returning person and the date that the prescription drug was returned.
- (h) For purposes of Section 499.003(31)(a), F.S., a manufacturer or repackager will have uniquely serialized an individual legend drug unit when the unit contains an electronic product code that meets industry standards for that type of legend drug unit. The department will adopt the industry standards for each type of legend drug unit when they are established. One pedigree record may be prepared for a group of serialized legend drugs, provided the only unique characteristic for the pedigree is the serialization codes.
- (i) If a manufacturer initiates an electronic pedigree and transmits this information to a wholesaler consistent with the standards in sub-subparagraph 64F-12.013(5)(d)1.f., F.A.C., (and that wholesaler provides a pedigree to its customer consistent with the standards in sub-subparagraph 64F-12.013(5)(d)1.f., F.A.C., the wholesaler must transmit the pedigree information initiated by the manufacturer in the pedigree the wholesaler provides to its customer.
- (j) A wholesaler that purchases multiple units of a prescription drug from a manufacturer in one transaction, but receives these units from multiple distribution sites of the manufacturer or on multiple dates from the manufacturer, may reference the first occurrence of receipt in pedigree papers the wholesaler prepares for subsequent wholesale distributions unless all applicable information is received from the manufacturer as set forth in paragraph (j) above.
- (k) A contract distributor for the manufacturer is deemed an agent of the manufacturer and therefore is not required under Section 499.0121(6)(d), F.S., to provide a pedigree paper upon distribution of the manufacturer's prescription drug provided the manufacturer retains title to the prescription drug and the contract distributor meets the requirements to be permitted and is permitted under Chapter 499, F.S., as a prescription drug manufacturer or non-resident prescription drug manufacturer, as applicable based on its relationship with the manufacturer, and further provided that: the manufacturer or non-resident manufacturer, as applicable, is permitted by the department at the establishment from which the prescription drugs are shipped by the contract distributor and the

manufacturer establishment from which the manufacturer's billing for change of title of the prescription drug originates, is permitted as a prescription drug manufacturer or non-resident prescription drug manufacturer, as applicable, by the department.

(1) Emergency Distributions. Notwithstanding Sections 499.0121(6)(d)1. and 499.005(29), F.S., a wholesale distributor may distribute and a purchasing pharmacy or health care practitioner authorized by law to purchase prescription drugs, may accept a prescription drug when the prescription drug is required to treat a specific patient with an emergency medical condition as defined by Section 395.002(9)(a), F.S. The prescribing physician or a health care practitioner otherwise licensed to prescribe the drug shall supply a statement to the supplying wholesale distributor(s) stating that the emergency meets this rule paragraph's requirements. The supplying wholesale distributor(s) must maintain such statement in compliance with the timeframes in Section 499.0121(6)(b), F.S. The supplying wholesale distributor must otherwise comply fully with all other applicable provisions of Sections 499.001 through 499.081, F.S., with respect to such drug. In addition, the supplying wholesale distributor must submit to the recipient within 14 calendar days of the emergency distribution a written statement, invoices, or other documentation identifying all prior sales or distributions of the specific unit of the prescription drug that is subject to this distribution.

(a)1. The pedigree papers required by Sections 499.0121(6)(d), (e) and (f), F.S., must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from which it was shipped if different from the owner's; and the transaction dates. The pedigree paper must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.

2. A copy of the pedigree paper must be maintained by each wholesaler preparing a pedigree paper and by each recipient. This copy may be maintained in an electronic medium that is readily available and easily accessible to the wholesaler preparing the pedigree paper; each recipient; and authorized federal, state, and local regulators or law enforcement. If a wholesaler serves as the repository of its eustomer's pedigree, the wholesaler must specify on the eustomer's invoice or other distribution document the method for immediately accessing all pedigrees associated with each

prescription drug distributed and must enable access by the persons listed above for the duration of the applicable records retention period.

(b) If a wholesale distributor uses the statement contained in Section 499.0121(6)(e)1.a.(II), F.S., "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer" the wholesale distributor must provide to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group must provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(c) Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)," either Form DH 2129 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2129 must be used to comply with the requirement in Section 499.0121(6)(f), F.S., for the distribution of a prescription drug. Beginning July 1, 2006, a repackager must use either "Prescription (legend) Drug Pedigree - Repackager" Form DH 2135 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2135. A wholesaler that further distributes a repackaged prescription drug must include in the pedigree the information related to the repacked drug contained in Form DH 2135 or the electronic record that contains all the elements of Form DH 2135. These forms may be used prior to July 1, 2006, to comply with the pedigree paper requirements of Section 499.0121(6)(d) or (e), F.S., at the discretion of the wholesaler. An electronic signature may be used on a pedigree paper. An electronic record must be easily readable or easily rendered in a readable format, and capable of being reproduced in a paper medium. Data on an electronic pedigree may be transmitted via the internet, data communications, a portable medium such as a CD-Rom or smart card or similar devices. Additional information to that required by forms DH 2129 and DH 2135 may be included on a pedigree provided it does not detract from or confuse the history of the distribution of the drug.

(d) A copy of the pedigree paper must be maintained by each recipient. A copy of the pedigree paper provided to a wholesale distributor must be maintained by the wholesaler providing the pedigree paper.

(e) Effective March 1, 2004, a pedigree paper under Section 499.0121(6)(d), F.S., must trace a prescription drug back to the last authorized distributor of record. The department will maintain a database of authorized distributors of record on its web site at www.doh.state.fl.us/ pharmacy/drugs. A prescription drug wholesaler that receives or prepares a pedigree paper under Section 499.0121(6)(d), F.S., and this chapter that traces the previous distributions of a

prescription drug back to a prescription drug wholesaler that is not listed on the department's web site as an authorized distributor of record for the drug's manufacturer for the date in which the transaction occurred must maintain and have available for inspection documentation that supports the fact the prescription drug wholesaler is an authorized distributor of record in accordance with the criteria of Section 499.0121(6)(d)5.a., b., or c., F.S.

(f) Returns.

1. When a distribution of a prescription drug by a wholesaler to an authorized recipient is the result of a mistake in ordering or shipment, the return of that shipment by the authorized recipient to the wholesaler need not be reflected in the pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within seven calendar days after the date of receipt of the original shipment:

a. The authorized recipient ships the specific unit of the prescription drug back to the wholesaler from which that specific unit was purchased; or

b. The authorized recipient transmits a documented communication to the wholesaler from which the prescription drug was purchased stating the authorized recipient's intent to return the shipment in accordance with the wholesaler's prescribed written policies and procedures and the wholesaler communicates authorization for return of the product.

2. Any returns to a wholesaler by an authorized recipient that are not within the scope of subparagraph 1. shall be reflected in the pedigree paper trail for any further distributions of the returned drug product to the extent required by Section 499.0121(6)(d), (e) or (f), F.S.

3. An authorized recipient that returns a shipment to the wholesaler in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the returned product,

a. That the specific unit (exact unit) being returned was purchased from the receiving wholesaler (including the corresponding sales invoice number and the date of the sale from that wholesaler to the authorized recipient); and

b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser's custody and control.

e. The written declaration shall be printed or typed at the end of or immediately below the statements in sub-subparagraphs 3.a. and 3.b. and shall state: "Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true," followed by the signature of the person making the declaration.

(g) For purposes of Section 499.003(31)(b), F.S., a manufacturer or repackager will have uniquely serialized an individual legend drug unit when the unit contains an electronic product code that meets industry standards for that

- type of legend drug unit. The department will adopt the industry standards for each type of legend drug unit when they are established. One pedigree record may be prepared for a group of serialized legend drugs, provided the only unique characteristic for the pedigree is the serialization codes.
- (h) If a manufacturer initiates an electronic pedigree and transmits this information to a wholesaler consistent with the standards in sub-subparagraph 64F-12.013(5)(d)1.f., F.A.C., (and that wholesaler provides a pedigree to its customer consistent with the standards in sub-subparagraph 64F-12.013(5)(d)1.f., F.A.C., the wholesaler must transmit the pedigree information initiated by the manufacturer in the pedigree the wholesaler provides to its customer.
- (i) A wholesaler that purchases multiple units of a prescription drug from a manufacturer in one transaction, but receives these units from multiple distribution sites of the manufacturer or on multiple dates from the manufacturer, may reference the first occurrence of receipt in pedigree papers the wholesaler prepares for subsequent wholesale distributions unless all applicable information is received from the manufacturer as set forth in paragraph (h) above.
- (j) A contract distributor for the manufacturer is deemed an agent of the manufacturer and therefore is not required under Section 499.0121(6)(f), F.S., to provide a pedigree paper upon distribution of the manufacturer's prescription drug provided the manufacturer retains title to the prescription drug and the contract distributor meets the requirements to be permitted under Chapter 499, F.S., as a non-resident prescription drug manufacturer based on its relationship with the manufacturer.
- (k) Emergency Distributions. A wholesale distributor may distribute and a purchasing pharmacy or health care practitioner authorized by law to purchase prescription drugs may accept a prescription drug for which a pedigree that complies with Section 499.0121(6)(f), F.S., is not available, when the prescription drug is required immediately to treat a specific patient with a life threatening medical condition or a medical condition that will result in serious bodily harm. A pharmacist for the purchasing pharmacy, or the health care practitioner, shall supply a statement to the supplying wholesale distributor(s) that the emergency meets this rule paragraph's requirements and the supplying wholesale distributor(s) must maintain such statement in compliance with the timeframes in Section 499.0121(6)(b), F.S. The supplying wholesale distributor must otherwise comply fully with all other applicable provisions of Sections 499.001 through 499.081, F.S., with respect to such drug.
- (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 for medical oxygen must be in writing and in the possession of the retailer within 30 days of 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 purchaser beyond 12 months from the date of the original sale.
- (5) A copy of the Florida Drug and Cosmetic Act, Chapter 499, F.S., and Chapter 64F-12, F.A.C., Regulations for Drugs, Devices and Cosmetics, must be at the permitted establishment.
- (6)(a) Records for permittees not physically located within the state may be maintained at a central location outside of the state but must be made available for inspection at a permitted establishment or at the department's address within 2 working days after a request for inspection.
- (b) Records for permittees located in the state or persons located in Florida and required to be permitted under Chapter 499, F.S., may be stored by computer or other electronic means at a central location inside or outside of the state, but must be readily available and immediately retrievable, i.e., subject to inspection at the permitted establishment during the inspection.
- 1. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to Sections 499.001-.081, F.S., in that person's name.
- 2. If not maintained at a central location, records must be maintained at the permitted location or, if not otherwise permitted, at the address reflected on the product registration.
- 3. A permitted establishment in Florida that maintains records at a location outside of the state must have a method, such as computerized access, to make records readily available and immediately retrievable. These records must also be made available at the permitted establishment for copying or reproducing within two working days after a request.
- 4. An establishment permitted at an address outside of the state must make records available for inspection within two working days after a request.
- (c) Records for permittees may be copied or reproduced by the department or the Florida Department of Law Enforcement.
- (d) If hard copies (originals or true copies) of required records are not maintained at the permitted establishment in Florida, the department or Florida Department of Law Enforcement must be able to review automated records for any and all records required to be maintained under Chapter 499, F.S., without requesting a specific source, recipient, product, date, etc.
- (7) Except as provided in Section 499.012(2)(e), F.S., and paragraph (3)(b) of this rule, records of other persons not required to be permitted but subject to regulation under Chapter 499, F.S., must be made available to the department or

the Florida Department of Law Enforcement within five business days of the request for inspection, copying, or reproduction.

- (8) Records involving drugs, devices, or cosmetics may be maintained by electronic methods, such as computers or imaging devices. Originals or true copies of required records documentation must be maintained by the person involved in the transaction, including brokers and agents. If electronic methods are used to maintain records related to prescription drugs and these methods do not maintain a true copy of the original record, such as the actual image of the original document, then the security system of the permittee must provide protection against tampering with computers or electronic records.
- (9) Documentation provided to the department pursuant to an inspection may not be altered or defaced in any manner to obstruct or conceal any required or other information recorded on the document.
- (10) All required records must be retained for a period of two years following disposition of the drug, device or cosmetic, or three years after the creation of the records, whichever period is longer; and must be available to the department for such period or as long as records are retained if longer. Records must be retained beyond the retention period if the person has been notified that an investigation or inspection has been initiated by the department and the investigation has not been completed when the mandatory retention period expires.
- (11) Manufacturers shall maintain formulas of drugs and cosmetics, including all ingredients, and shall make these available to the department upon request, either during an inspection or by certified mail.
- (12) An establishment permitted under Chapter 499, F.S., that shares a facility with another person or business shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other person or business. A person permitted under Chapter 499, F.S., that also conducts other business activities not permitted under Chapter 499, F.S., shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other business activities. For the purpose of this rule, those operational systems required to be kept separate and distinct shall mean all records, inventory, storage areas, repackaging operations, quarantine areas, and manufacturing operations, but this rule shall not require separate entrances to the establishment nor partitioning. A Retail Pharmacy Wholesaler or a Restricted Prescription <u>Drug Distributor – Health Care Entity</u> however, is not required to maintain its stock of prescription drugs which may be distributed through a wholesale transaction separate from the stock of prescription drugs which may be dispensed by a retail pharmacy.

- (13) An establishment permitted to purchase or possess prescription drugs that has no records or has not done any business under the permit that would require such records, shall upon request, provide to the department a written statement to that effect.
- (14) The recordkeeping requirements of this subsection do not apply to the prescription dispensing records of a pharmacy or to the patient medical records of a licensed practitioner; however, such records may be required to be produced pursuant to a subpoena issued by the department under Section 499.0053, F.S.
- (15) Charitable Donations of Prescription Drug. A physician or other authorized recipient donating prescription drugs, including prescription drug samples, pursuant to Section 499.012(1)(a)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 D.E.A. number if a controlled substance is donated:
- (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 that authorizes the possession of prescription drugs by the charitable organization, if applicable; and
- (e) Within 48 hours of receipt, excluding holidays and weekends, the recipient charitable institution must provide a written receipt to the donor acknowledging receipt of the donated prescription drugs.
- (16) Establishing an ongoing relationship pursuant to Sections 499.0121(6)(d)5.b. and c., F.S. A wholesale distributor that is not listed as an authorized distributor of record on the list submitted to the department by a prescription drug manufacturer may request the department add the wholesale distributor to the department's web site of authorized distributors of record for a drug manufacturer for purposes of the pedigree paper requirements of Section 499.0121(6)(d), F.S., that become effective March 1, 2004, provided that such wholesale distributor satisfies the requirements of paragraph (a) or (b) below.
- (a) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.0121(6)(d)5.b., F.S. If the information submitted in subparagraphs 1. and 2. is based on the cumulative activity of an affiliated group, a wholesale distributor or its affiliated group must submit the information in subparagraph 3. below to document the eligibility of the individual wholesaler establishment that is a member of the affiliated group to be an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.0121(6)(d)5.b., F.S.

- 1. To document total annual prescription drug sales of \$100 million or more, submit either:
- a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least \$100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR
- b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of \$100 million or more in the most recent fiscal year, OR
- e. A computerized listing of prescription drug sales transactions during the period 10/1/02 9/30/03. or a 12-month period ending on the last day of the most recent calendar quarter, of at least \$100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least \$100 million in prescription drug sales, excluding customer returns. and
- 2. For each manufacturer for whom the wholesaler claims authorized distributor of record status, submit both subparagraphs a. and b. to document that the wholesaler annually purchases not less than 90%, based on dollar volume, of all of its purchases of a manufacturer's prescription drug products directly from that manufacturer.
- a. A computerized listing of all of a manufacturer's prescription drugs purchased by the wholesaler during the period 10/1/02 - 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, regardless of the source of those prescription drugs. This report must be totaled. **AND**
- b.i. A computerized listing of all purchases of a manufacturer's prescription drugs directly from the manufacturer during the same time period. This report must be totaled. The detail should include the invoice number, invoice date, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least 90% of the wholesaler's purchases of a manufacturer's prescription drug products directly from that manufacturer, excluding returns to the manufacturer. OR
- ii. Copies of the manufacturer's sales invoices of prescription drugs to the wholesaler. An adding machine tape, or equivalent, must be included that lists each invoice, in order, and provides a total of all invoices submitted. A statement must be provided that the invoices document at least 90% of the wholesaler's purchases of a manufacturer's prescription drug products directly from that manufacturer, excluding returns to the manufacturer.

- 3. Each wholesaler establishment that applies to the department to be listed as an authorized distributor of record of a drug manufacturer based upon its affiliated group's ongoing relationship with the manufacturer, or the affiliated group on behalf of each wholesaler establishment, must submit the names and address of all member wholesaler establishments of the affiliated group. In addition, each wholesaler establishment must either:
- a. Conduct its prescription drug wholesale activities under an establishment name that incorporates the same business name as the affiliated group upon which the eligibility criteria for the affiliated group was met, or
- b. Hold a valid prescription drug wholesaler permit or out-of-state prescription drug wholesaler permit issued under Chapter 499, F.S.
- (b) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.0121(6)(d)5.c., F.S.
- 1. To document total annual prescription drug sales of \$100 million or more, submit either:
- a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least \$100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR
- b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of \$100 million or more in the most recent fiscal year, OR
- c. A computerized listing of prescription drug sales transactions during the period 10/1/02 9/30/03, or a 12 month period based on the most recent calendar quarter, of at least \$100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least \$100 million in prescription drug sales, excluding customer
- 2. For each manufacturer for whom the wholesaler claims authorized distributor of record status, submit a., b., or c. to document that the wholesaler has a verifiable account number issued by the manufacturer and has made at least 12 purchases of prescription drugs directly from that manufacturer using the verifiable account number.
- a. If the wholesaler is a member of an affiliated group and all purchases from that manufacturer are made at a central location for the wholesaler, copies of at least 12 invoices dated during the previous 12 months from the date the information is submitted, which invoices document purchases of prescription drugs, at least one unit of which on each invoice was not

returned, under that central account number but shipped to the wholesaler's address for whom the authorized distributor of record status is claimed. A statement must be provided that the invoices document purchases of prescription drugs for the wholesaler for whom the authorized distributor of record status is claimed and that the wholesaler did not return to the manufacturer at least one unit of the prescription drugs on each invoice.

b. If the wholesaler is a member of an affiliated group and all purchases from that manufacturer are made at a central location and received at a central location for the wholesaler, copies of at least 12 invoices dated during the previous 12 months from the date the information was submitted, under the same account number which is clearly assigned to the wholesaler at the permitted address. Each invoice must document the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement must be provided that the invoices document purchases of prescription drugs by that central location and that the central location or wholesaler for which the drugs were obtained did not return to the manufacturer at least one unit of the prescription drugs on each invoice, and that the central location shipped at least 12 times to the individual wholesaler for whom the authorized distributor of record status is claimed during the 12 months based on the fiscal year or designated timeframe.

e. For all other wholesale distributors, copies of at least 12 invoices dated during the previous 12 months from the date the information was submitted, under the same account number that is clearly assigned to the wholesaler at the permitted address. Each invoice must document the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement must be provided that the invoices document purchases of prescription drugs by that wholesaler and that the wholesaler did not return to the manufacturer at least one unit of the prescription drugs on each invoice.

Specific Authority 499.003, 499.05, 499.0121, 499.0122, 499.013, 499.014, 499.052 FS. Law Implemented 499.01, 499.003, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 FS. History-New 1-1-77, Amended 12-12-82, 7-8-84, 1-30-85, Formerly 10D-45.53, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.053, Amended 1-26-99, 4-17-01, 10-7-03, 1-1-04, 6-15-04, 8-2-04, 1-19-06, 8-6-06,

NAME OF PERSON ORIGINATING PROPOSED RULE: Rebecca Poston, R.Ph., C.Ph., Executive Director

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Rebecca Poston, R.Ph., C.Ph., **Executive Director**

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 24, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 4, 2006

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE NO.: **RULE TITLE:**

64F-12.013 Prescription Drugs; Receipt, Storage

and Security

PURPOSE AND EFFECT: The 2006 Florida legislature enacted session law 2006-310, amending Chapter 499, Part I, F.S., which changed requirements for prescription drug pedigrees in some instances. It is the purpose of this rule to clarify authentication of pedigree requirements, clarify who is required to verify that a prescription drug, as of the time of receipt, matches the description on the corresponding pedigree provided with the drug, as well clarifying the information that should be found on the pedigree. The Department proposes to make changes in the authentication requirements for pedigrees, as well as delete out dated language no longer relevant because of statutory changes that became effective July 1, 2007 concerning prescription drug pedigrees.

SUMMARY: The proposed rule changes will clarify that establishment and adherence to policies and procedures for random authentication of copies of pedigrees according to statistically valid standards is required in some situations. The proposed rule changes will also require establishment and adherence to policies and procedures that provide for the random verification of the authenticity of pedigrees for the purposes of establishing a wholesaler purchased prescription drugs directly from the manufacturer according to statistically valid standards, in some situations. The proposed rule adds the requirement that a repackager notify the Department of discovery of a significant loss of prescription drugs. The proposed rule requires that a chain pharmacy warehouse or person authorized to administer or dispense a prescription drug that receives a prescription drug, is required to verify that the information on the corresponding pedigree matches up with the drug received.

STATEMENT SUMMARY OF OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 499.0121(1), 499.05 FS.

IMPLEMENTED: 499.004, 499.006, 499.007, 499.0121, 499.028(6), 499.052 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, R.Ph., Executive Director, Board of Pharmacy-Drugs Devices and Cosmetics, 4052 Bald Cypress Way, Mail Bin C-04, Tallahassee, Florida 32399

THE FULL TEXT OF THE PROPOSED RULE IS:

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

- (1) Establishments in which prescription drugs are stored, manufactured, repackaged, kept, held, used, sold, stored, offered for sale, or exposed for sale, shall be secured against unauthorized entry or unauthorized access to prescription drugs when establishment personnel are not present.
- (a) Establishments permitted under Chapter 499, F.S., that <u>are authorized to</u> take possession of prescription drugs, other than medical oxygen, must be secured by an alarm system which functionally and practically provides a deterrent to unauthorized entry to the establishment or the area where the prescription drugs are held or stored.
- (b) Prescription medical oxygen may be stored outside in an area surrounded by a fenced enclosure with a lock which must be secure when authorized persons are not present. Other compressed medical gases must be stored in accordance with paragraph (a).
- (2)(a) 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) 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) 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)(a) The storage temperature definitions in the U.S.P. are incorporated by reference herein. If no storage and temperature requirements are set forth by the manufacturer in the labeling or in the U.S.P., prescription drugs other than compressed medical gases must be stored at controlled room temperature. Compressed medical gases, unless otherwise indicated, may be stored in a manner so that they are protected from freezing and are not stored at or near excessive heat or open flame.
- (b) All establishments permitted under Chapter 499, F.S., that handle prescription drugs other than medical gases, must, in the absence of electronic monitoring devices, mount two thermometers in the immediate area of the stored prescription drugs. For purposes of this provision, immediate area of the stored prescription drugs is within six (6) feet of the prescription drugs in storage. One thermometer will be

- mounted in the warmest area of the stored prescription drugs and the other thermometer will be mounted in the coolest immediate area of the stored prescription drugs.
- (c) A record must be maintained recording the date; time; thermometer one temperature; thermometer two temperature; and the initials of the person recording the data or reviewing the data if electronically monitored. This record and temperature reading must be recorded at least five (5) days each week with the temperature readings taken between 2:00 p.m. and 4:00 p.m. E.S.T. Alternate times may be approved by the department in writing. This record must be kept on file by the facility for at least two years.
- (d) Facility requirements for the storage and handling of prescription drugs.
- 1. An applicant for an initial prescription drug wholesaler permit must have a facility that is large enough to store the estimated quantity of prescription drugs the applicant intends to possess under its initial application to comply with the requirements of Section 499.0121(1), F.S. An applicant for renewal of a prescription drug wholesaler permit must have a facility that is large enough for the ongoing operations of the wholesale establishment based on the prior year's volume of activity with prescription drugs, which may be modified for reasonable fluctuations in inventory management for the current year. These determinations will be based on the type of prescription drugs the applicant possesses, or intends to possess, considering the size of the containers as well as any other products the applicant possesses or intends to possess. Notwithstanding the contention that an applicant will distribute all prescription drugs the same day received, the facility must be large enough to accommodate prescription drugs as set forth herein in case the drugs are not distributed the same day received.
- 2. An applicant for an initial prescription drug wholesaler permit must have a refrigeration capacity and freezer capacity large enough to store the estimated quantity of prescription drugs that might require refrigeration or freezing that the applicant intends to possess under its initial application to comply with the requirements of Sections 499.0121(1) and (3), F.S., and this rule. An applicant for renewal of a prescription drug wholesaler permit must have a refrigeration capacity and freezer capacity that is large enough for the ongoing operations of the wholesale establishment based on the prior year's volume of activity with prescription drugs that required refrigeration or freezing, which may be modified for reasonable fluctuations in inventory management for the current year, to comply with the requirements of Sections 499.0121(1) and (3), F.S., and this rule. These determinations will be based on the type of prescription drugs the applicant possesses, or intends to possess, considering the size of the containers as well as any other products the applicant possesses or intends to possess that might require refrigeration or freezing. Notwithstanding the contention that an applicant will

distribute all prescription drugs the same day received, the refrigeration and freezer capacity must be large enough to accommodate prescription drugs as set forth herein in case the drugs are not distributed the same day received.

(4) Ouarantine.

- (a) A quarantine section shall be clearly marked and designated separate and apart from any other place where drugs are stored so that products therein shall not be confused with usable products being held for sale. Any prescription drug stored outside the quarantine area is a product held for sale or other distribution.
- (b) The requirement of Section 499.0121(5)(b), F.S., that prescription drugs must be quarantined if damage has occurred to the immediate or sealed outer or sealed secondary containers means: a prescription drug must be quarantined if obvious damage, determined by a visual inspection of the exterior of the product's packaging, has occurred to any part of the packaging that is or may be in direct contact with the dosage form of the drug or any additional part of the packaging which is provided to prevent adulteration of the drug in addition to "containing" the product.
- (c) A person who handles both prescription drugs and over-the-counter drugs or medical devices may have one quarantine section; however, the storage requirements for prescription drugs must be followed.
- (5) Examination of Prescription Drugs; Physical Product and Records.
- (a)1. Every person receiving prescription drugs other than the consumer receiving dispensed prescription drugs pursuant to Chapter 465, F.S., has a duty to examine the product to prevent acceptance of prescription drugs that are unfit for distribution or use. The extent of the examination should be predicated on the conditions surrounding the transaction, including but not limited to any previous sales of the product, i.e., purchase and delivery is not direct from the manufacturer; the conditions of transport; and environmental conditions to which the product may have been subjected.
- 2. A wholesaler, chain pharmacy warehouse, or person authorized to administer or dispense a prescription drug that physically receives a prescription drug must verify that the prescription drug received matches the prescription drug identified by lot number or unique serial number, when available, on the corresponding pedigree if a prescription drug is received from a person other than the manufacturer. The corresponding pedigree document shall contain all of the required information described in Sections 499.003(31)(a) or (b), F.S., as applicable, including the information required in the forms described in subsection 64F-12.012(3), F.A.C., for those distributions that are not eligible for the use of the direct purchase pedigree.
- (b) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of misbranded drugs, adulterated drugs or prescription drugs that

are otherwise unfit for distribution. If visual examination of the shipping container or other conditions surrounding the transaction suggest possible misbranding or adulteration, the person has a duty to examine further the contents or conditions

(c) Prescription Drug Wholesalers must employ personnel who can perform product examinations. Once the Prescription Drug Wholesaler has inspected the shipped drugs and elected to accept them, the wholesaler is responsible for the condition of the drugs. Until that time, the shipper or manufacturer remains responsible for delivering a prescription drug product in acceptable condition, unless responsibilities are modified by contract.

(d) Authentication.

- 1. A prescription drug wholesaler may use any, all, or any combination of the following methods to authenticate each transaction on a pedigree paper and must maintain the corresponding documentation regarding the authentication for the method used:
- a. Receipt of an invoice (or shipping document) from the seller to the purchaser, which may have the prices redacted. Documentation requirements include at a minimum a copy of the invoice or shipping document. If this method is used to authenticate a pedigree, the wholesaler must review the document received for signs of tampering, incompleteness, or inconsistency with other invoices or shipping documents from that manufacturer or wholesaler, and must randomly verify the authenticity of the invoice or shipping document with the seller or shipping point reflected on that document using one of the methods in sub-subparagraph b., c., or d. below. Each wholesaler shall should establish and adhere to policies and procedures for the random verification of the authenticity of the invoices or shipping documents according to statistically valid standards. However, more emphasis should be focused on those wholesalers in the chain with which the wholesaler performing the authentication does not have an established prescription drug vendor relationship.
- b. Telephone call to the seller. Documentation requirements include a signed statement by the person placing the telephone call identifying the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.
- c. E-mail communication with the seller. Documentation requirements include a copy of the e-mail that identifies the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

- d. Verification of the transaction per a web-based system established by the seller or an independent person that is secure from intentional or unintentional tampering or manipulation to conceal an accurate and complete history of the prescription drug transaction(s). Documentation requirements include a written representation from the seller or independent person that the seller or independent person, as applicable, is responsible for the information included on the web site and has adequate security on the information posted to prevent unauthorized tampering, manipulation, or modification of the information and a copy of the (dated) web site page that confirms the sales transaction between the parties, including the date of the transaction and the quantity of prescription drugs involved in the transaction.
- e. Receipt of a legible and unaltered copy of a previous transaction's pedigree paper that had been signed under oath at the time of the previous transaction to support the transaction to which the pedigree paper relates. If this method is used to authenticate a pedigree, the wholesaler must review the document received for signs of tampering, incompleteness, or inconsistency, and must randomly verify the authenticity of pedigrees using one of the methods in sub-subparagraph b., c., or d. above. Each wholesaler shall should establish and adhere to policies and procedures for the random verification of the authenticity of these copies of pedigrees according to statistically valid standards.
- f. Receipt of a pedigree in an electronic form from an automated system that complies with this sub-subparagraph that was successfully opened and decrypted by an automated system that complies with this sub-subparagraph. In order to rely on receipt of an electronic pedigree without employing additional authentication methods as set forth in sub-subparagraphs a.-e.,
- (I) The system used to digitally sign and electronically authenticate the electronic pedigree must at a minimum support the following digital signature standards or future revisions governed by the National Institute of Standard and Technology (NIST):
- (A) FIPS 140-2 validated cryptographic module which is hereby adopted by reference,
- (B) FIPS 186-2 validated digital signature system which is hereby adopted by reference,
- (C) FIPS 180-2 validated hash function which is hereby adopted by reference,
- (II) The system must employ controls to ensure the security and integrity of the private key so that it cannot be accessed by someone other than the certificate holder. At a minimum, the system must:
- (A) Control the activation of the private key with an authentication mechanism,
- (B) Employ a ten-minute inactivity time period after which the certificate holder must re-authenticate to access the private key,

- (C) When the signing module is deactivated, clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key,
- (III) The system must communicate with the Certification Authority directory, either each time authentication and validation steps in sub-subparagraph (IX) below occur or at least on a daily basis to download information to perform the authentication and validation which will occur on that day.
- (IV) The system must have a time system that is within five minutes of the official NIST time source and date and time stamp any and all digital signatures.
- (V) The system must archive digitally signed files unaltered, including the original hashes and reference to the public keys, in a manner that facilitates retrieval of the record consistent with the recordkeeping requirements.
- (VI) The system must prevent issuance of an outgoing pedigree paper if the total quantity of prescription drugs distributed in all pedigrees exceeds the quantity of prescription drugs received in the corresponding incoming electronic pedigrees.
- (VII) The system must maintain a history file of any outgoing electronic pedigree that is subsequently voided or altered and notify the recipient that the pedigree sent to it was voided or altered.
- (VIII) The system must maintain a history file of any incoming notification received pursuant to sub-sub-subparagraph (VII) above that a pedigree was voided or altered and prevent the issuance of an outgoing pedigree using a pedigree that was voided or altered.
 - (IX) The system must verify or perform the following:
- (A) Each transaction on the electronic pedigree must be digitally signed using certificates issued through a public key infrastructure system authorized by the department.
- (B) The electronic pedigree must contain each prior transaction digitally signed and unaltered, including the original hash and reference to the public key, with the new transaction information appended to the new document and the entire resulting pedigree digitally signed, including the resulting hash and reference to the public key.
- (C) The system must check the certificate expiration date of each signed transaction and compare it against the date and time that the transaction was signed to determine that the certificate has not or had not expired at the time the record was signed.
- (D) The system must check the digital signature for each signed transaction against the Certificate Authority's directory and the Certificate Revocation List and verify whether the certificate holder is or was authorized to sign electronic pedigrees at the time the transaction was signed.

- (E) The system must decrypt each digital signature for each signed transaction in the pedigree using each sender's public key and compare it against the message digest to determine that the record has not been altered since it was originally signed.
- (F) The system must require that all authentication and validation steps in the preceding paragraphs are carried out prior to allowing the acceptance of the transaction. The system should not allow the further processing of any transaction that has failed to pass any authentication or validation step.
- (X)(A) The manufacturer must initiate the pedigree; or, until such time as the manufacturer initiates a pedigree to the wholesaler, the wholesaler that purchased the prescription drug from the manufacturer must imbed a copy of the sales invoice or the manufacturer's EDI transmission or Advance Ship Notice (ASN) that contains all required data elements for a complete audit trail as set forth in Rule 64F-12.012, F.A.C., related to that wholesaler's acquisition of the prescription drug from the manufacturer. Price information related to the transaction may be redacted from the imbedded copy of the sales invoice, the EDI transmission, or the ASN.
- (B) If a pedigree complies with all provisions within sub-subparagraph f. except for sub-sub-sub-subparagraph (X)(A) above, then a prescription drug wholesaler must use another method authorized by this rule to authenticate the distribution from the manufacturer to the first wholesaler. Subsequent distributions may be authenticated in accordance with sub-subparagraph f.
- 2.g. If a pedigree cannot be authenticated because of a clerical error, the pedigree must be corrected by the sender.
- 3.h. If a pedigree cannot be authenticated and the reason is other than a clerical error, or the reason cannot be satisfactorily ascertained based on preliminary investigation, the prescription drug for which the pedigree cannot be authenticated must be quarantined and the department notified within 3 business days.
- 2.a. Authentication of the purchase of a prescription drug directly from the manufacturer by an affiliated group member for a prescription drug that is subject to the statement in Section 499.0121(6)(e)1.a., F.S., may be documented by a written agreement between or among the affiliated group members that each affiliated group member will only transfer prescription drugs included on the specified list that were purchased directly from the manufacturer to an affiliated group member that is required to include the statement in Section 499.0121(6)(e)1.a., F.S., on its wholesale distributions to other wholesale distributors.
- 4.2. b. A purchasing wholesaler may use a written contract agreement between the purchasing wholesaler and its wholesale supplier, which is a primary wholesaler as defined in Section 499.012(1)(d), F.S., that requires that all prescription drugs distributed to the purchasing wholesaler by the wholesale supplier must be purchased by the wholesale

- supplier from the manufacturer. If this method is used to authenticate a pedigree, the purchasing wholesaler shall must establish and adhere to policies and procedures for the random verification of the authenticity of the pedigrees that disclose the supplier wholesaler purchased the prescription drug from the manufacturer according to statistically valid standards.
- 5.3. The following persons in Florida that are authorized to purchase or possess prescription drugs are not required to authenticate a pedigree paper received from a person authorized by law to distribute prescription drugs to that person:
- a. A licensed pharmacy, unless it is also permitted as a retail pharmacy wholesaler and will engage in the wholesale distribution of that drug, or unless it is a member of an affiliated group and will distribute a prescription drug purchased or received directly from a prescription drug wholesaler that is not also a member of its affiliated group to another member of its affiliated group;
 - b. A medical practitioner; or
- c. A restricted prescription drug distributor health care entity.
- 6.4. In order to authenticate pedigrees, a manufacturer of a prescription drug that is sold or distributed in Florida must make available upon request information relevant to authenticating a pedigree for that drug regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.
- 7.5. Any wholesaler or repackager required under Chapter 499, F.S., to receive a pedigree paper must authenticate the pedigree pursuant to Section 499.0121(4), notwithstanding the absence of a pedigree paper or authentication by persons in the distribution chain not subject to the requirements of Chapter 499, F.S.
- (6) Any establishment that is permitted as a prescription drug wholesaler or repackager must notify the department in writing within three working days of discovery of a significant loss or theft of prescription drugs. Whether a loss or theft is significant is to be based on the prescription drug wholesaler's written policies and procedures that may take into account the actual quantity in relation to the type or size of the business; any pattern of losses or thefts; and local trends or other indicators of the diversion potential.
- Notification to the Drugs, Devices and Cosmetic Program Bureau may be made by facsimile to (850)413-6982 (850)922-5367 and must include at a minimum, identification of the permitted establishment reporting the loss or theft; a complete identification of the prescription drug(s) involved, including but not limited to the name of the manufacturer or distributor reflected on the label of the products, the dosage form, strength, container size, the quantity of each, the lot numbers if known; a brief description of the circumstances surrounding the theft or loss; and a contact person's name and telephone number to provide additional information.

(7) Due Diligence Inspection. With respect to the inspection required under Section 499.0121(12)(e), F.S., a prescription drug wholesaler may rely on a due diligence inspection performed by a person that is independent of both wholesalers for purposes of the requirement in Section 499.0121(12)(e), F.S.

Specific Authority 499.0121(1), 499.05 FS. Law Implemented 499.003,(31), 499.004, 499.006, 499.007, 499.0121, 499.028(6), 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, 4-17-01, 1-1-04, 1-19-06,

NAME OF PERSON ORIGINATING PROPOSED RULE: Rebecca Poston

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Rebecca Poston

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 24, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 4, 2006

FLORIDA HOUSING FINANCE CORPORATION

RULE NOS.:	RULE TITLES:
67-38.002	Definitions
67-38.0026	General Program Requirements and
	Restrictions
67-38.003	Application Submission Procedures
67-38.004	Incomplete Applications and
	Rejection Criteria
67-38.005	Application Evaluation and Award
	Guidelines
67-38.007	Terms of the PLP Loan
67-38.008	Eligible Uses for the Loan
67-38.010	Credit Underwriting Procedures
67-38.011	Fees
67-38.014	Disbursement Procedures

PURPOSE AND EFFECT: The purpose of Rule Chapter 67-38, Florida Administrative Code (F.A.C.) is to establish the procedures by which the Florida Housing Finance Corporation shall administer the Predevelopment Loan Program (PLP) which helps to fund the initial and up front costs associated with the building or rehabilitation of affordable housing. These funds may be requested by any unit of government, public housing authority established pursuant to Chapter 421, F.S., community-based or not-for-profit organization, for-profit entity wholly owned by one or more qualified not-for-profit limited partnership organizations, orwith community-based or not-for-profit organization that holds at least 51% of the ownership not owned by a for-profit entity and must materially participate in the development and operation of the Development. Revisions to the Rule are required to implement technical and clarifying changes. The adoption of

these revisions will increase the efficiency and effectiveness for program service delivery and will provide greater clarification of the program.

SUMMARY: The Corporation has reviewed the contents of this rule to ensure that the language contained herein is still in line with the Statute, current goals of the Corporation and reflects any material changes that have taken place within the structure or application process of the Predevelopment Loan Program.

SUMMARY OF **STATEMENT** OF **ESTIMATED** REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 420.528 FS.

LAW IMPLEMENTED: 420.507, 420.521-.529 FS.

A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: August 27, 2007, 10:00 a.m.

PLACE: Florida Housing Finance Corporation, Seltzer Room, Sixth Floor, 227 North Bronough Street, Tallahassee, Florida 32301

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Robert Dearduff (850)488-4197. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Robert Dearduff, Special Programs Administrator, (850)488-4197

THE FULL TEXT OF THE PROPOSED RULE IS:

67-38.002 Definitions.

- (1) through (4) No change.
- (5) "Application Package" means the forms and, instructions obtained from the Corporation at 227 North Bronough Street, Suite 5000, Tallahassee, Florida 32301-1329 or from the Corporation's Website, which shall be completed and submitted to the Corporation in order to apply for a specific Corporation program. With respect to PLP, Form PLP 1115 (Rev 10/07) is hereby adopted and incorporated herein by reference. Copies of such may be obtained by contacting the Special Programs Administrator at 227 North Bronough Street, Suite 5000, Tallahassee, Florida 32301-1329.
 - (6) through (15) No change.

- (16) "Development Plan" or "Form TAP 1215" (Rev 02/05) means the written description of the proposed Development submitted to the Corporation by the Technical Assistance Provider, with the concurrence of the Applicant, in the form created and approved by Corporation. Form TAP 1215 is hereby adopted and incorporated herein by reference. Copies of such may be obtained by contacting the Special Programs Administrator at 227 North Bronough Street, Suite 5000, Tallahassee, Florida 32301-1329.
 - (17) through (21) No change.
- (22) "Maturity Date" means the established date the loan is due for payment.
- (23)(22) "Mortgage" means Mortgage as defined in Section 420.503, F.S.
- (24) "Outstanding Loan" means a PLP Loan approved by the Board which has not been repaid or de-obligated by the developer.
- (25) "Public Housing Authority" means a public housing authority established pursuant to Chapter 421, F.S.
- (26)(23) "PLP" or "Predevelopment Loan Program" means the Predevelopment Loan Program established by the Act and this rule chapter.
- (27)(24) "PLP Loan" means a direct loan from the Predevelopment Loan Program.
- (28)(25) "Principal" means an Applicant, any general partner of an Applicant, and any officer, director, or any shareholder of any Applicant or shareholder of any general partner of an Applicant.
- (29)(26) "Rehabilitation" means to bring a Development back to its original state, or to bring back to its original state with added improvements with limitations as specified by the program or programs which provide construction or permanent financing to the Development.
- (30)(27) "Servicing and Compliance Monitoring Fees" means fees associated with the review and processing of requests for disbursement of funds, inspections and the monitoring of Developments.
- (31)(28) "Set-Aside" means the percentage of units within a Development that shall be reserved as affordable at or below the specified AMI to income qualified persons or households throughout the Compliance Period as outlined herein.
- (32)(29) "Technical Assistance Provider" or "TAP" means an independent contractor retained by the Corporation to provide technical assistance services.
- (33)(30) "Technical Assistance" means assistance to Applicants via telephone, through on-site visits and by responses to oral and written inquiries from Applicants throughout the entire Predevelopment process and to provide such other services as agreed to by the Technical Assistance Provider and the Corporation.

- "Threshold (34)(31)Requirements" means the requirements an Applicant shall meet as identified in the Application Package in order to receive an Invitation to Participate in the Predevelopment Loan Program.
- (35)(32) "Website" means the Corporation's website, the Universal Resource Locator (URL) for which www.floridahousing.org.
- Specific Authority 420.528 FS. Law Implemented 420.507, 420.521-.529 FS. History-New 3-23-93, Amended 1-16-96, Formerly 9I-38.002, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05,
- 67-38.0026 General Program Requirements Restrictions.
- (1) An Applicant may only apply for funding through the Predevelopment Loan Program if it is a legally formed entity that is:
 - (a) No change.
- (b) A Public local Hhousing Authority, established pursuant to Chapter 421, F.S.,
 - (c) No change.
- (d) A for-profit entity wholly owned by one or more qualified Not-For-Profit Oorganizations, or
 - (e) No change.
- (2) PLP Loans shall be limited to eligible predevelopment and site acquisition costs approved for the Development by the TAP and the Corporation and are limited to:
- (a) \$500,000 when no funds are being requested for site acquisition; or
- (b) \$750,000 when funds are being requested for site acquisition of which funds for the site acquisition cost (including good faith deposits applied to the sales price) shall be limited to \$500,000;
- (2) Loans shall be in an amount not to exceed \$500,000, or the predevelopment and acquisition costs outlined in Rule 67-38.008, F.A.C., that were incurred prior to the closing of permanent or construction loan financing for the Development, whichever is less.
- (3) All funds from the PLP loan shall be expended on the eligible expenses outlined in Rule 67-38.008, F.A.C.
- (4) Site acquisition cost shall be subject to approval of an assigned Credit Underwriter.
- (5) The Corporation may limit the PLP Loan to an amount which can be secured through a mortgage on the Development Site, the pledging of capital fund finance program funds as approved by HUD or other collateral approved by the Corporation. Such determination shall require written recommendation by the TAP or Credit Underwriter and be based on the following: mortgages currently on the Development Site, or value of the Development Site as determined by appraisal dated within 12 months of receipt of the Application.

(6)(3) For rental Developments:

- (a) No change.
- (b) Must set-aside the units for the duration of the Compliance Period. If the Development does not obtain construction or permanent financing from Corporation and no Corporation funds remain in the Development, the Compliance Pperiod this shall be fifteen (15) years from the date the PLP L-loan is paid off. If the Development obtains construction or permanent financing from other Corporation programs, then the most restrictive compliance requirements of the other Corporation programs shall be in effect and compliance monitoring shall be performed through those programs. the Compliance Period shall be in effect for a period equal to the compliance period committed to by the Applicant under the particular Corporation program providing the additional funding.
 - (7)(4) For home ownership Developments:
- (a) The Applicant must commit to sell a minimum of 50% 100% of completed housing units to persons or households whose income does not exceed 80% of the area median income, as determined by HUD and adjusted by household size, for the metropolitan statistical area or county in which the individual homes are located, and sell the remaining housing units to persons or households whose income does not exceed 120% of the area median income, and
- (b) If the Development obtains construction or permanent financing from other Corporation programs, the Set-Aside(s) committed to by the Applicant under the particular Corporation program providing the additional funding shall be in effect.
- (8)(5) Applicants are required to work with a Technical Assistance Provider (TAP) as assigned by the Corporation. The Corporation shall pay all fees required by the TAP.
- (9)(6) If the Applicant is utilizing PLP funds to purchase the Development Site, including good faith deposits applied to the sales price of the land, Credit Underwriting will be required by a Credit Underwriter assigned by Corporation. The Applicant is responsible for paying the Credit Underwriting fee, which is an eligible PLP expense.
- (10)(7) If awarded a PLP Loan, the proceeds of such may only be used for PLP eligible expenses as outlined in Rule 67-38.008, F.A.C.
- (11)(8) The Development must be consistent with the purposes of the Predevelopment Loan Program and conform to the requirements specified in the Act or this rule chapter.

Specific Authority 420.528 FS. Law Implemented 420.527, 420.528 FS. History–New 3-23-93, Amended 1-16-96, Formerly 9I-38.003, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05.

67-38.003 Application Submission Procedures.

(1) At any time during the year, Applicants may submit an Application to the Corporation for PLP funding. An Applicant, Affiliate, limited partnership, or general partner thereof <u>shall</u> may not have more than two (2) <u>Outstanding</u> Loans

outstanding at any given time, without the prior written approval of the Corporation Board. In order for an Applicant to be approved to have more than two Outstanding Loans, the Applicant shall submit a written request to the Corporation detailing the experience of all Developers and co-developers involved in the proposed Development(s) in producing affordable housing and a proposed plan for permanent or construction financing on the Development(s). For the purposes of this rule chapter, outstanding shall mean any PLP Loan that has not been fully repaid to the Corporation.

(2) through (6) No change.

Specific Authority 420.528 FS. Law Implemented 420.527, 420.528 FS. History–New 3-23-93, Amended 1-16-96, Formerly 9I-38.003, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05,______.

- 67-38.004 Incomplete Applications and Rejection Criteria.
- (1) Each Application shall be reviewed by the Corporation to determine if the Application meets Threshold Requirements. If the Application fails to meet Threshold Requirements, the Corporation shall notify the Applicant of any additional or revised information or material that is required. The Applicant may continue to submit requested material until the Application is complete and meets Threshold Requirements. The Application, however, shall not be placed in priority order or on a waiting list until such time that all information and documentation has been submitted and the Application is determined to have met Threshold Requirements.
 - (2) through (4) No change.

Specific Authority 420.528 FS. Law Implemented 420.527, 420.528 FS. History–New 3-23-93, Amended 1-16-96, Formerly 9I-38.004, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05,______

- 67-38.005 Application Evaluation and Award Guidelines.
- (1) through (4) No change.
- (5) The Invitation to Participate <u>letter</u> shall be signed <u>by</u> the <u>Applicant</u> and returned to the Corporation within <u>20</u> calendar <u>45</u> days from the date of the Invitation to Participate <u>letter</u>. of receipt by If the executed Invitation to Participate <u>letter</u> is not received by the Corporation within <u>20 calendar 45 days, the Invitation to Participate <u>letter</u> shall be withdrawn and the Applicant shall be so notified. The executed Invitation to Participate <u>letter</u> must be accompanied by an initial commitment fee as specified therein.</u>
- (6) Upon receipt of the executed Invitation to Participate letter and the Applicant's initial commitment fee, the Corporation shall assign a Technical Assistance Provider. In the event that technical assistance has begun and it is determined that the initial commitment fee has not been paid or is returned for insufficient funds, Technical Assistance shall be discontinued until full payment is received and determined to be sufficient. If payment has not been received within seven days of notification to the Applicant, the Invitation to Participate letter shall be withdrawn and the Applicant shall be so notified.

- (7) No change.
- (8) The Applicant shall be given up to six months from the Applicant's date of execution of the Corporation's receipt of the executed signed Invitation to Participate letter to complete and submit the Development Plan unless prior written approval of an extension is received from the Corporation. The Invitation to Participate letter shall be canceled if the Development Plan is not submitted within the six-month period. All PLP Loan documents, if any, shall be cancelled. Any commitment fees paid shall be retained by the Corporation. With the prior approval of the TAP, the Applicant may request an extension for submitting the Development Plan in writing to the Corporation at least 30 calendar thirty days prior to the end of the original six month period.
 - (9) No change.
- (10) Following the TAP and Corporation staff's approval of the Development Plan, the PLP Loan request shall be submitted to the Board for approval. Amendments to the Development Plan shall be allowed upon a favorable recommendation of the Technical Assistance Provider. If an increase to the PLP Loan is requested, or an Applicant name change is requested. Board approval is required.
- (11) Following approval of the PLP Loan, the Applicant will receive written notice of such approval in the form of a commitment letter issued by the Corporation. The Applicant shall submit the final commitment fee and return the executed acceptance of commitment to the Corporation within 20 calendar fifteen days from the date of the commitment letter of receipt of such notice.
- (12) If the Board does not approve the PLP Loan request, no funds shall be disbursed other than for expenses incurred for services of the Technical Assistance Provider. Any commitment fees paid by the Applicant shall be retained by the Corporation.
 - (13) No change.
- (14) Following receipt of the final commitment fee, a mortgage, a loan agreement, promissory note and any other customary loan documentation will be provided to the Applicant. Upon execution of all loan documents by both the applicant and the Corporation, funds will be available for disbursement for eligible predevelopment activities as specified in this rule chapter.
- (15) A positive Credit Underwriting Report is required for closing on any portion of the a PLP Loan that has been approved by the Board for site the acquisition costs including good faith deposits applied to the sales price of the Development Site.

Specific Authority 420.528 FS. Law Implemented 420.527, 420.528 FS. History-New 3-23-93, Amended 1-16-96, Formerly 9I-38.005, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05,

- 67-38.007 Terms of the PLP Loan.
- (1) If In the event that the Applicant entity is comprised of a 100% ownership interest by a Not-For Profit Organization, or a for-profit entity wholly-owned by one or more Not-For Profit Organizations, or if the Applicant is a Public Housing Authority, the PLP Lioan shall bear an interest rate of 1%. Otherwise, In the event that the Applicant entity has a for profit partner with any ownership interest in the Development the PLP Loan shall bear an interest rate of 3%.
 - (2) No change.
- (3) The PLP Loan shall be non-amortizing with principal and interest deferred until the Mmaturity Date. The Corporation is authorized to forgive such loan and thereby make a grant to the Applicant for any monies that are unable to be repaid due to the Applicant's inability to obtain construction or permanent financing for the Development. The Corporation shall not forgive the portion of the PLP Loan, if any, which is collateralized secured by a mortgage, pledged capital funds or other collateral approved to the Corporation to the extent such loan could be repaid from the sale of the mortgaged property or from other collateral securing the loan.
- (4) In the event PLP funds are used to purchase the Development Site, Tthe mortgage securing the PLP Loan shall be in a first or second lien position and shall not share priority with any other liens unless approved by the Board.
- (5) With respect to rental Developments, the PLP Loan's Maturity Date shall be mature on the earlier of:
 - (a) No change.
- (b) Three years from the date of execution of the loan documents by the Corporation or other such extended loan Mmaturity Delate approved by the Board.
- (6) With respect to home ownership Developments, the PLP Loan's Maturity Date shall be mature on the earlier of:
- (a) On a prorated basis upon the sale of each home, upon the recommendation of the Credit Underwriter or Technical Assistance Provider and a partial release payment in an amount acceptable to the Credit Underwriter or Technical Assistance Provider and the Corporation; or
 - (b) No change.
- (7) The Corporation shall extend the term of the PLP Loan for an additional period if extraordinary circumstances exist and if such extension would not jeopardize Corporation's security interest. Submission of a request for an extension of the term of a PLP Loan shall be subject to the following:
- (a) For an extension up to one year, the Developer shall submit, along with the TAP a written request detailing the progress of the Development, barriers to the Development's progress and a revised timeline.
- (b)(a) An additional extension of up to one year requested at the conclusion of the initial approved one year extension shall require tThe recommendation of the Credit Underwriter

or the Technical Assistance Provider <u>as directed by the Corporation</u> that an extension of the PLP Loan is likely to result in the successful completion of the Development; and

(c)(b) No change.

- (8) No change.
- (9) The Corporation may renegotiate and extend the PLP Loan. Such renegotiations shall be based upon:
- (a) Documentation and certification by the Applicant that funds are not available to repay the Note upon maturity;
- (b) A plan for the repayment of the loan at the new Maturity Date;
- (c) Assurance that the security interest of the Corporation will not be jeopardized by the new term(s); and
- (d) Industry standard terms which may include amortizing loans requiring regularly scheduled payments of principal and interest.

All loan renegotiation requests, including requests for extension, must be submitted in writing to the Director of Special Assets and contain the specific details of the renegotiation.

(10)(9) Upon determination by the Board that other remedies are ineffectual or non-existent and that the best interest of the Corporation is served by acceleration of the PLP Loan. The PLP Loan shall be accelerated if any of the following occurs:

(a) Proceeds of the PLP Loan are used for any purpose not specified in the Development Plan, the documents evidencing or securing the PLP Loan, the Act or this rule chapter; or

(b)(e) Sale, transfer, or conveyance of the Development without the prior written approval of the Corporation, as set forth in Rule 67-38.012, F.A.C.

(11)(10) The Applicant shall submit <u>electronic</u> progress reports evidencing successful completion of the requisite tasks and activities set forth in the Development Plan to the Technical Assistance Provider on <u>not more than</u> a quarterly basis <u>as determined by the Corporation</u>. The Technical Assistance Provider shall submit the reports to the Corporation. Reports are due to the Corporation by the 10th day of April, July, October, and January for so long as funds are outstanding.

(12)(11) The Corporation reserves the right to require an audit of Applicant's accounts and records relating to the PLP Loan funds. If the Applicant is required to perform an audit of its accounts and records, a copy of the same shall be delivered to the Corporation within ten (10) days of receipt of thereof by the Applicant.

(13)(12) The Applicant shall maintain all documents related to the Development, including copies of all contracts and performance bonds, during the term of the Loan and for three years following the maturity of the PLP Loan as the same may be extended pursuant to this rule chapter.

(14)(13) With respect to home ownership Developments, in order to assure that such Developments serve the target population, the Credit Underwriter or the Corporation shall, prior to release of an individual lot within the Development \underline{S} site, review appropriate documentation as necessary to determine the unit is being sold to an eligible purchaser.

(15)(14) With respect to rental Developments, in order to assure that such Developments serve the target population and maintain the minimum Set-Aside requirements, in addition to the execution and recordation of the Land Use Restriction Agreement (LURA), all deeds conveying title to real estate that is improved with rental units shall contain restrictive covenants that encompass all of the units in the Development and that provide for the continued rental of the units to persons within the target population for the Compliance Period. For those Developments which have occupied units, or will have occupied units, prior to closing of the construction or permanent financing, the Servicer or the Corporation shall conduct a review and physical inspection prior to closing of the construction or permanent financing to assure that the Development meets the minimum Set-Aside requirements and provides the intended benefit to the target population pursuant to the Act. The Corporation reserves the right to monitor each Development funded under the Predevelopment Loan Program at any time after completion of the Development to assure continued compliance with the applicable provisions of this rule chapter.

(16)(15) The loan shall not be assumable upon the sale, transfer or refinancing of the Development without the prior approval from the Board, which approval shall be conditioned upon a positive recommendation by the Technical Assistance Provider or Credit Underwriter.

Specific Authority 420.528 FS. Law Implemented 420.526, 420.527, 420.528 FS. History–New 3-23-93, Amended 1-16-96, Formerly 9I-38.007, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05,

- 67-38.008 Eligible Uses for the Loan.
- (1) No change.
- (2) The Corporation shall monitor all predevelopment activity expenditures through the designated Technical Assistance Provider and shall deny disbursements which have not been approved by the Technical Assistance Provider prior to submission to Corporation. <u>Draw requests shall not be processed without the Technical Assistance Provider's written approval.</u>
- (3) Eligible predevelopment expenses shall include the following expenses if such expenses or services were <u>required</u> to be incurred or rendered prior to closing of construction or permanent financing:
 - (a) through (f) No change.
- (g) <u>Development Third party</u> consultant fees. <u>Consultant fees incurred in connection with the submission or preparation of the PLP Application or for any other activities which can be</u>

provided by the Technical Assistance Provider shall not be eligible predevelopment expenses. The consultant shall demonstrate appropriate experience in affordable housing Development projects and shall be approved by acceptable to the TAP. No person, corporation, partnership, or entity having an identity of interest in the Development, or the Applicant, may act as a third party consultant;

- (h) No change.
- (i) <u>Customary</u>, gGood faith or earnest money deposit <u>for</u> the acquisition of the related to Development Site;
 - (j) through (u) No change.
- (4) If any of the requisite predevelopment activities to be completed are pending or have not been satisfactorily completed, Tthe Applicant shall be required to work with the Technical Assistance Provider to complete the predevelopment activities in a timely and satisfactory manner.
 - (5) No change.

Specific Authority 420.528 FS. Law Implemented 420.526, 420.527, 420.528 FS. History-New 3-23-93, Amended 1-16-96, 5-21-96. Formerly 9I-38.008, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05.

67-38.010 Credit Underwriting Procedures.

- (1) If an Applicant requests funds for site acquisition or requests an extension of the term of the PLP Loan,- tThe Corporation will assign a Credit Underwriter to perform the Credit Underwriting Report.
 - (2) through (5) No change.
- (6) The Credit Underwriter shall complete and submit make a written draft Credit Underwriting Report and recommendation to the Corporation within 80 calendar days from the date of assignment by the Corporation. The Technical Assistance Provider and the Applicant shall review the draft Report and provide written comments to the Corporation and Credit Underwriter within 72 hours of receipt. After the 72-hour review period, the Corporation shall provide comments on the draft Credit Underwriting Report and, as applicable, on the Applicant's and Technical Assistance Provider's comments, to the Credit Underwriter. The Credit Underwriter shall then review and consider the comments thereto and release the revised Report to the Corporation, the Technical Assistance Provider, and the Applicant. Any additional comments from the Applicant and Technical Assistance Provider shall be received by the Corporation and the Credit Underwriter within 72 hours of receipt of the revised Report. The Credit Underwriter shall provide to the Corporation a final Credit Underwriting Report which will address all comments made by the Applicant and the Technical Assistance Provider.
 - (7) No change.

Specific Authority 420.528 FS. Law Implemented 420.528 FS. History-New 3-23-93, Amended 1-16-96, Formerly 9I-38.010, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05,

67-38.011 Fees.

- (1) The following fees and charges pertaining to each Application shall be paid by the Applicant:
 - (a) through (b) No change.
- (c) An initial commitment fee as identified in the Application Package shall be paid to the Corporation;
- (d) Following approval an additional commitment fee shall be paid within 20 calendar 45 days of written notice to the Applicant that the Development Plan has been approved. In the event the Development Plan does not receive approval, the commitment fee paid at the time of acceptance of the Invitation to Participate letter shall be retained by the Corporation. In the Applicant successfully completes the Predevelopment Loan Program activities and obtains permanent or construction financing, the Applicant's PLP Loan repayment amount will be reduced by the full commitment fees paid:
- (e) Servicing and Compliance Monitoring Fees shall be paid for those multifamily rental Developments that obtain construction or permanent financing from sources other than Corporation programs. The total Servicing and Monitoring fee to be paid by the Applicant shall be submitted to the Corporation at the time of closing on the construction or permanent financing. The total Servicing and Monitoring fee is listed in the Application Package. For those Developments which obtain their construction or permanent financing from Corporation Programs, the Compliance Monitoring Fees shall be determined by the requirements of the particular program providing the financing in accordance with the rule chapter governing that particular program; and
- (f)(g) All Credit Underwriting, Technical Assistance, Servicing and Compliance Monitoring Fees, extraordinary services and late fees shall be determined by contracts between the Corporation and the provider.
 - (2) through (3) No change.

Specific Authority 420.507(4) FS. Law Implemented 420.528 FS. History-New 3-23-93, Amended 1-16-96, Formerly 9I-38.011, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05,

67-38.014 Disbursement Procedures.

After the PLP Loan has successfully closed, the PLP Loan shall be disbursed in partial payments by the Corporation to the Applicant, title company or third party contractors subsequent to compliance with the following conditions for either home ownership or rental Developments:

- (1) through (2) No change.
- (3) Disbursements for eligible activities, conducted prior to being awarded predevelopment financing, qualify for reimbursement from PLP funds provided that the eligible Predevelopment activities were performed or completed no earlier than twelve months prior to the submission of the Application. Consideration of expenditures that pre-date more than twelve months prior to the Application submission date

will be reviewed by Corporation staff on a case by case basis and will require approval by the TAP and the Corporation. Reimbursement for site acquisition which was completed prior to closing on the PLP loan shall not be allowed as a PLP expense unless otherwise recommended by the TAP and approved by Corporation staff and the Board.

(4) through (5) No change.

Specific Authority 420.528 FS. Law Implemented 420.528 FS. History–New 3-23-93, Amended 1-16-96, 5-21-96 Formerly 9I-38.014, Amended 3-26-98, 7-17-00, 7-21-03, 2-3-05,______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Robert Dearduff, Special Programs Administrator and Amanda Franklin, Special Programs Manager

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Nancy Muller, Policy Director

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: March 16, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: March 30, 2007

FINANCIAL SERVICES COMMISSION

OIR - Insurance Regulation

RULE NO.: RULE TITLE:

69O-149.002 Scope and Applicability

PURPOSE AND EFFECT: Rule 69O-149.002, F.A.C., is being amended to adopt the recent National Association of Insurance Commissioners (NAIC) interstate compact standard for defining incidental for accelerated death benefits.

SUMMARY: If the cost of an accelerated death benefit is incidental, less than 10% of the cost of the contract as a whole, the accelerated rider would not be subject to the health standards. These include such riders as accelerated long-term care and accelerated death benefits due to heart or other critical conditions. The standard provides for the formula to be used to meet the test

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 624.308(1), 627.410(6)(b) FS. LAW IMPLEMENTED: 624.307(1), 627.402, 627.410(1), (2), (6), (7), 627.411(1)(e), (2), 627.6515(2)(a), 627.6699 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: August 29, 2007, 9:30 a.m.

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

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Tracie Lambright, Life and Health Product Review, Office Insurance Regulation, E-mail: Tracie.Lambright@fldfs.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice). THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Tracie Lambright, Life and Health Product Review, Office of Insurance Regulation, E-mail: Tracie.Lambright@fldfs.com

THE FULL TEXT OF THE PROPOSED RULE IS:

69O-149.002 Scope and Applicability.

- (1) through (5) No change.
- (6) Pursuant to the provisions of Section 627.410(6)(b), F.S., rate filings required by Rule 69O-149.003, F.A.C. and ARC filings required by Rule 69O-149.007, F.A.C., are not required to be made for the following; however, the rating standards contained in this Part I and applicable statutes shall continue to apply as if the rate schedules were required to be filed for approval:
- (a)1. Annually rated group health insurance policies as defined by Section 627.652(1), F.S., including blanket insurance as defined by Section 627.659, F.S., issued in this state that provide availability of coverage only to groups with 51 or more employees/members.
- (b)2. This filing exemption does not apply to franchise policies issued pursuant to Section 627.663, F.S.
- (c)3. This filing exemption does not apply to stop-loss policy forms, unless the policy is issued only to employers with 51 or more employees.

(7)(a)(b)1. Forms that provide for the acceleration of the benefits of a life insurance policy that <u>are is</u> incidental to the total life insurance coverage <u>are not subject to the annual rate or ARC filing requirements of Section 627.410, F.S., or these rules. The insurer is required to submit an actuarial demonstration with the initial filing for approval demonstrating such incidental compliance.</u>

(b)2. The acceleration is considered incidental if the value of the accelerated benefit is less than 10 percent of the total value of the benefits provided by the life insurance coverage. These values shall be measured as:—a. tThe present values of the benefits determined as of the date of issue, determined according to the formula (NSP2-NSP1)/NSP1, applied over a range of underwriting classes and plans at which the benefit is being made available, is not in any case greater than 10%, where:; or

1. NSP1 and NSP2 are determined using an effective annual interest rate of 6%.

- 2. NSP1 is the net single premium for the base policy benefits assuming there is no accelerated death benefit.
- 3. NSP2 is the net single premium for the base policy benefits assuming that the full death benefit is paid at time of death or the occurrence of the non-death accelerated death benefit trigger.
- b. The relationship between the premiums if the premiums are separable and fixed at issue.
- (c) If a separate premium or cost of insurance (COI) charge is the only charge being charged for the accelerated benefit provided, the ratio of the present value of the accelerated benefit premiums or COI charges over the life of the policy to the present value of the policy premiums or COI charges exclusive of any riders, does not exceed 10%, the present values shall be determined using an effective annual interest rate of 6%.
- (d) Upon request of the Office, the insurer shall provide an actuarial demonstration that the accelerated death benefit continues to meet these standards. If it is determined that the accelerated death benefit fails to comply with these standards, the provisions of these rules shall apply.

Specific Authority 624.308(1), 627.410(6)(b) FS. Law Implemented 624.307(1), 627.402, 627.410(1), (2), (6), (7), 627.411(1)(e), (2), 627.6515(2)(a), 627.6699 FS. History—New 7-1-85, Formerly 4-58.02, 4-58.002, Amended 4-18-94, 4-9-95, 10-27-02, Formerly 4-149.002, Amended 5-18-04._______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Monica Rutkowski, Director, Life and Health Product Review, Office of Insurance Regulation

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 6, 2007

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: January 12, 2007

Section III Notices of Changes, Corrections and Withdrawals

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Division of Standards

RULE NOS.: RULE TITLES: 5F-8.0011 Standards Adopted

5F-8.0012 Bureau of Fair Rides Inspection

Forms

5F-8.003 Qualified Inspectors

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 33, No. 31, August 3, 2007 issue of the Florida Administrative Weekly.

THE FULL TEXT OF THE PROPOSED RULE IS:

5F-8.0011 Standards Adopted.

The following standards are adopted for the inspection of amusement rides in this state.

- (1) American Society for Testing and Materials F-24 (ASTM F-24) Standards on Amusement Rides and Devices, Seventh Fifth Edition, 2004 1995. A copy of the adopted ASTM standards can be obtained by writing the American Society for Testing and Materials at 100 Barr Harbor Drive, West Conshohocken, Pennsylvania 19428; Phone (610)832-9500.
- (2) Article 525, Carnivals, Circuses, Fairs and Similar Events, of the National Electrical Code (NEC) Handbook, 2005 1996 Edition. Notwithstanding the provisions of Article 525 13(a), all flexible cords or cables used shall meet the requirements for extra hard usage, damp location, as listed in Table 400 4 of the NEC. A copy of the adopted NEC standards can be obtained by writing the National Fire Protection Association at 1 Batterymarch Park, Quincy, Mass. 02269-0901; Phone 1 (800) 344-3555.
- (3) National Fire Protection Association 101, Life Safety Code, (NFPA 101), Chapter 3.3.28.10, 12.4.7 and 13.4.7 8-4.6 and 9-4.6, Special Provisions for Amusement Buildings, 2006 1991 Edition. A copy of the adopted NFPA standards can be obtained by writing the National Fire Protection Association at 1 Batterymarch Park, Quincy, Mass. 02269-0901; Phone 1 (800) 344-3555.
- (4) American Society for Testing and Materials (ASTM) Standards E 543-06, Standard Specification Practice for Agencies Performing Nondestructive Testing, 2006 1996 Edition. A copy of the adopted ASTM standards can be obtained by writing the American Society for Testing and Materials at 100 Barr Harbor Drive, West Conshohocken, Pennsylvania 19428; Phone (610)832-9500.
- (5) American Society For Nondestructive Testing (ASNT) Document SNT-TC-1A, Personnel Qualification and Certification in Nondestructive Testing, 2001 1996 Edition. A copy of the adopted ASNT standard can be obtained by writing the American Society For Nondestructive Testing, 1711 Arlingate Lane, Post Office Box 28518, Columbus, Ohio 43228-0518; Phone 1 (800)222-2768.

Specific Authority 616.165, 616.242(4) FS. Law Implemented 616.001, 616.242 FS. History–New 2-14-99, Amended