DEPARTMENT OF HEALTH

Vital Statistics	
RULE TITLES:	RULE NOS.:
Delayed Birth Registration Requirements; Fees	64V-1.001
Birth Certificate Amendments;	
Who May Apply; Fees	64V-1.002
Birth Certificate Amendments: Documentary	
Evidence Requirements	64V-1.003
Birth Certificate Amendments by Adoption	64V-1.0031
Birth Certificate Amendments by	
Paternity Establishment; Judicial	
and Administrative Process	64V-1.0032
Birth Certificate Amendment by Legal	
Change of Name; Judicial Process	64V-1.0033
Change of Paternity; Evidence Required	64V-1.004
Evidence Required for Births Occurring	
Outside of a Facility	64V-1.006
Death Certificate Amendments; Who May	
Apply; Fees; Documentary	
Evidence Requirements	64V-1.007
Delayed Death or Fetal Death Registration	64V-1.008
Presumptive Death Registration	64V-1.0081
Certifications of Vital Records	64V-1.0131
Fees for Vital Statistics Services	
Provided by State Registrar	64V-1.014
Florida Putative Father Registry	64V-1.016
Marriage Reporting	64V-1.019
Dissolution of Marriage Reporting	64V-1.020
Disposition of Fetal Demise	64V-1.021

PURPOSE AND EFFECT: Purpose of proposed amendments is to change certain practices used in the amendment of birth records, update forms incorporated in rule, incorporate forms dictated by recent passage of legislation and to set forth requirements for obtaining information deemed confidential by law.

SUBJECT AREA TO BE ADDRESSED: Restrict other than by departmental administrative clerical error or at the order of the court, the amendment of same fact on a birth record to once, allow for amendment of parent's name on child's birth record as a result of a legal name change of parent, to update forms used in the amendment process incorporated in rule, to require certain information and proof of identity when issuing documents that are deemed confidential and exempt from the provision of s. 119.07, Florida Statutes, to establish fees as provided for in law for filing a claim of paternity or conducting a diligent search of the Florida Putative Father Registry, to incorporate forms to be used for registering with, updating information and requesting diligent search of the Florida Putative Father Registry, require that a Presumptive Death Certificate contain sufficient identifying information on decedent, incorporate forms used in the registration of a Florida marriage or dissolution of marriage, and to incorporate in rule a form to be used for notifying a mother of her disposition rights in case of a spontaneous fetal demise. SPECIFIC AUTHORITY: 63.054, 382.003(7),(10),(11), 382.015(6), 382.016, 382.025, 382.0255(3), 383.33625(3) FS. LAW IMPLEMENTED: 63.054, 63.152, 68.07(4), 382.003(7),(11), 382.012, 382.013(2), 382.015, 382.016, 382.017, 382.019, 382.021, 382.023, 382.025, 382.0255(1), 383.33625, 742.10, 742.16 FS. IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE TIME, DATE AND PLACE SHOWN BELOW (IF NOT REQUESTED IN WRITING, THIS WORKSHOP WILL NOT BE HELD): TIME AND DATE: 10:00 a.m., December 1, 2003 PLACE: Department of Health, Office of Vital Statistics, 1217 Pearl St., Boorde Bldg., Rm. 420, Jacksonville, FL 32231-0042 THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Kathleen Dunkley Stephens, Sr. Management Analyst Supervisor, Department of Health, Office of Vital Statistics, P. O. Box 210, Jacksonville, Florida 32231-0042 THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS AVAILABLE AT NO CHARGE FROM THE CONTACT PERSON LISTED ABOVE.

Section II Proposed Rules

BOARD OF TRUSTEES OF THE INTERNAL IMPROVEMENT TRUST FUND

Pursuant to Chapter 2003-145, Laws of Florida, all notices for the Board of Trustees of the Internal Improvement Trust Fund are published on the Internet at the Department of Environmental Protection's home page at http://www.dep. state.fl.us/ under the link or button titled "Official Notices."

PUBLIC SERVICE COMMISSION

DOCKET NO. 030975-EI

RULE TITLE:RULE NO.:Cost of Service Load Research25-6.0437PURPOSE AND EFFECT: To update the rule to reflect currentneed for information, to reduce the frequency of filing the load

need for information, to reduce the frequency of filing the load research studies, and eliminate reporting data that are no longer used.

SUMMARY: Requires investor-owned electric utilities subject to this rule to submit a current, revised load research sampling plan at least every three years and perform a complete load research study every three years. SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: None.

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

SPECIFIC AUTHORITY: 366.05(1), 350.127(2) FS.

LAW IMPLEMENTED: 350.117, 366.03, 366.04(2)(f), 366.05(1), 366.06(1), 366.82(3),(4) FS.

Written comments or suggestions on the proposed rule may be submitted to the FPSC, Division of the Commission Clerk and Administrative Services, within 21 days of the date of this notice for inclusion in the record of the proceeding.

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

If any person decides to appeal any decision of the Commission with respect to any matter considered at the rulemaking hearing, if held, a record of the hearing is necessary. The appellant must ensure that a verbatim record, including testimony and evidence forming the basis of the appeal is made. The Commission usually makes a verbatim record of rulemaking hearings.

Any person requiring some accommodation at this hearing because of a physical impairment should call the Division of the Commission Clerk and Administrative Services, (850)413-6770, at least 48 hours prior to the hearing. Any person who is hearing or speech impaired should contact the Florida Public Service Commission by using the Florida Relay Service, 1(800)955-8771 (TDD).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Christiana T. Moore, Florida Public Service Commission, 2540 Shumard Oak Blvd., Tallahassee, Florida 32399-0862, (850)413-6098

THE FULL TEXT OF THE PROPOSED RULE IS:

25-6.0437 Cost of Service Load Research.

(1) Applicability. This rule shall apply to all investorowned electric utilities over which the Commission has jurisdiction and which <u>provide electric service to more than</u> 50,000 retail customers at the end of any calendar year had gross annual retail sales of 500 GWH or more in 1983.

(2) Purpose. The primary purpose of this rule is to require that load research that supports cost of service studies used in ratemaking proceedings is of sufficient precision to reasonably assure that tariffs are equitable and reflect the true costs of serving each class of customer. Load research data gathered and submitted in accordance with this rule will also be used by the Commission to allocate costs to the customer classes in cost recovery clause proceedings, in evaluating proposed and operating conservation programs, for research, and for other purposes consistent with the Commission's responsibilities.

(3) Sampling Plan. Within 90 days of becoming subject to this rule, each utility All utilities subject to this rule shall, within 90 days of the effective date of this rule, shall submit to the Commission a proposed load research sampling plan. The plan shall provide for sampling all rate classes that account for more than 1 percent of a utility's annual retail sales. The plan shall provide that all covered rate classes shall be sampled within two years of the effective date of this rule. The sampling plan shall be designed to provide estimates of the summer and winter peak demand by class and the averages of the 12 monthly coincident peaks for each class within plus or minus 10 percent at the 90 percent confidence level. The sampling plan shall also be designed to provide estimates of the summer and winter peak demands for each rate class within plus or minus 10 percent at the 90 percent confidence level, except for the General Service Non-Demand rate class. The sampling plan shall be designed to provide estimates of the summer and winter peak demands for the General Service Non-Demand rate class within plus or minus 15 percent at the 90 percent confidence level Any utility subject to this rule may apply to the Commission to waive the requirements hereof for any specific covered rate class.

(4) Review of Proposed Plan. Except where a utility has requested a formal ruling by the Commission, within 90 days after submission, the Commission's Division of Economic Regulation Electric and Gas Department shall review each utility's plan to determine whether it satisfies the criteria set forth in Section 3 above and shall notify the utility in writing of its decision accepting or rejecting the proposed sampling plan. If a proposed plan is rejected, the written notice of rejection shall state clearly the reasons for rejecting the proposed plan. If a utility's proposed plan is rejected the utility shall submit a revised sampling plan to the Commission within 60 days after receiving the notice of rejection. Where a utility has requested staff review of its sampling plan and the plan has been rejected the utility may petition the Commission for approval of the plan. If a utility has not submitted a satisfactory sampling plan within 6 months following the submission of the initially proposed plan, the Commission may prescribe by order a sampling plan for the utility.

(5) Use of Approved Sampling Plan. The approved sampling plan shall be used for all load research performed for cost of service studies and other studies submitted to the Commission until a new sampling plan is approved by the Commission.

(6) Revised Sampling Plans. Each utility subject to this rule shall submit a current, revised sampling plan to the Commission no less <u>often</u> than every <u>three two</u> years after the <u>most recent initial</u> sampling plan <u>was required to be submitted</u> is approved. Any new or revised plan shall be developed using data from the utility's most current load research to determine

the required sampling plan to achieve the precision required in Section 3 of this rule. New or revised plans shall be reviewed by the Commission pursuant to Section 4 of this rule.

(7) Load Research Data to be Reported. Each utility subject to this rule shall perform a complete load research study in accordance with the specifications of this rule by December 31, 1985 and no less often than every three years two years thereafter. Each utility shall, within 120 days following completion of the study, submit to the Commission the results of each load research study completed after the effective date of this rule. The submission shall include a detailed calculation of the average 12 coincident peak and class load factors for each covered rate class based upon the load research results This submission shall include the hourly load data described in Section (8) for the residential class. The load research results of each study shall be submitted in a form prescribed by the Commission.

(8) Hourly Data to be Available Upon Request. Each utility subject to this rule shall make available within 30 90 days of a request by the Commission the estimated hourly demands by class for all 8760 hours in the year derived from this Load Research.

Specific Authority 366.05(1), 350.127(2) FS. Law Implemented 350.117, 366.03, 366.04(2)(f), 366.05(1), 366.06(1), 366.82(3),(4) FS. History–New 3-11-84, Formerly 25-6.437, Amended ______.

NAME OF PERSON ORIGINATING PROPOSED RULE: David Wheeler

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Florida Public Service Commission DATE PROPOSED RULE APPROVED BY AGENCY HEAD: November 3, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: Vol. 29, No. 27, July 3, 2003

DEPARTMENT OF ELDER AFFAIRS

Aging and Assisted Living Programs

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RULE CHAPTER TITLE:	RULE CHAPTER NO.:
Adult Day Care Center	58A-6
RULE TITLES:	RULE NOS.:
Licensure Application Procedu	res 58A-6.003
Change of Owner or Operator;	Marketing 58A-6.0051

Change of Owner or Operator; Marketing 58A-6.0051 PURPOSE AND EFFECT: The proposed amendments to Rules 58A-6.003 and 58A-6.051, F.A.C., were developed in consultation with the Agency for Health Care Administration. The purpose of the proposed amendments to Rule 58A-6.003, F.A.C., is to (a) revise the licensure application for Adult Day Care Center, ADCC Form-1, by omitting the request for social security information as the Department does not have rule authority to require this confidential information, and (b) implement Section 27 of Chapter 2003-57, Laws of Florida, which provides that license renewal notification shall be provided electronically or by mail delivery by the Agency for Health Care Administration. The proposed amendments to Rule 58A-6.0051, F.A.C., is to (a) implement Section 12 of Chapter 2002-400, Laws of Florida, which provides standards of enforcement applicable to all entities licensed or regulated by the Agency for Health Care Administration, (b) delete the reference to "abuse registry" forms which are no longer required, and (c) inserts the reference to the Adult Day Care Center licensure application that is to be submitted when there is a change of ownership.

SUMMARY: The proposed amendments to Rule 58A-6.003, F.A.C., will (a) revise the adult day care center licensure application, ADCC Form-1, and (b) provide that license renewal notification shall be provided electronically or by mail delivery by the Agency for Health Care Administration. The proposed amendments to Rule 58A-6.0051, F.A.C., will provide standards of enforcement applicable to all entities licensed or regulated by the Agency for Health Care Administration and delete reference to forms no longer required.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: No statement of estimated regulatory cost has been prepared.

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

SPECIFIC AUTHORITY: 400.562, 408.831 FS.

LAW IMPLEMENTED: 400.557(1), 400.5565(1)(b), 400.559, 400.562(3), 408.831(2) FS.

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

TIME AND DATE: 1:00 p.m. – 2:00 p.m., December 8, 2003

PLACE: Department of Elder Affairs, Conference Room 309, 4040 Esplanade Way, Tallahassee, FL

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Linda Macdonald, Office of Legal Affairs, Department of Elder Affairs, 4040 Esplanade Way, Tallahassee, Florida 32399-7000, (850)414-2000

THE FULL TEXT OF THE PROPOSED RULES IS:

58A-6.003 Licensure Application Procedures.

(1) through (4) No change.

(5) Owners or operators of adult day care centers subject to licensure shall submit a completed application for a license through the Agency for Health Care Administration, 2727 Mahan Dr., Tallahassee, FL 32308. The Licensure Application for Adult Day Care Center, ADCC Form-1, dated <u>August 2003</u> January 2001, which is incorporated by reference, may be obtained from the AHCA, Adult Day Care Program, 2727 Mahan Drive, Tallahassee, Florida <u>32308</u>32399. The cost of

the application package, which includes Chapter 400, Part V, F.S., and this rule chapter, is 5.00, in accordance with Section 400.562(3), F.S. Attached to the application shall be:

(a) through (b) No change.

(6) The agency shall notify a licensee <u>electronically or</u> by <u>eertified</u> mail <u>delivery</u> at least 120 days before the expiration date of the center's license. Applications for relicensure must be submitted to the agency at least 90 days before the expiration date of the existing license. Failure to file a timely renewal application will result in a fine of \$75.00 pursuant to Chapter 400.5565(1)(b) and 400.557(1), F.S., being assessed against the center.

(7) No change.

Specific Authority 400.562 FS. Law Implemented Ch. 400, Part V, 400.557(1), 400.555(1)(b), 400.562(3) FS. History–New 7-8-81, Amended 2-27-84, Formerly 10A-6.03, 10A-6.003, 59A-16.003, Amended 11-9-95, 3-29-98, 10-23-01,_____.

58A-6.0051 Change of Owner or Operator; Marketing.

(1) The center must notify the <u>Assisted Living Unit</u>, AHCA at 2727 Mahan Drive, Tallahassee, FL 32301<u>-5402</u>, at least 60 days before the date of a change of ownership. The new owner must request and submit a check for \$5.00 for the <u>Licensure Application for Adult Day Care Center, ADCC</u> Form-1, dated August 2003, incorporated by reference in Rule 58A-6.003, F.A.C., dated (effective date of the rule) and obtainable from Assisted Living Unit, AHCA, 2727 Mahan Drive, Tallahassee, FL 32308-5402, (850)487-2515 initial application package, which includes the ADC rules and regulations.

(2) No change.

(3) The transferor shall, prior to agency approval of a change of ownership, repay or make arrangements to repay any outstanding fine amounts owed the agency pursuant to Section 408.831(2), F.S.

(4)(3) If the center's owner changes operators, the owner or new operator must notify the AHCA within 30 days at the address in subsection (1), and include the completed abuse registry and criminal background check forms.

Specific Authority 400.562, 408.831 FS. Law Implemented Ch. 400, Part V, 400.559, 408.831(2) FS. History–New 11-9-95, Amended 3-29-98.______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Linda Macdonald

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Terry White, Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 3, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 8, 2003

DEPARTMENT OF ENVIRONMENTAL PROTECTION

Pursuant to Chapter 2003-145, Laws of Florida, all notices for the Department of Environmental Protection are published on the Internet at the Department of Environmental Protection's home page at http://www.dep.state.fl.us/ under the link or button titled "Official Notices."

DEPARTMENT OF HEALTH

Division of Medical Quality Assurance

RULE TITLE:	RULE NO.:
Diagnostic Testing	64B-3.004

PURPOSE AND EFFECT: Senate Bill 32A (2003), authorized the Department of Health (Department) in consultation with the appropriate licensing Boards, to adopt by rule a list of diagnostic tests deemed not to be medically necessary for use in the treatment of persons sustaining injury covered by personal injury protection benefits. In response to the Legislature's mandate, the Department sought input from the Boards of Medicine, Osteopathy, Chiropractic, and Dentistry, and held a workshop to receive public input, on September 9th, 2003, in Tallahassee, Florida. Upon review of the testimony provided at the workshop, input received from the Boards, written opinions by members of the health care and insurance communities, and literature in support thereof, the Department proposes new Rule 64B-3.004, F.A.C.

SUMMARY: Proposed new Rule 64B-3.004, F.A.C., lists four (4) diagnostic tests deemed by the Department of Health to not be medically necessary for use in the treatment of persons sustaining injury covered by personal injury protection benefits SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: No Statement of Estimated Regulatory Cost was prepared.

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

SPECIFIC AUTHORITY: 627.736 FS.

LAW IMPLEMENTED: 627.736 FS.

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

TIME AND DATE: 9:00 a.m., November 18, 2003

PLACE: Betty Easley Conference Center, 4075 Esplanade Way, Room 182, Tallahassee, Florida 32399

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Larry McPherson, Executive Director, Department of Health, 4052 Bald Cypress Way, Bin #C03, Tallahassee, Florida 32399

THE FULL TEXT OF THE PROPOSED RULE IS:

MISCELLANEOUS

64B-3.004 Diagnostic Testing.

For the purposes of Section 627.736(5)(b)6., Florida Statutes (2003), the Department of Health, in consultation with the appropriate licensing boards, hereby adopts the following list of diagnostic tests based on their demonstrated medical value and level of general acceptance by the provider community:

(1) Spinal ultrasound, also known as sonography, ultrasonography, and echography, is deemed not to be medically necessary for use in the diagnosis and treatment of persons sustaining bodily injury covered by personal injury protection benefits.

(2) Surface electromyography, also known as SEMG or Surface EMG, is deemed not to be medically necessary for use in the diagnosis of persons sustaining bodily injury covered by personal injury protection benefits.

(3) Somatosensory Evoked Potentials (SSEP) are deemed not to be medically necessary for use in the diagnosis of radiculopathy or distal nerve entrapment when treating persons sustaining bodily injury covered by personal injury protection benefits.

(4) Dermatomal Evoked Potentials (DEP) are deemed not to be medically necessary for use in the diagnosis and treatment of persons sustaining bodily injury covered by personal injury protection benefits.

Specific Authority 627.736(5) FS. Law Implemented 627.736(5) FS History-New

NAME OF PERSON ORIGINATING PROPOSED RULE: Larry McPherson, Executive Director, Department of Health, 4052 Bald Cypress Way, Bin #C03, Tallahassee, Florida 32399

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Amy Jones, Division Director, Department of Health, 4052 Bald Cypress Way, Bin C00, Tallahassee, Florida 32399

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 30, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 29, 2003

DEPARTMENT OF HEALTH

Board of Opticianry

RULE TITLE: RULE NO .: Administrative Fees for Apprenticeships 64B12-11.015 PURPOSE AND EFFECT: The Board proposes to repeal the existing rule text.

SUMMARY: The Board has decided to repeal this unnecessary rule.

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

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

SPECIFIC AUTHORITY: 484.005, 484.007 FS.

LAW IMPLEMENTED: 484.007(1)(d) 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: Sue Foster, Executive Director, Board of Opticianry, 4052 Bald Cypress Way, Bin #C08, Tallahassee, Florida 32399-3258

THE FULL TEXT OF THE PROPOSED RULE IS:

64B12-11.015 Administrative Fees for Apprenticeships.

Specific Authority 484.005, 484.007 FS. Law Implemented 484.007(1)(d) FS. History–New 4-22-90, Formerly 21P-11.015, 61G13-11.015, Amended 12-4-95, Formerly 59U-11.015, Repealed ______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Opticianry

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 25, 2003

DEPARTMENT OF HEALTH

School Psychology

RULE TITLE:

Exemption of Spouses of Members of Armed Forces from License

64B21-502.006

RULE NO .:

Renewal Requirements PURPOSE AND EFFECT: The Department proposes new Rule 64B21-502.006, F.A.C., allowing licensees who are spouses of members of the Armed Forces of the United States to be exempt from all licensure renewal provisions during a specified period of time.

SUMMARY: Pursuant to s. 456.024, F.S., the Department proposes a new rule exempting spouses of military personnel from certain licensure renewal provisions.

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

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

SPECIFIC AUTHORITY: 456.024, 490.015 FS. LAW IMPLEMENTED: 456.024 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: Kaye Howerton, Executive Director, Department of Health, 4052 Bald Cypress Way, Bin #C05, Tallahassee, Florida 32399-3255

THE FULL TEXT OF THE PROPOSED RULE IS:

CONTINUING EDUCATION REQUIREMENTS

<u>64B21-502.006</u> Exemption of Spouses of Members of Armed Forces from License Renewal Requirements.

A licensee who is the spouse of a member of the Armed Forces of the United States shall be exempt from all licensure renewal provisions for any period of time which the licensee is absent from the State of Florida due to the spouse's duties with the Armed Forces. The licensee must document the absence and the spouse's military status to the department.

Specific Authority 456.024, 490.015 FS. Law Implemented 456.024 FS. History-New_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Kaye Howerton, Executive Director, Department of Health, 4052 Bald Cypress Way, Bin #C05, Tallahassee, Florida 32399-3255

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Amy Jones, Division Director

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 29, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 31, 2003

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE TITLE:	RULE NO .:
General Regulations; Definitions	64F-12.001
DUDDOSE AND EFFECT: The proposed	rula adda tha

PURPOSE AND EFFECT: The proposed rule adds the prescription drug, Lipitor, to the specified list of prescription drugs for which a pedigree paper back to the manufacturer is required for the wholesale distribution of Lipitor to a wholesale distributor pursuant to s. 499.0121(6)(e), F.S.

SUMMARY: The proposed rule amends the definition of a specified drug by adding the prescription drug Lipitor, in all strengths and sizes, to the list of prescription drugs qualifying as a specified drug. The wholesale distribution of a specified drug to a wholesale distributor requires special recordkeeping requirements that trace the history of all prior sales of the specified drug back to the manufacturer. The Prescription Drug

Advisory Council recommended to the Secretary of the Department of Health, by unanimous vote on October 8, 2003, to place Lipitor on the list of specified drugs in accordance with the procedures established in s. 499.0121(6)(e), F.S., in order to protect the public health.

SUMMARY OF STATEMENT OF **ESTIMATED** REGULATORY COST: This rule will affect prescription drug wholesalers permitted to wholesale prescription drugs in or into the state of Florida that purchase Lipitor from sources other than directly from the manufacturer and sell Lipitor to prescription drug wholesalers. Prescription drug wholesalers that purchase Lipitor from sources other than directly from the manufacturer will be required to verify a pedigree paper that traces all prior sales of each container of Lipitor back to Lipitor's manufacturer. In addition, a prescription drug wholesaler that sells Lipitor to a prescription drug wholesaler will be required to either state on the invoice or accompanying documentation that each container of Lipitor was purchased by that establishment or a member of that establishment's affiliated group directly from the manufacturer, or provide a pedigree paper that traces all prior sales of each container of Lipitor back to the manufacturer.

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

SPECIFIC AUTHORITY: 499.0121(6)(e), 499.05 FS.

LAW IMPLEMENTED: 499.0121 FS.

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

TIME AND DATE: 1:00 p.m. (EST), Monday, December 8, 2003

PLACE: 2818-A Mahan Drive, Tallahassee, Florida

If special accommodations are needed to attend this workshop because of a disability, please contact: Maxine Wenzinger, (850)922-5190.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Sandra Stovall, Compliance Officer, 2818-A Mahan Drive, Tallahassee, Florida 32308, (850)487-1257, Ext. 210, sandra_stovall@doh.state.fl.us.fl

THE FULL TEXT OF THE PROPOSED RULE IS:

64F-12.001 General Regulations; Definitions.

(1) No change.

(2) In addition to definitions contained in Sections 499.003, 499.012(1), 499.0122(1), 499.028(1), and 499.61, F.S., the following definitions apply to Rule Chapter 64F-12, F.A.C.:

(a) through (u) No change.

(v) "Specified drug" means all dosage forms, strengths and container sizes of the following prescription drugs:

- 1. Combivir (lamivudine/zidovudine);
- 2. Crixivan (indinavir sulfate);
- 3. Diflucan (fluconazole);
- 4. Epivir (lamivudine);
- 5. Epogen (epoetin alfa);
- 6. Gamimune (globulin, immune);
- 7. Gammagard (globulin, immune);
- 8. Immune globulin;
- 9. Lamisil (terbinafine);

10. Lipitor (atorvastatin calcium)

11.10. Lupron (leuprolide acetate);

12.11. Neupogen (filgrastim);

13.12. Nutropin AQ (somatropin, e-coli derived);

<u>14.13.</u> Panglobulin (globulin, immune);

- 15.14. Procrit (epoetin alfa);
- 16.15. Retrovir (zidovudine);
- 17.16. Risperdal (risperidone);

18.17. Rocephin (ceftriaxone sodium);

19.18. Serostim (somatropin, mannalian derived);

20.19. Sustiva (efavirenz);

21.20. Trizivir (abacavir sulfate/lamivudine/zidovudine);

22.21. Venoglobulin (globulin, immune);

- 23.22. Videx (didanosine);
- 24.23. Viracept (nelfinavir mesylate);
- 25.24. Viramune (nevirapine);

26.25. Zerit (stavudine);

27.26. Ziagen (abacavir sulfate);

28.27. Zocor (simvastatin);

29.28. Zofran (ondansetron);

30.29. Zoladex (goserelin acetate); and

<u>31.30.</u> Zyprexa (olanzapine).

(w) through (x) No change.

Specific Authority 499.05, 499.61, 499.701 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, 499.0122, 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, 499.066, 499.066, 499.067, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.071, 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 12-26-99, 4-17-01, 6-30-03, 10-7-03, ______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Jerry Hill, Chief of Statewide Pharmaceutical Services NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Phil E. Williams, Director, Division of Health Awareness and Tobacco DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 21, 2003 DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 31, 2003

Section III Notices of Changes, Corrections and Withdrawals

DEPARTMENT OF STATE

Division of Historical Resources

RULE NOS.:	RULE TITLES:
1A-35.005	Grant Funding
1A-35.007	Application Requirements
NOTICE OF WITHDRAWAL	

Notice is hereby given that the above rules as noticed in Vol. 28, No. 18, May 3, 2002 of the Florida Administrative Weekly has been withdrawn.

DEPARTMENT OF INSURANCE

RULE NO .:	RULE TITLE:
4-154.203	Categories of Reserves
	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. 29, No. 37, September 12, 2003, of the Florida Administrative Weekly.

These changes are being made to address concerns expressed by the Joint Administrative Procedures Committee.

4-154.203(1)(b)2.c.(I)(B) is changed to read:

(B)b. A reasonable method approved by the Office Department after a public hearing prior to the statement date. A reasonable method is one where the company is able to demonstrate that the claim reserves calculated using the company's method would not be less than those calculated using a generally accepted actuarial method; or

The remainder of the rule reads as previously published.

DEPARTMENT OF REVENUE

Property Tax Administration Program

RULE NO.:	RULE TITLE:
12D-8.0068	Assessment Reduction for Living
	Quarters of Parents or
	Grandparents
	NOTICE OF CHANGE

Notice is hereby given that the following change has been made to this proposed rule, as published in Vol. 29, No. 44, October 31, 2003, issue of the Florida Administrative Weekly. This change is in accordance with s. 120.54(3)(d)1., F.S.