THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Captain Alan S. Richard, Boating Law and Waterway Management Coordinator, Office of Enforcement Planning and Policy, 620 South Meridian Street, Tallahassee, Florida 32399-1600 THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

FISH AND WILDLIFE CONSERVATION COMMISSION

Division of Law Enforcement

RULE CHAPTER TITLE: RULE CHAPTER NO.:

68D-36

Minimum Standards for Mandatory

Boating Safety Courses

PURPOSE AND EFFECT: This rulemaking action will update the boating safety training requirements to include a component on diving safety, incorporate changes in the curriculum approved by the National Association of State Boating Law Administrators, establish guidelines under which liveries, marinas, and other persons the Commission has appointed as its agents administer the course, course equivalency examination, or temporary certificate examination and issue identification cards, and provide specifications for training and information that must be provided by vessel liveries.

SUBJECT AREA TO BE ADDRESSED: Boating safety information, training, curricula, and examinations.

SPECIFIC AUTHORITY: 327.39, 327.395, 327.54 FS.

LAW IMPLEMENTED: 327.39, 327.395, 327.54 FS.

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Captain Alan S. Richard, Boating Law and Waterway Management Coordinator, Office of Enforcement Planning and Policy, 620 South Meridian Street, Tallahassee, Florida 32399-1600

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

Section II Proposed Rules

DEPARTMENT OF STATE

Division of Library and Information Services

RULE CHAPTER TITLE:	RULE CHAPTER NO .:
Public Records Scheduling	
and Dispositioning	1B-24
RULE TITLES:	RULE NOS .:
Definitions	1B-24.002
Developing Requests for Records	
Retention Schedules	1B-24.004
Submitting Proposed Records	
Retention Schedules	1B-24.005
Division Criteria for Processing Propo	osed
Records Retention Schedules	1B-24.006
Division Action	1B-24.007
Revising Records Retention Schedule	s 1B-24.008
General Records Schedules	1B-24.009
Records Disposition	1B-24.010
Division Criteria for Approval of Reco	ords
Disposition Requests	1B-24.011
Disposition Certificate	1B-24.012

PURPOSE AND EFFECT: This repeal eliminates certain rules relating to the records management program of the Department of State which have been revised, to become effective January 2000. The above rules are redundant following the revision of Chapter 1B-24. The purpose is to comply with the revision of section 257.36, Florida Statutes.

SUMMARY: Repeals 1B-24.002, 1B-24.004, 1B-24.005, 1B-24.006, 1B-24.007, 1B-24.008, 1B-24.009, 1B-24.010, 1B-24.011 and 1B-24.012.

SPECIFIC AUTHORITY: 120.53(1)(b) FS.

LAW IMPLEMENTED: 120.53(1)(b) 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:

TIME AND DATE: 9:00 a.m., January 16, 2001

PLACE: Florida Records Storage Center, 4319 Shelfer Road, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Lynn Rawls, Bureau of Archives and Records Management, Department of State, Mail Station 9A, The Capitol, Tallahassee, Florida 32399-0250 Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in the hearing should advise the Department at least 5 calendar days before the hearing by contacting Lynn Rawls, (850)487-2180.

THE FULL TEXT OF THE PROPOSED RULES IS:

1B-24.002 Definitions.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Amended 1-4-86, Formerly 1A-24.02, 1A-24.002, Amended 1-7-88, 3-23-93, Repealed

1B-24.004 Developing Requests for Records Retention Schedules.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Amended 1-4-86, Formerly 1A-24.04, 1A-24.004, Amended 1-7-88, 3-23-93. <u>Repealed</u>.

1B-24.005 Submitting Proposed Records Retention Schedules.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Formerly 1A-24.05, 1A-24.005, Amended 1-7-88, 3-23-93, Repealed ______.

1B-24.006 Division Criteria for Processing Proposed Records Retention Schedules.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Formerly 1A-24.06, 1A-24.006, Amended 1-7-88, 3-23-93, Repealed ______.

1B-24.007 Division Action.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Formerly 1A-24.07, 1A-24.007, Amended 1-7-88, 3-23-93, Repealed ______.

1B-24.008 Revising Records Retention Schedules.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Amended 1-4-84, Formerly 1A-24.09, 1A-24.009, Amended 1-7-88, 3-23-93, Repealed _____.

1B-24.009 General Records Schedules.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Formerly 1A-24.07, 1A-24.007, Amended 1-7-88, 3-23-93, <u>Repealed</u>______.

1B-24.010 Records Disposition.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Amended 1-4-84, Formerly 1A-24.10, 1A-24.010, Amended 1-7-88, 3-23-93, 7-1-95, <u>Repealed</u>.

1B-24.011 Division Criteria for Approval of Records Disposition Requests.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Formerly 1A-24.11, 1A-24.011, Amended 1-7-88, 3-23-93, Repealed ______.

1B-24.012 Disposition Certificate.

Specific Authority 257.14, 257.36(7) FS. Law Implemented 257.36 FS. History–New 1-8-80, Formerly 1A-24.12, 1A-24.012, Amended 1-7-88, 3-23-93, Repealed ______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Lynn Rawls

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Barratt Wilkins, Director, Division of Library and Information Services, Department of State, 500 S. Bronough Street, R. A. Gray Building, Tallahassee, Florida 32399-0250

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 13, 2000

DEPARTMENT OF BANKING AND FINANCE

Board of Funeral and Cemetery ServicesRULE TITLE:RULE NO.:Minor Violating; Notice of Noncompliance3F-11.002PURPOSE AND EFFECT: The Board proposes to revise thisrule to update the list of minor violations for which theDepartment may issue a notice of noncompliance in keepingwith the statutes.

SUMMARY: Pursuant to statute, this rule sets forth minor violations which the Department may issue notices of noncompliance.

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: 497.103, 497.413 FS.

LAW IMPLEMENTED: 497.131(3) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Diana M. Evans, Executive Director, Board of Funeral and Cemetery Services, 101 East Gaines Street, Tallahassee, Florida 32399-0350

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

3F-11.002 Minor Violations; Notice of Non-Compliance.

(1) Pursuant to section 497.131(3), F.S., the Department may issue notice of non-compliance to a certificateholder, licensee, or registrant for an initial offense of a minor violation. Failure of the person, to whom a notice of non-compliance is issued, to take corrective action which is set forth in the notice of violation, within 15 days of the receipt of the notice may result in further disciplinary action.

(2) The following violations are minor violations for which the Department may issue a notice of non-compliance:

(a) Failure to display a license, in violation of section 497.301, F.S.

<u>(a)(b)</u> Unintentional failure to remit <1% of the amounts required to be deposited to a trust fund for an examination period, in violation of Section 497.233(1)(d), F.S.

(b)(c) Failure to provide any person, upon request, with a copy of the cemetery bylaws, in violation of Section 497.233(1)(s)(r), F.S.

(c)(d) Failure to make timely deposits to any trust fund, in violation of Section 497.245(2), F.S.

(d)(e) Failure to register a branch name for a common business enterprise, in violation of Section 497.407(4), F.S.

(e)(f) Failure to have records available at all reasonable times for examination by the Department, in violation of Section 497.309, F.S.

 $(\underline{f})(\underline{g})$ Establishing a condition for entry or access to a cemetery, in violation of Section 497.317(3), F.S.

(3) The Department shall not issue a notice of non-compliance for a violation of the same provision of the law to the same licensee, registrant or certificateholder, within a three-year period.

Specific Authority 497.103, 497.131(3) FS. Law Implemented 497.131(3) FS. History–New 8-9-94, Amended 10-25-94, 8-4-97._____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Funeral and Cemetery Services

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Funeral and Cemetery Services

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: November 15, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: December 1, 2000

DEPARTMENT OF TRANSPORTATION

RULE CHAPTER TITLE:	RULE CHAPTER NO.:	
Incorporation by Reference	14-15	
RULE TITLE:	RULE NO.:	
Policy and Guidelines for Vehicular Connections		
to Roads on the State Highway System		
(Driveway Regulation Manual)	14-15.013	

PURPOSE AND EFFECT: The Policy and Guidelines for Vehicular Connections to Roads on the State Highway System (Driveway Regulation Manual) was incorporated by reference in 1985. Later, with the adoption of Rule Chapters 14-96 and 14-97, most of the old manual was covered in those rule chapters. In 1990, the incorporation by reference statement in the rule was made more restrictive to only include certain specified sections of the manual. The rule is being repealed because the obsolete manual no longer is used.

SUMMARY: The Policy and Guidelines for Vehicular Connections to Roads on the State Highway System (Driveway Regulation Manual), which was incorporated by reference under this rule is obsolete so the rule is being repealed.

SPECIFIC AUTHORITY: 120.53(2)(a), 334.044(2), 335.18 FS.

LAW IMPLEMENTED: 120.53(2)(a), 334.044(14), 335.18 FS.

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.

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, Administrative and Management Support Level IV, 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:

14-15.013 Policy and Guidelines for Vehicular Connections to Roads on the State Highway System (Driveway Regulation Manual).

Specific Authority 120.53(2)(a), 334.044(2), 335.18 FS. Law Implemented 120.53(2)(a), 334.044(14), 335.18 FS. History–New 8-15-85, Formerly 14-15.13, Amended 4-18-90, Repealed

NAME OF PERSON ORIGINATING PROPOSED RULE: Gary Sokolow

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Thomas F. Barry, Jr., P.E., Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 1, 2000

AGENCY FOR HEALTH CARE ADMINISTRATION

Certificate	of Need
-------------	---------

Open Heart Surgery

RULE TITLES:

Definitions

	RULE NOS.:
	59C-1.002
Program	59C-1.033

PURPOSE AND EFFECT: The agency is proposing to amend rule 59C-1.002(41), eliminating adult open heart surgery from the list of tertiary services; and proposing to amend rule 59C-1.033 by revising the methodology used to calculate need for additional adult open heart surgery programs. The amendments include new DRG 109 in the definition of open heart surgery. Elimination of DRG 110 is also proposed, based on comments received and an analysis of agency data. The amendments also implement the provisions of s. 408.043(4), F.S., which prohibits use of accreditation by a private organization as a requirement for issuance or maintenance of a certificate of need.

It is expected that the revised need methodology will show a greater need for additional adult open heart surgery programs than is shown by the current methodology. Additional programs could then be approved, provided other criteria are met.

The agency has recently adopted rule amendments that renumber subsection 59C-1.002(43) as 59C-1.002(41), with no changes in the text of that subsection. The renumbering is reflected in this Notice.

SUMMARY: The proposed amendments eliminate adult open heart surgery from the list of services defined as tertiary, and revise the methodology used to determine need for additional adult open heart surgery programs.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: None 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: 408.034(5), 408.15(8) FS.

LAW IMPLEMENTED: 408.036(1)(f),(h) 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: 11:00 a.m., January 17, 2001

PLACE: Agency for Health Care Administration, 2727 Mahan Drive, Building 3, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Jeff Gregg, Certificate of Need Office, 2727 Mahan Drive, Tallahassee, Florida

THE FULL TEXT OF THE PROPOSED RULES IS:

59C-1.002 Definitions.

(1) through (40) No change.

(41) "Tertiary health service" means a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost effectiveness of such service. Examples of such service include, but are not limited to, organ transplantation, specialty burn units, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The types of tertiary services to be regulated under the Certificate of Need Program in addition to those listed in Florida Statutes include:

(a) Heart transplantation;

(b) Kidney transplantation;

(c) Liver transplantation;

(d) Bone marrow transplantation;

- (e) Lung transplantation;
- (f) Pancreas and islet cells transplantation;
- (g) Heart/lung transplantation;

(h) Adult open heart surgery;

(h)(i) Neonatal and pediatric cardiac and vascular surgery; and

(i)(j) Pediatric oncology and hematology.

In order to determine whether services should be added or deleted, the listing shall be reviewed annually by the agency.

(42) through (43) No change.

Specific Authority 408.034(5), 408.15(8) FS. Law Implemented 408.031, 408.032, 408.033(1)(a), 408.033(2), 408.036(1),(2)(d), 408.036(1),(h), 408.037(1),(2)(a), 408.039(1),(2), 400.6015, 651.118(2)(3) FS. History–New 1-1-77, Joint Administrative Procedures Committee Objection Filed – See FAW. Vol. 3 No. 10 March 11, 1977, Amended 11-1-77, 9-1-78, 6-5-79, 4-25-80, 2-1-81, 3-31-82, 7-29-82, 12-23-82, Formerly 10-5.02, Amended 11-17-79, 12-5-90, 1-31-91, 1-1-92, Formerly 10-5.002, Amended 12-14-92, 2-27-94, 6-23-94, 10-18-95, 10-8-97.

59C-1.033 Open Heart Surgery Program.

(1) Agency Intent. This rule specifies the requirements for the establishment of an adult or pediatric open heart surgery program, including minimum requirements for staffing and equipment; and it specifies a methodology for determining the numeric need for <u>additional</u> a new programs. A certificate of need for the establishment of an open heart surgery program shall not normally be approved unless the applicant meets the applicable review criteria in section 408.035, F.S., and the standards and need determination criteria set forth in this rule. Hospitals operating more than one hospital on separate premises under a single license shall obtain a separate certificate of need for the establishment of open heart surgery services in each facility. Separate certificates of need are required for the establishment of an adult or a pediatric open heart surgery program.

(2) through (f) No change.

(g) "Open Heart Surgery Operation." <u>Surgical procedures</u> Surgery assisted by a heart-lung by-pass machine that <u>are is</u> used to treat conditions such as congenital heart defects, <u>and</u> heart and coronary artery diseases, including replacement of heart valves, cardiac vascularization, and cardiac trauma. One open heart surgery operation equals one patient admission to the operating room. Open heart surgery operations are classified under the following diagnostic related groups (DRGs): DRGs 104, 105, 106, 107, 108, <u>and 109</u>, and <u>110</u>.

(h) through (4) No change.

(5) Service Quality.

(a) Accreditation. Any institution proposing to provide adult or pediatric open heart surgery must meet the Joint Commission on Accreditation of Healtheare Organizations accreditation standards for special care units or standards for accreditation by the American Osteopathic Association.

(b) through (c) renumbered (a) through (b) No change.

(6) No change.

(7) Adult Open Heart Surgery Program Need Determination.

(a) Except as provided in paragraphs (c) and (d), additional A new adult open heart surgery programs shall not normally be approved in the district if any of the following conditions exist:

1. There is an approved adult open heart surgery program in the district;

2. One or more of the operational adult open heart surgery programs in the district that were operational for at least 12 months as of 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than $250 \ 350$ adult open heart surgery operations during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool; or,

3. One or more of the adult open heart surgery programs in the district that were operational for less than 12 months during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than an average of 21 29 adult open heart surgery operations per month.

(b) Provided that the provisions of paragraphs (7)(a) and (7)(c) do not apply, the agency shall determine the net need for one additional adult open heart surgery programs in <u>a</u> the district based on the following formula:

NN = (POH/500) – OP, with the result rounded up or down to the nearest whole integer ((Ue X Px)/ 350)) - OP ≥ 0.5 where:

1. NN = The need for one additional adult open heart surgery programs in the district projected for the applicable planning horizon. The additional adult open heart surgery program may be approved when NN is 0.5 or greater.

2. <u>POH = The projected number of adult open heart</u> surgery operations that will be performed in the district in the 12-month period beginning with the planning horizon. To determine POH, the agency will calculate COH/CPOP x <u>PPOP</u>, where:

a. COH = the current number of adult open heart surgery operations, defined as the number of adult open heart surgery operations performed in the district during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool.

b. CPOP = the current district population age 15 years and over.

c. PPOP = the projected district population age 15 years and over. Ue = Actual use rate, which is the number of adult open heart surgery operations performed in the district during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool, divided by the population age 15 years and over. For applications submitted between January 1 and June 30, the population estimate used for CPOP in calculating Ue shall be for January of the preceding year; for applications submitted between July 1 and December 31, the population estimate used for CPOP in calculating Ue shall be for July of the preceding year. The population estimates used for CPOP and PPOP shall be the most recent population estimates of the Executive Office of the Governor that are available to the agency 3 weeks prior to publication of the fixed need pool.

3. Px = Projected population age 15 and over in the district for the applicable planning horizon. The population projections shall be the most recent population projections of the Executive Office of the Governor that are available to the agency 3 weeks prior to publication of the fixed need pool.

<u>3.4.</u> OP = the number of operational adult open heart surgery programs in the district.

(c) Regardless of whether need for <u>additional</u> a new adult open heart surgery programs is shown in paragraph (b) above, <u>need for one</u> a new adult open heart surgery program is demonstrated for a county that meets the following criteria:

<u>1. None of the hospitals in the county has an existing or approved open heart surgery program:</u>

2. Residents of the county are projected to generate at least 1200 annual hospital discharges with a principal diagnosis of ischemic heart disease, as defined by ICD-9-CM codes 410.0 through 414.9. The projected number of county residents who will be discharged with a principal diagnosis of ischemic heart disease will be determined as follows:

PIHD = (CIHD/CoCPOP X CoPPOP)

where:

<u>PIHD = the projected 12-month total of discharges with a</u> <u>principal diagnosis of ischemic heart disease for residents of</u> <u>the county age 15 and over;</u>

<u>CIHD = the most recent 12-month total of discharges with</u> <u>a principal diagnosis of ischemic heart disease for residents of</u> <u>the county age 15 and over, as available in the agency's</u> <u>hospital discharge data base:</u>

<u>CoCPOP = the current estimated population age 15 and</u> over for the county, included as a component of CPOP in subparagraph 7(b)2.;

 $\underline{\text{CoPPOP}}$ = the planning horizon estimated population age 15 and over for the county, included as a component of PPOP in subparagraph 7(b)2.

If the result is 1200 or more, need for one adult open heart surgery program is demonstrated for the county will not normally be approved for a district if the approval would reduce the 12 month total at an existing adult open heart surgery program in the district below 350 open heart surgery operations. In determining whether this condition applies, the agency will calculate (Ue X Px)/(OP + 1). If the result is less than 350 no additional open heart surgery program shall normally be approved.

(d) County-specific need identified under paragraph (c) is a need occurring because of the special circumstances in that county, and exists independent of, and in addition to, any district need identified under the provisions of paragraph (b).

(e) A program approved pursuant to need identified in paragraph (c) will be included in the subsequent identification of approved and operational programs in the district, as specified in paragraph (a).

(8) No change.

Specific Authority <u>408.034(5)</u>, 408.15(8) <u>408.034(3)(5)</u> FS. Law Implemented 408.034(3), <u>408.035</u>, 408.036(1)(<u>f)(e)</u>(h) FS. History–New 1-1-77, Amended 11-1-77, 6-5-79, 4-24-80, 2-1-81, 4-1-82, 11-9-82, 2-14-83, 4-7-83, 6-9-83, 6-10-83, 12-12-83, 3-5-84, 5-14-84, 7-16-84. 8-30-84, 10-15-84, 12-25-84, 4-9-85, Formerly 10-5.11, Amended 6-19-86, 11-24-86, 1-25-87, 3-2-87, 3-12-87, 6-11-87, 8-11-87, 8-7-88, 8-28-88, 9-12-88, 4-19-89, 10-19-89, 5-30-90, 7-11-90, 8-6-90, 10-10-90, 12-23-90, Formerly 10-5.011(1)(f), Amended 1-26-92, Formerly 10-5.033, Amended 6-17-93, 8-24-93.

NAME OF PERSON ORIGINATING PROPOSED RULE: Jeff Gregg, Chief, Health Facility Regulation

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Ruben J. King-Shaw, Jr., Secretary, Agency for Health Care Administration

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 11, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 6, 2000

AGENCY FOR HEALTH CARE ADMINISTRATION

Certificate of Need

RULE TITLES:	RULE NOS.:
Certificate of Need Application Procedures	59C-1.008
Certificate of Need Application	

59C-1.010 **Review Procedures** PURPOSE AND EFFECT: Section 408.039(3)(a), Florida Statutes, requires an applicant for a certificate of need (CON) to provide a copy of the application to the Local Health Council. No deadline for this action is specified in statute. Existing Rules 59C-1.008(1)(f)1. and 59C-1.008(4) specify that the Local Health Council must receive a copy of the CON application no later than 5 p.m. on the same day that the application must be submitted to the agency. Additionally, existing Rules 59C-1.010(3)(a)3. and 59C-1.010(4)(d)3. require that a copy of the applicant's additional information, submitted in response to omissions in the CON application, must be received by the Local Health Council no later than 5 p.m. on the same day that the omissions response must be submitted to the agency. There is no specific statutory requirement for submission to the Local Health Council.

These rules also state that the agency cannot accept an application for review, or must withdraw the application from review, if the Local Health Council fails to receive a copy of the application and the omissions response by the deadlines specified.

The proposed rule amendments eliminate the language that prohibits the agency from proceeding with review of the application and review of the omissions response. To ensure that the local health councils remain informed about proposals submitted for CON review, and can fulfill obligations specified in s. 408.033(1)(b) and (c), F.S., the proposed amendments specify that the applicant must provide a copy of the application and the omissions response to the Local Health Council bearing a postmark or shipping date that is no later than the agency's deadline dates.

The amendments also correct references to the agency Director appearing elsewhere in Rule 59C-1.010.

SUMMARY: The amendments revise the applicant's deadline for submitting a completed CON application to the Local Health Council, and allow the agency to proceed with review independent of deadlines for submission to the Local Health Council.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: None 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: 408.034(5), 408.15(8) FS.

LAW IMPLEMENTED: 408.033(1)(b),(c), 408.039(3) 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: 2:00 p.m., January 17, 2001

PLACE: Agency for Health Care Administration, 2727 Mahan Drive, Building 3, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: John Davis, Certificate of Need Office, 2727 Mahan Drive, Tallahassee, Florida

THE FULL TEXT OF THE PROPOSED RULES IS:

59C-1.008 Certificate of Need Application Procedures.

(1) Letters of Intent and applications subject to comparative review shall be accepted in two batching cycles annually each for hospital projects, and for nursing facility projects, as specified in paragraph (g) of this subsection. All other projects subject to comparative review shall be reviewed in the hospital batching cycle. "All other projects" include projects by or for hospices and intermediate care facilities for the developmentally disabled.

(a) through (e) No change.

(f) Certificate of Need Application Submission. An application for a certificate of need shall be submitted on AHCA Form CON-1, July 2000, which includes Schedules A or A-Trn, B or B-Trn, C, D, D-1, 1 or 1-Trn, 2, 3, 4, 5, 6, 6A, 7, 7A, 7B, 8, 8A, 9, 10, and 11-Trn which are incorporated by reference herein. A copy of Form CON-1 and the Schedules may be obtained from:

Agency for Health Care Administration Certificate of Need

2727 Mahan Drive, Building 3

Tallahassee, FL 32308

1. The application must be actually received by the agency by 5 p.m. local time and a copy must actually be received by the local health council by 5 p.m. local time on or before the application due date. The Local Health Council must receive a copy of the application bearing a postmark or shipping date that is no later than the application due date.

2. An application submitted to the agency shall not be accepted by the agency, and the application fee will be returned if a copy of the application is not received by the appropriate local health council as provided above.

<u>2.3.</u> Applications for projects which exceed the proposed number of beds contained in the letter of intent shall not be deemed complete for review by the agency.

<u>3.4.</u> Applications may propose a lesser number of beds than that contained in the letter of intent.

(g) through (3) No change.

(4) Submission to Local Health Council. Each applicant shall submit a copy of its application to the applicable Lłocal <u>Hh</u>ealth Ceouncil consistent with the requirements established <u>under subsection (1)(f)1. of this rule</u> at the same time the application is submitted to the agency. Failure to timely file with the local health council as set forth in paragraph (1)(f) of this rule will result in the application not being accepted by the agency.

(5) through (6) No change.

Specific Authority 408.034(5), 408.15(8) FS. Law Implemented <u>408.033</u>, 408.037, 408.038, 408.039 FS. History–New 1-1-77, Amended 11-1-77, 9-1-78, 6-5-79, 2-1-81, 4-1-82, 7-29-82, 9-6-84, Formerly 10-5.08, Amended 11-24-86, 3-2-87, 6-11-87, 11-17-87, 3-23-88, 5-30-90, 12-20-90, 1-31-91, 9-9-91, 5-12-92, 7-1-92, 8-10-92, Formerly 10-5.008, Amended 4-19-93, 6-23-94, 10-12-94, 10-18-95, 2-12-96, 7-18-96, 9-16-96, 11-4-97, 7-21-98, 12-12-00.

59C-1.010 Certificate of Need Application Review Procedures.

(1) through (2) No change.

(3) Comparative Review. Applications subject to comparative review shall be reviewed according to the following timetable:

(a) Completeness Review.

1. Within 15 calendar days after the application submission deadline promulgated under rule 59C-1.008(1)(g), F.A.C., the agency shall determine whether the application is complete.

2. If the application is deemed incomplete by the agency, the agency shall request in writing from the applicant specific information necessary for the application to be deemed complete.

3. If an applicant does not provide the specific additional information required by statute and rule in writing to the agency and the Local Health Council within 21 calendar days of the receipt of the agency's request, the application shall be deemed withdrawn from consideration. The applicant's response must be received by the agency and the Local Health Council no later than 5 p.m. local time on or before the omissions due date promulgated under Rule 59C-1.008(1)(g), F.A.C. The Local Health Council must receive a copy of the additional information bearing a postmark or shipping date that is no later than the omissions due date.

(b) through (d) No change.

(4) Expedited Review. Applications subject to expedited review shall be reviewed according to the following timetable:

(a) through (c) No change.

(d) Completeness Review.

1. Within 15 calendar days of receipt of an application by the agency, the agency shall determine whether the application is complete.

2. If the application is deemed incomplete by the agency, the agency shall request in writing from the applicant specific information necessary for the application to be deemed complete.

3. If an applicant does not provide the specific additional information required by statute and rule in writing to the agency and the Local Health Council within 21 calendar days of the receipt of the agency's request, the application shall be deemed withdrawn from consideration. The Local Health Council must receive a copy of the additional information bearing a postmark or shipping date that is no later than the omissions due date.

(e) through (g) No change.

(5) Issuance of State Agency Action Report.

(a) No change.

(b) If there is no challenge to all or any part of the agency decision embodied in the State Agency Action Report within 21 days after the publication of the notice of intent, consistent with section 59C-1.012, F.A.C., the State Agency Action Report shall become the final order of the agency. The certificate of need shall be signed by the <u>Secretary Director</u> of the agency or his designee and shall become effective on the date when the final order is filed in the Office of the Agency Clerk.

(c) If a request for an administrative hearing is filed timely, and a final order is subsequently entered which grants a certificate of need in whole or in part, a certificate of need shall be signed by the <u>Secretary Director</u> of the agency or his designee. The certificate of need shall become effective on the date when the final order is filed in the Office of the Agency Clerk. The agency shall provide a copy of the final order to the local health councils.

(d) through (7) No change.

Specific Authority 408.034(5), 408.15(8) FS. Law Implemented <u>408.033(1)</u>, 408.036(2), 408.039(3),(4) FS. History–New 1-1-77, Amended 11-1-77, 9-1-78, 6-5-79, 4-25-80, 2-1-81, 3-31-82, 12-23-82, Formerly 10-5.10, Amended 11-24-86, 11-17-87, 3-23-88, 8-28-88, 1-31-91, 7-1-92, 7-14-92, Formerly 10-5.010, Amended 10-8-97, 12-12-00_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Jeff Gregg, Chief, Health Facility Regulation

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Liz Dudek, Assistant Deputy Director, Managed Care and Health Quality

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 7, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 9, 2000

AGENCY FOR HEALTH CARE ADMINISTRATION

Certificate of Need

RULE TITLES:	RULE NOS.:
Acquisition of Health Care Facilities	59C-1.023
Medicare Certified Home Health Agencies	59C-1.031

Medicare Certified Home Health Agencies 59C-1.031 PURPOSE AND EFFECT: Statutory changes effective July 1, 2000 eliminated former s. 408.036(1)(h), F.S., which required certificate of need (CON) review of the acquisition of a health care facility under specified circumstances; and eliminated former s. 408.036(1)(e), F.S., which required CON review of the establishment of a Medicare-certified home health agency. The repeal of Rules 59C-1.023 and 59C-1.031 eliminates rules adopted to implement the former statutory requirements. Repeal of 59C-1.023 does not eliminate the need for notification to the CON Office when there is an application for licensure that would change the licensed operator of an existing hospital or nursing home.

SUMMARY: The repeals reflect statutory changes which eliminated CON review of proposed acquisition of a health care facility and review of proposed establishment of a Medicare-certified home health agency.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: None 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: 408.034(5), 408.15(8) FS.

LAW IMPLEMENTED: 408.036(1)(e),(h) 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: 3:00 p.m., January 17, 2001

PLACE: Agency for Health Care Administration, 2727 Mahan Drive, Building 3, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: John Davis, Certificate of Need Office, 2727 Mahan Drive, Tallahassee, Florida

THE FULL TEXT OF THE PROPOSED RULES IS:

59C-1.023 Acquisition of Health Care Facilities.

Specific Authority 408.034(5), 408.036(1)(i) FS. Law Implemented 408.032, 408.034, 408.036(1)(i) FS. History–New 7-25-89, Amended 5-15-90, Formerly 10-5.023, Repealed_____.

59C-1.031 Medicare Certified Home Health Agencies.

Specific Authority 408.034(5), 408.15(8) FS. Law Implemented 408.034(3), 408.036(1)(f) FS. History–New 1-1-77, Amended 11-1-77, 6-5-79, 4-24-80, 2-1-81, 4-1-82, 11-9-82, 2-14-83, 4-7-83, 6-9-83, 6-10-83, 12-12-83, 3-5-84, 5-14-84, 7-16-84. 8-30-84, 10-15-84, 12-25-84, 4-9-85, Formerly 10-5.11, Amended 6-19-86, 11-24-86, 1-25-87, 3-2-87, 3-12-87, 6-11-87, 8-7-88, 8-28-88, 9-12-88, 4-19-89, 10-19-89, 5-30-90, 7-11-90, 8-6-90, 10-10-90, 12-23-90, Formerly 10-5.011(1)(d), Amended 1-26-92, Formerly 10-5.031, Amended 6-17-93, 8-24-93, 4-17-97, Repealed

NAME OF PERSON ORIGINATING PROPOSED RULE: Jeff Gregg, Chief, Health Facility Regulation

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Liz Dudek, Assistant Deputy Director, Managed Care and Health Quality

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 7, 2000

AGENCY FOR HEALTH CARE ADMINISTRATION

Medicaid

RULE TITLE: RULE NO.:
Outpatient Hospital Services 59G-4.160
PURPOSE AND EFFECT: The purpose of this rule
development is to incorporate by reference the Florida
Medicaid Hospital Coverage and Limitations Handbook, May
2000. The handbook revision incorporates Florida legislature's
July 1, 2000, increase of the outpatient hospital cap from
\$1000 to \$1500 for adult Medicaid recipients. It includes
narrative revisions of existing policy in Chapters 1, 2, and 3,
deleting unnecessary and duplicative language, realignment of
topics, and rewording policy items for greater clarity.
Appendices B through J in the handbook contain codes for
different billing circumstances and all have been updated with
current year 2000 code revisions, effective January 1, 2000.
Portions of Appendix K have been deleted and certain
narrative sections have been reworded for greater clarity. The
effect will be to incorporate by reference in the rule the current
Florida Medicaid Hospital Coverage and Limitation
Handbook. The rule development is also for the purpose of
repealing portions of the rule that are duplicated in the
Medicaid handbooks, other Medicaid rules of general
applicability, Florida Statutes, or federal regulations. The

effect will be to incorporate by reference in the rule the current Florida Medicaid Hospital Coverage and Limitations Handbook and to eliminate duplication.

SUMMARY: The proposed rule incorporates by reference the Florida Medicaid Hospital Coverage and Limitations Handbook, May 2000. The handbook is revised to incorporate the outpatient hospital cap increase approved by the Florida Legislature, from \$1000 to \$1500, effective July 1, 2000. The policy narrative in Chapters 1, 2, and 3 is revised to reflect current and existing policy; delete unnecessary or duplicative language; realign topics for easier reading; reword policy items for greater clarity. Appendices B through J contain codes for different billing circumstances and have been updated with current year 2000 code revisions, effective January 1, 2000. Portions of Appendix K have been deleted and certain narrative sections have been reworded for greater clarity.

The rule promulgation is also for the purpose of repealing portions of the rule that are duplicated in the Medicaid handbooks, other Medicaid rules of general applicability, Florida Statutes, or federal regulations.

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: 409.919 FS.

LAW IMPLEMENTED: 409.905, 409.908, 409.9081 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: 9:00 – 10:00 a.m., January 8, 2001

PLACE: 2728 Fort Knox Boulevard, Building 3, Conference Room C, Tallahassee, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Ouida Mazzoccoli, Medical/Health Care Program Analyst, Medicaid Program Development Office, 2728 Fort Knox Boulevard, Building 3, Tallahassee, FL 32308, (850)922-7351

THE FULL TEXT OF THE PROPOSED RULE IS:

(Substantial rewording of 59G-4.160 follows. See Florida Administrative Code for present text.)

59G-4.160 Outpatient Hospital Services.

(1) This rule applies to all hospital providers enrolled in the Medicaid program.

(2) All hospital providers enrolled in the Medicaid program must comply with the Florida Medicaid Hospital Coverage and Limitations Handbook, May 2000, and the Florida Medicaid Provider Reimbursement Handbook, UB-92, October 1998, both incorporated by reference in this rule. Both handbooks are available from the fiscal agent contractor.

Specific Authority 409.919 FS. Law Implemented 409.905, 409.908, 409.9081 FS. History–New 1-1-77, Revised 12-7-78, 1-18-82, Amended 7-1-83, 7-16-84, 7-1-85, 10-31-85, Formerly 10C-7.40, Amended 9-16-86, 2-28-89, 5-21-91, 5-13-92, 7-12-92, 1-5-93, 6-30-93, 7-20-93, 12-21-93, Formerly 10C-7.40, Amended 6-13-94, 12-27-94, 2-21-95, 9-11-95, 11-12-95, 2-20-96, 10-27-98, 5-12-99, 10-18-99,

NAME OF PERSON ORIGINATING PROPOSED RULE: Ouida Mazzoccoli

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Ruben King-Shaw, Jr., AHCA Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 8, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: September 15, 2000

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Electrical Contractors Licensing Board

RULE TITLE:

RULE NO.:

Continuing Education Exemption for Spouses

of Military Personnel 61G6-9.0105 PURPOSE AND EFFECT: The Board proposes to promulgate a new rule that will set forth the requirements for continuing education exemption for spouses of military personnel.

SUMMARY: This rule elucidates the continuing education requirement of a licensed spouse of a member of the armed forces.

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: 489.507(3) FS.

LAW IMPLEMENTED: 489.507(3), 489.517 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE NEXT AVAILABLE ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Anthony Spivey, Executive Director, Electrical Contractors Licensing Board, Northwood Centre, 1940 N. Monroe Street, Tallahassee, Florida 32399-0750 THE FULL TEXT OF THE PROPOSED RULE IS:

<u>61G6-9.0105</u> Continuing Education Exemption for Spouses of Military Personnel.

A licensee who is the spouse of a member of the Armed Forces of the United States and was caused to be absent from the State of Florida because of the spouse's duties with the armed forces shall be exempt from all licensure renewal provisions under these rules during such absence. The licensee must show proof to the Board of the absence and the spouse's military status.

Specific Authority 489.507(3) FS. Law Implemented 489.507(3), 489.517 FS. History-New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Electrical Contractors' Licensing Board

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Electrical Contractors' Licensing Board

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 19, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: September 8, 2000

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Engineers

RULE TITLE:	RULE NO.:
Definitions	61G15-18.011
DUDDORE AND EFFECT. The	

PURPOSE AND EFFECT: The purpose is to amend this rule to delete rule text that is not necessary.

SUMMARY: The Board has determined that it is necessary to amend this rule to delete subsection (5) of this rule because it is no longer desired by the Board.

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: 471.008, 471.003(2)(f), 471.013(1)(a)1.,2. FS.

LAW IMPLEMENTED: 471.005(6), 471.025(3), 471.033(1)(j), 471.003(2)(f), 471.013(1)(a)1., 2. FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE NOTICED IN THE NEXT ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Natlie Lowe, Administrator, Board of Professional Engineers, 1208 Hays Street, Tallahassee, Florida 32301

THE FULL TEXT OF THE PROPOSED RULE IS:

61G15-18.011 Definitions.

(1) through (4) No change.

(5) A "registered engineer whose principal practice is civil or structural engineering," as used in the ss. 471.003(3) and 481.229(4), F.S., shall mean an engineer licensed in Florida who either has a degree in civil or structural engineering, or has successfully completed the principles and practice examination in either discipline.

Specific Authority 471.008, 471.003(2)(f), 471.013(1)(a)1.,2. FS. Law Implemented 471.005(6), 471.025(3), 471.033(1)(j), 471.003(2)(f), 471.013(1)(a)1., 2. FS. History–New 6-23-80, Amended 12-19-82, 11-22-83, Formerly 21H-18.11, Amended 1-16-91, 4-4-93, Formerly 21H-18.011, Amended 12-22-99.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Professional Engineers

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 5, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 27, 2000

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Engineers

RULE TITLE:

RULE NO .:

State of Florida, Security Policies,

Procedures and Guidelines 61G15-21.008 PURPOSE AND EFFECT: The Board is repealing this rule because the rule is no longer desired by the Board.

SUMMARY: Repeal of Rule 61G15-21.008.

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: 120.54(8), 455.217 FS.

LAW IMPLEMENTED: 455.217 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE NOTICED IN THE NEXT AVAILABLE ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Natlie Lowe, Administrator, Board of Professional Engineers, 1208 Hays Street, Tallahassee, Florida 32301

THE FULL TEXT OF THE PROPOSED RULE IS:

61G15-21.008 State of Florida, Security Policies, Procedures and Guidelines.

Security procedures for the Professional Engineers Examination given in the State of Florida shall be those contained in the State of Florida, Security Policies, Procedures, and Guidelines booklet incorporated herein by reference.

Specific Authority 455.217, 120.54(8) FS. Law Implemented 455.217 FS. History–New 7-14-82, Formerly 21H-21.08, 21H-21.008, Repealed

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Professional Engineers

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Professional Engineers DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 5, 2000

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Engineers RULE TITLE:

RULE TITLE:RULE NO.:Continuing Education Requirements for
Reactivation of Inactive License61G15-22.001

PURPOSE AND EFFECT: The purpose is to amend this rule to change the score to a percentage.

SUMMARY: The Board has determined that it is necessary to amend this rule to change the score from 36 to 90%.

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: 471.019(2) FS.

LAW IMPLEMENTED: 471.019(2) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE NOTICED IN THE NEXT ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Natlie Lowe, Administrator, Board of Professional Engineers, 1208 Hays Street, Tallahassee, Florida 32301

THE FULL TEXT OF THE PROPOSED RULE IS:

61G15-22.001 Continuing Education Requirements for Reactivation of Inactive License.

A license which has been inactive for more than one year may be reactivated upon application to FEMC and demonstration to the Board by the licensee of having attended twelve hours of engineering related education per inactive year. The education shall be related to the licensee's field of practice. Of the first twelve hours of such education, at least four shall involve the law and rules governing the practice of engineering in a course approved by the Board. Completion of the Board's Study Guide with a score of <u>90%</u> 36 or above shall satisfy the laws and rules requirement. Licensees who can demonstrate that they have continued the active practice of engineering during the inactive period, either through an active license to practice in another state or through practice in an exempt setting during that period, shall only be required to comply with the laws and rules requirement. Verification of the above-mentioned education shall be in the form of tuition or registration receipts, records, or letters of verification from the institutions or entities providing the training in question.

Specific Authority 471.019(2) FS. Law Implemented 471.019(2) FS. History– New 8-19-80, Formerly 21H-22.01, Amended 5-14-86, Formerly 21H-22.001, Amended 6-22-99, 6-13-00._____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Professional Engineers

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 5, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 2, 2000

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Engineers

RULE TITLE:RULE NO.:Seal, Signature and Date Shall be Affixed61G15-23.002PURPOSE AND EFFECT: The purpose of these ruleamendments is to update the rule text with regard to signingand sealing documents.

SUMMARY: The Board proposes to amend this rule to include final bid documents and the requirements for a title block, and the sealing of plans.

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: 471.025 FS.

LAW IMPLEMENTED: 471.025 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE NOTICED IN THE NEXT ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY. THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Natlie Lowe, Administrator, Board of Professional Engineers, 1208 Hays Street, Tallahassee, Florida 32301

THE FULL TEXT OF THE PROPOSED RULE IS:

61G15-23.002 Seal, Signature and Date Shall be Affixed.

(1) A professional engineer shall sign his name and affix his seal to all plans, specifications, reports, <u>final bid documents</u> <u>provided to the owner or the owner's representative</u>, or other documents prepared or issued by said registrant and being filed for public record. The date that the signature and seal is affixed as provided herein shall be entered on said plans, specifications, reports, or other documents immediately under the signature of the professional engineer.

(2) Each sheet of plans and prints which must be sealed under the provisions of Chapter 471 shall be sealed, signed and dated by the professional engineer in responsible charge. Engineers shall legibly indicate their name, address, and license number on each sheet. If practicing through a duly authorized engineering business, engineers shall legibly indicate their name and license number, as well as, the name, address, and certificate of authorization number of the engineering business number shall be legibly indicated on each sheet. A title block on each sheet containing the printed name, address, and license number of the engineer or if applicable, the name and license number of the engineer, and the name, address and certificate of authorization number of the engineering business will satisfy this requirement. Engineers working for local, State or Federal Government agencies shall legibly indicate their name and license number, and may indicate the name and address of the agency. A cover or index sheet for engineering specifications may be used and that sheet must be signed, sealed and dated by those professional engineers in responsible charge of the production and preparation of each section of the engineering specification or other engineering document with sufficient information on the cover sheet or index so that the user will be aware of each portion of the specifications for which each professional engineer is responsible. Engineering reports must be signed, sealed and dated on a signature page or cover letter by each professional engineer who is in responsible charge of any portion of the report. A professional engineer may only seal an engineering report, plan, print or specification if that professional engineer was in responsible charge of the preparation and production of the engineering document and the professional engineer has the expertise in the engineering discipline used in producing the engineering document in question.

(3) No change.

(4) A professional engineer should not seal preliminary plans which are not intended for permit, construction, or bidding purposes. If a permitting agency requires that preliminary plans submitted for review purposes be signed and sealed, then the engineer should clearly note such limitations on the face of the plans, by using terms such as "Preliminary." "For Review Only," "Not for Construction," or any other suitable statement which denotes that the documents are for design review only and are not intended for permit, construction, or bidding purposes.

(5)(4) Engineers who wish to sign and seal electronically transmitted plans, specifications, reports, <u>final bid documents</u>, or other documents shall follow the procedures set forth in Rule 61G15-23.003, F.A.C.

Specific Authority 471.025 FS. Law Implemented 471.025 FS. History–New 1-8-80, Amended 1-20-85, Formerly 21H-23.02, Amended 5-14-86, Formerly 21H-23.002, Amended 11-15-94, 8-18-98, 2-3-00,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Professional Engineers

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 18, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 2, 2000

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Engineers

RULE TITLE:

RULE NO.:

Design of Structures Utilizing Prefabricated

Relline

Wood Components 61G15-31.003 PURPOSE AND EFFECT: The purpose of the rule amendments is to update the rule text with regard to a truss design package.

SUMMARY: The Board proposes to amend the rule text to add additional rule text which will include information for a truss design package and the requirements.

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: 471.033(2), 471.008 FS.

LAW IMPLEMENTED: 471.033(1)(g) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE NOTICED IN THE NEXT AVAILABLE ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Natlie Lowe, Administrator, Board of Professional Engineers, 1208 Hays Street, Tallahassee, Florida 32301 THE FULL TEXT OF THE PROPOSED RULE IS:

61G15-31.003 Design of Structures Utilizing Prefabricated Wood Components.

(1) Apportionment of responsibilities between Structural Engineer of Record (Building Designer) and Delegated Engineer (Truss Designer) shall be as set forth in Chapter 2 of ANSI/TPI 1-1995.

(2) In the case of a truss design package, a cover or index sheet may be signed and sealed in lieu of signing and sealing each individual sheet, provided that the cover or index sheet contains the following information:

(a) The name, address and license number of the Engineer of Record for the truss design package.

(b) Identification of the project, name of the authority having jurisdiction (City, County), the loads, and the name and date of the applicable building code that the truss design is intended to meet and all loads imposed on the structure.

(c) Truss engineering design criteria with full identification of the source of the criteria. The source will be either the Engineer of Record (if there is an Engineer of Record for the structural engineering documents), or the engineer employed by the truss manufacturer. If there is an Engineer of Record for the structural engineering documents, that engineer shall be identified with his/her name, license number and address, along with a checkmark to ensure that the drawings have been reviewed as required by Rule 61G15-30.006(3).

(d) A truss layout plan by the Engineer of Record showing the location and designation of each component.

(e) Identification of the computer program used for engineering the trusses.

(f) An index of the attached drawings. The naming and numbering system utilized for the drawings shall be clear as to how many drawings there are in the set and the date of each of these drawings.

(g) Each of the drawings in the package shall bear a title block bearing the printed name, address, and license number of the Engineer of Record for the truss design, and the date of the drawing.

Specific Authority 471.033(2), 471.008 FS. Law Implemented 471.033(1)(g) FS. History–New 1-26-93, Formerly 21H-31.003, Amended 6-16-99.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Professional Engineers

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 6, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 17, 2000

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Geologists

RULE TITLE:	RULE NO.:
Definitions	61G16-1.009
PURPOSE AND EFFECT: The J	purpose and effect of the rule

is to establish procedures for "Long-term, ongoing relationship."

SUMMARY: The rule provides guidelines for "Long-term, ongoing relationship".

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: None.

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: 492.104 FS.

LAW IMPLEMENTED: 492.105 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: D. A. O'Connor, Executive Director, Board of Professional Geologists, 1940 North Monroe Street, Tallahassee, Florida 32399-0750

THE FULL TEXT OF THE PROPOSED RULE IS:

61G16-1.009 Definitions.

As used in Chapter 492 and in these rules where the context will permit the following terms have the following meanings:

(1) "Responsible Position" shall mean direct control and personal supervision of geological work done by oneself or by others over whom which the applicant exercises supervisory authority.

(2) "Long-term, ongoing relationship" shall mean a contractual relationship between the professional geologist and the firm, corporation, or partnership, in which the professional geologist performed or is responsible for the supervision, direction, or control of the work contained in the geological papers, reports, or documents that are signed, dated, and sealed by the professional geologist.

Specific Authority 492.104 FS. Law Implemented 492.105<u>492.111</u> FS. History–New 4-27-88, Formerly 21DD-1.009, Amended 11-15-93, 5-14-97.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Professional Geologists

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 24, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 10, 2000

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Professional Geologists

Procedures for Signing and Sealing Geological

RULE TITLE:

RULE NO.:

Paper, Reports, or Other Documents 61G16-2.005 PURPOSE AND EFFECT: The purpose of the rule amendments is to update the rule text with regard to the procedures for signing and sealing geological papers, reports, or other documents.

SUMMARY: The rule amendment is for the purpose of updating procedures for signing and sealing geological paper, reports, or other documents.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: None.

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: 282.75, 492.104, 492.107 FS.

LAW IMPLEMENTED: 282.75, 492.107 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: D. A. O'Connor, Executive Director, Board of Professional Geologists, 1940 North Monroe Street, Tallahassee, Florida 32399-0750

THE FULL TEXT OF THE PROPOSED RULE IS:

61G16-2.005 Procedures for Signing and Sealing Geological Papers, Reports, or Other Documents.

(1) All geological papers, reports, or other documents prepared or issued by a licensed professional geologist shall be signed, dated, and sealed by the professional geologist who performed or is responsible for the supervision, direction, or control of the work contained in the papers, reports, or documents actually prepared the geological papers, reports, or documents or who had direct responsibility for the supervision, direction, or control of their preparation.

(2) through (4) No change.

Specific Authority 282.75, 492.104, 492.107 FS. Law Implemented 282.75, 492.107 FS. History–New 2-9-00, Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Professional Geologists

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Professional Geologists DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 24, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 10, 2000

DEPARTMENT OF ENVIRONMENTAL PROTECTION

Division of Beaches and Shores	
RULE CHAPTER TITLE:	RULE CHAPTER NO.:
Setback Line	62B-26
RULE TITLE:	RULE NO.:
Description of the Pinellas County	

Coastal Construction Control Line 62B-26.011 PURPOSE AND EFFECT: To amend rule 62B-26.011, reestablishing the Pinellas County Coastal Construction Control Line to more accurately define that portion of the beach dune system which is subject to severe fluctuations based upon the 100-year storm surge and storm waves, and thus define the area within which special siting and design considerations are required to ensure protection of the beach dune system, proposed or existing structures, adjacent properties, and the preservation of public beach access.

SUMMARY: The proposed rule amendments consist of a legal description of the location of the Coastal Construction Control Line in Pinellas County.

SUMMARY OF STATEMENT OF **ESTIMATED REGULATORY COST:** The estimated cost to the Department for administration of the coastal construction control line program for the affected properties in Pinellas County was calculated as \$148,969. One-time costs for rulemaking including staffing, advertising, professional fees, travel, and notice for three public hearings, inclusive, are estimated to be approximately \$637,899. Upon reestablishment of the Pinellas County Coastal Construction Control Line, construction, excavation or alteration on property seaward of such line will be subject to the requirements of section 161.053, Florida Statutes and chapter 62B-33, Florida Administrative Code. Thus, developers of property will incur higher construction and regulatory costs and will benefit only as member of the general public or only if they intend to live in the constructed units. Owners of developed property will directly benefit through a lessened chance of damage to property and a lower probability of damage from adjacent properties. The general public will not bear direct costs and will receive certain benefits, including preservation of the beach dune system, less damage due to storm waves, and lower costs for disaster relief. This rule has no economic impact on those properties seaward of the existing Pinellas County Coastal Construction Control Line, as established in 1979.

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: 161.053, 370.021 FS.

LAW IMPLEMENTED: 161.053, 370.021 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:

TIME AND DATE: 1:00 p.m., January 30, 2001

PLACE: Pinellas County, City Hall, Commission Chambers, 112 S. Osceola Ave., Clearwater, FL

If accommodation for a disability is needed to participate in this activity, please notify Rosaline Beckham, (850)487-1262, Extension 186, or 1(800)955-8771 (TDD), or 1(800)955-8770 (Voice), VIA, Florida Relay Service, at least seven days before the meeting.

Aerial photo maps depicting the coastal construction control line, as recommended, a copy of the Statement of Estimated Regulatory Cost, a copy of the Pinellas County Storm Surge Model Study, a copy of the Pinellas County Coastal Construction Control Line Study, and a copy of the proposed rule, section 62B-26.011, Florida Administrative Code, are available for inspection at the Office of Beaches and Coastal Systems, 5050 West Tennessee Street, Capital Center, Building B, Tallahassee, Florida and commencing December 22, 2000, will be on display at the following locations:

Belleair	Belleair Beach	Clearwater
Town Hall, Lobby	Town Hall, Lobby	112 S. Osceola Ave.
901 Ponce de Leon Blvd.	444 Causeway Blvd	City Hall, Lobby.
Indian Rocks Beach	Indian Shores	Madeira Beach
1507 Bay Palm Blvd.	19305 Gulf Blvd.	300 Municipal Dr.
Town Hall, Auditorium	Town Hall, Auditorium	Town Hall, Lobby
North Redington Beach	Redington Beach	Redington Shores
190 173rd Ave.	105 164th Ave.	17725 Gulf Blvd.
Town Hall, Lobby	Town Hall, Lobby	Town Hall, Lobby
St. Pete Beach	Treasure Island	
7701 Boca Ciega Dr.	120 108th Ave.	
Town Hall, Lobby	Town Hall, Auditorium	
Town Hall, Auditorium North Redington Beach 190 173rd Ave. Town Hall, Lobby St. Pete Beach 7701 Boca Ciega Dr.	Town Hall, Auditorium Redington Beach 105 164th Ave. Town Hall, Lobby Treasure Island 120 108th Ave.	Town Hall, Lobby Redington Shores 17725 Gulf Blvd.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Rosaline Beckham, Environmental Specialist, The Florida Department of Environmental Protection, Office of Beaches and Coastal Systems, Mail Station #300, Tallahassee, Florida 32399-3000, (850)487-1262, Extension 186

THE FULL TEXT OF THE PROPOSED RULE IS:

(Substantial rewording of 62B-26.011 follows. See Florida Administrative Code for current text.)

62B-26.011 Description of the Pinellas County Coastal Construction Control Line.

(1) There is hereby established, pursuant to Section 161.053, Florida Statutes, the Pinellas County Coastal Construction Control Line. The legal description of said line is attached hereto.

(2) This rule shall take effect on the date of filing with the Florida Department of State; and the rule shall be recorded in the public records in the office of the Clerk of the Circuit Court, in and for Pinellas County, Florida, together with each affected municipality.

(3) After this rule becomes effective, a permit under Section 161.053, Florida Statutes, and Chapter 62B-33, Florida Administrative Code, to alter, excavate or construct on property seaward of the established control line is required from the Department of Environmental Protection.

METES AND BOUNDS DESCRIPTION FOR THE COASTAL CONSTRUCTION CONTROL LINE PINELLAS COUNTY, FLORIDA

DESCRIPTION OF THE COASTAL CONSTRUCTION CONTROL LINE (CCCL) IS ESTABLISHED IN COMPLIANCE WITH SECTION 161.053 OF THE FLORIDA STATUTES. SAID CONTROL LINE LYING ALONG THE COAST OF THE GULF OF MEXICO FROM MEAN HIGH WATER LINE AT THE NORTHERN END OF HONEYMOON ISLAND SOUTHERLY TO THE MEAN HIGH WATER LINE AT THE SOUTHERN END OF HONEYMOON ISLAND. THENCE RECOMMENCING AT THE MEAN HIGH WATER LINE AT THE NORTHERN END OF CALADESI ISLAND SOUTHERLY TO THE NORTH MEAN HIGH WATER LINE OF DUNEDIN PASS. THENCE RECOMMENCING AT THE SOUTH MEAN HIGH WATER LINE OF DUNEDIN PASS SOUTHERLY TO THE NORTH MEAN HIGH WATER LINE OF LITTLE PASS. THENCE RECOMMENCING AT THE SOUTH MEAN HIGH WATER LINE OF LITTLE PASS SOUTHERLY TO THE NORTH MEAN HIGH WATER LINE OF JOHNS PASS. THENCE RECOMMENCING AT THE SOUTH MEAN HIGH WATER LINE OF JOHNS PASS SOUTHERLY TO THE NORTH MEAN HIGH WATER LINE OF BLIND PASS. THENCE RECOMMENCING AT THE SOUTH MEAN HIGH WATER LINE OF BLIND PASS SOUTHERLY TO THE NORTH MEAN HIGH WATER OF PASS-A-GRILLE CHANNEL. LINE THENCE RECOMMENCING AT THE SOUTH MEAN HIGH WATER LINE OF BUNCES PASS ON MULLET KEY SOUTHERLY AND EASTERLY TO ITS TERMINUS AT THE MEAN HIGH WATER LINE OF TAMPA BAY. SAID COASTAL CONSTRUCTION CONTROL LINE IS RELATED TO A SERIES OF "PERMANENT REFERENCE MONUMENTS" (P.R.M.) DESIGNATED AND HEREINAFTER REFERRED TO AS "15-90-DA01 THRU 15-90-DA03", "R001 PNLS 1990", "R022 PNLS 1974", "R032 PNLS 1974", "15-99-DA08A", "15-90-DA08", "R036 PNLS 1974". "15-99-DA07" "15-90-DA09" "15-99-DA10A", "15-99-DA11A", "NOS 6724 N". "15-77-B09A", "15-77-B09". "15-90-DA12". "15-90-DA12A" "15-99-DA13A" "R050 PNLS 1974". "15-99-DA13B", "1<u>5-90-DA14",</u> "15-99-DA15A THRU 15-99-DA15D", "15-90-DA16", "15-90-DA17", "15-90-DA17A". "NARROW-D", "15-90-DA17B", "NARROW 1973". "NARROW-F" "15-99-DA17D". "15-90-DA18", "15-99-DA17E" "15-90-DA19", "15-90-DA19A", "REDINGTON-B THRU REDINGTON-D", "15-90-DA20", "15-99-DA21B", "15-77-B08", "15-90-DA22 THRU 15-90-DA25", "RAINEY 1973", "MADERIA", "15-90-DA25A THRU 15-90-DA25C", "<u>15-90-DA26",</u> "15-90-DA27", "15-90-DA27A", "RAINEY-J", "RAINEY-K", 68". "15-90-DA27B", "PBE 144 "BLIND-D", "15-90-DA27D", "15-90-DA28". "15-90-DA29". "COE BLIND PASS", "PBE 133", "BLIND-P", "15-77-B04" "NOAA-D", "15-99-DA31", "NOAA 1973", "15-99-DA31A", "15-99-DA32", "NOAA-A", "NOS 6430 J 1988", "R170 PNLS 1974", "R172 PNLS 1990", "T174 PNLS 1977", "T177 "15-90-DA30". "DESOTO PNLS 1977", <u>1973",</u> "15-90-B01-2", "DESOTO-B".

MONUMENTS FOR ESTABLISHED BY THE DEPARTMENT OF ENVIRONMENTAL PROTECTION, STATE OF FLORIDA, OR REFERRED TO BY STATION NAME FOR MONUMENTS ESTABLISHED BY NATIONAL GEODETIC SURVEY (N.G.S.). SAID MONUMENTS PERMANENT REFERENCE ARE ESTABLISHED ON THE WEST ZONE OF THE STATE OF FLORIDA PLANE COORDINATE SYSTEM. ALL STATIONS IN THIS DESCRIPTION ARE BASED ON NORTH AMERICAN 1983 DATUM ADJUSTMENT OF 1990.

THE BEARING BASE FOR THIS DESCRIPTION IS GRID NORTH, DETERMINED BY GLOBAL POSITIONING SYSTEM (G.P.S.) OBSERVATIONS MADE AT ALL PERMANENT REFERENCE MONUMENTS (P.R.M.).

COMMENCE AT P.R.M. R001 PNLS 1990; THENCE S 34 DEG. 00 MIN. 00 SEC. E A DISTANCE OF 595.00 FEET TO THE POINT OF BEGINNING; THENCE N 16 DEG. 55 MIN. 07 SEC. E TO THE POINT OF INTERSECTION WITH THE MEAN HIGH WATER LINE OF SAINT JOSEPH SOUND. SAID POINT BEING THE NORTHERN TERMINUS OF THE COASTAL CONSTRUCTION CONTROL LINE FOR PINELLAS COUNTY; THENCE RETURN ALONG THE SAME COURSE TO THE POINT OF BEGINNING; SAID POINT BEING S 34 DEG. 00 MIN. 00 SEC. E A DISTANCE OF 595.00 FEET FROM (P.R.M.) R001 PNLS 1990.

THENCE S 16 DEG. 55 MIN. 07 SEC. W A DISTANCE OF 370.11 FEET TO A POINT; THENCE S 05 DEG. 40 MIN. 31 SEC. W A DISTANCE OF 661.90 FEET TO A POINT; THENCE S 06 DEG. 12 MIN. 57 SEC. W A DISTANCE OF 945.06 FEET TO A POINT; THENCE S 01 DEG. 31 MIN. 21 SEC. W A DISTANCE OF 1146.15 FEET TO A POINT; THENCE S 03 DEG. 42 MIN. 56 SEC. E A DISTANCE OF 763.91 FEET TO A POINT; THENCE S 00 DEG. 03 MIN. 53 SEC. E A DISTANCE OF 207.31 FEET TO A POINT; THENCE S 00 DEG. 37 MIN. 05 SEC. E A DISTANCE OF 1003.95 FEET TO A POINT; SAID POINT BEING N 44 DEG. 45 MIN. 09 SEC. E A DISTANCE OF 1512.10 FEET FROM P.R.M. 15-90-DA-01. THENCE S 27 DEG. 58 MIN. 45 SEC. E A DISTANCE OF 862.90 FEET TO A POINT; THENCE S 42 DEG. 09 MIN. 25 SEC. E A DISTANCE OF 1075.26 FEET TO A POINT; SAID POINT BEING N 73 DEG. 07 MIN. 36 SEC. E A DISTANCE OF 1429.70 FEET FROM P.R.M. 15-90-DA-02.

THENCE S 45 DEG. 42 MIN. 01 SEC. E A DISTANCE OF 1024.55 FEET TO A POINT; THENCE S 56 DEG. 30 MIN. 30 SEC. E A DISTANCE OF 1107.39 FEET TO A POINT; THENCE S 65 DEG. 18 MIN. 05 SEC. E A DISTANCE OF 663.85 FEET TO A POINT; SAID POINT BEING N 57 DEG. 18 MIN. 26 SEC. E A DISTANCE OF 1537.30 FEET FROM P.R.M. 15-90-DA-03.

THENCE S 65 DEG. 18 MIN. 09 SEC. E TO THE POINT OF INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE NORTHERN SHORE OF HURRICANE PASS; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 57 DEG. 18 MIN. 26 SEC. E A DISTANCE OF 1537.30 FEET FROM P.R.M. 15-90-DA03.

RECOMMENCE AT P.R.M. R022 PNLS 1974, THENCE N 37 DEG. 56 MIN. 38 SEC. E A DISTANCE OF 1031.43 FEET TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE; THENCE N 09 DEG. 14 MIN. 01 SEC. E TO THE INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE WESTERN SHORE OF SAINT JOSEPH SOUND; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 37 DEG. 56 MIN. 38 SEC. E A DISTANCE OF 1031.43 FEET FROM P.R.M. R022 PNLS 1974.

THENCE S 09 DEG. 06 MIN. 51 SEC. W A DISTANCE OF 954.86 FEET TO A POINT; THENCE S 33 DEG. 22 MIN. 48 SEC. W A DISTANCE OF 1092.11 FEET TO A POINT; THENCE S 19 DEG. 22 MIN. 56 SEC. W A DISTANCE OF 1021.21 FEET TO A POINT; THENCE S 27 DEG. 16 MIN. 23 SEC. E A DISTANCE OF 1588.30 FEET TO A POINT; THENCE S 13 DEG. 39 MIN. 47 SEC. W A DISTANCE OF 1009.83 FEET TO A POINT; THENCE S 22 DEG. 29 MIN. 50 SEC. W A DISTANCE OF 1005.17 FEET TO A POINT; THENCE S 22 DEG. 34 MIN. 25 SEC. W A DISTANCE OF 930.69 FEET TO A POINT; THENCE S 05 DEG. 06 MIN. 23 SEC. W A DISTANCE OF 940.49 FEET TO A POINT; THENCE S 03 DEG. 58 MIN. 35 SEC. W A DISTANCE OF 1017.58 FEET TO A POINT; SAID POINT BEING N 52 DEG. 31 MIN. 51 SEC. E A DISTANCE OF 1676.16 FEET FROM P.R.M. R032 PNLS 1974.

THENCE S 02 DEG. 38 MIN. 40 SEC. W TO THE POINT OF INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE NORTHERN SHORE OF DUNEDIN PASS. THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 52 DEG. 31 MIN. 51 SEC. E A DISTANCE OF 1676.16 FEET FROM P.R.M. R032 PNLS 1974.

RECOMMENCE AT P.R.M. 15-99-DA08A, THENCE S 40 DEG. 09 MIN. 26 SEC. W A DISTANCE OF 230.05 FEET TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE; THENCE N 08 DEG. 36 MIN. 10 SEC. E A DISTANCE OF 548.17 FEET TO A POINT; THENCE N 47 DEG. 59 MIN. 58 SEC. E TO THE POINT OF INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE SOUTHERN SHORE OF DUNEDIN PASS; THENCE RETURN ALONG THE SAME COURSES TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING S 40 DEG. 09 MIN. 26 SEC. W A DISTANCE OF 230.05 FEET FROM P.R.M. 15-99-DA08A.

THENCE S 04 DEG. 45 MIN. 03 SEC. E A DISTANCE OF 362.24 FEET TO A POINT; THENCE S 07 DEG. 12 MIN. 57 SEC. E A DISTANCE OF 1019.07 FEET TO A POINT; SAID POINT BEING N 70 DEG. 39 MIN. 14 SEC. W A DISTANCE OF 557.46 FEET FROM P.R.M. 15-90-DA-08. THENCE S 01 DEG. 08 MIN. 12 SEC. E A DISTANCE OF 1122.52 FEET TO A POINT; THENCE S 15 DEG. 19 MIN. 17 SEC. W A DISTANCE OF 960.89 FEET TO A POINT; SAID POINT BEING N 82 DEG. 07 MIN. 00 SEC. W A DISTANCE OF 1344.80 FEET FROM P.R.M. 15-99-DA-07. THENCE S 01 DEG. 08 MIN. 17 SEC. W A DISTANCE OF 994.66 FEET TO A POINT; THENCE S 00 DEG. 00 MIN. 32 SEC. E A DISTANCE OF 976.10 FEET TO A POINT; THENCE S 00 DEG. 14 MIN. 03 SEC. W A DISTANCE OF 1009.25 FEET TO A POINT; SAID POINT BEING S 32 DEG. 48 MIN. 40 SEC. E A DISTANCE OF 171.68 FEET FROM P.R.M. 15-90-DA-09.

THENCE S 00 DEG. 24 MIN. 35 SEC. W A DISTANCE OF 1044.61 FEET TO A POINT; THENCE S 04 DEG. 29 MIN. 19 SEC. E A DISTANCE OF 1061.44 FEET TO A POINT; SAID POINT BEING N 35 DEG. 49 MIN. 11 SEC. E A DISTANCE OF 574.18 FEET FROM P.R.M. 15-99-DA-10A. THENCE S 08 DEG. 45 MIN. 37 SEC. W A DISTANCE OF 974.92 FEET TO A POINT; THENCE S 08 DEG. 12 MIN. 29 SEC. W A DISTANCE OF 1121.67 FEET TO A POINT; SAID POINT BEING N 21 DEG. 41 MIN. 45 SEC. E A DISTANCE OF 1017.42 FEET FROM P.R.M. 15-99-DA-11A.

THENCE S 08 DEG. 52 MIN. 07 SEC. W A DISTANCE OF 1034.34 FEET TO A POINT; SAID POINT BEING N 10 DEG. 21 MIN. 07 SEC. E A DISTANCE OF 196.23 FEET FROM P.R.M. NOS 6724 N.

THENCE S 00 DEG. 03 MIN. 59 SEC. E A DISTANCE OF 975.89 FEET TO A POINT; SAID POINT BEING S 37 DEG. 17 MIN. 36 SEC. E A DISTANCE OF 301.23 FEET FROM P.R.M. 15-77-B-09A. THENCE S 07 DEG. 22 MIN. 33 SEC. W A DISTANCE OF 1038.28 FEET TO A POINT; THENCE S 07 DEG. 22 MIN. 35 SEC. W A DISTANCE OF 417.55 FEET TO A POINT; THENCE S 21 DEG. 47 MIN. 15 SEC. W A DISTANCE OF 461.78 FEET TO A POINT; SAID POINT BEING S 62 DEG. 24 MIN. 42 SEC. W A DISTANCE OF 126.53 FEET FROM P.R.M. 15-77-B-09.

THENCE S 42 DEG. 14 MIN. 02 SEC. E A DISTANCE OF 996.91 FEET TO A POINT; SAID POINT BEING S 80 DEG. 24 MIN. 23 SEC. W A DISTANCE OF 333.91 FEET FROM P.R.M. 15-90-DA-12.

THENCE S 57 DEG. 38 MIN. 09 SEC. E A DISTANCE OF 1038.26 FEET TO A POINT; SAID POINT BEING S 37 DEG. 20 MIN. 25 SEC. W A DISTANCE OF 314.52 FEET FROM P.R.M. 15-99-DA-12A.

THENCE S 66 DEG. 53 MIN. 59 SEC. E A DISTANCE OF 876.82 FEET TO A POINT; SAID POINT BEING N 30 DEG. 00 MIN. 00 SEC. E A DISTANCE OF 39.00 FEET FROM P.R.M. R050 PNLS 1974.

THENCE S 66 DEG. 53 MIN. 58 SEC. E TO THE POINT OF INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE NORTHERN SHORE OF LITTLE PASS; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 30 DEG. 00 MIN. 00 SEC. E A DISTANCE OF 39.00 FEET FROM P.R.M. R050 PNLS 1974.

RECOMMENCE AT P.R.M. 15-99-DA13A, THENCE N 74 DEG. 08 MIN. 53 SEC. W A DISTANCE OF 561.49 FEET TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE; THENCE N 49 DEG. 14 MIN. 18 SEC. E TO THE INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE SOUTHERN SHORE OF LITTLE PASS; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 74 DEG. 08 MIN. 53 SEC. W A DISTANCE OF 561.49 FEET FROM P.R.M. 15-99-DA13A.

THENCE S 60 DEG. 49 MIN. 53 SEC. W A DISTANCE OF 1351.13 FEET TO A POINT; THENCE S 20 DEG. 49 MIN. 30 SEC. W A DISTANCE OF 523.18 FEET TO A POINT; SAID POINT BEING N 79 DEG. 14 MIN. 27 SEC. W A DISTANCE OF 949.37 FEET FROM P.R.M. 15-99-DA-13B. THENCE S 21 DEG. 26 MIN. 17 SEC. W A DISTANCE OF 1201.11 FEET TO A POINT; THENCE S 33 DEG. 14 MIN. 07 SEC. W A DISTANCE OF 87.63 FEET TO A POINT; THENCE S 32 DEG. 38 MIN. 56 SEC. W A DISTANCE OF 1109.83 FEET TO A POINT; SAID POINT BEING N 89 DEG. 12 MIN. 19 SEC. W A DISTANCE OF 188.67 FEET FROM P.R.M. 15-90-DA-14.

THENCE S 21 DEG. 19 MIN. 46 SEC. W A DISTANCE OF 1035.41 FEET TO A POINT; THENCE S 25 DEG. 20 MIN. 58 SEC. W A DISTANCE OF 996.90 FEET TO A POINT; THENCE S 28 DEG. 29 MIN. 36 SEC. W A DISTANCE OF 2014.70 FEET TO A POINT; THENCE S 18 DEG. 58 MIN. 04 SEC. W A DISTANCE OF 1044.56 FEET TO A POINT; THENCE S 14 DEG. 31 MIN. 51 SEC. W A DISTANCE OF 955.26 FEET TO A POINT; THENCE S 17 DEG. 55 MIN. 52 SEC. W A DISTANCE OF 889.75 FEET TO A POINT; THENCE S 15 DEG. 08 MIN. 30 SEC. W A DISTANCE OF 894.64 FEET TO A POINT; THENCE S 15 DEG. 21 MIN. 58 SEC. W A DISTANCE OF 1009.26 FEET TO A POINT; SAID POINT BEING N 75 DEG. 11 MIN. 13 SEC. W A DISTANCE OF 100.26 FEET FROM P.R.M. 15-99-DA-15A. THENCE S 15 DEG. 35 MIN. 07 SEC. W A DISTANCE OF 1111.93 FEET TO A POINT; THENCE S 11 DEG. 10 MIN. 40 SEC. W A DISTANCE OF 948.55 FEET TO A POINT; THENCE S 12 DEG. 37 MIN. 53 SEC. W A DISTANCE OF 922.91 FEET TO A POINT; SAID POINT BEING S 83 DEG. 43 MIN. 06 SEC. W A DISTANCE OF 179.55 FEET FROM P.R.M. 15-99-DA-15B.

THENCE S 12 DEG. 21 MIN. 06 SEC. W A DISTANCE OF 960.23 FEET TO A POINT; THENCE S 12 DEG. 50 MIN. 56 SEC. W A DISTANCE OF 1005.99 FEET TO A POINT; SAID POINT BEING S 54 DEG. 43 MIN. 47 SEC. W A DISTANCE OF 294.71 FEET FROM P.R.M. 15-99-DA-15C. THENCE S 14 DEG. 34 MIN. 58 SEC. W A DISTANCE OF 1021.79 FEET TO A POINT; THENCE S 08 DEG. 58 MIN. 38 SEC. W A DISTANCE OF 1068.46 FEET TO A POINT: SAID POINT BEING N 18 DEG. 23 MIN. 53 SEC. W A DISTANCE OF 445.48 FEET FROM P.R.M. 15-99-DA-15D. THENCE S 07 DEG. 32 MIN. 47 SEC. W A DISTANCE OF 1042.35 FEET TO A POINT; THENCE S 11 DEG. 21 MIN. 09 SEC. W A DISTANCE OF 1068.35 FEET TO A POINT; THENCE S 08 DEG. 34 MIN. 07 SEC. W A DISTANCE OF 937.18 FEET TO A POINT; SAID POINT BEING S 52 DEG. 55 MIN. 00 SEC. W A DISTANCE OF 391.59 FEET FROM P.R.M. 15-90-DA-16.

THENCE S 09 DEG. 02 MIN. 22 SEC. W A DISTANCE OF 925.87 FEET TO A POINT; THENCE S 08 DEG. 26 MIN. 56 SEC. W A DISTANCE OF 842.15 FEET TO A POINT; SAID POINT BEING S 83 DEG. 18 MIN. 33 SEC. W A DISTANCE OF 294.00 FEET FROM P.R.M. 15-90-DA-17.

THENCE S 08 DEG. 58 MIN. 42 SEC. W A DISTANCE OF 1003.31 FEET TO A POINT; THENCE S 09 DEG. 44 MIN. 12 SEC. W A DISTANCE OF 999.70 FEET TO A POINT; THENCE S 07 DEG. 06 MIN. 36 SEC. W A DISTANCE OF 1018.74 FEET TO A POINT; SAID POINT BEING S 58 DEG. 34 MIN. 03 SEC. W A DISTANCE OF 286.29 FEET FROM P.R.M. 15-90-DA-17A.

THENCE S 03 DEG. 13 MIN. 41 SEC. W A DISTANCE OF 945.73 FEET TO A POINT; SAID POINT BEING N 81 DEG. 56 MIN. 00 SEC. W A DISTANCE OF 185.57 FEET FROM P.R.M. NARROW-D. THENCE S 03 DEG. 04 MIN. 13 SEC. E A DISTANCE OF 1007.95 FEET TO A POINT; SAID POINT BEING S 65 DEG. 19 MIN. 29 SEC. W A DISTANCE OF 224.06 FEET FROM P.R.M. 15-90-DA-17B. THENCE S 07 DEG. 10 MIN. 52 SEC. E A DISTANCE OF 992.16 FEET TO A POINT; THENCE S 01 DEG. 26 MIN. 06 SEC. E A DISTANCE OF 1052.88 FEET TO A POINT; SAID POINT BEING N 38 DEG. 18 MIN. 22 SEC. W A DISTANCE OF 165.58 FEET FROM P.R.M. NARROW 1973 THENCE S 06 DEG. 16 MIN. 25 SEC. E A DISTANCE OF 1026.24 FEET TO A POINT; THENCE S 05 DEG. 09 MIN. 02 SEC. E A DISTANCE OF 987.26 FEET TO A POINT; THENCE S 05 DEG. 44 MIN. 05 SEC. E A DISTANCE OF 1008.15 FEET TO A POINT; THENCE S 09 DEG. 31 MIN. 40 SEC. E A DISTANCE OF 1026.84 FEET TO A POINT; THENCE S 10 DEG. 15 MIN. 12 SEC. E A DISTANCE OF 1055.82 FEET TO A POINT; THENCE S 08 DEG. 21 MIN. 08 SEC. E A DISTANCE OF 807.89 FEET TO A POINT; SAID POINT BEING S 47 DEG. 45 MIN. 21 SEC. W A DISTANCE OF 198.85 FEET FROM P.R.M. NARROW-F. THENCE S 16 DEG. 22 MIN. 08 SEC. E A DISTANCE OF 945.97 FEET TO A POINT; THENCE S 14 DEG. 05 MIN. 54 SEC. E A DISTANCE OF 1055.33 FEET TO A POINT; THENCE S 18 DEG. 31 MIN. 36 SEC. E A DISTANCE OF 1000.74 FEET TO A POINT; THENCE S 20 DEG. 00 MIN. 49 SEC. E A DISTANCE OF 955.41 FEET TO A POINT; THENCE S 23 DEG. 14 MIN. 21 SEC. E A DISTANCE OF 1143.32 FEET TO A POINT; SAID POINT BEING N 33 DEG. 07 MIN. 28 SEC. W A DISTANCE OF 306.41 FEET FROM P.R.M. 15-99-DA-17D. THENCE S 26 DEG. 26 MIN. 13 SEC. E A DISTANCE OF 1042.97 FEET TO A POINT; THENCE S 27 DEG. 40 MIN. 08 SEC. E A DISTANCE OF 909.61 FEET TO A POINT; SAID POINT BEING S 21 DEG. 34 MIN. 34 SEC. E A DISTANCE OF 413.73 FEET FROM P.R.M. 15-99-DA-17E. THENCE S 23 DEG. 13 MIN. 08 SEC. E A DISTANCE OF 1041.21 FEET TO A POINT; SAID POINT BEING S 52 DEG. 14 MIN. 08 SEC. W A DISTANCE OF 243.78 FEET FROM P.R.M. 15-90-DA-18. THENCE S 32 DEG. 43 MIN. 28 SEC. E A DISTANCE OF 986.47 FEET TO A POINT; SAID POINT BEING S 81 DEG. 06 MIN. 22 SEC. W A DISTANCE OF 372.27 FEET FROM P.R.M. 15-90-DA-19. THENCE S 30 DEG. 01 MIN. 06 SEC. E A DISTANCE OF 1141.23 FEET TO A POINT; SAID POINT BEING S 87 DEG. 31 MIN. 26 SEC. W A DISTANCE OF 310.01 FEET FROM P.R.M. 15-90-DA-19A. THENCE S 28 DEG. 33 MIN. 11 SEC. E A DISTANCE OF 1019.19 FEET TO A POINT; THENCE S 29 DEG. 48 MIN. 05 SEC. E A DISTANCE OF 1055.71 FEET TO A POINT; SAID POINT BEING S 64 DEG. 59 MIN. 28 SEC. W A OF 479.72 FEET DISTANCE FROM P.R.M.

THENCE S 32 DEG. 33 MIN. 47 SEC. E A DISTANCE OF 897.43 FEET TO A POINT; THENCE S 28 DEG. 13 MIN. 59 SEC. E A DISTANCE OF 1251.16 FEET TO A POINT; SAID POINT BEING S 05 DEG. 58 MIN. 41 SEC. E A DISTANCE OF 368.31 FEET FROM P.R.M. REDINGTON-B.

THENCE S 30 DEG. 16 MIN. 33 SEC. E A DISTANCE OF 1049.54 FEET TO A POINT; SAID POINT BEING N 48 DEG. 34 MIN. 19 SEC. W A DISTANCE OF 431.12 FEET FROM P.R.M. REDINGTON-D.

THENCE S 41 DEG. 35 MIN. 40 SEC. E A DISTANCE OF 994.66 FEET TO A POINT; THENCE S 41 DEG. 22 MIN. 31 SEC. E A DISTANCE OF 1026.81 FEET TO A POINT; THENCE S 42 DEG. 16 MIN. 24 SEC. E A DISTANCE OF 1014.78 FEET TO A POINT; THENCE S 44 DEG. 17 MIN. 33 SEC. E A DISTANCE OF 1093.62 FEET TO A POINT; THENCE S 51 DEG. 16 MIN. 25 SEC. E A DISTANCE OF 1007.73 FEET TO A POINT; SAID POINT BEING S 42 DEG. 47 MIN. 55 SEC. E A DISTANCE OF 416.81 FEET FROM P.R.M. 15-90-DA-20.

THENCE S 53 DEG. 28 MIN. 17 SEC. E A DISTANCE OF 1021.65 FEET TO A POINT; THENCE S 53 DEG. 16 MIN. 45 SEC. E A DISTANCE OF 1013.94 FEET TO A POINT; THENCE S 49 DEG. 58 MIN. 44 SEC. E A DISTANCE OF 946.38 FEET TO A POINT; SAID POINT BEING N 55 DEG. 03 MIN. 21 SEC. W A DISTANCE OF 935.27 FEET FROM P.R.M. 15-99-DA-21B.

THENCE S 48 DEG. 27 MIN. 21 SEC. E A DISTANCE OF 1246.53 FEET TO A POINT; THENCE S 47 DEG. 56 MIN. 03 SEC. E A DISTANCE OF 664.00 FEET TO A POINT; THENCE S 49 DEG. 28 MIN. 22 SEC. E A DISTANCE OF 1004.20 FEET TO A POINT; SAID POINT BEING S 32 DEG. 26 MIN. 37 SEC. W A DISTANCE OF 76.33 FEET FROM P.R.M. 15-77-B-08.

THENCE S 48 DEG. 37 MIN. 59 SEC. E A DISTANCE OF 1138.52 FEET TO A POINT; THENCE S 46 DEG. 15 MIN. 52 SEC. E A DISTANCE OF 1018.71 FEET TO A POINT; SAID POINT BEING S 45 DEG. 27 MIN. 31 SEC. E A DISTANCE OF 146.57 FEET FROM P.R.M. 15-90-DA-22.

THENCE S 48 DEG. 24 MIN. 15 SEC. E A DISTANCE OF 999.23 FEET TO A POINT; SAID POINT BEING N 61 DEG. 25 MIN. 44 SEC. W A DISTANCE OF 281.75 FEET FROM P.R.M. 15-90-DA-23.

THENCE S 45 DEG. 40 MIN. 42 SEC. E A DISTANCE OF 1048.59 FEET TO A POINT; THENCE S 46 DEG. 48 MIN. 16 SEC. E A DISTANCE OF 1032.67 FEET TO A POINT; SAID POINT BEING S 08 DEG. 42 MIN. 56 SEC. E A DISTANCE OF 231.93 FEET FROM P.R.M. 15-90-DA-23A. THENCE S 38 DEG. 53 MIN. 00 SEC. E A DISTANCE OF 1111.85 FEET TO A POINT; SAID POINT BEING S 75 DEG. 47 MIN. 09 SEC. W A DISTANCE OF 265.95 FEET FROM P.R.M. 15-90-DA-24. THENCE S 33 DEG. 36 MIN. 42 SEC. E A DISTANCE OF 898.50 FEET TO A POINT; THENCE S 40 DEG. 23 MIN. 00 SEC. E A DISTANCE OF 1023.41 FEET TO A POINT; SAID POINT BEING S 32 DEG. 21 MIN. 48 SEC. W A DISTANCE OF 317.22 FEET FROM P.R.M. 15-90-DA-25.

THENCE S 40 DEG. 20 MIN. 19 SEC. E A DISTANCE OF 518.63 FEET TO A POINT; SAID POINT BEING N 17 DEG. 38 MIN. 08 SEC. W A DISTANCE OF 477.58 FEET FROM P.R.M. RAINEY 73.

THENCE S 30 DEG. 22 MIN. 57 SEC. E TO THE POINT OF INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE NORTHERN SHORE OF JOHNS PASS; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 17 DEG. 38 MIN. 08 SEC. W A DISTANCE OF 477.58 FEET FROM P.R.M. RAINEY 1973.

RECOMMENCE AT P.R.M. MADERIA 1934, THENCE N 09 DEG. 49 MIN. 49 SEC. E A DISTANCE OF 392.71 FEET TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE; THENCE N 30 DEG. 23 MIN. 13 SEC. W TO THE INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE SOUTHERN SHORE OF JOHNS PASS; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 09 DEG. 49 MIN. 49 SEC. E A DISTANCE OF 392.71 FEET FROM P.R.M. MADERIA 1934.

THENCE S 07 DEG. 28 MIN. 16 SEC. E A DISTANCE OF 1210.21 FEET TO A POINT; SAID POINT BEING N 64 DEG. 59 MIN. 06 SEC. W A DISTANCE OF 707.25 FEET FROM P.R.M. 15-90-DA-25A.

THENCE S 27 DEG. 10 MIN. 23 SEC. E A DISTANCE OF 1091.59 FEET TO A POINT; SAID POINT BEING S 65 DEG. 59 MIN. 32 SEC. W A DISTANCE OF 412.19 FEET FROM P.R.M. 15-90-DA-25B.

THENCE S 60 DEG. 18 MIN. 50 SEC. E A DISTANCE OF 809.87 FEET TO A POINT; THENCE N 22 DEG. 51 MIN. 04 SEC. E A DISTANCE OF 184.68 FEET TO A POINT; THENCE S 64 DEG. 27 MIN. 27 SEC. E A DISTANCE OF 302.05 FEET TO A POINT; SAID POINT BEING S 13 DEG. 11 MIN. 12 SEC. E A DISTANCE OF 302.57 FEET FROM P.R.M. 15-90-DA-25C.

THENCE S 48 DEG. 21 MIN. 53 SEC. E A DISTANCE OF 1071.55 FEET TO A POINT; SAID POINT BEING S 23 DEG. 23 MIN. 36 SEC. E A DISTANCE OF 440.40 FEET FROM P.R.M. 15-90-DA-26.

THENCE S 48 DEG. 24 MIN. 04 SEC. E A DISTANCE OF 542.26 FEET TO A POINT; THENCE S 40 DEG. 54 MIN. 58 SEC. E A DISTANCE OF 706.14 FEET TO A POINT; SAID POINT BEING S 24 DEG. 39 MIN. 00 SEC. E A DISTANCE OF 521.14 FEET FROM P.R.M. 15-90-DA-27. THENCE S 30 DEG. 07 MIN. 48 SEC. E A DISTANCE OF 1172.16 FEET TO A POINT; SAID POINT BEING S 04 DEG. 05 MIN. 13 SEC. W A DISTANCE OF 465.39 FEET FROM P.R.M. 15-90-DA-27A.

THENCE S 24 DEG. 33 MIN. 20 SEC. E A DISTANCE OF 1142.70 FEET TO A POINT; SAID POINT BEING S 10 DEG. 24 MIN. 32 SEC. E A DISTANCE OF 126.62 FEET FROM P.R.M. RAINEY-J.

THENCE S 21 DEG. 11 MIN. 28 SEC. E A DISTANCE OF 1047.43 FEET TO A POINT; SAID POINT BEING S 15 DEG. 42 MIN. 34 SEC. W A DISTANCE OF 195.52 FEET FROM P.R.M. RAINEY-K.

THENCE S 15 DEG. 15 MIN. 18 SEC. E A DISTANCE OF 1211.04 FEET TO A POINT; SAID POINT BEING S 11 DEG. 16 MIN. 44 SEC. E A DISTANCE OF 722.72 FEET FROM P.R.M. PBE 144 68.

THENCE S 21 DEG. 41 MIN. 59 SEC. E A DISTANCE OF 893.40 FEET TO A POINT; SAID POINT BEING S 24 DEG. 02 MIN. 29 SEC. E A DISTANCE OF 495.77 FEET FROM P.R.M. BLIND-D.

THENCE S 16 DEG. 18 MIN. 40 SEC. E A DISTANCE OF 1119.54 FEET TO A POINT; SAID POINT BEING S 21 DEG. 01 MIN. 38 SEC. E A DISTANCE OF 323.48 FEET FROM P.R.M. 15-90-DA-27B.

THENCE S 18 DEG. 49 MIN. 11 SEC. E A DISTANCE OF 1041.18 FEET TO A POINT; SAID POINT BEING S 20 DEG. 51 MIN. 53 SEC. E A DISTANCE OF 108.74 FEET FROM P.R.M. 15-90-DA-27D.

THENCE S 22 DEG. 13 MIN. 09 SEC. E A DISTANCE OF 1009.65 FEET TO A POINT; SAID POINT BEING S 30 DEG. 19 MIN. 29 SEC. E A DISTANCE OF 501.40 FEET FROM P.R.M. 15-90-DA-28.

THENCE S 23 DEG. 02 MIN. 00 SEC. E A DISTANCE OF 1021.67 FEET TO A POINT; THENCE S 26 DEG. 50 MIN. 32 SEC. E A DISTANCE OF 987.89 FEET TO A POINT; SAID POINT BEING S 33 DEG. 41 MIN. 42 SEC. E A DISTANCE OF 607.43 FEET FROM P.R.M. 15-90-DA-29.

THENCE S 34 DEG. 21 MIN. 25 SEC. E A DISTANCE OF 1117.77 FEET TO A POINT; THENCE S 34 DEG. 46 MIN. 44 SEC. E A DISTANCE OF 748.16 FEET TO A POINT; SAID POINT BEING N 03 DEG. 24 MIN. 18 SEC. W A DISTANCE OF 133.78 FEET FROM P.R.M. COE BLIND PASS.

THENCE S 49 DEG. 54 MIN. 18 SEC. E TO THE POINT OF INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE NORTHERN SHORE OF BLIND PASS; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 03 DEG. 24 MIN. 18 SEC. W A DISTANCE OF 133.78 FEET FROM P.R.M. COE BLIND PASS. RECOMMENCE AT P.R.M. COE BLIND PASS, THENCE S 58 DEG. 33 MIN. 41 SEC. E A DISTANCE OF 645.07 FEET TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE; THENCE N 49 DEG. 56 MIN. 13 SEC. W TO THE INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE SOUTHERN SHORE OF BLIND PASS; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING S 58 DEG. 33 MIN. 41 SEC. E A DISTANCE OF 645.07 FEET FROM P.R.M. COE BLIND PASS.

THENCE S 42 DEG. 42 MIN. 17 SEC. E A DISTANCE OF 855.96 FEET TO A POINT; THENCE S 43 DEG. 56 MIN. 11 SEC. E A DISTANCE OF 1032.75 FEET TO A POINT; SAID POINT BEING N 80 DEG. 51 MIN. 12 SEC. W A DISTANCE OF 1193.82 FEET FROM P.R.M. PBE 133.

THENCE S 42 DEG. 11 MIN. 00 SEC. E A DISTANCE OF 818.84 FEET TO A POINT; THENCE S 38 DEG. 19 MIN. 30 SEC. E A DISTANCE OF 978.15 FEET TO A POINT; SAID POINT BEING S 76 DEG. 01 MIN. 02 SEC. W A DISTANCE OF 710.43 FEET FROM P.R.M. BLIND-P.

THENCE S 31 DEG. 31 MIN. 26 SEC. E A DISTANCE OF 1091.23 FEET TO A POINT; SAID POINT BEING N 56 DEG. 08 MIN. 09 SEC. W A DISTANCE OF 995.38 FEET FROM P.R.M. 15-77-B-04.

THENCE S 24 DEG. 27 MIN. 48 SEC. E A DISTANCE OF 1060.89 FEET TO A POINT; THENCE S 23 DEG. 59 MIN. 02 SEC. E A DISTANCE OF 1073.57 FEET TO A POINT; SAID POINT BEING S 55 DEG. 13 MIN. 27 SEC. W A DISTANCE OF 403.40 FEET FROM P.R.M. NOAA-D.

THENCE S 22 DEG. 31 MIN. 21 SEC. E A DISTANCE OF 1032.35 FEET TO A POINT; THENCE S 14 DEG. 48 MIN. 07 SEC. E A DISTANCE OF 1018.07 FEET TO A POINT; THENCE S 12 DEG. 10 MIN. 52 SEC. E A DISTANCE OF 1020.19 FEET TO A POINT; SAID POINT BEING N 33 DEG. 39 MIN. 35 SEC. W A DISTANCE OF 562.29 FEET FROM P.R.M. 15-99-DA-31.

THENCE S 08 DEG. 27 MIN. 55 SEC. E A DISTANCE OF 1012.46 FEET TO A POINT; THENCE S 09 DEG. 10 MIN. 34 SEC. E A DISTANCE OF 989.34 FEET TO A POINT; SAID POINT BEING N 18 DEG. 08 MIN. 28 SEC. W A DISTANCE OF 384.88 FEET FROM P.R.M. NOAA 1973.

THENCE S 08 DEG. 15 MIN. 54 SEC. E A DISTANCE OF 1060.18 FEET TO A POINT; SAID POINT BEING S 88 DEG. 33 MIN. 46 SEC. W A DISTANCE OF 360.21 FEET FROM P.R.M. 15-99-DA-31A.

THENCE S 05 DEG. 32 MIN. 47 SEC. E A DISTANCE OF 1034.32 FEET TO A POINT; THENCE S 01 DEG. 22 MIN. 16 SEC. E A DISTANCE OF 1011.97 FEET TO A POINT; THENCE S 01 DEG. 22 MIN. 34 SEC. E A DISTANCE OF 1033.06 FEET TO A POINT; SAID POINT BEING S 19 DEG. 27 MIN. 36 SEC. W A DISTANCE OF 768.07 FEET FROM P.R.M. 15-99-DA-32. THENCE S 00 DEG. 14 MIN. 44 SEC. E A DISTANCE OF 982.27 FEET TO A POINT; THENCE S 00 DEG. 52 MIN. 40 SEC. W A DISTANCE OF 927.60 FEET TO A POINT; THENCE S 05 DEG. 44 MIN. 48 SEC. W A DISTANCE OF 997.35 FEET TO A POINT; SAID POINT BEING N 48 DEG. 49 MIN. 24 SEC. E A DISTANCE OF 461.65 FEET FROM P.R.M. NOAA-A.

THENCE S 07 DEG. 12 MIN. 21 SEC. W A DISTANCE OF 990.24 FEET TO A POINT; THENCE S 00 DEG. 53 MIN. 52 SEC. E A DISTANCE OF 949.29 FEET TO A POINT; THENCE S 00 DEG. 36 MIN. 47 SEC. E A DISTANCE OF 556.34 FEET TO A POINT; SAID POINT BEING S 90 DEG. 00 MIN. 00 SEC. E A DISTANCE OF 120.00 FEET FROM P.R.M. NOS 6430 J 1988.

THENCE S 02 DEG. 09 MIN. 26 SEC. E TO THE POINT OF INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE NORTHERN SHORE OF PASS-A-GRILLE CHANNEL; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING S 90 DEG. 00 MIN. 00 SEC. E A DISTANCE OF 120.00 FEET FROM P.R.M. NOS 6430 J 1988.

RECOMMENCE AT P.R.M. R170 PNLS 1974, THENCE N 68 DEG. 46 MIN. 13 SEC. E A DISTANCE OF 2327.41 FEET TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE; THENCE N 11 DEG. 17 MIN. 25 SEC. E TO THE INTERSECTION WITH THE MEAN HIGH WATER LINE OF THE SOUTHERN SHORES OF BUNCES PASS; THENCE RETURN ALONG THE SAME COURSE TO A POINT ON THE COASTAL CONSTRUCTION CONTROL LINE, SAID POINT BEING N 68 DEG. 46 MIN. 13 SEC. E A DISTANCE OF 2327.41 FEET FROM P.R.M. R170 PNLS 1974.

THENCE S 16 DEG. 08 MIN. 36 SEC. W A DISTANCE OF 1036.48 FEET TO A POINT; THENCE S 14 DEG. 26 MIN. 12 SEC. W A DISTANCE OF 619.62 FEET TO A POINT; THENCE S 70 DEG. 44 MIN. 02 SEC. W A DISTANCE OF 566.74 FEET TO A POINT; THENCE S 23 DEG. 22 MIN. 06 SEC. E A DISTANCE OF 739.95 FEET TO A POINT; SAID POINT BEING N 65 DEG. 00 MIN. 00 SEC. E A DISTANCE OF 410.00 FEET FROM P.R.M. R172 PNLS 1990.

THENCE S 16 DEG. 33 MIN. 13 SEC. E A DISTANCE OF 608.99 FEET TO A POINT; THENCE S 03 DEG. 23 MIN. 06 SEC. E A DISTANCE OF 831.97 FEET TO A POINT; THENCE S 05 DEG. 51 MIN. 59 SEC. W A DISTANCE OF 1007.45 FEET TO A POINT; SAID POINT BEING N 85 DEG. 00 MIN. 00 SEC. E A DISTANCE OF 130.00 FEET FROM P.R.M. T174 PNLS 1977.

THENCE S 06 DEG. 22 MIN. 44 SEC. W A DISTANCE OF 1068.28 FEET TO A POINT; THENCE S 01 DEG. 44 MIN. 54 SEC. W A DISTANCE OF 1013.78 FEET TO A POINT; THENCE S 01 DEG. 16 MIN. 36 SEC. E A DISTANCE OF

1027.75 FEET TO A POINT; SAID POINT BEING N 77 DEG. 13 MIN. 35 SEC. W A DISTANCE OF 23.74 FEET FROM P.R.M. T177 PNLS 1977.

THENCE S 07 DEG. 24 MIN. 14 SEC. W A DISTANCE OF 993.28 FEET TO A POINT; THENCE S 42 DEG. 09 MIN. 08 SEC. E A DISTANCE OF 1037.55 FEET TO A POINT; THENCE S 78 DEG. 06 MIN. 46 SEC. E A DISTANCE OF 423.20 FEET TO A POINT; THENCE N 55 DEG. 36 MIN. 33 SEC. E A DISTANCE OF 811.86 FEET TO A POINT; THENCE N 60 DEG. 27 MIN. 43 SEC. E A DISTANCE OF 1077.90 FEET TO A POINT; THENCE N 61 DEG. 06 MIN. 45 SEC. E A DISTANCE OF 943.54 FEET TO A POINT; THENCE N 69 DEG. 34 MIN. 48 SEC. E A DISTANCE OF 1106.49 FEET TO A POINT; THENCE N 62 DEG. 48 MIN. 13 SEC. E A DISTANCE OF 942.77 FEET TO A POINT; THENCE N 62 DEG. 38 MIN. 22 SEC. E A DISTANCE OF 985.06 FEET TO A POINT; SAID POINT BEING S 80 DEG. 51 MIN. 05 SEC. W A DISTANCE OF 520.44 FEET FROM P.R.M. 15-90-DA-30.

THENCE N 62 DEG. 07 MIN. 42 SEC. E A DISTANCE OF 1206.85 FEET TO A POINT; SAID POINT BEING N 34 DEG. 11 MIN. 57 SEC. E A DISTANCE OF 589.49 FEET FROM P.R.M. DESOTO 1973.

THENCE N 62 DEG. 25 MIN. 10 SEC. E A DISTANCE OF 996.75 FEET TO A POINT; THENCE N 66 DEG. 29 MIN. 17 SEC. E A DISTANCE OF 992.41 FEET TO A POINT; THENCE N 60 DEG. 09 MIN. 37 SEC. E A DISTANCE OF 855.64 FEET TO A POINT; SAID POINT BEING N 71 DEG. 52 MIN. 35 SEC. W A DISTANCE OF 165.70 FEET FROM P.R.M. 15-90-B01-2.

THENCE N 53 DEG. 04 MIN. 23 SEC. E A DISTANCE OF 686.16 FEET TO A POINT; THENCE N 29 DEG. 43 MIN. 08 SEC. E A DISTANCE OF 800.27 FEET TO A POINT; THENCE N 23 DEG. 47 MIN. 42 SEC. E A DISTANCE OF 2362.79 FEET TO A POINT; SAID POINT BEING N 47 DEG. 13 MIN. 03 SEC. W A DISTANCE OF 198.20 FEET FROM P.R.M. DESOTO-B.

THENCE N 23 DEG. 47 MIN. 41 SEC. E; TO THE INTERSECTION WITH THE MEAN HIGH WATER LINE OF TAMPA BAY, SAID POINT BEING THE SOUTHERN TERMINUS OF THE COASTAL CONSTRUCTION CONTROL LINE FOR PINELLAS COUNTY.

Specific Authority 370.021(1) FS. Law Implemented 161.053 FS. History-New 1-16-79, Amended_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Rosaline Beckham, Environmental Specialist, Office of Beaches and Coastal Systems

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Dr. Alfred Devereaux, Director, Office of Beaches and Coastal Systems

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 8, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: February 4, 2000

DEPARTMENT OF HEALTH

Board of Acupuncture

RULE TITLES:	RULE NOS .:
Definitions	64B1-8.001
Monitoring Sterilization and Infection Control	64B1-8.002

PURPOSE AND EFFECT: The proposed changes to the current Rules will remove references to staples, and will further specify sterilization and infection control requirements. SUMMARY: The proposed change to Rule 64B1-8.001 will remove the word "staples" from the definition of "Needles." The proposed changes to Rule 64B1-8.002 will clarify the requirement to sterilize non-presterilized needles, and will delete the provisions of the current Rule which address the procedures for the sterilization of contaminated needles.

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: 457.102(1), 457.104, 457.1085 FS. LAW IMPLEMENTED: 457.102(1), 457.1085 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT A TIME, DATE AND PLACE TO BE PUBLISHED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: William Buckhalt, Executive Director, Board of Acupuncture, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256

THE FULL TEXT OF THE PROPOSED RULES IS:

64B1-8.001 Definitions.

(1) Needles: solid filiform instruments used in the practice of acupuncture. This includes, but is not limited to, dermal needles, plum blossom needles, press needles, staples, prismatic needles and disposable lancets.

(2) No change

Specific Authority 457.104, 457.1085 FS. Law Implemented 457.1085 FS. History–New 5-6-87, Amended 12-23-87, 6-7-89, Formerly 21AA-8.001, 61F1-8.001, 59M-8.001, Amended

64B1-8.002 Monitoring Sterilization and Infection Control.

(1) through (2) No change.

(3) <u>Non-presterilized</u> Contaminated acupuncture needles shall be sterilized <u>prior to use</u>, in the following manner:

(a) Prior to handling and inspection the contaminated acupuncture needles shall be sterilized by autoclave.

(b) The acupuncture needles shall then be thoroughly cleansed with an antiseptic solution and hot water.

(c) Finally, said needles shall be sterilized again by autoclave prior to use.

(4) All equipment must be packaged properly and loaded correctly in the autoclave.

(4)(5) All sterilized items must be stored and handled in a manner which maintains sterility.

(6) Autoclaves must be cleaned regularly and serviced at least once a year.

(5)(7) Each acupuncture office utilizing autoclave sterilization techniques shall post the sterilization procedures and shall maintain documentation of all annual autoclave service.

(6)(8) It shall be the responsibility of the Certified Acupuncturist to insure that personnel responsible for performing sterilization procedures pursuant to this Rule shall be adequately trained.

(7)(9) The procedures and equipment used for sterilization must have their efficacy tested periodically. Adequacy of steam under pressure (e.g., autoclave) must have its efficacy verified by appropriate biological monitoring at least once every 40 hours (2400 minutes) of use or at least once every thirty days, whichever comes first.

Specific Authority 457.104, 457.1085 FS. Law Implemented 457.1085 FS. History–New 5-6-87, Amended 12-23-87, 6-7-89, 11-13-89, Formerly 21AA-8.002, 61F1-8.002, Amended 2-22-96, Formerly 59M-8.002, Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Acupuncture

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 1, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: April 28, 2000

DEPARTMENT OF HEALTH

Board of Medicine	
RULE TITLE:	RULE NO .:
Disciplinary Guidelines	64B8-30.015
PURPOSE AND EFFECT: The proposed rule	amendments are
intended to set forth penalties for first	and subsequent
violations for physician assistants.	

SUMMARY: The proposed rule amendments set forth penalties for first and subsequent violations for physician assistants.

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: 456.072, 456.079, 458.309, 458.331(4) FS.

LAW IMPLEMENTED: 456.079, 456.072, 458.331(4) 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: 10:00 a.m., December 17, 2000

PLACE: Room 324, Collins Building, 107 W. Gaines Street, Tallahassee, FL

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

THE FULL TEXT OF THE PROPOSED RULE IS:

(Substantial Rewording of Rule 64B8-30.015 follows. See Florida Administrative Code for present text.)

64B8-30.015 Disciplinary Guidelines.

(1) Purpose. Pursuant to Section 456.072, F.S., the Boards provide within this rule disciplinary guidelines which shall be imposed upon physician assistant applicants or licensees whom it regulates under Chapters 458 and 459, F.S. The purpose of this rule is to notify such applicants and licensees of the ranges of penalties which will routinely be imposed unless the Boards find it necessary to deviate from the guidelines for the stated reasons given within this rule. The ranges of penalties provided below are based upon a single count violation of each provision listed; for multiple counts of the violated provisions or a combination of the violations the Boards shall consider a higher penalty than that for a single, isolated violation. Each range includes the lowest and highest penalty and all penalties falling between. The purposes of the imposition of discipline are to punish the applicants or licensees for violations and to deter them from future violations; to offer opportunities for rehabilitation, when appropriate; and to deter other applicants or licensees from violations.

(2) Violations and Range of Penalties. In imposing discipline upon physician assistant applicants and licensees, in proceedings pursuant to Section 120.57(1) and 120.57(2), Florida Statutes, the Board shall act in accordance with the following disciplinary guidelines and shall impose a penalty within the range corresponding to the violations set forth below. The verbal identification of offenses are descriptive only; the full language of each statutory provision cited must be consulted in order to determine the conduct included.

VIOLATIONS	RECOMMENDED PENALTIES	
	First Offense	Subsequent Offenses
10	revocation, with ability to reapply, or	(a) From denial of license to revocation of license with ability to reapply in not less than three years and a fine up to \$5,000.00 to denial of license without ability to reapply.
(458.331(1)(a), F.S.) (456.072(1)(h),F.S.)		
C C	would have been imposed if the substantive violation had occurred in Florida to reprimand through suspension or denial of the license until the license is unencumbered in the jurisdiction in which disciplinary	comparable to the discipline which would have been imposed if the substantive

5886 Section II - Proposed Rules

license by another jurisdiction relating to healthcare fraud in dollar	reapply in three (3) years, and an	1. From permanent revocation and an administrative fine ranging from \$2,500.00 to \$5,000.00, or in the case of application for licensure, denial of licensure.
license by another jurisdiction relating to healthcare fraud in dollar	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the license, or in case of application for	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for
•	(c) From reprimand to revocation or	licensure, denial of licensure. (c) From probation to revocation or denial of the license, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
related to healthcare fraud in	reapply in three (3) years, and an	<u>1. From permanent revocation and an administrative fine ranging from \$2,500.00 to \$5,000.00, or in the case of application for licensure, denial of licensure.</u>
related to healthcare fraud in	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure.
(d) False, deceptive, or misleading advertising. (458.331(1)(d), F.S.)	reprimand, or denial of licensure, and	(d) From a letter of concern to reprimand, or denial of licensure, and an administrative fine ranging from \$1,000.00 to \$2,500.00.
(e) Failure to report another licensee in violation. (458.331(1)(e), F.S.); (456.072(1)(i), F.S.)		(e) From reprimand to suspension or denial of licensure, and an administrative fine from \$2,500.00 to \$5,000 .00.
(f) Aiding unlicensed practice. (458.331(1)(f), F.S.); (456.072(1)(j), F.S.)		(f) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(g) Failure to perform legal obligation. (458.331(1)(g), F.S.); (456.072(1)(k), F.S.)	listed herein, based upon the severity of the offense and the potential for patient harm, from a reprimand to	(g) For any offense not specifically listed herein, based upon the severity of the offense and the potential for patient harm, from a reprimand to revocation or denial and an administrative fine from \$2,500.00 to \$5,000.00.

education (CME) violations. (456.072(1)(e), F.S.); (456.072(1)(s), F.S.);	-	1. Document compliance with the CME requirements for the relevant period; AND:
(456.033(9), F.S.). a. Failure to document required HIV/AIDS, or end of life care, or palliative health care.	<u>\$250.00 to \$500 .00.</u>	<u>a. An administrative fine ranging from</u> <u>\$500.00 to \$1,000.00.</u>
b. Failure to document required domestic violence <u>CME or substitute end-of-life</u> care CME.	•••	b. An administrative fine of \$500.00 to \$1,000.00.
<u>c. Failure to document</u> required HIV/AIDS, or end-of-life-care, or palliative healthcare, and failure to document domestic violence <u>CME.</u>	•••	<u>c. An administrative fine ranging from</u> <u>\$1,000.00 to \$2,000.00.</u>
Board within 30 days after	from \$1,000.00 to \$5,000.00 and a reprimand or denial of licensure, with	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00 and a reprimand or denial of licensure, without the ability to reapply.
3. Failing to disclose financial interest to patient. (456.052, F.S.)	of the patient and from an administrative fine of \$1,000.00 to a	3. A refund of fees paid by or on behalf of the patient and from a reprimand and an administrative fine of \$2,500.00 to a reprimand and an administrative fine of \$5,000.00.
• • •		(h) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
•	reapply in three (3) years, and an	1. From permanent revocation and an administrative fine ranging from \$2,500.00 to \$5,000.00, or in the case of application for licensure, denial of licensure.

	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure.
(i) Kickbacks or split fee arrangements. (458.331(1)(i), F.S.)	behalf of the patient and from a reprimand and an administrative fine	(i) A refund of fees paid by or on behalf of the patient and from suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
-		(j) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
· · · ·		(k) From probation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00 to revocation.
fraudulent representations in the practice of medicine relating to healthcare fraud in	reapply in three (3) years, and an	1. From permanent revocation and an administrative fine ranging from \$2,500.00 to \$5,000.00, or in the case of application for licensure, denial of licensure.
fraudulent representations in the practice of medicine	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the license, or in case of application for	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure.
(1) Improper solicitation of patients. (458.331(1)(1), F.S.)		(1) From suspension to revocation or denial of licensure, and an administrative fine from \$2,500.00 to \$5,000.00.
(m) Failure to keep legible written medical records. (458.331(1)(m), F.S.)	reprimand, or denial of licensure, and	(m) From a reprimand to suspension followed by probation, and an administrative fine ranging from \$2,500.00 to \$5,000.00, or denial of licensure.
written medical records relating to healthcare fraud in	reapply in three (3) years, and an	1. From permanent revocation and an administrative fine ranging from \$2,500.00 to \$5,000.00, or in the case of application for licensure, denial of licensure.

written medical records relating to healthcare fraud in dollar amounts of \$5,000.00 or less.	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the license, or in case of application for licensure, denial of licensure. (n) Payment of fees paid by or on behalf of the patient and from a reprimand to probation, or denial of	 2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure. (n) Payment of fees paid by or on behalf of the patient and from probation to revocation, or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(o) Improper advertising of pharmacy. (458.331(1)(o), F.S.)	(o) From a letter of concern to probation, or a denial of licensure, and	(o) From a reprimand and an administrative fine of \$2,500.00 to probation, and an administrative fine from \$2,500.00 to \$5,000.00, or denial of licensure.
(p) Performing professional services not authorized by patient. (458.331(1)(p), F.S.)		(p) From a reprimand to revocation, or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(q) Inappropriate or excessive prescribing. (458.331(1)(q), F.S.)		(q) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
of a scheduled drug by the		(r) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
	which may be stayed to allow a period of probation with supervision, and a demonstration by the licensee of the	(s) From probation to revocation, until the licensee is able to demonstrate ability to practice with reasonable skill and safety, followed by probation, or denial of licensure, and an administrative fine from \$2,500.00 to \$5,000.00.
· · · · · ·		(t)1. From reprimand to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
2. Gross Malpractice	denial of licensure, and an	2. From suspension followed by probation to revocation or denial, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
3. Repeated Malpractice.	-	3. From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.

(u) Performing of experimental treatment without informed consent. (458.331(1)(u), F.S.) (v) Practicing beyond scope	 suspension, or denial of licensure, and an administrative fine ranging from \$1,000.00 to \$5,000.00. (v) From a letter of concern to 	(v) From probation to suspension or
<u>permitted.</u> (458.331(1)(v), F.S.); (456.072(1)(o), F.S.).	· · ·	revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(w) Delegation of professional responsibilities to unqualified person. (458.331(1)(w), F.S.); (456.072(1)(p), F.S.).	· · ·	(w) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
		(x)1. From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
2. Violation of an order of the Board.	administrative fine of \$1,000.00 to a	2. From a reprimand and an administrative fine of \$2,500.00 to a reprimand and an administrative fine of \$5,000.00 and probation.
	· · ·	(y) From a reprimand and an administrative
<u>advertising services.</u> (458.331(1)(y), F.S.)	ranging from \$1,000.00 to \$2,500.00.	fine of \$2,500.00 to a reprimand and an administrative fine of \$5,000.00.
advertising services. (458.331(1)(y), F.S.)	ranging from \$1,000.00 to \$2,500.00. (z) From probation to revocation, or	administrative fine of \$5,000.00. (z) From suspension to revocation or denial of licensure, and an administrative fine
advertising services. (458.331(1)(y), F.S.) (z) Aiding an unlawful abortion. (458.331(1)(z), F.S.)	ranging from \$1,000.00 to \$2,500.00.(z) From probation to revocation, or denial of licensure, and an administrative fine ranging from \$1,000.00 to \$5,000.00.(aa) From a letter of concern to a	administrative fine of \$5,000.00. (z) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00. (aa) From a reprimand to probation, and an administrative fine ranging from \$2,500.00
advertising services. (458.331(1)(y), F.S.) (z) Aiding an unlawful abortion. (458.331(1)(z), F.S.) (aa) Presigning prescription forms. (458.331(1)(aa), F.S.)	 ranging from \$1,000.00 to \$2,500.00. (z) From probation to revocation, or denial of licensure, and an administrative fine ranging from \$1,000.00 to \$5,000.00. (aa) From a letter of concern to a reprimand and a administrative fine of \$1,000.00 to a letter of concern and an administrative fine of \$2,500.00. (bb) From a reprimand to probation, or denial of licensure, and an 	administrative fine of \$5,000.00. (z) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00. (aa) From a reprimand to probation, and an administrative fine ranging from \$2,500.00
advertising services. (458.331(1)(y), F.S.) (z) Aiding an unlawful abortion. (458.331(1)(z), F.S.) (aa) Presigning prescription forms. (458.331(1)(aa), F.S.) (bb) Failure to adequately supervise assisting personnel. (458.331(1)(dd), F.S.) (cc) Improper use of substances for muscle	 ranging from \$1,000.00 to \$2,500.00. (z) From probation to revocation, or denial of licensure, and an administrative fine ranging from \$1,000.00 to \$5,000.00. (aa) From a letter of concern to a reprimand and a administrative fine of \$1,000.00 to a letter of concern and an administrative fine of \$2,500.00. (bb) From a reprimand to probation, or denial of licensure, and an administrative fine ranging from \$1,000.00 to \$2,500.00. (cc) From a reprimand to suspension. 	administrative fine of \$5,000.00.(z) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.(aa) From a reprimand to probation, and an administrative fine ranging from \$2,500.00 to \$5,000.00.(bb) From probation to suspension followed by probation, or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.(cc) From suspension to revocation or denial of licensure, and an administrative fine

<u>concealing a material fact.</u> (458.331(1)(gg), F.S.) (ff) Improperly interfering with an investigation or a disciplinary proceeding. (458.331(1)(hh), F.S.);	and an administrative fine ra from \$500.00 to \$2,500.00, or denial of licensure with the abi reapply, upon payment of a \$5 fine. (ff) From a reprimand to probati denial of licensure, and	500.00
M.D., D.O. or PA, who is in violation of law.	probation, or denial of licensure	ern to (gg) From probation to revocation or denial re, and of licensure, and an administrative fine from ranging from \$2,500.00 to \$5,000.00.
opinion without reasonable investigation.		to a (hh) From probation to revocation or denial re, and of licensure, and an administrative fine from from \$2,500.00 to \$5,000.00.
an examination.	(ii) Suspension to revocation, or of licensure without an abili reapply.	denial (ii) Revocation or denial of licensure without ity to ability to reapply.
upon consideration of aggrava present in an individual case, the penalties recommended above. ' aggravating or mitigating factors (a) Exposure of patients or injury, physical or otherwise; non (b) Legal status at the time o legal constraints; (c) The number of counts or s (d) The number of times the s previously been committed by the (e) The disciplinary history of any jurisdiction and the length of	 Board may deviate from the The Board shall consider as the following: public to injury or potential public to injury or potential public, slight, severe, or death; f the offense; no restraints, or separate offenses established; same offense or offenses have e licensee or applicant; of the applicant or licensee in 	 concern, a reprimand, a 60-day suspension and/or a fine up to \$2,500.00; and for any subsequent offense, a fine up to \$5,000.00 and/or revocation of the certificate. Specific Authority 455.627 456.079, 458.309, 458.331(4) FS. Law Implemented 455.627 456.079, 458.331(4) FS. s. 25, Chapter 88-1, Florida Laws_ 456.072 FS. History-New 3-13-89, Formerly 21M-17.015, 61F6-17.015, 59R-30.015, Amended 6-7-98 NAME OF PERSON ORIGINATING PROPOSED RULE: Council on Physician Assistants NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Medicine DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 2, 2000 DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 27, 2000
(g) Any other relevant mitiga	Physician Assistant may be after due notice and a hearing s of this rule, it shall find: that ld himself out or permitted ensed physician. If any person ant in a medical setting as nt must immediately inform sistant is not a doctor. Upon a to immediately inform the	DEPARTMENT OF HEALTH Board of Osteopathic Medicine RULE TITLE: RULE NO.: Disciplinary Guidelines 64B15-6.011 PURPOSE AND EFFECT: The Board has determined that it is necessary to substantially reword the rule text to further clarify the rule text. SUMMARY: The Board proposes a substantial rewording of the disciplinary guidelines rule, which will set forth the penalties for second and subsequent violations for physician assistants.

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: 456.079, 459.015, 459.015(5) FS. LAW IMPLEMENTED: 456.072, 456.079, 459.015(5) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: William Buckhalt, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256

THE FULL TEXT OF THE PROPOSED RULE IS:

(Substantial rewording of Rule 64B15-6.011 follows. See Florida Administrative Code for present text.)

64B15-6.011 Disciplinary Guidelines.

(1) Purpose. Pursuant to Section 456.072, F.S., the Boards provide within this rule disciplinary guidelines which shall be imposed upon physician assistant applicants or licensees whom it regulates under Chapters 458 and 459, F.S. The purpose of this rule is to notify such applicants and licensees of the ranges of penalties which will routinely be imposed unless the Boards find it necessary to deviate from the guidelines for the stated reasons given within this rule. The ranges of penalties provided below are based upon a single count violation of each provision listed; for multiple counts of the violated provisions or a combination of the violations the Boards shall consider a higher penalty than that for a single, isolated violation. Each range includes the lowest and highest penalty and all penalties falling between. The purposes of the imposition of discipline are to punish the applicants or licensees for violations and to deter them from future violations; to offer opportunities for rehabilitation, when appropriate; and to deter other applicants or licensees from violations.

(2) Violations and Range of Penalties. In imposing discipline upon physician assistant applicants and licensees, in proceedings pursuant to Section 120.57(1) and 120.57(2), Florida Statutes, the Board shall act in accordance with the following disciplinary guidelines and shall impose a penalty within the range corresponding to the violations set forth below. The verbal identification of offenses are descriptive only; the full language of each statutory provision cited must be consulted in order to determine the conduct included.

VIOLATIONS	RECOMMENDED PENALTIES	
	First Offense	Subsequent Offenses
license or certificate by bribery, fraud or through an error of the Department or the Board. (459.015(1)(a), F.S.);	revocation, with ability to reapply, or	(a) From denial of license to revocation of license with ability to reapply in not less than three years and a fine up to \$5,000.00 to denial of license without ability to reapply.
(456.072(1)(h), F.S.)		
e e	comparable to the discipline which would have been imposed if the substantive violation had occurred in Florida to reprimand through suspension or denial of the license until the license is unencumbered in the jurisdiction in which disciplinary	(b) From imposition of discipline comparable to the discipline which would have been imposed if the substantive violation had occurred in Florida to suspension and revocation or denial of the license until the license is unencumbered in the jurisdiction in which disciplinary action was originally taken, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
license by another jurisdiction relating to	reapply in three (3) years, and an	<u>1. From permanent revocation and an administrative fine ranging from \$2,500.00</u> to \$5,000.00, or in the case of application for licensure, denial of licensure.
amounts in excess of \$5,000.00.	of application for licensure, denial of licensure.	
license by another jurisdiction relating to	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the license, or in case of application for	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure.
· · · · ·	· · · · · · · · · · · · · · · · · · ·	(c) From probation to revocation or denial of the license, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
related to healthcare fraud in	reapply in three (3) years, and an	1. From permanent revocation and an administrative fine ranging from \$2,500.00 to \$5,000.00, or in the case of application for licensure, denial of licensure.
	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure.

(d) False, deceptive, or misleading advertising. (459.015(1)(d), F.S.)		(d) From reprimand to suspension or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(e) Failure to report another licensee in violation. (459.015(1)(e), F.S.); (456.072(1)(i), F.S.)		(e) From reprimand to suspension or denial of licensure, and an administrative fine from \$2,500.00 to \$5,000 .00.
(f) Aiding unlicensed practice. (459.015(1)(f), F.S.); (456.072(1)(j), F.S.)		(f) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(g) Failure to perform legal obligation. (459.015(1)(g), F.S.); (456.072(1)(k), F.S.)	listed herein, based upon the severity of the offense and the potential for patient harm, from a reprimand to	(g) For any offense not specifically listed herein, based upon the severity of the offense and the potential for patient harm, from a reprimand to revocation or denial and an administrative fine from \$2,500.00 to \$5,000.00.
		<u>1. Document compliance with the CME</u> requirements for the relevant period; AND:
a. Failure to document required HIV/AIDS, or end of life care, or palliative health care.		a. An administrative fine ranging from \$500.00 to \$1,000.00.
b. Failure to document required domestic violence CME or substitute end-of-life-care CME.	6 6	b. An administrative fine of \$500 .00 to \$1,000.00.
c. Failure to document required HIV/AIDS, or end-of-life-care, or palliative health care, and failure to document domestic violence <u>CME.</u>	•••	<u>c. An administrative fine ranging from</u> \$1,000.00 to \$2,000.00.
Board within 30 days after	from \$1,000.00 to \$5,000.00 and a reprimand or denial of licensure, with	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00 and a reprimand or denial of licensure, without the ability to reapply.
Or failing to report to the Board convictions prior to the enactment of this section, in writing, on or before October 1, 1999. (456.072(1)(w), F.S.)		

3. Failing to disclose financial interest to patient. (456.052, F.S.)	of the patient and from an administrative fine of \$1,000.00 to a	3. A refund of fees paid by or on behalf of the patient and from a reprimand and an administrative fine of \$2,500.00 to a reprimand and an administrative fine of \$5,000.00.
	· · · ·	(h) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
· · · · ·		(i) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
•	reapply in three (3) years, and an	1. From permanent revocation and an administrative fine ranging from \$2,500.00 to \$5,000.00, or in the case of application for licensure, denial of licensure.
	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure.
(j) Kickbacks or split fee arrangements. (459.015(1)(j), F.S.)	behalf of the patient from a reprimand and an administrative fine of	(j) A refund of fees paid by or on behalf of the patient from suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(k) Improper refusal to provide healthcare. (459.015(1)(k), F.S.)		(k) From a reprimand to probation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(1) Sexual Misconduct. (459.015(1)(1), F.S.); (456.072(1)(u), F.S.)	· · · · ·	(1) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
fraudulent representations in		(m) From probation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00 to revocation.

fraudulent representations in the practice of osteopathic medicine relating to healthcare fraud in dollar	reapply in three (3) years, and an	1. From permanent revocation and an administrative fine ranging from \$2,500.00 to \$5,000.00, or in the case of application for licensure, denial of licensure.
fraudulent representations in the practice of osteopathic medicine relating to	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure.
(n) Improper solicitation of patients. (459.015(1)(n), F.S.).		(n) From suspension to revocation or denial of licensure, and an administrative fine from \$2,500.00 to \$5,000.00.
(o) Failure to keep written medical records. (459.015(1)(o), F.S.)	reprimand, or denial of licensure, and	(o) From a reprimand to suspension followed by probation, and an administrative fine ranging from \$2,500.00 to \$5,000.00, or denial of licensure.
written medical records relating to healthcare fraud in	reapply in three (3) years, and an	<u>1. From permanent revocation and an administrative fine ranging from \$2,500.00</u> to \$5,000.00, or in the case of application for licensure, denial of licensure.
written medical records relating to healthcare fraud in	from \$1,000.00 to \$5,000.00, and a reprimand through suspension of the	2. From an administrative fine ranging from \$2,500.00 to \$5,000.00, and suspension of the license, followed by a period of probation to revocation, or in case of application for licensure, denial of licensure.
(p) Fraudulent alteration or destruction of patient records. (459.015(1)(p), F.S.)		(p) From probation to revocation, or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(q) Exercising influence on patient for financial gain. (459.015(1)(q), F.S.); (456.072(1)(n), F.S.)	behalf of the patient and from a reprimand to probation, or denial of	(q) Payment of fees paid by or on behalf of the patient and from probation to suspension, or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(r) Improper advertising of pharmacy. (459.015(1)(r), F.S.)	probation, or a denial of licensure, and	(r) From a reprimand and an administrative fine of \$2,500.00 to probation, and an administrative fine from \$2,500.00 to \$5,000.00, or denial of licensure.
(s) Performing professional services not authorized by patient. (459.015(1)(s), F.S.)		(s) From a reprimand to revocation, or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.

(t) Inappropriate or excessive prescribing. (459.015(1)(t), F.S.)		(t) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(u) Prescribing, dispensing, administering of a scheduled drug by the physician assistant to himself or herself. (459.015(1)(u), F.S.)	denial of licensure, and an administrative fine ranging from	(u) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
<u>(v) Use of amygdalin</u> <u>(laetrile).</u> (459.015(1)(v), F.S.)	· · ·	(v) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(w) Inability to practice osteopathic medicine with skill and safety. (459.015(1)(w), F.S.)	which may be stayed to allow a period of probation with supervision, and a demonstration by the licensee of the	(w) From probation to revocation, until the licensee is able to demonstrate ability to practice with reasonable skill and safety, followed by probation, or denial of licensure, and an administrative fine from \$2,500.00 to \$5,000.00.
		(x)1. From reprimand to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
2. Gross Malpractice	denial of licensure, and an	2. From suspension followed by probation to revocation or denial, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
3. Repeated Malpractice	-	3. From probation to revocation or denial of licensure, and an administrative fine from \$5,000.00 to \$5,000.00.
		(y) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(z) Practicing beyond scope permitted. (459.015(1)(z), F.S.).	reprimand and probation, or denial of	(z) From probation to suspension or revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(aa)Delegationofprofessionalresponsibilitiesto unqualified person.(459.015(1)(aa), F.S.);(456.072(1)(p), F.S.)		(aa) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.

or failure to comply with		(bb)1. From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
2. Violation of an order of the Board.	administrative fine of \$1,000.00 to a	2. From a reprimand and an administrative fine of 2,500.00 to a reprimand and an administrative fine of \$5,000.00 and probation.
		(cc) From a reprimand and an administrative fine of \$2,500.00 to a reprimand and an administrative fine of \$5,000.00.
(dd) Aiding an unlawful abortion. (459.015(1)(dd), F.S.)	· · · · · · · · · · · · · · · · · · ·	(dd) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
(ee) Presigning prescription forms. (459.015(1)(ee), F.S.)		(ee) From a reprimand to probation, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
	denial of licensure, and an	(ff) From probation to revocation or denial of licensure without ability to re-apply, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
		(gg) From probation to revocation or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
	denial of licensure, and an	(hh) From probation to suspension followed by probation, or denial of licensure, and an administrative fine ranging from \$2,500.00 to \$5,000.00.
substances for muscle	· · · ·	(ii) From suspension to revocation or denial of licensure, and an administrative fine ranging from \$1,000.00 to \$5,000.00.
concealing a material fact	an administrative fine ranging from	(jj) From probation to revocation or denial of licensure without the ability to reapply, and an administrative fine ranging from \$500.00 to \$5,000.00.

(kk) Providing medical	(kk) From a letter of concern to a	(kk) From probation to revocation or denial
opinion on claim without	reprimand, or denial of licensure, and	of licensure, and an administrative fine from
reasonable investigation.	an administrative fine ranging from	<u>\$2,500.00 to \$5,000.00.</u>
(459.015(1)(mm), F.S.)	\$1,000.00 to \$2,500.00.	
(11) Theft or reproduction of	(11) Suspension to revocation, or denial	(11) Revocation or denial of licensure without
an examination.	of licensure without an ability to	ability to reapply.
<u>(456.018, F.S.)</u>	<u>reapply.</u>	

(3) Aggravating and Mitigating Circumstances. Based upon consideration of aggravating and mitigating factors present in an individual case, the Board may deviate from the penalties recommended above. The Board shall consider as aggravating or mitigating factors the following.

(a) Exposure of patients or public to injury or potential injury, physical or otherwise; none, slight, severe, or death;

(b) Legal status at the time of the offense; no restraints, or legal constraints;

(c) The number of counts or separate offenses established;

(d) The number of times the same offense or offenses have previously been committed by the licensee or applicant;

(e) The disciplinary history of the applicant or licensee in any jurisdiction and the length of practice;

(f) Pecuniary benefit or self-gain inuring to the applicant or licensee:

(g) Any other relevant mitigating factors.

(4) The certification of a Physician Assistant may be disciplined by the Board when, after due notice and a hearing in accordance with the provisions of this rule, it shall find: that the Physician Assistant has held himself out or permitted another to represent him as a licensed physician. If any person addresses the Physician Assistant in a medical setting as "Doctor," the Physician Assistant must immediately inform that person that the Physician Assistant is not a doctor. Upon a finding by the Board of failure to immediately inform the person, the following penalty shall be imposed: a letter of concern, a reprimand, a 60-day suspension and/or a fine up to \$2,500.00; and for any subsequent offense, a fine up to \$5,000.00 and/or revocation of the certificate.

Specific Authority <u>456.079</u>, 459.0015, 459.015(5), 455.2273 FS Law Implemented <u>456.072</u>, <u>456.079</u> <u>455.2273</u>, 459.015(5) FS., s. 35, Chapter 88 1, Florida Laws. History–New 4-18-89, Formerly 21R-6.011, Amended 11-4-93, Formerly 61F9-6.011, 59W-6.011, Amended 6-7-98._____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Osteopathic Medicine

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 1, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 20, 2000 DEPARTMENT OF HEALTH

Board of Osteopathic Medicine RULE TITLE:

RULE NO.: 64B15-12.007

Inactive Status License 64B15-12.007 PURPOSE AND EFFECT: The Board proposes to amend this rule to update the rule text with regard to inactive status license of a licensee, and to delete rule text that is no longer desired by the Board.

SUMMARY: Additional language clarifies the renewal fee of an active/inactive license, and unnecessary language is being stricken.

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: 456.036 FS.

LAW IMPLEMENTED: 456.036 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE NEXT AVAILABLE ISSUE OF THE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: William Buckhalt, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256

THE FULL TEXT OF THE PROPOSED RULE IS:

64B15-12.007 Inactive Status License.

(1) No change.

(2) An inactive status licensee may change to active status at any time provided the licensee meets the continuing education requirements of rule 64B15-13.001, pays the reactivation fee <u>and the active status renewal fee.</u>, and if If the request to change licensure status is made at any time other than at the beginning of a licensure cycle, <u>the licensee shall</u> <u>only pay the difference between the inactive status renewal fee</u> and the active status renewal fee and pays the additional processing fee. However, a licensee whose license has been in inactive status for more than two consecutive biennial licensure cycles shall be required to appear before the board before the license can be placed into active status. The board at the time of the appearance shall impose upon the licensee reasonable conditions necessary to insure that the licensee can practice with the care and skill sufficient to protect the health, safety and welfare of the public.

(3) Any inactive licensee who elects active status is not eligible to elect to return to inactive status until the next licensure renewal period.

 Specific Authority
 456.036
 455.711
 FS. Law Implemented
 456.036
 455.711

 FS.
 History–New
 11-28-94, Amended
 3-28-95, Formerly
 59W-12.007, Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Osteopathic Medicine

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 15, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 17, 2000

DEPARTMENT OF HEALTH

Division of Family Health Services

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

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

SUMMARY: The proposed rule clarifies terms used in the law and rule; repeals language that is redundant to recently enacted legislation; updates references to federal laws and regulations incorporated by reference; articulates another condition qualifying as an emergency medical reason exception to the prohibition of wholesaling by a health care entity; provides that a prescription or order for medical oxygen must be in the hands of the medical oxygen retailer within 30 days of delivery of the drug to the patient; clarifies recordkeeping requirements for pharmacies and other persons transferring prescription drugs to reverse distributors and destruction facilities; articulates recordkeeping requirements for donations of prescription drugs by health care entities; updates application forms incorporated by reference in the rule; clarifies that notification of a change of address of a permitted person must be in writing; identifies additional permit applications that do not require an on-site inspection or an initial application/on-site inspection fee prior to approval; requires submission of a clearance letter for new Prescription Drug Wholesaler and Prescription Drug Wholesaler - Broker Only applicants; reduces the fee requirements for certain restricted prescription drug distributor permit applicants; reinstates language regarding inspections, investigations and monitoring; provides for transfers of prescription drugs to institutional researchers under certain conditions; and modifies the administrative enforcement provisions.

SUMMARY OF STATEMENT OF **ESTIMATED** REGULATORY COST: There would be an additional administrative cost associated with recording the lot number on the donation record for prescription drugs donated by a health care entity to a charitable organization. Lot numbers tend to be five to ten digits in length and we estimate it would take an additional three to five seconds per item to record the lot number. The additional cost associated with a clearance letter for a new Prescription Drug Wholesaler and Prescription Drug Wholesaler – Broker Only permit applicant is estimated at \$25 per owner, officer, and manager-in-charge of a sole proprietorship, partnership, and closely held corporation. The cost for a Restricted Rx Drug Distributor - Institutional Research permit applicant is \$400 for a two-year permit.

Any person who wishes to provide information regarding the statement of estimatee 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: 499.01, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.028, 499.03, 499.04, 499.041, 499.05, 499.052, 499.61, 499.62, 499.63, 499.64, 499.66, 499.67, 499.701 FS.

LAW IMPLEMENTED: Chapter 499, Parts I and II 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: 10:00 a.m., Monday, January 22, 2001 PLACE: 2818-A Mahan Drive, Tallahassee, Florida 32308; in the Bureau of Pharmacy Services Conference Room THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Sandra Stovall, Compliance Officer, 2818-A Mahan Drive, Tallahassee, Florida 32308; (850)487-1257 ext. 210; sandra_stovall@doh.state.fl.us.fl. You may also obtain information regarding the rule

promulgation at the bureau's web site at doh.state.fl.us/pharm.

THE FULL TEXT OF THE PROPOSED RULES IS:

64F-12.001 General Regulations; Definitions.

(1) A word or phrase defined in 21 U.S.C. ss. 301 et seq. or federal regulations promulgated thereunder in Title 21 Code of Federal Regulations(CFR), (as of 1/1/01 + 2/1/98) which are incorporated by reference, shall have the same meaning as in those provisions unless specifically defined otherwise in Chapter 499, F.S., or rule chapter 64F-12, F.A.C.

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

(a) No change.

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

(c) "Broker" – means a person participating in the wholesale distribution of a prescription drug that buys and sells the drug but does not take physical possession such that the drug is "sold to" the broker and "shipped to" a third party. (d)(c) "Change in Ownership" – means a majority (50% or more) of the ownership or controlling interest changes. A change in ownership occurs when there has been any change in a partnership amounting to 50% or more of the ownership or controlling interest. For a <u>publicly traded</u> corporation, the changing of officers or directors is not a change in ownership <u>nor is the change in ownership of a parent company</u> provided that such change does not result in a 50% change in the ownership or controlling interest <u>of any permitted</u> <u>establishment</u>.

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

(e) No change.

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

(g) through (h) renumbered (f) through (g) No change.

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

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

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

(j) "Practitioner" means a persons 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. (k) "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.

(l) through (s) No change.

(t) "State Current Good Manufacturing Practices" means current good manufacturing practices and quality system regulations as prescribed as of 1/1/01 12/1/98 in Title 21 Code of Federal Regulations, Parts 210, 211, 600-610, and 820, and the federal guidelines which are incorporated by reference herein and made a part of this rule, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the guidelines for manufacturing cosmetics as set forth in rule in 64F-12.010.

(u) "Unapproved new drug" – means any drug which is a new drug and has not been approved <u>or otherwise authorized</u> for use under the federal act, 21 U.S.C. ss. 301 et seq., <u>and the regulations promulgated thereunder or</u> which does not have a Notice of Claimed Investigational Exemption on file with the United States Food and Drug Administration, or is not authorized in Florida under s. 499.018, F.S.

(v) No change.

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

64F-12.002 False and Misleading Labeling or Advertising.

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

64F-12.003 Guaranty or Undertaking.

(1) No change.

(2) A guaranty or undertaking may be limited or general and continuing as set forth in Title 21 CFR Sections 7.12 and 7.13, (as of $\frac{1/1/01}{12/1/98}$) which are incorporated by reference.

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

64F-12.004 Prohibited Acts.

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

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

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

64F-12.006 Drugs and Devices; Labeling Requirements.

(1) The department adopts and incorporates by reference the labeling requirements for prescription drugs and over-the-counter drugs as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 1-1299 (as of $\frac{1}{1/101} \frac{12}{12/1/98}$).

(a) through (c) No change.

(2) The department adopts and incorporates by reference the labeling requirements for medical devices as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 800-895 (as of $\frac{1}{1/01} \frac{12}{12/1/98}$).

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

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

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

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

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

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

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

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

(1) Distributions of complimentary or sample packages of prescription drugs listed within the provisions of s. 893.03, F.S., must also comply with provisions in Rule Chapter 64B-16-28, F.A.C., Chapter 465, F.S., and Title 21 CFR 1301, (as of _____ 12/1/98) which is incorporated by reference herein.

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

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

(a) through (b) No change.

(c) A complete and accurate donation record must be prepared and maintained by the donor and recipient. The donation record shall include the elements set forth in Rule 64F-12.012(15).

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

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

3. the date of the donation;

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

5. the signature of the donor; and

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

(d) No change.

(2)(3) Disposal. All complimentary or sample packages of prescription drugs which are expired shall be returned to the manufacturer or distributor. Complimentary or sample packages of prescription drugs which are otherwise unsuitable for the purpose of administering or dispensing may be returned to the manufacturer or distributor or may be destroyed in accordance with the provisions of paragraph (4)(5). Prescription drug samples may be sent to a reverse distributor if the manufacturer of the sample has authorized the reverse distributor to handle that manufacturer's prescription drug sample returns.

(3)(4) Complimentary or sample packages of prescription drugs returned to the manufacturer or distributor from which obtained or to a reverse distributor acting on behalf of the manufacturer, must be documented with records which include the date of the return; the name, form and quantity of the substance by lot number; the name, address, and license or permit number, of the person making the return; and the name, address, and license or permit number, of the manufacturer or person to whom the prescription drug samples are returned.

(4)(5) The destruction of complimentary or sample packages of prescription drugs which may be destroyed as provided in paragraph (3) must be documented with a complete inventory identifying the items destroyed and a notation on the inventory as to the date and method of destruction.

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

64F-12.009 Cosmetic Labeling Requirements.

The department adopts and incorporates by reference the labeling requirements for cosmetics as set forth in the federal act at 21 U.S.C. ss. 301 et seq. and in Title 21 Code of Federal Regulations Parts 700-799 (as of $1/1/01 \frac{12/1/98}{12/1/98}$).

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

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

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

(a) through (e) No change.

(f) transfers of prescription drugs from a health care entity to a pharmacy or other end-user practitioner for a named patient to treat or prevent a serious medical condition when a shortage of the product is documented by the manufacturer;

but does not include regular and systematic sales of prescription drugs to licensed practitioners that will be used for routine office procedures.

(2) The revocation of a sale or the return of a prescription drug purchased by a hospital or other health care entity, or acquired at a reduced price by or donated to a charitable institution to the manufacturer or the wholesale distributor that sold, donated, or supplied the prescription drug, is not a wholesale distribution prohibited by s. 499.005(21), F.S., provided:

(a) through (b) No change.

(c) Prescription drugs returned or to be returned to a manufacturer or wholesale distributor must be kept under proper conditions for storage, handling, and shipping <u>as set</u> forth in s. 499.0121; and written otherwise documentation showing that <u>these</u> proper conditions were <u>or were</u> not maintained must be provided to the manufacturer or wholesale distributor to which the prescription drugs are returned.

Specific Authority 499.012, 499.014, 499.03, 499.05 FS. Law Implemented 499.012, 499.014, 499.03 FS. History–New 7-1-96, Formerly 10D-45.0525, Amended 1-26-99._____.

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

(1) No change.

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

(d) Records to document the distribution of prescription drugs required by s. 499.0121(6) 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 Rule 64F-12.023(3)(a).

(e) through (3) No change.

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

(5) <u>A copy of the Florida Drug and Cosmetic Act, Chapter</u> 499, Florida Statutes, and Rule 64F-12, Florida Administrative <u>Code</u>, Regulation for Drugs, Devices and Cosmetics, must be at the permitted establishment. Any person who manufactures devices, over-the-counter drugs, or cosmetics must maintain records which include the following information on one document: the name and principal address of the seller or transferor, the address of the location from which the products were shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person purchasing the product.

(6) through (14) No change.

(15) Charitable Donations of Prescription Drug. A physician or other authorized recipient donating prescription drugs, including prescription drug samples, pursuant to s. 499.012(1),(2)(e), F.S., must prepare and maintain a donation record that includes at a minimum: Additional recordkeeping requirements for complimentary prescription drugs are detailed in Rule 64F-12.008.

(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.

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

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

(1) No change.

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

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

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

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

(3) through (5) No change.

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

64F-12.015 Licensing, Application, Permitting.

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

(1) No change.

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

(a) No change.

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

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

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

<u>1.3.</u> a Restricted Rx Drug Distributor – Charitable Organization permit will be issued in the name of the charitable organization or health care entity, and

<u>2.4.</u> a Medical Oxygen Retailer permit may be issued in the name of a nursing home's Class I Institutional Pharmacy permit.

(c) No change.

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

(a)<u>1.</u> A person permitted as Prescription Drug Manufacturer that is applying for additional manufacturing permits or a Prescription Drug Wholesaler permit at that address does not require another on-site inspection and is not required to pay an initial application/on-site inspection fee when applying for the additional permits.

2. A person permitted as an Over-the Counter Drug Manufacturer that is applying for a Device Manufacturer permit or Cosmetic Manufacturer permit at that address does not require another on-site inspection and is not required to pay an initial application/on-site inspection fee when applying for the additional permit.

3. A person permitted as a Cosmetic Manufacturer or Device Manufacturer that is applying for a Device Manufacturing permit or Cosmetic Manufacturing permit does not require another on-site inspection and is not required to pay an initial application/on-site inspection fee when applying for the additional permit.

(b) through (c) No change.

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

(4) No change.

(5) Notification to the department regarding the <u>change of</u> <u>address of a permitted establishment must be in writing</u>. <u>A</u> <u>Change of Address form is available on the bureau's web site</u>. <u>Notification regarding the</u> closing of a permitted establishment shall also include the name <u>and</u>, address, and telephone number of a person to contact for up to two years after the closing of the business <u>for regarding</u> access to required records.

(6) MANUFACTURER PERMITS.

(a) No change.

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

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

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

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

3. through 5. No change.

(7) WHOLESALER PERMITS.

(a) through (c) No change.

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

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

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

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

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

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

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S." effective <u>JUN00</u> Jan. 1999, which is incorporated by reference herein.

3. Submit a photocopy of the resident state's license or permit that authorizes the wholesale distribution of prescription drugs. If the resident state does not require a license or permit for the wholesale distribution activities of the applicant in that state, submit a written confirmation on the resident state's letterhead that permitting of the applicant establishment is not required by that state. The Out-of-State Prescription Drug wholesaler application will not be approved until the license or permit status in the resident state is verified.

4. through 5. No change.

(f) Application requirements for Retail Pharmacy Wholesalers include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

3. through 5. No change.

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

(a) Application requirements for Complimentary Drug Distributors include:

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

3. through 5. No change.

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

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

3. through 5. No change.

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

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

3. through 6. No change.

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

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

3. through 4. No change.

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

1. No change.

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

3. No change.

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

5. through 6. No change.

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

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

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective JUN00, which is incorporated by reference herein.

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

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

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

1. Contact the department's Bureau of Pharmacy Services to request an application or download the application from the bureau's web site. 2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference herein.

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

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

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

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

2. File with the department a completed application for a permit using an original DOH Form 1033, "Application for Permit Under Chapter 499, F.S.," effective <u>JUN00</u> January 1999, which is incorporated by reference to this rule.

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

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

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

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

(a) No change.

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

1. file with the department a completed application for a permit using an "Application for Permit Renewal Under Chapter 499, F.S., " DOH Form 1034, effective <u>JUN00</u> January 1999, which is incorporated by reference herein. The permittee should contact the department if the renewal application has not been received at least 30 days prior to the permit's expiration date.

2. through 5. No change.

(c) No change.

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

64F-12.016 Product Registration.

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

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

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

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

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

(c)(f) The separate and distinct drug, device, or cosmetic product for a person who performs limited manufacturing operations at an establishment such as only encapsulating, sterilizing or other processing or manipulation of the product, but not labeling, may be the product resulting from such processing and not each separate and distinct product to which the limited manufacturing operation is performed.

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

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

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

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

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

(b) No change.

(3) No change.

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

64F-12.017 Certificates of Free Sale.

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

(2) No change.

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

64F-12.018 Fees.

(1) through (2) No change.

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

Permit Biennia	l Fee
Complimentary Drug Distributor	\$500
Veterinary Legend Drug Retail Establishment	\$500
Medical Oxygen Retail Establishment	\$500
Restricted <u>Rx</u> Drug Distributors – <u>Health Care Entity</u>	\$500
Restricted Rx Drug Distributor – Charitable	
<u>Organization</u>	<u>\$400</u>
Restricted Rx Drug Distributor – Reverse Distributor	<u>\$500</u>
Restricted Rx Drug Distributor – Destruction	<u>\$500</u>
Restricted Rx Drug Distributor – Government Programs	
<u>Restricted Rx Drug Distributor – Institutional Research</u>	
(4) Miscellaneous other fees are as follows:	
Description of other service fees	Fee
Initial Application/On-site Inspection	
(initial application)	\$150
(The initial application/on-site inspection fee	<u>e is</u>
<u>non-refundable.)</u>	
Prescription Drug Wholesaler Bond (refundable)	\$200

Change of Address Fee:

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

Product Registration (per <u>drug or cosmetic</u> product registered) \$ 20 *

* The registration fee for a <u>drug or cosmetic</u> product being amended to an existing product registration that has 12 months or less until it expires is \$10.

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

(5) No change.

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

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

64F-12.019 Inspections, Investigations, Monitoring.

(1) An inspection or investigation is a review or examination of an establishment permitted under the provisions of chapter 499 or any rule adopted thereunder, or of a non-permitted establishment for the purpose of protecting public health from misbranded or adulterated drugs, devices, or cosmetics or from any other violation of chapter 499 and chapter 893 or any rules adopted thereunder. An inspection may also take place in a non-permitted establishment to assess whether the establishment complies with the requirements for a chapter 499 permit.

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

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

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

(a) Review and copying of all records pertaining to the manufacture, advertisement, storage, holding, and distribution of any prescription, over-the-counter or investigational drug, device or cosmetic. These records include, but are not limited

to receiving documents, shipping documents, purchase orders, purchase requisitions, invoices, paid receipts, contracts, checks, deposits, and credits or debits in any form whatsoever;

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

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

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

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

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

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

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

(i) Observations and identification of:

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

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

<u>3. Any unsanitary conditions or practices which may</u> render a drug, device or cosmetic injurious to health;

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

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

<u>6. Any deviation from FDA requirements for the label and labeling of any drug, device or cosmetic;</u>

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

(j) Taking of evidence related to a drug, device or cosmetic that is or may be in violation of chapter 499 or 893 or any rules adopted thereunder; and

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

(5) The department shall take reasonable steps to assure that a sampled product is not reintroduced into commerce if it is or has become adulterated or misbranded. Specific Authority 499.05 FS. Law Implemented Chapter 499, Parts I and II FS. History–New 7-8-84, Formerly 10D-45.545, Amended 11-26-86, 7-1-96, Formerly 10D-45.0545, 64F-12.019 invalidated 2-22-00, Amended

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

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

(1) through (b) No change.

(c) The charitable organization may transfer prescription drugs on a daily basis to a Florida licensed medical practitioner providing services to patients of the charitable organization on behalf of the charitable organization. <u>If the practitioner leaves</u> the charitable organization establishment with prescription <u>drugs of the charitable organization</u>, a A record documenting the daily transfer to the practitioner must be prepared as well as a record of the prescription drugs administered or dispensed and the prescription drugs returned by the practitioner to the charitable organization upon completion of providing services for the charitable organization on that date.

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

(3) through (4) No change.

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

(a) No change.

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

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

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

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

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

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

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

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

(a) A non-practitioner recipient researcher is not required to obtain an exemption letter pursuant to rule 64F-12.011(4) if the researcher and research activities are located on the university campus. However, if the researcher is not located on the university campus and the drug is not stored on the university campus, then an exemption letter is required prior to the transfer of any prescription drugs to the researcher. (b) The Restricted Rx Drug Distributor – Institutional Research permit holder must maintain records that include at a minimum, the researcher; specific research project/grant number; location in which the research is done and/or storage location of the prescription drug and the researcher's exemption number if applicable; and the name, strength, dosage form, and quantity of the drug transferred to the researcher. The researcher's DEA number is also required if a controlled substance has been transferred to the researcher. The researcher must sign for the prescription drug with an acknowledgement that the drug cannot be sold, traded or transferred to anyone not directly involved in the specific research project for which the drug was obtained. If the permit holder is a pharmacy, these records must be maintained separate from the pharmacy dispensing records.

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

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

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

64F-12.024 Administrative Enforcement.

(1) through (3) No change.

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

3 = Warning Letter,

Letter of Violation with no fine or

Notice of Violation or Administrative Complaint with a fine ranging from \$250* to \$1,000 per violation per day.

(*) If medical oxygen is the prescription drug involved, the range of the fine is \$50 to \$1,000.

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

1 = Notice of Violation or Administrative Complaint with a fine ranging from 1,000 - 5,000 per violation per day;

Suspension of the permit with a fine; or Revocation of the permit with a fine.

<u>CITE</u> 499 refers to Cha	VIOLATION ptor 400, E S	<u>GENERAL</u> <u>SEVERITY</u>	499.013(2)(d)	Device Manufacturer not following GMP	3-1
12 refers to Rule	-	<u>SEVERITT</u>	12.010	Cosmetic Manufacturer	5-1
			12.010	not following GMP/guidelines	3-1
FACILITY, STO	<u>KAGE:</u>		499.005(1)	Activity with drug which	51
No change.			$\frac{499.005(1)}{12.004(2)}$	left regulatory control, GMP	3-1
MISCELLANEO	<u>108:</u>		<u>COUNTERFEIT:</u>	for regulatory control, chil	51
No change.			No change.		
OPERATING:			FALSE & MISLE	ADING	
499.005(6) &			499.005(5) &	<u>ADINO.</u>	
499.67(5)	Refusing entry, inspection,	0.1	12.002	Disseminating false/	
100.005(6)	taking evidence	2-1	12.002	misleading ad	3
499.005(6)	Inaccessible during	2	499.005(7)	Giving a false guaranty	5
10.015(0)(.).10.0	business hours	3	499.003(7)	or undertaking	2
<u>12.015(2)(c)</u> 12.0			499.005(10)	Forging, counterfeiting,	2
499.005(22); 499			499.003(10)	falsely representing a product	2-1
12.015	Failure to obtain proper		499.005(11) &	Labeling or advertisement	2-1
	permit; (cost of permit	-	$\frac{12.002}{12.002}$	of effectiveness when not	3
	plus fine)	3	499.005(19); 499.		5
499.015 &	Failure to register products				
12.012	(\$50 per product	2	499.66 & 499.67	Making false or fraudulent statements	2-1
	per year)	3	400.005(10)		2-1
499.01(4)(a) &			499.005(19) 499.64(4),499.67	Providing department with false/fraudulent records/	
12.012(4)	Failure to notify dept. of	-	499.04(4),499.07	statements	2-1
	address change	3	499.0054	Advertising Violations	2-1 3
RECORDKEEPI	<u>NG:</u>		499.0034 499.005(19) &	•	3
No change.			499.005(19) & 499.005(23)	Obtaining/attempting to obtain by fraud, deceit,	
SAMPLES:			499.003(23)	misrepresentation, subterfuge	2-1
499.005(17)	Sample drug distribution –		499.005(13)	Activity w/ self-testing	2-1
	activity with	1	499.003(13)	HIV/AIDS products	2
12.004(1)	Repackaging sample drugs	1	UNAUTUODIZE	D SOURCE OR RECIPIENT:	2
499.005(25)	Charging a dispensing fee for		499.005(14) &	Purchase or receipt of	
12.004(5)	a prescription sample	<u>2-</u> 1	$\frac{12.004(6)}{12.004(6)}$	prescription drug from	
	D & MISBRANDED:		12.00+(0)	unauthorized source	3*
499.005(1)	Activity with adulterated or		499.005(16)	Purchase/receipt of Comp	5
	misbranded product	3-1	499.003(10)	Med Gas from unauthorized	
499.005(2)	Adulterating or misbranding			source	3*
	a product	3-1	499.005(15) &	Sale or transfer of	5
499.005(3)	Receiving adulterated/		$\frac{12.004(4)}{12.004(4)}$	prescription drug to	
	misbranded product	3	12.001(1)	unauthorized person	3*
499.005(9)	Making a product misbranded	1 3-1	499.005(24)	Sale or transfer of legend	5
12.007(3)	Improper labeling on medical		<u>1)),005(21)</u>	device to unauthorized person	<u>3</u>
	oxygen	3	12.004(7)	Distributing investigational	<u>~</u>
499.013(2)(a)	Prescription Drug		12.004(7)	drug to unauthorized person	3
	Manufacturer not		499.0122(1)(d) &	drug to unautionized person	5
	following GMP	3-1	12.012(4)	Improper sale of	
499.013(2)(b)	OTC Drug Manufacturer		12.012(4)	veterinary prescription drug	3
	not following GMP	3-1	12.012(4)	Distribution of medical	5
499.013(2)(c) &			12.012(4)	oxygen by a medical oxygen	
12.007(1)	Compr. Med. Gas			retailer without a	
	Manufacturer not following			prescription (order)	3
	GMP	3-1		Drescribtion (order)	7

499.66	Sale or transfer of ether	
	to unauthorized person	3-2

POSSESSION:

No change.

(5) No change.

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

NAME OF PERSON ORIGINATING PROPOSED RULE: Jerry Hill, R.Ph, C.Ph, Chief of the Bureau of Pharmacy Services

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Leslie M. Beitsch, M.D., J.D., Assistant State Health Officer

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 8, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: September 1, 2000

FISH AND WILDLIFE CONSERVATION COMMISSION

Freshwater Fish and Wildlife

RULE TITLE:

RULE NO.:

Specific Fish Management Area Regulations 68A-20.005 PURPOSE AND EFFECT: The proposed rule would close the newly-acquired Hardee Park Fish Management Area (FMA) in Hardee County to public fishing until park development is completed and fish populations develop sufficiently to support public use. The proposed rule would also establish fishing, angler access, and boating regulations in order to open Lake Piney Z FMA in Leon County to public fishing and effectively manage public use of freshwater fisheries resources to provide a quality fishing area and quality fishing opportunities for freshwater anglers.

SUMMARY: The proposed rule would close the newly established Hardee County Park FMA, Hardee County to fishing. The proposed rule establishes public access, fish harvest, and boating regulations for the Lake Piney Z FMA, Leon County.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: It is estimated that the proposed action will cost the agency approximately \$120 for administrative preparation, \$100 for advertising, and \$400 for signs and brochures.

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: Art. IV, Sec. 9, Fla. Const.

LAW IMPLEMENTED: Art. IV, Sec. 9, Fla. Const.

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

TIME AND DATES: 8:30 a.m., each day, January 24-26, 2001 PLACE: Radisson Mart Plaza Hotel, 711 Northwest 72 Avenue, Miami, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE AND ECONOMIC STATEMENT IS: James Antista, General Counsel, Florida Fish and Wildlife Conservation Commission, 620 South Meridian Street, Tallahassee, Florida 32399-1600

THE FULL TEXT OF THE PROPOSED RULE IS:

68A-20.005 Specific Fish Management Area Regulations.(1) Northwest Region:

(a) through (h) No change.

(i) Lake Piney Z, Leon County: Closed to fishing.

1. Swimming, possession of firearms or possession of alcoholic beverages is prohibited.

2. <u>Watercraft shall be allowed only as prescribed by the</u> <u>City of Tallahassee</u>. Boats are prohibited.

3. Motor vehicles are prohibited on dams, spillways and earthen fishing fingers.

4. Use or possession of minnow seines or castnets is prohibited.

5. No person shall kill or possess any black bass.

<u>6. No person shall take in any one day more than 20 panfish, in the aggregate.</u>

7. Access is prohibited from sunset until sunrise.

(2) through (3) No change.

(4) South Region:

(a) through (t) No change.

(u) Hardee County Park, Hardee County – All water bodies closed to fishing.

(5) No change.

(6) This rule shall become effective on April 1, 2001.

Specific Authority Art. IV, Sec. 9, Fla. Const. Law Implemented Art. IV, Sec. 9, Fla. Const. History–New 8-1-79, Amended 2-19-80, 5-19-80, 6-4-81, 9-28-81, 6-21-82, 7-1-83, 11-17-83, 7-1-84, 7-1-85, Formerly 39-20.05, Amended 2-27-86, 6-1-86, 5-10-87, 4-13-88, 12-12-88, 7-1-89, 7-1-90, 4-11-91, 7-1-91, 7-1-92, 7-2-92, 8-23-92, 4-20-93, 7-1-94, 8-15-95, 10-23-95, 4-1-96, 2-16-97, 6-1-97, 6-29-97, 1-1-98, 3-24-98, 7-1-98, 11-2-98, Formerly 39-20.005, Amended 4-30-00, 7-1-00, 10-10-00, 4-11-01.

NAME OF PERSON ORIGINATING PROPOSED RULE: Darrell L. Scovell

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Dr. Allan L. Egbert

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 1, 1999

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: September 15, 2000

FISH AND WILDLIFE CONSERVATION COMMISSION

Freshwater Fish and Wildlife

RULE TITLE:

Designation of Species of Special Concern; Prohibitions; Permits 68A-27.005

RULE NO.:

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to remove the common snook (*Centropomus undecimalis*) from the list of species of special concern.

SUMMARY: A petition to remove the common snook from the list of species of special concern was received in September 10, 1999. The Commission approved starting Phase 1 of the listing action process at its December 8-9, 1999 meeting. A notice requesting written comments on the biological status of the common snook was issued on December 23, 1999. No comments were received. A biological status report was developed that recommended that the common snook be removed from the list of species of special concern. The Commission determined at its September 6-8, 2000 meeting that removing the common snook from the Species of Special Concern list was warranted, thereby ending Phase 1 and beginning Phase 2 of the listing action process. A notice requesting information on the conservation needs of the common snook and any economic and social factors that should be considered in its management was issued October 20, 2000. No comments have been received as of the date of this Notice of Proposed Rule. Commission staff believe that existing regulations of snook in Rule 68B-21 are sufficient for managing common snook and no additional management plan is necessary. Therefore, staff has recommended that Phase 2 be closed and the common snook removed from the list of species of special concern at the January 24-26, 2001 Commission meeting.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: It is estimated that the proposed action will cost the agency approximately \$215 for administrative preparation and \$235 for advertising. No other significant economic impacts are expected.

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: Art. IV, Sec. 9, Fla. Const.

LAW IMPLEMENTED: Art. IV, Sec. 9, Fla. Const.

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

TIME AND DATES: 8:30 a.m., January 24-26, 2001

PLACE: Radisson Mart Plaza Hotel, 711 Northwest 72nd Avenue, Miami, Florida 33126

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE AND ECONOMIC STATEMENT IS: Mr. James Antista, General Counsel, Florida Fish and Wildlife Conservation Commission, 620 South Meridian Street, Tallahassee, Florida 32399-1600

THE FULL TEXT OF THE PROPOSED RULE IS:

68A-27.005 Designation of Species of Special Concern; Prohibitions; Permits.

(1) The following species are hereby declared to be of special concern, and shall be afforded the protective provisions specified.

(a) No person shall take, possess, transport, or sell any species of special concern included in this subsubsection or parts thereof or their nests or eggs except as authorized by Commission regulations or by permit from the executive director or by statute or regulation of any other state agency, permits being issued upon reasonable conclusion that the permitted activity will not be detrimental to the survival potential of the species.

1. No change.

2. Common snook (*Centropomus undecimalis*) (1, 4) Deleted.

3. through 50. renumbered 2. through 49. No change.

The above listed species have been further categorized by the numbers in parentheses under the following criteria:

(1) through (5) No change.

Specific Authority Art. IV, Sec. 9, Fla. Const. Law Implemented Art. IV, Sec. 9, Fla. Const. History–New 8-1-79, Amended 6-22-80, 6-21-82, 7-1-84, 7-1-85, Formerly 39-27.05, Amended 6-1-86, 5-10-87, 4-27-89, 10-22-92, 5-26-94, 6-23-99, Formerly 39-27.005, Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Mr. Timothy A. Breault

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Dr. Allan L. Egbert

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 8, 2000

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 22, 2000

FISH AND WILDLIFE CONSERVATION COMMISSION

Marine Fisheries

RULE CHAPTER TITLE: Cobia

RULE IIILES:	RULE NOS.
Definitions	68B-19.001
Cobia, Size Limit	68B-19.002
Designation as Restricted Species; Bag	
and Possession Limits	68B-19.004

DULE NOS .

PURPOSE AND EFFECT: The purpose of these rule amendments is to address complaints received from the public concerning increasing sales of recreationally-harvested cobia and the effect such harvest and sales have on the abundance of the species. Cobia is one of the few commercially-valuable marine fish not designated as a restricted species, allowing recreational harvesters to sell the fish with only the purchase of a \$50 saltwater products license. Appropriately, the rule amendments include designation of cobia as a restricted species, reduction of the recreational daily bag limit to one fish, and establishment of a uniform possession limit aboard a vessel of 4 cobia. Standard language is also included to aid in the enforcement of size and bag limits. The effect of these rule amendments should be to safeguard the abundance of cobia and alleviate the need to adopt more stringent regulations in the future.

SUMMARY: Rule 68B-19.001, F.A.C., is amended to add definitions of the terms "fishing pier," "land," and "trip" for purposes of the chapter. Subsection (2) of Rule 68B-19.002, F.A.C., is amended to update provisions requiring cobia to be landed in a whole condition to include possession on fishing piers, bridges, and jetties within the ambit of the requirement. Rule 68B-19.004, F.A.C., is amended to designate cobia as a restricted species, decrease the daily bag limit for recreational harvesters from 2 to 1 cobia, establish a commercial daily bag limit of 2 cobia, and establish a maximum possession limit for all harvesters aboard a vessel to 4 cobia at any time.

A STATEMENT OF ESTIMATED REGULATORY COST HAS NOT BEEN PREPARED REGARDING THESE PROPOSED RULES.

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

SPECIFIC AUTHORITY: Article IV, Section 9, Florida Constitution.

LAW IMPLEMENTED: Article IV, Section 9, Florida Constitution.

THE FISH AND WILDLIFE CONSERVATION COMMISSION WILL CONDUCT A PUBLIC RULEMAKING HEARING ON THE PROPOSED RULES DURING ITS REGULAR MEETING AT THE TIME, DATE AND PLACE SHOWN BELOW:

TIME AND DATES: 8:30 a.m. – 5:00 p.m. each day, January 24-26, 2001

PLACE: Radisson Mart Plaza Hotel, 711 N. W. 72nd Avenue, Miami, 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 calendar days before the workshop/meeting by contacting Andrena Knicely at (850)487-1406. If you are hearing or speech impaired, please contact the agency by calling (850)488-9542.

All written material received by the Commission within 21 days of the date of publication of this notice shall be made a part of the official record.

SECTION 286.0105, FLORIDA STATUTES, PROVIDES THAT, IF A PERSON DECIDES TO APPEAL ANY DECISION MADE BY THE COMMISSION WITH RESPECT TO ANY MATTER CONSIDERED AT THIS HEARING, HE WILL NEED A RECORD OF PROCEEDINGS, AND FOR SUCH PURPOSES, HE MAY NEED TO ENSURE THAT A VERBATIM RECORD OF THE PROCEEDINGS IS MADE, WHICH RECORD INCLUDES THE TESTIMONY AND EVIDENCE UPON WHICH THE APPEAL IS BASED.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: James V. Antista, General Counsel, Fish and Wildlife Conservation Commission, 620 South Meridian Street, Tallahassee, Florida 32399-1600

THE FULL TEXT OF THE PROPOSED RULE IS:

68B-19.001 Definitions.

For purposes of this chapter, except where the context clearly requires otherwise:

(1) "Cobia", also referred to in some areas as ling, means any fish of the species *Rachycentron canadum*.

(2) "Fishing pier" means a platform extending from shore over water, used primarily to provide a means for persons to harvest or attempt to harvest fish therefrom. The term shall not be construed to include any residential dock, marina, or facility at which vessels are launched or moored, but shall include any abandoned bridge serving the function of a fishing pier.

(3)(2) "Fork length" means the length of a fish as measured from the tip of the snout to the rear center edge of the tail.

(4)(3) "Harvest" means the catching or taking of a fish by any means whatsoever, followed by a reduction of such fish to possession. Fish that are caught but immediately returned to the water free, alive and unharmed are not harvested. In addition, temporary possession of a fish for the purpose of measuring it to determine compliance with the minimum size requirements of this chapter shall not constitute harvesting such fish, provided that it is measured immediately after taking, and immediately returned to the water free, alive and unharmed if undersize.

(5) "Land", when used in connection with the harvest of a fish, means the physical act of bringing the harvested fish ashore.

(6)(4) "Person" means any natural person, firm, entity or corporation.

(7) "Trip" means a fishing trip of whatever duration which begins with departure of the fishing vessel from a dock, berth, beach, seawall, or ramp and which terminates with return to a dock, berth, beach, seawall, or ramp. Specific Authority Art. IV, Sec. 9, Fla. Const. Law Implemented Art. IV, Sec. 9, Fla. Const. History–New 6-13-85, Amended 1-1-90, Formerly 46-19.001, Amended

68B-19.002 Cobia, Size Limit.

(1) No person shall harvest in or from the waters of the state or sell or offer for sale any cobia with a fork length less than 33 inches.

(2) All cobia shall be landed in a whole condition. The possession, while in or on state waters, <u>on any public or private</u> fishing pier, on a bridge or catwalk attached to a bridge from which fishing is allowed, or on any jetty, of a cobia that has have been deheaded, sliced, divided, filleted, ground, skinned, scaled, or deboned is prohibited. Mere evisceration or "gutting" of cobia, or mere removal of gills, before landing is not prohibited.

Specific Authority Art. IV, Sec. 9, Fla. Const. Law Implemented Art. IV, Sec. 9, Fla. Const. History–New 6-13-85, Amended 1-1-90, 8-31-98, Formerly 46-19.002, Amended

68B-19.004 <u>Designation as Restricted Species</u>; Bag and <u>Possession Limits</u> Limit.

(1) Cobia are hereby designated as a restricted species pursuant to s. 370.01(21), Florida Statutes.

(2) Bag Limits:

(a) Recreational Daily Bag Limit – Except as provided in paragraph (b), no person shall harvest more than $1 \neq cobia$ per day from waters of the state. No such person shall possess more than $1 \neq cobia$ while fishing in, on, or above the waters of the state or on any dock, pier, bridge, beach, or other fishing site adjacent to such waters.

(b) Commercial Daily Bag Limit – No person who fishes pursuant to a valid saltwater products license with a restricted species endorsement shall harvest more than 2 cobia per day from waters of the state. No such person shall possess more than 2 cobia while fishing in, on, or above the waters of the state or on any dock, pier, bridge, beach, or other fishing site adjacent to such waters.

(c) Vessel Possession Limit – Whether fishing pursuant to paragraph (a) or (b), the possession of more than the applicable daily bag limit of cobia multiplied by the number of persons fishing aboard any vessel, or 4 cobia, whichever is less, is prohibited. On any single trip aboard a vessel, harvest of cobia shall either be recreational pursuant to paragraph (a) or commercial pursuant to paragraph (b), and the possession of recreational and commercial bag limits simultaneously aboard a vessel is prohibited.

(3) The possession <u>limits of this rule</u> limit shall not apply to any licensed seafood dealer or customer thereof possessing a receipt evidencing purchase of cobia.

Specific Authority Art. IV, Sec. 9, Fla. Const. Law Implemented Art. IV, Sec. 9, Fla. Const. History–New 1-1-90, Formerly 46-19.004, Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: Fish and Wildlife Conservation Commission, 620 South Meridian Street, Tallahassee, Florida 32399-1600 NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Allan L. Egbert, Ph.D., Executive Director, Fish and Wildlife Conservation Commission, 620 South Meridian Street, Tallahassee, Florida 32399-1600 DATE PROPOSED RULE APPROVED BY AGENCY HEAD: November 8, 2000 DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: December 8, 2000

Section III Notices of Changes, Corrections and Withdrawals

DEPARTMENT OF STATE

Division of Library and Information Services

RULE NOS .:	RULE TITLES:
1B-24.001	General
1B-24.003	Records Retention Scheduling and
	Dispositioning

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. 26, No. 43, October 27, 2000, issue of the Florida Administrative Weekly.

The rule shall now read as follows:

(Substantial rewording of Rules 1B-24.001 and 1B-24.003 follows. See Florida Administrative Code for present text.)

1B-24.001 General.

(1) This chapter establishes standards and procedures for the scheduling and dispositioning of public records to promote economical and efficient management of records and to ensure that records of archival value under an agency's control are so designated and ultimately transferred to the Florida State Archives.

(2) Each agency in the State of Florida is responsible for complying with the provisions of this chapter.

(3) For the purpose of this chapter:

(a) "Agency" means any state, county, or municipal officer, department, district, division, board, bureau, commission or other separate unit of government created or established by law.

(b) "Custodian" means the elected or appointed state, county, district, or municipal officer charged with the responsibility of maintaining the office having public records, or his or her designee.