employees who may recover benefits under Chapter 440, Florida Statutes, the subcontractor shall provide a copy of the certificate of exemption for the exempt officer or officers to the contractor, and is not required to provide the contractor with evidence of workers' compensation insurance.

SUBJECT AREA TO BE ADDRESSED: Requirement for subcontractors to show contractor that the subcontractor is in compliance with Chapter 440, Florida Statutes.

SPECIFIC AUTHORITY: 440.05(9), 440.591 FS.

LAW IMPLEMENTED: 440.02(15), 440.05(14), 440.10(1)(c) FS.

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

TIME AND DATE: 1:00 p.m., October 21, 2003

PLACE: Room 104J, Hartman Building, 2012 Capital Circle, Southeast, Tallahassee, Florida

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this program, please advise the Department at least 5 calendar days before the program by contacting the person listed below.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Bruce Brown, Bureau Chief, Bureau of Compliance, Division of Workers' Compensation, Department of Financial Services, 200 East Gaines Street, Tallahassee, Florida 32399-4228, (850)488-2333

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

69L-6.024 Subcontractors Requirement Regarding Proof of Coverage.

Under Section 440.05(14), Florida Statutes, an officer of a corporation who elects to be exempt from Chapter 440, Florida Statutes, may not recover benefits or compensation under Chapter 440, Florida Statutes, and a carrier may not consider any officer of a corporation who holds a valid certificate of election to be exempt for purposes of determining the appropriate premium for workers' compensation coverage. In order to be consistent with the provisions of Section 440.05(14), Florida Statutes, in instances where a subcontractor is a corporation and has an officer or officers who elect to be exempt, and the subcontractor provides a copy of the officer or officers certificate of election to be exempt to a contractor pursuant to Section 440.10(1)(c), Florida Statutes, the subcontractor is not required to also provide evidence of workers' compensation insurance to the contractor if the subcontractor has no employees who may recover benefits under Chapter 440, Florida Statutes.

PROPOSED EFFECTIVE DATE: January 1, 2004.

Specific Authority 440.05(9), 440.591 FS. Law Implemented 440.02(15), 440.05(14), 440.10(1)(c) FS. History–New 1-1-04.

Section II
Proposed Rules

DEPARTMENT OF EDUCATION

Florida School for the Deaf and the Blind

RULE TITLE: RULE NO.:

Discrimination Complaint Procedures for Student Access 6D-3.008

PURPOSE AND EFFECT: The purpose of this Rule is to establish procedures to be followed by students wishing to file complaints regarding discrimination issues.

SUMMARY: This rule indicates procedures and timelines to be followed in filing a discrimination complaint regarding issues related to race, sex, national origin, disability, marital status, age, religion or political affiliation.

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: 1002.36(4)(c) FS.

LAW IMPLEMENTED: 1002.36(4)(d) FS.

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

TIME AND DATE: 1:30 p.m., November 7, 2003

PLACE: Wilson Music Building Auditorium, FSDB Campus, St. Augustine, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Elaine F. Ocuto, Executive Assistant to the President, Florida School for the Deaf and the Blind, 207 N. San Marco Avenue, St. Augustine, FL 32084-2799

THE FULL TEXT OF THE PROPOSED RULE IS:

6D-3.008 Discrimination Complaint Procedures for Student Access.

(1) The following procedures shall be followed by individuals wishing to file complaints regarding issues related to race, sex, national origin, or disability ~~handicapping conditions~~, and shall serve as complaint procedures for Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, ~~and~~ Section 504 of the Rehabilitation Act of 1973, as amended, and the Americans with Disabilities Act of 1990.

(2) In complaints relating to admissions to the Florida School for the Deaf and the Blind, the President or designee shall conduct an investigation and render a decision within

thirty (30) days of receiving the complaint. A complaint must be filed in writing with the President within thirty (30) calendar days of written notification.

(3) The President has designated the Principal in the Department for the Deaf or Department for the Blind to be responsible for the coordination of investigations and management of complaint procedures initiated by students, parents or guardians.

(4) The procedure is as follows:

(a) Students, student applicants, parents or guardians are responsible for filing a written complaint of an alleged incident within sixty (60) ~~ten (10)~~ calendar days of occurrence.

(b) The Principal shall conduct an appropriate investigation and, in consultation with the President make a final decision within thirty (30) days of the receipt of the filing. ~~the principal shall forward a written recommendation regarding the complaint to the President within fifteen (15) calendar days of the date of filing~~.

~~(c) The President shall review the recommendation, make a final decision and transmit the decision in writing to the complainant within fifteen (15) days of the receipt of the recommendations.~~

Specific Authority 1002.36(4)(c) ~~120.53(1)(b), 242.331(3)~~ FS. Law Implemented 1002.36(4)(d) ~~120.53(1)(b),242.331(4)~~ FS. History–New 6-2-81, Amended _____. Formerly 6D-3.08. Cf. Title VI, Civil Rights Act of 1964 (Title 34, Part 100 CFR); Title IX of the Education Amendments of 1972 (Title 34, Part 106 CFR); Section 504, Title V, Rehabilitation Act of 1973 (Title 34, Part 104 CFR).

NAME OF PERSON ORIGINATING PROPOSED RULE: Elmer Dillingham, Jr., President, Florida School for the Deaf and the Blind

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Trustees of the Florida School for the Deaf and the Blind

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 23, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: Vol. 29, No. 31, August 1, 2003

DEPARTMENT OF EDUCATION

Florida School for the Deaf and the Blind

RULE TITLE: RULE NO.:

Discrimination Complaint Procedures for Employment 6D-6.020

PURPOSE AND EFFECT: The purpose of this Rule is to establish procedures to be followed by individuals wishing to file complaints regarding discrimination issues.

SUMMARY: This rule indicates procedures and timelines to be followed in filing a discrimination complaint regarding issues related to race, sex, national origin, disability, marital status, age, religion or political affiliation.

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: 1002.36(4)(c) FS.

LAW IMPLEMENTED: 1002.36(4)(d) FS.

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

TIME AND DATE: 1:30 p.m., November 7, 2003

PLACE: Wilson Music Building Auditorium, FSDB Campus, St. Augustine, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Elaine F. Ocuto, Executive Assistant to the President, Florida School for the Deaf and the Blind, 207 N. San Marco Avenue, St. Augustine, FL 32084-2799

THE FULL TEXT OF THE PROPOSED RULE IS:

6D-6.020 Discrimination Complaint Procedures for Employment.

(1) The following procedures shall be followed by individuals wishing to file complaints regarding issues related to race, sex, national origin, disability ~~handicapping conditions~~, marital status, age, religion, or political affiliation, and shall serve as complaint procedures for Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, ~~and~~ Section 504 of the Rehabilitation Act of 1973, as amended, and The Americans with Disabilities Act of 1990.

(2) The Human Resources Director ~~Personnel Officer~~ shall be responsible for the coordination of investigations and management of complaint procedures initiated by employees or applicants for employment regarding issues related to race, sex, national origin, disabilities, ~~handicapping conditions~~ marital status, age, religion or political affiliation.

(3) The procedure is as follows:

(a) Employees or applicants are responsible for filing a written complaint of an alleged incident within sixty (60) ~~ten (10)~~ calendar days of occurrence.

(b) The Human Resources Director ~~Personnel Officer~~ shall conduct an appropriate investigation and in consultation with the President, make a final decision within thirty (30) days of the receipt of the filing ~~the Human Resources Director Personnel Officer shall forward a written recommendation regarding the complaint to the President within fifteen (15) calendar days of the date of filing~~.

~~(c) The President shall review the recommendation, make a final decision and transmit the decision in writing to the complainant within fifteen (15) days of the receipt of the recommendation.~~

Specific Authority 1002.36(4)(c) ~~120.53(1)(b), 242.331(3)~~ FS. Law Implemented 1002.36(4)(d) ~~120.53(1)(b),242.331(4)~~ FS. History–New 6-2-81, Amended _____. Formerly 6D-3.08. Cf. Title VI, Civil Rights Act of 1964 (Title 34, Part 100 CFR); Title IX of the Education Amendments of 1972 (Title 34, Part 106 CFR); Section 504, Title V, Rehabilitation Act of 1973 (Title 34, Part 104 CFR).

NAME OF PERSON ORIGINATING PROPOSED RULE: Elmer Dillingham, Jr., President, Florida School for the Deaf and the Blind

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Trustees of the Florida School for the Deaf and the Blind

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 23, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: Vol. 29, No. 31, August 1, 2003

DEPARTMENT OF EDUCATION

Florida School for the Deaf and the Blind

RULE TITLE: RULE NO.:
Campus Security/Police Department 6D-12.002

PURPOSE AND EFFECT: The purpose of this Rule is to indicate that the Policies and Procedures Manual of the Campus Security/Police Department of the Florida School for the Deaf and the Blind has been revised.

SUMMARY: This rule establishes guidelines and directives for the Florida School for the Deaf and the Blind Campus/ Security Police Department.

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: 1002.36(4)(c) FS.

LAW IMPLEMENTED: 1002.36(4)(d) FS.

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

TIME AND DATE: 1:30 p.m., November 7, 2003

PLACE: Wilson Music Building Auditorium, FSDB Campus, St. Augustine, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Elaine F. Ocuto, Executive Assistant to the President, Florida School for the Deaf and the Blind, 207 N. San Marco Avenue, St. Augustine, FL 32084-2799

THE FULL TEXT OF THE PROPOSED RULE IS:

6D-12.002 Campus Security/Police Department.

(1) through (5) No change.

(6) The Board of Trustees shall satisfy all requirements specified in s. 1002.36(8), F.S.

(7) No change.

(8) Each campus security/police officer shall be provided with the "Florida School for the Deaf and the Blind Campus Security/Police Manual" revised June 2003 ~~January 1997~~, adopted by the Board of Trustees pursuant to the provisions of Sections 1002.36(4)(c) ~~242.331(3)~~, F.S., shall be incorporated by this rule and made a part of the rules of the Board of Trustees.

(9) No change.

Specific Authority 1002.36(4)(c) ~~242.331(3)~~ FS. Law Implemented 1002.36(4)(d) ~~242.331(3)~~ FS. History–New 4-8-92, Amended 10-26-94, 4-28-97, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Elmer Dillingham, Jr., President, Florida School for the Deaf and the Blind

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Trustees of the Florida School for the Deaf and the Blind

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 23, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: Vol. 29, No. 31, August 1, 2003

DEPARTMENT OF EDUCATION

Florida School for the Deaf and the Blind

RULE TITLE: RULE NO.:
Human Resources, Management
and Development 6D-16.002

PURPOSE AND EFFECT: The purpose of this Rule is to establish the role of the Human Resource Management and Development Department of the Florida School for the Deaf and the Blind.

SUMMARY: This rule establishes guidelines for the Florida School for the Deaf Human Resource, Management and Development Department. The Policies and Procedures were reviewed and amended to comply with state and federal mandates.

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: 242.331(3) FS.

LAW IMPLEMENTED: 242.331(4) FS.

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

TIME AND DATE: 1:30 p.m., November 7, 2003

PLACE: Wilson Music Building Auditorium, FSDB Campus, St. Augustine, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Elaine F. Ocuto, Executive Assistant to the President, Florida School for the Deaf and the Blind, 207 N. San Marco Avenue, St. Augustine, FL 32084-2799

THE FULL TEXT OF THE PROPOSED RULE IS:

6D-16.002 Human Resources, Management and Development.

(1) through (4) No change.

(5) The Human Resources Management and Development Policies and Procedures Manual revised, June 2003 ~~August 2001~~, adopted by the Board of Trustees pursuant to the provisions of Sections 242.331(3), F.S. shall be incorporated by this rule and made a part of the rules of the Board of Trustees.

(6) No change.

Specific Authority 1002.36(4)(c) ~~242.331(3)~~ FS. Law Implemented 1002.36(4)(d) ~~2242.331(4)~~ FS. History–New 10-26-94, Amended 11-30-98, 9-29-99, 7-30-01, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Elmer Dillingham, Jr., President, Florida School for the Deaf and the Blind

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Trustees of the Florida School for the Deaf and the Blind

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 23, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: Vol. 29, No. 31, August 1, 2003

DEPARTMENT OF EDUCATION

Florida School for the Deaf and the Blind

RULE TITLE: RULE NO.:
Purchasing Department 6D-17.002

PURPOSE AND EFFECT: The purpose of this Rule is to establish written Policies and Procedures, in concert with state and federal mandates, to be followed by the Purchasing Department of the Florida School for the Deaf and the Blind.

SUMMARY: This rule establishes guidelines and directives for the Purchasing Department of the Florida School for the Deaf and the Blind.

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: 1002.36(4)(c) FS.

LAW IMPLEMENTED: 1002.36(4)(d) FS.

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

TIME AND DATE: 1:30 p.m., November 7, 2003

PLACE: Wilson Music Building Auditorium, FSDB Campus, St. Augustine, Florida

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Elaine F. Ocuto, Executive Assistant, Florida School for the Deaf and the Blind, 207 N. San Marco Avenue, St. Augustine, FL 32084-2799

THE FULL TEXT OF THE PROPOSED RULE IS:

6D-17.002 Purchasing Department.

(1) through (4) No change.

(5) The Florida School for the Deaf and the Blind Purchasing Manual, revised in June 2003 adopted by the Board of Trustees pursuant to the provisions of Sections 1002.36(4)(c) and 1002.36(4)(d), F.S. shall be incorporated by this rule and made a part of the rules of the Board of Trustees ~~effective October 26, 1994~~.

(6) No change.

Specific Authority 1002.36(4)(c) ~~242.331(3)~~ FS. Law Implemented 1002.36(4)(d) ~~120.53(1)(a), 242.331(4)~~ FS. History–New 10-26-94, Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Elmer Dillingham, Jr., President, Florida School for the Deaf and the Blind

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Trustees of the Florida School for the Deaf and the Blind

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: Vol. 29, No. 31, August 1, 2003

BOARD OF TRUSTEES OF THE INTERNAL IMPROVEMENT TRUST FUND

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

PUBLIC SERVICE COMMISSION

DOCKET NO. 030715-WS

RULE TITLE: RULE NO.:
Depreciation 25-30.140

PURPOSE AND EFFECT: The purpose of the rule is to clarify how to determine the appropriate amount of depreciation expense, to add definitions and new accounts to conform with the National Association of Regulatory Commissions (NARUC) Uniform System of Accounts (USOA).

SUMMARY: Definitions are added to clarify the meaning of terms that are used to analyze depreciation in order to assure both capital recovery and reasonable rates. New accounts are added to provide for depreciation of investment in new types of equipment and to bring the list of accounts into accord with the current NARUC Uniform System of Accounts (USOA) that

Rule 25-30.115, F.A.C., requires the utilities to follow. Specific directions for computing depreciation expense are included to clearly show the appropriate method for calculating depreciation expense for a monthly period.

Any person who wishes to provide information regarding a 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: 350.127(2), 367.121(1) FS.

LAW IMPLEMENTED: 350.115, 367.081(2), 367.121(1) FS.

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

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

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

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Christiana T. Moore, Florida Public Service Commission, 2540 Shumard Oak Blvd., Tallahassee, Florida 32399-0862, (850)413-6245

THE FULL TEXT OF THE PROPOSED RULE IS:

25-30.140 Depreciation.

(1) through (d) No change.

~~(e) Average Service Life Depreciation Rate – The depreciation rate based on the expected average service to be experienced by the investment or account in question.~~

~~A.S.L. Rate = 100% – Average Net Salvage %~~
~~Average Service Life~~

(e)~~(f)~~ Average Service Life – The period of ~~economic~~ service ~~life~~ that can be reasonably expected from the plant type in question. It is measured by the period of time the subject plant and its associated investment is included on the company's books as in service to the public. The average service life will typically be less than the potential physical life due to factors such as governmental requirements, growth or adverse operating conditions.

(f) Average Service Life Depreciation Rate – The depreciation rate based on the expected average service to be experienced by the investment or account in question.

A.S.L. Rate = 100% – Average Net Salvage %
Average Service Life

(g) through (h) No change.

(i) Continuing Property Record (CPR) – A perpetual collection of records required by the NARUC Uniform System of Accounts showing the detailed original costs, quantities, and locations of plant in service. Generally, a CPR should contain 1) an inventory of property record units which can be readily checked for proof of physical existence, 2) the association of costs with such property record units to ensure accurate accounting for retirements, and 3) the dates of installation and removal of plant to provide data for use in connection with depreciation studies.

(j)~~(i)~~ No change.

(k) Depreciation Accounting – The process of charging the book cost of depreciable property, adjusted for net salvage, to operations over the associated useful life.

(l) Depreciation Expense – The periodic charge to expense to allocate the original cost of a depreciable group of assets over the life of those assets.

(m) Depreciable Group – A homogeneous grouping of assets expected to experience similar life and salvage patterns. Unless otherwise ordered by the Commission, depreciable groups are the accounts defined in the NARUC Uniform System of Accounts adopted by Rule 25-30.115, F.A.C.

(n)~~(j)~~ Function – defined as follows:

Water	Wastewater
Source of Supply (Accounts 304 to 311, ~~309~~ and 339)	Collection Plant (Accounts 354, 355, and 360 to 367 ~~364~~)
~~Pumping Plant (Accounts 304, 310, 311)~~	Pumping Plant (Accounts 354, 355, 370, 371)
Water Treatment Plant (Accounts 304, 310, 311, 320, and 339)	Treatment & Disposal Plant (Accounts 354 and 380 to 389)
	Reclaimed Water Treatment Plant (Accounts 354, 355, 371, 374, 380, 381, 389)
Transmission & Distribution Plant (Accounts 304, 310, 311, and 330 to 339)	
	Reclaimed Water Distribution Plant (Accounts 354, 355, 366, 367, 371, 375, 389)
General Plant (Accounts 304 and 340 to 348)	
	General Plant (Accounts 354 and 390 to 398)

(o) Group Depreciation – An accounting procedure under which depreciation charges are accrued on the basis of the original cost of all property included in each depreciable group. Under the group concept, no attempt is made to keep track of the accumulated provision for depreciation applicable to individual assets of property, in view of the many items making up a utility system. The group approach recognizes that some assets within the group may live longer or shorter than the average life of the group but the group is expected to live the average service life. Every item in the group is assumed to be fully depreciated at retirement.

(k) through (l) renumbered (p) through (q) No change.

(r)~~(m)~~ Original Cost – The cost of acquiring an asset and placing it into service for first utility use. This includes the direct costs of acquiring the asset and the cost of labor, materials, and associated costs of installation to prepare the asset for first utility use. The cost is used in the computation of depreciation expense. In the event that an asset is acquired that is already in public service, the original historic cost of the asset should be recorded in plant in service, and the historic accumulated depreciation should be charged to the accumulated depreciation account. In the event the historic cost of an asset that is already in utility service cannot be determined, an independent engineer's evaluation based on an original cost study may be used. ~~Original Cost – As applied to utility plant, the cost of such property to the person first devoting it to public service.~~

(n) through (q) renumbered (s) through (v) No change.

(w)~~(r)~~ Reserve – The accumulated provision for depreciation. The accumulated depreciation reserve is the net of depreciation accruals (expenses) and retired investment with related gross salvage and cost of removal as well as any appropriate adjustments or transfers.

(x)~~(s)~~ Reserve Activity Data – Annual depreciation expense, retirements, transfers or adjustments, gross salvage realized, cost of removal, and end of year balance for the accumulated provision for depreciation.

(t) through (u) renumbered (y) through (z) No change.

(aa) Straight-Line Method – A depreciation method by which the service value of a depreciable group is charged to depreciation expense (or a clearing account) and credited to the accumulated provision for depreciation account through equal annual charges over the service life of the group.

(bb) Unit Depreciation – An accounting procedure under which the original cost, depreciation expense, and accumulated provision for depreciation, and all associated activity are maintained for each individual asset. Service life and salvage parameters are estimated for each individual asset with a depreciation rate designed to recover each asset's original cost over its related life. If the asset lives longer than its expected life, depreciation expense stops accruing when the asset is fully recovered. If the asset retires earlier than its expected service life, the associated unrecovered amount is immediately written-off as a loss.

(cc) Unrecovered Amount – Original cost less the accumulated provision for depreciation less expected net salvage.

(2) The average service life and salvage components for each class of utility are as follows:

(a) Water System Guideline Average Service Lives

Account Description	Large Utility (Class A & B)	Small Utility (Class C)	Small Utility Function Composite[3]	Net Salvage %[4]
1. Intangible Plant				
351 Organization	40	40		
352 Franchise Cost	40[5]	40[5]		
2.~~1.~~ Source of Supply			28	
304 [1]Structures & Improvements	32[1]	27		
Wood ~~Frame~~	28	25		
Masonry	30	27		
Reinforced Concrete	40	37		
Steel Building ~~(tanks or sheds)~~	40	35		
Tanks or Sheds	25	20		
Fiberglass	20	18		
305 Collecting and Impounding Reservoirs	50	40		
306 Lake, River and Other Intakes	40	40		
307 Wells and Springs	~~30~~	~~27~~		
Drilled & Cased Well	30	27		
(Floridan or Non-Corrosive)				
Shallow Well	20	18		
(Sand Aquifer or Corrosive Water)				
308 Infiltration Galleries				
and Tunnels	40	N/A		
309 Supply Mains	35	32		
310 Power Generation Equip.	20	17		
311 Pumping Equipment	20[1]	17[1]		
Pumping Equip. Electric	20	15		
Pumping Equip. Chemical	8	6		

339 Other Miscellaneous Equip.	18	15		
3. Water Treatment Plant			21	
~~2. Pumping Plant~~			~~20~~	
304 Structures and Improvements (see "Source of Supply" for subcategory lives)	32[1]	27[1]		
310 Power Generation Equipment	20	17		
311 Pumping Equipment	20[1]	17[1]		
Pumping Equipment-Electric	20	15		
~~Electric Pumping Equip.~~	~~20~~	~~15~~		
Pumping Equipment-Chemical	8	6		
320 Water Treatment Equip.	22[1]	17[1]		
Chlorination Equip.	10	7		
Membrane Elements	5	5		
Other Mechanical Equip.	25	20		
339 Other Miscellaneous Equip.	18	15		
4. Transmission & Distribution Plant			36	
304 Structures & Improvements (See "Source of Supply" for subcategory lives)	32[1]	27[1]		
310 Power Generation Equip.	20	17		
311 Pumping Equipment	20[1]	17[1]		
Pumping Equipment-Electric	20	15		
Pumping Equipment-Chemical	8	6		
330 Distribution Reservoirs & Stand Pipes	37[1]	33[1]		
Steel Pneumatic Tank	35	30		
Concrete Ground Storage Reservoir	40	37		
331 Transmission & Distribution				
Mains	43[1]	38[1]		
Galvanized Steel Pipe & Fittings	35	33		
Black Steel Pipe	20	18		
Plastic Pipe[2]	45	40		
Asbestos – Cement	40	35		
Cast Iron or Ductile Iron	40	35		
Valves & Valve Boxes	25	20		
Fire Mains	33	30		
333 Services[2]	40	35		
334 Meters and Meter Installation	20	17		
335 Hydrants	45	40		
336 Backflow Prevention Devices	15	10		
339 Other Plant and Miscellaneous Equipment	25	20		
5. General Plant				
304 Structures & Improvements	40[1]	35[1]		
Wood Building	35	30		
~~Reinforced Concrete Bldg.~~	~~45~~	~~40~~		
Masonry Building	40	35		
Reinforced Concrete Bldg.	40	37		
~~Wood Building~~	~~35~~	~~30~~		
Steel Building	40	35		
Tanks or Sheds	25	20		
340 Office Furniture & Equip.	15	15		
Computers	6	6		
341 Transportation Equipment	6	6		10
342 Stores Equipment	18	N/A	14 (composite of 342-348)	
343 Tools, Shop & Garage Equip.	16	15		
344 Laboratory Equip.	15	N/A		
345 Power Operated Equip.	12	10		5
346 Communication Equip.	10	N/A		10
347 Miscellaneous Equip.	15	N/A		
348 Other Tangible Plant	10	10		

(b) Wastewater System Guideline Average Services Lives

Account Description	Large Utility (Class A & B)	Small Utility (Class C)	Small Utility Function Composite[3]	Net Salvage %[4]
1. Intangible Plant				
351 Organization	40	40		
352 Franchise Cost	40[5]	40[5]		
2.~~1.~~ Collection System			35	
354 Structures & Improvements	32[1]	27[1]		
Above Grade				
Wood	28	25		
~~Reinforced Concrete Bldg.~~	~~38~~	~~35~~		
Masonry	30	27		
Reinforced Concrete ~~Frame~~	38 ~~28~~	35 ~~25~~		
Steel	25	22		
Below Grade				
Concrete	35	32		
Steel	22	20		
Lift Stations	25	22		
355 Power Generation Equipment	20	17		
360 Collection Sewers-Force[2]	30[1]	27[1]		
361 Collection Sewers-Gravity[2]	45	40		
Manholes	30	27		
362 Special Collecting Structures	40	37		
363 Services to Customers[2]	38	35		
364 Flow Measuring Devices	5	5		
365 Flow Measuring Installations	38	35		
389 Other Miscellaneous Equip.	18	15		
3.~~2.~~ Pumping Plant			18	
354 Structures & Improvements	32[1]	27[1]		
355 Power Generating Equipment	20	17		
370 Receiving Wells	30	25		
~~Pumping Equip.~~	~~N/A~~	~~15~~		
371 Pumping Equipment	18	15		
~~371 Pumping Equip.~~	~~18~~	~~N/A~~		
Pumping Equipment -Electric	18	15		
Pumping Equipment – Chemical	7	5		
389 Other Miscellaneous Equip.	18	15		
4.~~3.~~ Treatment and Disposal Plant			18	
354 Structures & Improvements (see "Collection System" for subcategory lives)	32[1]	27[1]		
355 Power Generating Equipment	20	17		
371 Pumping Equipment	18[1]	15[1]		
Pumping Equipment – Electric	18	15		
Pumping Equipment – Chemical	7	5		
380 Treatment & Disposal Equip.	18[1]	15[1]		
Blowers, Motors, Pumps, Electric Controls	15	12		
Chlorination Equipment	10	7		
Other Mechanical Equipment	23	18		
381 Plant Sewers	35	32		
382 Outfall Sewer Lines	30	30		
389 Other Plant and Miscellaneous Equipment	18	15		
5. Reclaimed Water Treatment Plant			21	
354 Structures & Improvements (see "Collection System" for subcategory lives)	32[1]	27[1]		
355 Power Generating Equipment	20	17		
371 Pumping Equipment	18[1]	15[1]		
Pumping Equipment-Electric	18	15		

Pumping Equipment-Chemical	7	5		
374 Reuse Distribution				
Reservoirs	37[1]	33[1]		
Steel Pneumatic Tank	35	30		
Concrete Ground Storage Reservoir	40	37		
380 Treatment & Disposal Equip.	18[1]	15[1]		
Blowers, Motors, Pumps, Electric Controls	15	12		
Chlorination Equipment	10	7		
Other Mechanical Equipment	23	18		
381 Plant Sewers	35	32		
389 Other Plant and Miscellaneous Equipment	18	15		
6. Reclaimed Water Distribution Plant			36	
354 Structures & Improvements (see "Collection System" for subcategory lives	32[1]	27[1]		
355 Power Generating Equipment	20	17		
366 Reuse Services	40	35		
367 Reuse Meters and Meter Installation	20	17		
371 Pumping Equipment	18[1]	15[1]		
Pumping Equipment-Electric	18	15		
Pumping Equipment-Chemical	7	5		
375 Reuse Transmission & Distribution System	43[1]	38[1]		
Plastic Pipe[2]	45	40		
Valves & Valve Boxes	25	20		
Fire Mains	33	30		
389 Other Plant and Miscellaneous Equipment	18	15		
7.4. General Plant				
354 Structures & Improvements	40[1]	35[1]		
Wood Building	35	30		
Masonry Building	40	35		
Reinforced Concrete Bldg.	45	40		
Steel Building	40	35		
Tanks or Sheds	25	20		
390 Office Furniture & Equip.	15	15		
Computers	6	6		
391 Transportation Equipment	6	6		10
392 Stores Equipment	18	N/A	14 (composite of 392-398)	
393 Tools, Shop & Garage Equip.	16	15		
394 Laboratory Equipment	15	N/A		
395 Power Operated Equipment	12	10		5
396 Communication Equipment	10	N/A		10
397 Miscellaneous Equipment	15	N/A		
398 Other Tangible Plant	10	10		

(c) For the purposes of paragraphs (2)(a) and (b), the following apply:

1. through 4. No change.

5. [5]Franchise costs shall be amortized over a period of 40 years unless a specific time period is designated in the utility franchise agreement.

(3)(a) Average service life depreciation rates based on guideline lives and salvages shall be used in any Commission proceeding in which depreciation rates are addressed, except for those utilities using depreciation rates in accordance with the requirements listed in subsections (6) and (7) of this rule. ~~Except as listed in subsections (5) and (6) of this rule average service life depreciation rates based on the guideline lives and salvages shall be used in any proceeding before this Commission that involves the setting of rates.~~ A utility shall also implement the applicable guideline rates for any new plant to be placed in service.

(b) A utility may implement applicable guideline rates without specific approval by the Commission. Guideline rates, if implemented for any account, must be implemented for all accounts. If a utility implements applicable guideline rates outside of a rate proceeding, the utility shall provide written notification to the Director of Economic Regulation within 30 days of such implementation.

(c) If guideline depreciation rates have been implemented, the rates shall not be changed unless approved by the Commission.

(4)(a) All Class A and B utilities shall maintain depreciation rates and reserve activity data by account as prescribed by this Commission.

(b) No change.

(5) Computation of depreciation expense. Regulatory book depreciation expense shall be computed on a monthly basis in conformity with group depreciation accounting procedures.

(6)(a)~~(5)(a)~~ No change.

(b) A utility filing for such a revision of depreciation rates shall submit ten copies of the filing to the Director of the Commission Clerk and Administrative Services ~~office of the Commission Clerk~~.

(c) through 4. No change.

(7)~~(6)~~(a) A Class A, B, or C utility may apply for guidelines for a proposal for implementation of remaining life depreciation rates if the ~~under the following conditions:~~

~~(a) A Class A or B~~ utility has maintained both plant activity data by account and accumulated provision for depreciation (reserve) data by account, function or total depreciable plant generally in accord with the Uniform System of Accounts for either at least ten years or since the inception of the utility, whichever is less.

~~(b) A Class C utility has maintained both plant activity data and accumulated provision for depreciation (reserve) data by account, function or total depreciable plant generally in accord with the Uniform System of Accounts for either at least ten years or since the inception of the utility, whichever is less.~~

(g)~~(c)~~ No change.

(8)~~(7)~~ No change.

(9)(a) Beginning with the year ending December 31, 2003, all Class A and B utilities shall maintain separate sub-accounts for: (1) each type of Contributions-in-Aid-of-Construction (CIAC) charge collected including, but not limited to, plant capacity, meter installation, main extension or system capacity; (2) contributed plant; (3) contributed lines; and (4) other contributed plant not mentioned previously. Establishing balances for each new sub-account may require an allocation based upon historical balances. Each CIAC sub-account shall be amortized in the same manner that the related contributed plant is depreciated. Separate sub-accounts for accumulated amortization of CIAC shall be maintained to correspond to each sub-account for CIAC.

(b) Beginning with the year ending December 31, 2003, for Class C utilities, where adequate CIAC records are maintained in sub-accounts, by type of charge or contributed plant, CIAC amortization rates shall be applied separately to each sub-account. Where CIAC records are not kept by sub-account, a composite depreciation rate for total plant, excluding general plant, shall be applied to the entire CIAC account.

(c) Any composite rate used shall be recalculated each year based on the applicable plant balances and depreciation rates.

~~(8)(a) Contributions in Aid of Construction - Adequate records to account for CIAC must be maintained by the utility. Where adequate records separating CIAC from utility investments are maintained by account, depreciation rates shall be applied separately to contributed and non-contributed plant with the resulting amortization of contributed plant not considered an expense for ratemaking purposes. Where CIAC records are not kept by account, the depreciation rates shall be applied to the entire depreciable plant. The CIAC plant shall then be amortized either by account, function or bottom line depending on availability of supporting information. The amortization rate shall be that of the appropriate account or function where supporting documentation is available to identify the account or function of the related CIAC plant. Otherwise, the composite plant amortization rate shall be used. The depreciation expense then is the net of depreciation expense for total plant less the amortization of CIAC plant. The non-CIAC depreciation reserve is the net of depreciation reserve for total plant less the accumulated amortization of CIAC plant.~~

Specific Authority 350.127(2), 367.121(1) FS. Law Implemented 350.115, 367.081(2), 367.121(1) FS. History–New 3-22-84, Formerly 25-10.32, 25-10.032, Amended 11-9-86, 5-8-88, 11-21-95, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Pat Lee

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Florida Public Service Commission

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 16, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: Vol. 26, No. 52, December 29, 2000

DEPARTMENT OF CORRECTIONS

RULE TITLE: RULE NO.:
Offender Orientation 33-302.109

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to clarify procedures for notifying offenders of the restoration of civil rights review process.

SUMMARY: The proposed rule clarifies procedures for notifying offenders of the restoration of civil rights review process.

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: 944.09 FS., 45 CFR 164.520
LAW IMPLEMENTED: 20.315, 944.09 FS., 45 CFR Part 160
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Perri King Dale, Office of the General Counsel, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE FULL TEXT OF THE PROPOSED RULE IS:

33-302.109 Offender Orientation.

(1) through (3) No change.

(4) Restoration of Civil Rights

(a) No change.

(b) If the offender was adjudicated guilty, t~~T~~he officer shall advise the offender that more information regarding the restoration of civil rights process shall be provided within 60 to 90 days of ~~as~~ the offender's scheduled termination date ~~approaches~~. Within 60 to 90 days of the scheduled termination date, the officer shall utilize Form NI1-027, Notification of Civil Rights Review Process, to review this process. Form NI1-027 is incorporated by reference in Rule 33-302.111, F.A.C.

(c) through (7) No change.

Specific Authority 944.09 FS., 45 CFR 164.520 Law Implemented 20.315, 944.09 FS, 45 CFR Part 160, 164. History–New 7-19-01, Amended 9-15-02, 7-30-03, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Tina Hayes
NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: James V. Crosby, Jr.
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 23, 2003
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: September 5, 2003

DEPARTMENT OF CORRECTIONS

RULE TITLE: RULE NO.:
Maximum Management 33-601.820
PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to ensure the efficient and timely review for maximum management and the on-site monitoring of inmates in this status to ensure their level of supervision is reduced as soon as their level of threat to the safety and security of the staff, inmates and the institution indicates that action is appropriate.
SUMMARY: The proposed rule establishes membership for the institutional classification team for maximum management review and deletes obsolete and unnecessary language.
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: 944.09 FS.
LAW IMPLEMENTED: 944.09 FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Perri King Dale, Office of the General Counsel, Department of Corrections, 2601 Blair Stone Road, Tallahassee, Florida 32399-2500

THE FULL TEXT OF THE PROPOSED RULE IS:

33-601.820 Maximum Management.

(1) No change.

(2) Definitions.

(a) No change.

(b) Institutional Classification Team (ICT) for Maximum Management Review – refers to the team responsible for making local classification decisions. The Institutional Classification Team shall be comprised of the ~~Warden or~~ Assistant Warden who shall serve as Chairperson, Classification Supervisor, Chief of Security, and other members as necessary when appointed by the warden or designated by rule.

(c) through (d) No change.

~~(e) Maximum Management Review Team (MMRT) – refers to the committee in Central Office that has approval authority for recommendations for placement in maximum management. The MMRT shall consist of the following staff or those acting in that capacity: Chief, Bureau of Classification and Central Records (Chairperson); Chief, Bureau of Security Operations; Deputy Director of Health Services (Clinical), and the applicable Regional Director.~~

(e)~~(f)~~ Shift Supervisor – the highest-ranking Correctional Officer ~~of the~~ on-duty ~~shift~~.

(f)~~(g)~~ No change.

~~(h) State Classification Office (SCO) – refers to a staff member at the central office level who is responsible for the review of the inmate classification decisions. Duties include approving or rejecting Institutional Classification Team (ICT) recommendations.~~

(3) Maximum Management Placement Criteria.

(a) No change.

(b) Whenever an inmate has met at least one of the conditions above, and the Shift Supervisor believes that the inmate cannot be controlled in a status less than maximum management, the Shift Supervisor shall recommend immediate placement in maximum management by completing Section 1 of Form DC6-101, Referral for Maximum Management. Form

DC6-101 is incorporated by reference in (6) of this rule. Approval from the warden or Duty Warden shall be received prior to placement of the inmate in maximum management.

(c) The warden or Duty Warden shall approve or disapprove the immediate placement of an inmate in maximum management by signing Form DC6-101, Referral for Maximum Management.

(d) Whenever an inmate has met at least one of the conditions in subsection 33-601.820(3)~~(a)~~, F.A.C., and the Shift Supervisor believes that the inmate should be reviewed for but not immediately placed in maximum management at the present time, then the Shift Supervisor shall recommend placement by completing Section 1 of Form DC6-101, Referral for Maximum Management. The Shift Supervisor shall notify the Classification Supervisor in writing of the recommendation no later than the following administrative workday.

(e) The Classification Supervisor shall docket the inmate's hearing before the Institutional Classification Team for considering placement in maximum management status in accordance with subsection 33-601.820(3)~~(6)~~, F.A.C.

(4) Conditions of Placement in Maximum Management.

(a) During initial placement of an inmate into maximum management the following will be provided:

1. through 2. No change.

3. Solid Door – Should an inmate's behavior require that the solid door be closed for security reasons, the Shift Supervisor may authorize this immediate restriction. The Shift Supervisor shall notify the ICT the following day and the ICT shall approve, disapprove or modify this restriction. The ICT shall notify the warden ~~State Classification Office Chairperson~~ for final approval, disapproval or modification of the ICT decision as described in (5) of this rule.

4. through 10. No change.

(b) Inmates in maximum management status shall not be allowed to make routine bank transactions or canteen purchases, with the exception of stamp, paper and envelope purchases for mail.

(c) The conditions set forth in (a) and (b) above shall be reviewed at least weekly by the ICT, and when the ICT determines the inmate has sufficiently demonstrated positive adjustment, consideration shall be given to adjusting the inmate's conditions to the extent authorized for Close Management I inmates. The Institutional Classification Team shall document their justification for adjustment on Form DC6-101, Referral for Maximum Management. ~~The State Classification Office, upon their review, may also consider adjusting the inmate's conditions. Any adjustment to the conditions made by the State Classification Office shall be documented on Form DC6-101.~~

(5) Maximum Management Conditions After Initial Placement. Should the inmate's behavior require alteration of initial placement conditions or previously relaxed conditions as described in (4)(a) and (b), the Institutional Classification Team shall make the recommendation to the warden ~~State Classification Office chairperson~~ on Form DC6-101, Referral for Maximum Management. The warden ~~State Classification Office chairperson~~ shall approve, disapprove or modify the recommendations.

(6) No change.

(7) Conducting the Hearing.

(a) through (h) No change.

(i) If the Institutional Classification Team approves placement, the decision will be forwarded to the warden ~~Chairperson of the State Classification Office~~ who will ~~schedule the referral for~~ review ~~by~~ the recommendation ~~MMRT~~.

(8) Final Review of Placement.

(a) The warden ~~MMRT~~ shall approve or disapprove the ICT recommendation based on the criteria in paragraph (3)(a). If the ICT recommendation is incomplete or additional data is needed, the warden ~~MMRT~~ shall return the recommendation to the ICT for additional information.

(b) If the warden ~~MMRT~~ disapproves placement, the inmate shall immediately be reclassified to his original status~~, unless the Institutional Classification Team appeals the decision of the MMRT as outlined in 33-601.820(10)~~.

(9) No change.

~~(10) Appeal of an MMRT Decision.~~

~~(a) The Institutional Classification Team may appeal an MMRT decision to the Deputy Director of Institutions (Classification).~~

~~(b) The inmate shall remain in maximum management status pending the Institutional Classification Team appeal.~~

~~(c) The Deputy Director shall approve or modify the MMRT decision or reclassify the inmate.~~

(10)~~(11)~~ Security Requirements.

(a) All security requirements outlined in Rule~~s~~ 33-601.800, F.A.C., ~~33-601.801 through 33-601.813~~ for close management inmates are applicable for all maximum management inmates.

(b) No change.

(11)~~(12)~~ Other Conditions of Confinement.

(a) through (d) No change.

(e) Inmates who are housed in Maximum Management will have health care services to the same extent as all ~~other~~ close management inmates. Monitoring of inmates will be as described in Rule 33-601.800~~9~~, F.A.C.~~, Close Management – Case Management Responsibilities.~~

Specific Authority 944.09 FS. Law Implemented 944.09 FS. History–New 12-7-00, Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Michael J. Rathmann

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: James V. Crosby, Jr.

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 18, 2003
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 29, 2003

DEPARTMENT OF ENVIRONMENTAL PROTECTION

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

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

RULE TITLES:	RULE NOS.:
Application for Licensure	64B15-6.002
Physician Assistant Licensure	64B15-6.003
Requirements and Limitations of Prescribing Privileges	64B15-6.0037
Formulary	64B15-6.0038
Physician Assistant Fees	64B15-6.013

PURPOSE AND EFFECT: The proposed rule amendments are intended to conform the rule with regard to physician assistants to those promulgated by the Board of Medicine.

SUMMARY: The Board of Medicine and Board of Osteopathic Medicine rules regarding physician assistants must be similar. The proposed rule amendments conform these rules to those promulgated by the Board of Medicine.

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 regulatory cost alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 459.005, 459.022, 458.347(7) FS.

LAW IMPLEMENTED: 120.53(1)(a), 456.013, 456.031, 456.033, 459.022 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 RULES IS: Pamela King, Executive Director, Board of Osteopathic Medicine/MQA, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256

THE FULL TEXT OF THE PROPOSED RULES IS:

64B15-6.002 Application for Licensure.

(1) All persons applying for licensure as a physician assistant shall submit an application to the Department on forms approved by the Council and the Board and provided by the Department. ~~The application shall be accompanied by the application fee.~~

(2) The application may not be used for more than one year from the date of ~~receipt by the Council of the~~ original submission of the application ~~form~~ and fee. The fee to be paid at the time of application for licensure shall be as set forth in Rule 64B15-6.013 ~~10.002~~, F.A.C. After one year from the date that the original application and fee have been received in the Council office, a new application and fee shall be required from any applicant who desires licensure as a physician assistant.

(3) All application information must be submitted no later than 15 days prior to the Council meeting at which the applicant desires the application to be considered.

Specific Authority 459.005 FS. Law Implemented 459.022 FS. History–New 10-18-77, Formerly 21R-6.02, Amended 10-28-87, 4-21-88, 5-20-91, 3-16-92, Formerly 21R-6.002, 61F9-6.002, 59W-6.002, Amended 6-7-98, 3-10-02, _____.

64B15-6.003 Physician Assistant Licensure.

(1) Requirements for Licensure. All applicants for licensure ~~certification~~ as physician assistants shall submit an ~~must make~~ application to the Department on forms approved by the Council and Boards and provided by the Department. ~~Council on form PA/APP001, entitled "Application for Licensure as a Physician Assistant," effective 6-7-98, (rev. 10-15-97) which is incorporated herein by reference and available from the Council office~~ The applicant must meet all of the requirements of Section 458.347(7), Florida Statutes, or Section 459.022(7), Florida Statutes, and the applicant must submit two personalized and individualized letters of recommendation from physicians. Letters of recommendation must be composed and signed by the applicant's supervising physician, or, for recent graduates, the preceptor physician, and give details of the applicant's clinical skills and ability. Each letter must be addressed to and directed to the Council on Physician Assistants and must have been written no more than six months prior to the filing of the application.

(2) through (3) No change.

(4) The applicant must submit notarized statements containing ~~attesting to~~ the following information:

(a) completion of three hours of all Category I, American Osteopathic Association or American Medical Association Continuing Medical Education which includes the topics of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome: the disease and its spectrum of clinical manifestations; epidemiology of the disease; related infections including TB; treatment, counseling, and prevention; transmission from healthcare worker to patient and patient to healthcare worker; universal precautions and isolation techniques; and legal issues related to the disease. If the applicant has not already completed the required continuing medical education, upon submission of an affidavit of good cause, the applicant will be allowed six months to complete this requirement.

(b) Completion of one hour of continuing medical education on domestic violence which includes information on the number of patients in that professional's practice who are likely to be victims of domestic violence and the number who are likely to be perpetrators of domestic violence, screening procedures for determining whether a patient has any history of being either a victim or a perpetrator of domestic violence, and instruction on how to provide such patients with information on, or how to refer such patient to, resources in the local community, such as domestic violence centers and other advocacy groups, that provide legal aid, shelter, victim counseling, batterer counseling, or child protection services, and which is approved by any state or federal government agency, or nationally affiliated professional association, or any provider of Category I or II American Osteopathic Association or American Medical Association Continuing Medical Education. Home study courses approved by the above agencies will be acceptable. If the applicant has not already completed the required continuing medical education, upon submission of an affidavit of good cause, the applicant will be allowed six months to complete this requirement.

(c) Completion of two hours of continuing medical education relating to prevention of medical errors which includes a study of root cause analysis, error reduction and prevention, and patient safety, and which is approved by any state or federal government agency, or nationally affiliated professional association, or any provider of Category I or II American Osteopathic Association or American Medical Association Continuing Medical Education. One hour of a two hour course which is provided by a facility licensed pursuant to Chapter 395, F.S. for its employees may be used to partially meet this requirement.

(5) Licensure as a Prescribing Physician Assistant.

(a) An applicant ~~All persons applying~~ for licensure as a prescribing physician assistant shall, together with the supervising physician, jointly file the application for licensure ~~submit an application~~ to the Department ~~Council~~ on a form approved by the Council and Boards and provided by the Department. The same application may be utilized by any alternate supervising physicians, provided that all supervising physicians practice in the same specialty area and in the same practice setting. A separate application form shall be required for each distinct specialty area of practice, as well as for each distinct practice setting. Satellite offices within the same practice do not constitute distinct practices. ~~The application shall be accompanied by the application fee.~~

(b) The applicant shall have completed a 3 hour course approved by the Board ~~Council~~ in prescriptive practice, which shall cover the limitations, responsibilities, and privileges involved in prescribing medicinal drugs.

(c) through (d) No change.

Specific Authority 459.005, 459.022, 458.347(7) FS. Law Implemented 120.53(1)(a), 456.013, 456.031, 456.033, 459.022 FS. History–New 10-18-77, Formerly 21R-6.03, Amended 10-28-87, 4-21-88, 4-18-89, 9-26-90, 5-20-91, 10-28-91, 3-16-92, Formerly 21R-6.003, Amended 11-4-93, 3-29-94, Formerly 61F9-6.003, Amended 2-1-95, Formerly 59W-6.003, Amended 6-7-98, 3-10-02, _____.

64B15-6.0037 Requirements and Limitations of Prescribing Privileges.

Written prescriptions shall be subject to the following requirements:

Each supervising physician and prescribing physician assistant shall enter into and keep on file a written agreement outlining which ~~of the~~ medicinal drugs not prohibited by ~~in~~ the formulary the supervising osteopathic physician has specifically authorized the physician assistant to prescribe. Each agreement must be signed and dated by all parties and maintained on file for at least five (5) years. Any such agreement must be provided to the Department, the Council, or any of their agents upon request.

Specific Authority 459.022 FS. Law Implemented 459.022 FS. History–New 2-20-94, Formerly 61F9-6.0037, Amended 2-1-95, Formerly 59W-6.0037, Amended 5-12-98, _____.

64B15-6.0038 Formulary.

(1) No change.

(2) A supervising physician may delegate to a prescribing physician assistant only such authorized medicinal drugs as are used in the supervising physician's practice, not listed in paragraph (1).

(3) through (4) No change.

Specific Authority 458.347, 459.022(4)(e) FS. Law Implemented 459.022(4)(e) FS. History–New 3-12-94, Formerly 61F9-6.0038, Amended 11-30-94, 4-17-95, 8-27-95, 11-13-96, Formerly 59W-6.0038, Amended 5-12-98, 3-10-99, 3-9-00, 6-19-00, 11-23-00, 2-26-02, _____.

64B15-6.013 Physician Assistant Fees.

The following fees are prescribed by the Council and adopted by the Boards:

(1) through (3) No change.

(4) The application fee for a person applying to be certified as a prescribing physician assistant shall be $200.00. The fee for initial certification as a prescribing physician assistant shall be $200.00. The renewal fee for a prescribing physician assistant shall be $200.00. No additional fees will be required for any separate application for a distinct area of practice or a change in practice setting during the same biennium.

(5) through (9) No change.

Specific Authority 456.036(5),(7), 459.005, 459.009, 459.022(7) FS. Law Implemented 456.036(5),(7), 459.009, 459.022(7) FS. History–New 11-4-93, Amended 2-20-94, Formerly 61F9-6.013, 59W-6.013, Amended 8-11-98, _____.

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: September 6, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 27, 2003 (64B15-6.003) and July 3, 2003

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

RULE TITLE: RULE NO.:

Continuing Education for Biennial Renewal 64B15-13.001

PURPOSE AND EFFECT: The proposed rule amendments are intended to clarify requirements for continuing education.

SUMMARY: The proposed rule amendments clarify the number of hours for specified continuing medical education and address the criteria for the Laws and Rules course.

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 regulatory cost alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 459.005, 459.008(4) FS.

LAW IMPLEMENTED: 456.013(5),(6),(7), 459.008, 459.008(4) 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: Pamela King, 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:

64B15-13.001 Continuing Education for Biennial Renewal.

(1)(a) Every person licensed pursuant to Chapter 459, F.S., except those licensed as physician assistants pursuant to Section 459.022, F.S., shall be required to complete forty (40) hours of continuing medical education courses approved by the Board in the twenty-four (24) months preceding each biennial renewal period as established by the Department. Five ~~Seven~~ of the continuing medical education hours required for renewal shall be one hour HIV/AIDS course, one hour Domestic Violence, ~~one hour Risk Management Course,~~ one hour Florida Laws and Rules, ~~one hour Managed Care Course,~~ and two hours Prevention of Medical Errors Course.

(b) No change.

(2) No change.

(3)(a) One hour Domestic Violence, one hour Risk Management Course, one hour Florida Laws and Rules, one hour Managed Care Course, and two hours Prevention of Medical Errors Course shall be obtained by the completion of live, participatory attendance courses, as provided in (4) of this rule. ~~For purposes of this rule, risk management means the identification, investigation, analysis, and evaluation of risks and the selection of the most advantageous method of correcting, reducing, or eliminating identifiable risks and domestic violence as defined in Section 741.30, F.S.~~

~~(b) The seven (7) hours of continuing medical education found in paragraph 64B15-13.001(1)(a), F.A.C.,~~ shall be obtained by the completion of live, participatory attendance courses, as provided in (4) of this rule.

~~(c) For purposes for this rule, managed care means a discussion on quality assurance; utilization review; chart documentation; contracting with medical organizations; conflicts with the medical practice act; and ethical, moral and legal issues as it relates to the physician's ability to impact on the patient's health, safety and welfare.~~

(b)~~(d)~~ No change.

(c)~~(e)~~ One ~~The one~~ hour of continuing medical education ~~Risk Management~~ may be fulfilled by attending at least three (3) hours of disciplinary hearings at a regular meeting of the Board of Osteopathic Medicine in compliance with the following:

1. through 4. No change.

(d)~~(f)~~ No change.

(e) The one hour of Law and Rules may be fulfilled by attending a Board of Osteopathic Medicine rule workshop in compliance with the following:

1. The licensee must sign in with the Executive Director of the Board,or designee, before the workshop begins.

2. The licensee must remain in continuous attendance.

3. The licensee must sign out with the Executive Director of the Board, or designee, at the end of the workshop or at such other earlier time as affirmatively authorized by the Board. The licensee may receive CME credit in Laws and Rules for attending the rules workshop only if the licensee is attending on that day solely for that purpose; the licensee may not receive such credit if appearing for another purpose.

(4) through (5) No change.

(6) In addition to the continuing medical education credits authorized above, a volunteer expert witness who is providing expert witness opinions for cases being reviewed pursuant to Chapter 459, F.S., shall receive 5.0 hours of credit ~~in the area of risk management~~ for each case reviewed. Former Board members serving on the Probable Cause Panel shall be allowed a maximum of 15 hours of credit per biennium pursuant to Section 456.013. F.S. A volunteer expert may not accrue in excess of 15 hours of credit per biennium pursuant to this paragraph.

(7) through (8) No change.

Specific Authority 459.005, 459.008(4) FS. Law Implemented 456.013(5),(6),(7), 459.008, 459.008(4) FS. History–New 10-23-79, Amended 1-29-86, Formerly 21R-13.01, Amended 12-5-89, 4-8-91, 2-16-92, Formerly 21R-13.001, Amended 1-10-94, Formerly 61F9-13.001, Amended 10-25-95, Formerly 59W-13.001, Amended 1-19-98, 6-3-98, 4-14-99, 5-26-02, _____.

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 6, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 1, 2003

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

RULE TITLE: RULE NO.:

Standards for Office Based Opioid Addiction Treatment 64B15-14.009

PURPOSE AND EFFECT: The proposed rule is intended to set forth appropriate criteria for office based opioid addiction treatment.

SUMMARY: The proposed rule sets forth appropriate guidelines for physicians with regard to office based treatment of opioid addiction.

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 regulatory cost alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 459.005, 459.015(1)(z) FS.

LAW IMPLEMENTED: 459.015(1)(z) 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: Pamela King, 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:

64B15-14.009 Standards for Office Based Opioid Addiction Treatment.

(1) Treatment Principles.

(a) The Board of Osteopathic Medicine recognizes that the prevalence of addiction to heroin and other opioids has risen sharply in the United States and that the people of the State of Florida should have access to modern, appropriate and effective addiction treatment. The appropriate application of up-to-date knowledge and treatment modalities can successfully treat patients who suffer from opioid addiction and reduce the morbidity, mortality and costs associated with opioid addiction, as well as public health problems such as HIV, HBV, HCV and other infectious diseases. The Board encourages osteopathic physicians to assess their patients for a history of substance abuse and potential opioid addiction. The Board has developed these guidelines in an effort to balance the need to expand treatment capacity for opioid addicted patients with the need to prevent the inappropriate, unwise or illegal prescribing of opioids.

(b) The Board is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate and non-medical uses.

(c) Qualified physicians need not fear disciplinary action from the Board or other state regulatory or enforcement agency for appropriate prescribing, dispensing or administering approved opioid drugs in Schedules III, IV, or V, or combinations thereof, for a legitimate medical purpose in the usual course of opioid addiction treatment. The Board will consider appropriate prescribing, ordering, administering, or dispensing of these medications for opioid addiction to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of opioid addiction and in compliance with applicable state and federal law.

(d) The Board will determine the appropriateness of prescribing based on the physician's overall treatment of the patient and on available documentation of treatment plans and outcomes. The goal is to document and treat the patient's addiction while effectively addressing other aspects of the patient's functioning, including physical, psychological, medical, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of accepted professional practice.

(2) Definitions.

(a) Addiction. For the purposes of this rule "addiction" is defined as a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm and craving.

(b) Agonists. For the purposes of this rule "agonist" drugs are substances that bind to the receptor and produce a response that is similar in effect to the natural ligand that would activate it. Full mu opioid agonists activate mu receptors, and increasing doses of full agonists produce increasing effects. Most opioids that are abused, such as morphine and heroin are full mu opioid agonists.

(c) Approved Schedule III-V Opioids. For the purposes of this rule "approved schedule III-V opioids" are those drugs referred to by the Drug Addiction Treatment Act of 2002 as specifically approved by the FDA for treatment of opioid dependence or addiction.

(d) Antagonists. For the purposes of this rule "antagonists" bind to but do not activate receptors. They prevent the receptor from being activated by an agonist compound.

(e) Maintenance Treatment. For the purposes of this rule "maintenance treatment" means the dispensing for a period in excess of 21 days of an opioid medication(s) at stable dosage levels in the treatment of an individual for dependence upon heroin or other opioids.

(f) Opioid Dependence. For the purposes of this rule "opioid dependence" is a maladaptive pattern of substance use, leading to clinically significant impairment or distress, manifested by 3 or more of the following, occurring at any time in the same 12-month period:

1. A need for markedly increased amounts of the substance to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount of substance;

2. The characteristic withdrawal syndrome for the substance or the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms;

3. The substance was taken in larger amounts or over a longer period of time than was intended;

4. There is a persistent desire or unsuccessful efforts to cut down or control substance use;

5. Significant time is spent on activities to obtain the substance, use the substance, or recover from its effects;

6. Important social, occupational, or recreational activities are discontinued or reduced because of substance use;

7. Substance use is continued despite knowledge of having a persistent physical or psychological problem that is caused or exacerbated by the substance.

(g) Opioid Drug. For the purposes of this rule "opioid drug or opiate" means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction sustaining liability.

(h) Opioid Treatment Program (OTP). For the purposes of this rule "Opioid treatment program means a licensed program or practitioner engaged in the treatment of opioid addicted patients with approved Scheduled II opioids (methadone and/or LAAM) in a methadone clinic or narcotic treatment program.

(i) Partial Agonists. For the purposes of this rule "partial agonists" occupy and activate receptors. At low doses, like full agonists, increasing doses of the partial agonist produce increasing effects. However, unlike full agonists, the receptor-activation produced by a partial agonist reaches a plateau over which increasing doses do not produce an increasing effect. The plateau may have the effect of limiting the partial agonist's therapeutic activity as well as its toxicity.

(j) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(k) Tolerance. For the purpose of this rule, "tolerance" is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(l) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as a maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one or more of the following, occurring within a 12-month period:

1. Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home;

2. Recurrent substance use in situations in which it is physically hazardous;

3. Recurrent substance-related legal problems;

4. Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance.

(3) Physician Qualifications.

(a) Osteopathic physicians who consider office-based treatment of opioid addiction must be able to recognize the condition of drug or opioid addiction and be knowledgeable about the appropriate use of opioid agonist, antagonist, and partial agonist medications;

(b) Demonstrate required qualifications as defined under and in accordance with the "Drug Addiction Treatment Act of 2000" (DATA) (Public Law 106-310, Title XXXV, Sections 3501 and 3502);

(c) Obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA), as authorized by the Secretary of HHS. For the purpose of this rule, "waiver" is a documented authorization from the Secretary of HHS issued by SAMHSA under the DATA that exempts qualified physicians from the rules applied to OTPs.

(d) Must have a valid DEA registration number and a DEA identification number that specifically authorizes such office-based treatment. If an osteopathic physician wishes to prescribe or dispense narcotic drugs for maintenance or detoxification treatment on an emergency basis in order to facilitate the treatment of an individual patient before the issuance of the special DEA identification number, the physician musty notify SAMHSA and the DEA of the intent to provide such treatment.

(4) Qualifications for Waiver.

(a) In order to qualify for a waiver, physicians must hold a current license in the State of Florida and, at a minimum, meet one or more of the following conditions to be considered as qualified to treat opioid addicted patients in an office-based setting in this state:

1. Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;

2. Subspecialty board certification in addiction medicine from the American Osteopathic Association;

3. Addiction certification from the American Society of Addiction Medicine;

4. Completion of not less than 8 hours of training related to the treatment and management of opioid-dependent patients provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or other organization approved by the Board;

5. Participation as an investigator in one or more clinical trials leading to the approval of a narcotic drug in Schedule III, IV, or V or a combination of such drugs for treatment of opioid addicted patients, that is evidenced by a statement submitted to the Secretary of Health and Human Services by the sponsor of such approved drug.

(5) Guidelines. The Board has adopted the following guidelines when evaluating the documentation and treatment of opioid addiction under the Drug Addiction Treatment Act:

(a) Compliance with Controlled Substances Laws and Regulations.

(b) Evaluation of the Patient. A recent, complete medical history and physical examination must be documented in the medical record. The medical record should document the nature of the patient's addiction(s), evaluate underlying or coexisting diseases or conditions, the effect on physical and psychological function, and history of substance abuse and any prior treatments.

(c) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as freedom from intoxication, improved physical function, psychosocial function and compliance and should indicate if any further diagnostic evaluations are planned, as well as mental health and/or substance abuse counseling, psychiatric management or other ancillary services including development and compliance with a recovery program. This plan should be reviewed periodically. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Treatment goals, other treatment modalities or a rehabilitation program should be evaluated and discussed with the patient. If possible, every attempt should be made to involve significant others or immediate family members in the treatment process, with the patient's consent. The treatment plan should also contain contingencies for treatment failure.

(d) Informed Consent and Agreement for Treatment. The physician should discuss the risks and benefits of the use of approved opioid medications with the patient and, with appropriate consent of the patient or when appropriate the patient's agent. The patient should receive opioids from only one physician and/or one pharmacy when possible. The physician should employ the use of a written agreement between physician and patient or patient's agent addressing such issues as:

1. Alternative treatment options;

2. Regular toxicologic testing for drugs of abuse and therapeutic drug levels (if available and indicated);

3. Number and frequency of all prescription refills; and

4. Reasons for which drug therapy may be discontinued (i.e.; violation of agreement).

(e) Periodic Patient Evaluation. Patients should be seen at reasonable intervals (at least weekly during initial treatment) based upon the individual circumstance of the patient. Periodic assessment is necessary to determine compliance with the dosing regimen, effectiveness of treatment plan, and to assess how the patient is responding to the prescribed medication. Once a stable dosage is achieved and urine (or other toxicologic) tests are free of illicit drugs, less frequent office visits may be initiated (monthly may be reasonable for patients on a stable dose of the prescribed medication(s) who are making progress toward treatment objectives). Continuation or modification of opioid therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as:

1. Absence of toxicity;

2. Absence of medical or behavioral adverse effects;

3. Responsible handling of medications;

4. Compliance with all elements of the treatment plan (including recovery-oriented activities, psychotherapy and/or other psychosocial modalities); and

5. Abstinence from illicit drug use. If reasonable treatment goals are not being achieved, the physician should re-evaluate the appropriateness of continued treatment or modification.

(f) Consultation. The physician should refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The physician should pursue a team approach to the treatment of opioid addiction, including referral for counseling and other ancillary services. Ongoing

communication between the physician and consultants is necessary to ensure appropriate compliance with the treatment plan. This may be included in the formal treatment agreement between the physician and patient. Special attention should be given to those patients who are at risk for misusing their medications and those whose living or work arrangements pose a risk for medication misuse or diversion. The management of addiction in patients with comorbid psychiatric disorders requires extra care, monitoring, documentation and consultation with or referral to a mental health professional.

(g) Medical Records. The medical record should document the suitability of the patient for office-based treatment based upon recognized diagnostic criteria (Buprenorphine Clinical Practice Guidelines), Patient Placement Criteria 2nd Edition, and the DSM-IV-TR Substance Dependence Criteria identified in the American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 4th ed. Text Revision, Washington, D.C. Records should remain current and be maintained in an accessible manner and readily available for review. The physician must adhere to the special confidentiality requirements of 42CFR, Part 2, which apply to the treatment of drug and alcohol addiction, including the prohibition against release of records or other information, except pursuant to a proper patient consent or court order in full compliance with 42CFR2, or the Federal or State officials listed in 42CFR2, or in cases of true medical emergency or for the mandatory reporting of child abuse. The prescribing physician must keep accurate and complete records to include:

1. The medical history and physical examination;

2. Diagnostic, therapeutic and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Discussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed and/or dispensed to each patient);

8. A physical inventory of all Schedules III, IV, and V controlled substances on hand that are dispensed by the physician in the course of maintenance or detoxification treatment of an individual;

9. Instructions and agreements; and

10. Periodic reviews.

Specific Authority 459.005, 459.015(1)(z) FS. Law Implemented 459.015(1)(z) FS. History–New _____.

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 6, 2003

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: May 9, 2003

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE TITLES:	RULE NOS.:
General Regulations; Definitions	64F-12.001
Guaranty or Undertaking	64F-12.003
Drugs and Devices; Labeling Requirements	64F-12.006
Compressed Medical Gases	64F-12.007
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
Fees	64F-12.018
Forms	64F-12.020
Administrative Enforcement	64F-12.024

PURPOSE AND EFFECT: These proposed rules implement the Florida Prescription Drug Protection Act (SB 2312) passed by the 2003 Legislature and signed into law on June 13, 2003. The rules set forth new permitting requirements for the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, including new and updated application forms and fees increases. The primary focus is to implement the new requirements related to the wholesale distribution of prescription drugs from, in, and into the state of Florida.

SUMMARY: The proposed rules provide for additional definitions to new terms and concepts used in the new legislation and new rules; update the effective date of federal materials incorporated by reference throughout the rule; delete obsolete language; provide guidance to industry on recordkeeping requirements related to pedigree papers, including activities that will 'authenticate' a pedigree paper; provide instructions to the industry on submission requirements to demonstrate that a wholesaler is an authorized distributor of record under the Act if the wholesaler is not listed on a manufacturer's list of authorized distributors of record; require wholesalers to notify the department upon the discovery of significant losses or thefts of prescription drugs; provide application forms and procedures for permits issued under the Act; require Florida manufacturers that are registering their drug or cosmetic products to submit copies of labeling associated with those products if the labeling contains additional information from that reflected on the label on the product; establish fees for new permits, certification, and activities and provide for increased fees for certain permits related to prescription drugs; and provide guidance to the industry regarding the common administrative penalties associated with violations of new prohibited acts.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: Applicants for certain new and renewal permits related to prescription drugs will pay an increased permit fee. Currently the fees are set on a biennial basis and some permits will be converted to annual permits. The following fee increases, based on a biennial period are proposed: prescription drug manufacturers and repackagers ($200 biennially); non-resident prescription drug manufacturer ($250 biennially); prescription drug wholesaler permits, including the broker only permit, ($200 biennially); and out-of-state prescription drug wholesaler ($200 biennially). Two new permits/certifications and related fees are established for a freight forwarder ($250 biennially) and a one-time fee for certification as a designated representative ($150). All of these fees are within the range set by the legislature. Some applicants will also need to submit fingerprint cards and a $47 fee per card for the actual cost of processing the card through the Florida Department of Law Enforcement. There will be a cost to wholesalers for complying with the increased recordkeeping requirements related to pedigree papers, including the cost of receiving, authenticating, and passing on pedigree papers when required. Although these costs could be significant for some wholesalers, these recordkeeping requirements are specified in the legislation. There may also be an increased cost associated with the requirement that wholesalers have 'adequate' storage, refrigeration, and freezer capacity for the volume of prescription drugs handled. A method to measure 'adequate' is now included in the proposed rules which could require some wholesalers to increase their storage capacity. Finally, since the wholesaler permits are issued on an annual basis as opposed to a biennial basis and additional information is required, the cost to these companies for processing applications more frequently and providing more extensive information will increase.

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

SPECIFIC AUTHORITY: 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.03, 499.04, 499.041, 499.05, 499.052, 499.61, 499.62, 499.63, 499.64, 499.67, 499.701 FS.

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

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

TIME AND DATE: 10:00 a.m. – 1:00 p.m. (EST), Monday, October 27, 2003

PLACE: 2585 Merchants Row Boulevard, (Prather Building) Room 301, Capital Circle Office Complex, Tallahassee, Florida

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED 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

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 (C.F.R.), (as of 10/1/03 ~~1/1/01~~) 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), 499.0121(6), 499.0122(1), 499.028(1), and 499.61, F.S., the following definitions apply to Rule Chapter 64F-12, F.A.C.:

(a) through (e) No change.

(f) "Directly from the manufacturer" means, for purposes of s. 499.0121(6)(d) and (e), F.S., the manufacturer sold the prescription drug to the establishment, or member of the establishment's affiliated group if applicable, as reflected on a true and accurate invoice of sale from the manufacturer to the establishment or affiliated group member. The prescription drug may be shipped directly to another establishment.

(f) through (x) renumbered (g) through (y) No change.

(z) "Verifiable account" means an number issued by the manufacturer when the wholesale distributor sets up an account with the manufacturer for purchases of prescription drugs from that manufacturer that uniquely identifies the wholesaler distributor and that is to be used on a recurring basis.

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

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

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

PROPOSED EFFECTIVE DATE: January 1, 2004.

Specific Authority 499.0121, 499.05, 499.61, 499.701 FS. Law Implemented 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS. History–New 1-1-77, Amended 12-12-82, 1-30-85, Formerly 10D-45.31, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.031,Amended 1-26-99, 4-17-01, 6-30-03, 10-7-03, 1-1-04.

64F-12.003 Guaranty or Undertaking.

PROPOSED EFFECTIVE DATE: January 1, 2004.

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, 4-17-01, Repealed 1-1-04.

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 10/1/03 ~~1/1/01~~).

(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 10/1/03 ~~1/1/01~~).

PROPOSED EFFECTIVE DATE: January 1, 2004.

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, 4-17-01, 1-1-04.

64F-12.007 Compressed Medical Gases.

(1) through (2) No change.

(3) Labels and Labeling. In those instances where the FDA has not promulgated a final regulation related to labeling of a compressed medical gas, the label must include the general requirements of: name and address of the manufacturer or distributor; established name of the gas; contents in terms of the volume of gas in liters or cubic feet at specified temperature and 1 atmosphere of pressure; lot number; statement of ingredients (for mixtures); directions for use statement; applicable warning statements; and the prescription statement. Although oxygen intended to treat a medical condition is regarded as a prescription drug, the FDA has not objected to emergency use oxygen being marketed without a prescription. If Oxygen U.S.P. is sold for emergency use, then the label is required to contain the statement: "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, prescription statement". The prescription statement is "Rx Only" or the prescription symbol followed by the word "Only." ~~For currently approved products, a manufacturer may continue to use "Caution: Federal law prohibits dispensing without prescription" for the prescription statement until the time of the next revision of its labels, or by February 19, 2003, whichever comes first.~~ All prescription medical oxygen must also include the following:

(a) through (d) No change.

PROPOSED EFFECTIVE DATE: January 1, 2004.

Specific Authority 499.05, 499.012(2)(b) FS. Law Implemented 499.006, 499.007, 499.012, 499.0122, 499.013 FS. History–New 7-1-96, Formerly 10D-45.0442, Amended 1-26-99, 1-1-04.

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 10/1/03 ~~1/1/01~~).

PROPOSED EFFECTIVE DATE: January 1, 2004.

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, 4-17-01, 1-1-04.

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

(1) through (2) No change.

(3) A person authorized to possess non-dispensed prescription drugs ~~hospital or other health care entity~~ can donate prescription drugs that are not misbranded or adulterated to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs provided the transfer is not for sale or trade and the donor receives no financial benefit (except for tax benefits related to charitable contributions) either directly or indirectly. Records to document the transfer must comply with Section 499.0121(6), F.S., and paragraph 64F-12.008(2)(c), F.A.C.

(4) No change.

PROPOSED EFFECTIVE DATE: January 1, 2004.

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, 4-17-01, 1-1-04.

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

(1) through (2) No change.

(3) Pedigree Papers.

(a)~~(3)~~ The pedigree papers required by s. 499.0121(6)(d) and (e), F.S., must include either the proprietary name or the generic name with the name of the manufacturer or distributor reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from which it was shipped if different from the owner's; and the transaction dates. The pedigree paper must clearly identify the invoice to which it relates. A copy of the pedigree paper must be maintained by each recipient.

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

(c) Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)," form DH 2129 effective January 2004, which is incorporated by reference herein, must be used to comply with the requirement in s. 499.0121(6)(f), F.S., for the distribution of a prescription drug. This form may be used prior to July 1, 2006, to comply with the pedigree paper requirements of 499.0121(6)(d) or (e), F.S., at the discretion of the wholesaler.

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

(e) Effective March 1, 2004, a pedigree paper under s. 499.0121(6)(d), F.S., must trace a prescription drug back to the last authorized distributor of record. The department will maintain a database of authorized distributors of record on its website at www.doh.state.fl.us/pharmacy/drgus. A prescription drug wholesaler that receives or prepares a pedigree paper under s. 499.0121(6)(d), F.S., that traces the previous distributions of a prescription drug back to a prescription drug wholesaler that is not listed on the department's website as an authorized distributor of record for the drug's manufacturer for the date in which the transaction occurred must maintain and have available for inspection documentation that supports the fact the prescription drug wholesaler is an authorized distributor of record in accordance with the criteria of s. 499.0121(6)(d)5.a., b., or c.

(4) through (6) No change.

(7) Except as provided in s. 499.012(2)(e), F.S., and paragraph (3)(b) of this rule, r~~R~~ecords of other persons not required to be permitted but subject to regulation under Chapter 499, F.S., must be made available to the department or the Florida Department of Law Enforcement within five business days of the request for inspection, copying, or reproduction.

(8) through (9) No change.

(10) All required records must be retained for a period of two years following disposition of the drug, device or cosmetic, or three years after the creation of the records, whichever period is longer; and must be available to the department for such period or as long as records are retained if~~, whichever is~~ longer. Records must be retained beyond the retention ~~two-year~~ period if the person has been notified that an investigation or inspection has been initiated by the department and the investigation has not been completed when the mandatory ~~two-year~~ retention period expires.

(11) through (15) No change.

PROPOSED EFFECTIVE DATE: January 1, 2004.

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, 2-4-93, 7-1-96, Formerly 10D-45.053, Amended 1-26-99, 4-17-01, 1-1-04.

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

(1) through (2) No change.

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

(d) Facility requirements for the storage and handling of prescription drugs.

1. An applicant for an initial prescription drug wholesaler permit must have a facility that is large enough to store the estimated quantity of prescription drugs the applicant intends to handle under its initial application to comply with the requirements of s. 499.0121(1), F.S. An applicant for renewal of a prescription drug wholesaler permit must have a facility that is large enough for the ongoing operations of the wholesale establishment based on the prior year's volume of activity with prescription drugs, which may be modified for reasonable fluctuations in inventory management for the current year. These determinations will be based on the type of prescription drugs the applicant handles, or intends to handle, considering the size of the containers as well as any other products the applicant handles or intends to handle. Notwithstanding the contention that an applicant will distribute all prescription drugs the same day received, the facility must be large enough to accommodate prescription drugs as set forth herein in case the drugs are not distributed the same day received.

2. An applicant for an initial prescription drug wholesaler permit must have a refrigeration capacity and freezer capacity large enough to store the estimated quantity of prescription drugs the applicant intends to handle under its initial application to comply with the requirements of s. 499.0121(1) and (3), F.S., and this rule. An applicant for renewal of a prescription drug wholesaler permit must have a refrigeration capacity and freezer capacity that is large enough for the ongoing operations of the wholesale establishment based on the prior year's volume of activity with prescription drugs, which may be modified for reasonable fluctuations in inventory management for the current year, to comply with the requirements of s. 499.0121(1) and (3), F.S., and this rule. These determinations will be based on the type of prescription drugs the applicant handles, or intends to handle, considering the size of the containers as well as any other products the applicant handles or intends to handle that might require refrigeration or freezing. Notwithstanding the contention that

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

(4) No change.

(5) Examination of Prescription Drugs; Physical Product and Records.

(a) through (c) No change.

(d) Authentication.

1. A prescription drug wholesaler may use any of the following methods to authenticate a pedigree paper and maintain the following documentation regarding the authentication:

a. Receipt of an invoice (or shipping document) from the seller to the purchaser, which may have the prices redacted. Documentation requirements include at a minimum a copy of the invoice or shipping document.

b. Telephone calls to the seller. Documentation requirements include a signed statement by the person placing the telephone call identifying the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

c. E-mail communication with the seller. Documentation requirements include a copy of the email that identifies the person's name and position title representing the seller who provides the information, that date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

d. Verification of the transaction per a web-based system established by the seller. Documentation requirements include a general purpose letter from the seller that the seller is responsible for the information included on the website and has adequate security on the information posted to prevent unauthorized tampering or modification of the information and a copy of the (dated) website page that confirms the sales transaction between the parties, including the date of the transaction and the quantity of prescription drugs involved in the transaction.

2. Authentication of the purchase of a prescription drug directly from the manufacturer by an affiliated group member for a prescription drug that is subject to the statement in s. 499.0121(6)(e)1.a., F.S., may be documented by a written agreement between or among the affiliated group members that each affiliated group member will only transfer prescription drugs included on the specified list that were purchased directly from the manufacturer to an affiliated group member that is required to include the statement in s. 499.0121(6)(e)1.a., F.S., on its wholesale distributions to other wholesale distributors.

(6) Any establishment that is permitted as a prescription drug wholesaler must notify the department in writing within three working days of discovery of a significant loss or theft of prescription drugs. Whether a loss or theft is significant is to be based on the prescription drug wholesaler's written policies and procedures that may take into account the actual quantity in relation to the type or size of the business; any pattern of losses or thefts; and local trends or other indicators of the diversion potential. Notification to the Bureau may be made by facsimile to (850)922-5367 and must include at a minimum, identification of the permitted establishment reporting the loss or theft; a complete identification of the prescription drug(s) involved, including but not limited to the name of the manufacturer or distributor reflected on the label of the products, the dosage form, strength, container size, the quantity of each, the lot numbers if known; a brief description of the circumstances surrounding the theft or loss; and a contact person's name and telephone number to provide additional information.

(7) Due Diligence. An inspection is not required under s. 499.0121(12)(d), F.S., for established relationships between wholesalers that were active and in effect during the period January 1, 2003 – January 1, 2004. However, all other due diligence provisions in s. 499.0121, F.S., must be adhered to by each prescription drug wholesaler. A prescription drug wholesaler that establishes a new relationship or renews a relationship with a prescription drug wholesaler that was not active during the period January 1, 2003 – January 1, 2004, may use an agent to conduct the inspection required by s. 499.0121(12)(e), F.S.

PROPOSED EFFECTIVE DATE: January 1, 2004.

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, 4-17-01, 1-1-04.

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) Any person that is required under Sections 499.001-.081, F.S., to have a permit shall apply to the department for the appropriate permit on forms indicated in this rule. Inquiries regarding requests for an application or licensing may be directed to Bureau of Statewide Pharmaceutical ~~Pharmacy~~ Services, 2818-A Mahan Drive, Tallahassee, Florida 32308 or telephone number (850)922-5190. Applications may be downloaded from the bureau's web site at www.doh.state.fl.us/pharmacy/drugs.

(2) 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, Freight Forwarder, Veterinary Legend Drug Retailer, Medical Oxygen Retailer, and Restricted Rx 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)1. A person permitted as a Prescription Drug Manufacturer that is applying for additional manufacturing permits, a Complimentary Drug Distributor permit, 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 (d) No change.

(4) through (5) No change.

(6) MANUFACTURER PERMITS.

(a) through (b) No change.

(c) Application requirements for manufacturers and prescription drug repackagers located in Florida include:

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

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

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

5. Have an FDA establishment registration number, or unless the application is for a cosmetic manufacturer, provide documentation to the department supporting an exemption from FDA registration.

(d) Application requirements for Non-resident prescription drug (Rx) manufacturers.

1. A person may qualify as a Non-resident Rx drug manufacturer if:

a. The establishment is not located in Florida; and

b.i. The person and establishment physically manufacture a prescription drug either for itself or as a contract manufacturer; or

ii. The person is the holder of an approved New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or New Animal Drug Application (NADA); or

iii. The person and establishment is a private label distributor and the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or

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

v. The person and establishment import prescription drugs, including active pharmaceutical ingredients also referred to as bulk ingredients that are lawful in interstate commerce.

2. A non-resident Rx drug manufacturer that also distributes prescription drugs that it did not manufacture (as meeting one of the criteria above) will also need to apply for an out-of-state prescription drug wholesaler permit and meet all of the requirements for obtaining that permit.

3. Contact the department's Bureau of Statewide Pharmaceutical Services to request an application or download the application from the bureau's web site.

4. File with the department a completed application for a permit using an original DOH-Form, DOH-Form 1033, "Application for Permit Under Chapter 499, F.S.," effective January 2004, which is incorporated by reference herein.

5. Submit a photocopy of all permits or licenses issued to the applicant's address which authorize the manufacture or possession of prescription drugs at that address, regardless of the issuing agency. If the issuing agency prohibits photocopying the permit or license, the applicant may submit a state verification of any permits or licenses issued to the applicant's address.

6. If the non-resident Rx drug manufacturer is importing prescription drugs, FDA approval can be documented with:

i. An NDA number for the product; or

ii. Evidence of an FDA establishment number for the manufacturing site and inclusion of the particular product on the manufacturer's drug listing with the FDA; or

iii. For an active pharmaceutical ingredient, evidence that the manufacturer's substance is identified as an ingredient in an FDA approved finished product; or

iv. Other direct evidence of FDA authorization for the importation and commercial distribution of the product.

Updates to the list of prescription drugs being imported and documentation of FDA approval must be submitted to the department prior to importation of any prescription drug under the non-resident Rx drug manufacturer's permit. It is the non-resident manufacturer's responsibility to assure that it is only importing approved prescription drugs into Florida and is complying with s. 499.023, F.S. Compliance with submission of the information required in this rule does not mean that the prescription drug does in fact comply with all provisions of the Federal Act and Chapter 499, F.S., and may be imported.

7. Pay the appropriate fee(s) as required by Rule 64F-12.018, F.A.C.

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

(7) WHOLESALER PERMITS.

(a) A person applying for or renewing a permit as a prescription drug wholesaler must have an area for the storage of prescription drugs under controlled room temperature and refrigeration, as required by paragraph 64F-12.013(3)(d), F.A.C., whether or not the person intends to wholesale prescription drugs requiring storage under controlled room temperature conditions or refrigeration; except that a person who will act as a broker only of prescription drugs may apply for a "broker only" designation on the Prescription Drug Wholesaler permit and then the requirement that the permitted address provide for "controlled room temperature" and refrigeration is waived. A "broker only" cannot take possession of prescription drugs under any circumstances.

(b) The Prescription Drug Wholesaler's bond and the bond for an out-of-state prescription drug wholesaler~~, if applicable,~~ will be transferred by the department to subsequent permits issued pursuant to renewal applications if the bond or other equivalent means of security is in a form that will allow for such transfer. The bond will be refunded without interest, consistent with the provisions of Section 499.012(2), F.S. In order for another means of security to satisfy the bond requirement, the security must be in a form that the applicant or permittee cannot revoke, withdraw, cancel, or otherwise reduce the department's interest until the conditions upon which the bond can be refunded or released, as set forth in Section 499.012(2), F.S., have been satisfied. If the bond or other security is in a form that requires the department to initiate release of the bond or security, a prescription drug wholesaler or out-of-state prescription drug wholesaler should request in writing that the department release the bond or security within 45 days of satisfaction of the conditions in s. 499.012(2)(a) and (c), F.S., that release department's interest in the bond or other security. The department must initiate release of the bond or security within 10 working days of satisfaction of the conditions in s. 499.012(2)(a) and (c), F.S., unless the department has otherwise made a claim against the bond or security.

(c) A Prescription Drug Wholesaler is authorized to wholesale all prescription drugs, including compressed medical gases and therefore does not require dual permits.

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

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

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

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

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

(e) Application requirements for Prescription Drug Wholesalers, Prescription Drug Wholesalers – Broker Only, or Out-of-State Prescription Drug Wholesalers include:

1. Contact the department's Bureau of Statewide Pharmaceutical ~~Pharmacy~~ Services for an application form(s) and fingerprint cards. Both the sales transaction (seller) and the physical movement (location from which the drugs are shipped) of prescription drugs are considered wholesale distribution. Therefore, if the seller (name and address as reflected on the invoice) is not the same as the location from which the drugs are shipped (name and address), such as in the case of brokers, different branches of the same company, or a contract warehouse, then both persons (the seller and location from which shipped) must be permitted under the Florida Drug and Cosmetic Act ~~as an Out-of-State Prescription Drug Wholesaler~~.

2. File with the department a completed application for a permit using an original form DH 2124, "Prescription Drug Wholesaler/Out-of-State Prescription Drug Wholesaler Application" effective January 2004, ~~DOH-Form 1033, "Application for Permit Under Chapter 499, F.S." effective March 2001,~~ which is incorporated by reference herein.

3. File with the department an original form DH 2125, "Personal Information Statement" effective January 2004, which is incorporated by reference herein for the applicant's manager, next four highest ranking employees that are responsible for prescription drug operations, and all affiliated parties.

4. Submit a legible fingerprint card and $47.00 per fingerprint card for each person required to submit a fingerprint card. These fingerprint cards must have been obtained from the department so that the cards will have the proper coding for processing and reporting.

5. Submit a $100,000 bond or security as specified in s. 499.012(2)(a) and (c), F.S., and sub-paragraph (b) above. If you are using a surety bond, the required bond form is DH 2128, "Surety Bond Form," effective January 2004, which is incorporated by reference herein.

6. If the applicant is located outside of Florida, s~~S~~ubmit a photocopy of the resident state's license or permit that authorizes the wholesale distribution of prescription drugs. If the resident state does not allow photocopying of the license or permit, the applicant may submit a verification of the license or permit from the issuing agency. If the resident state does not require a license or permit for the wholesale distribution activities of the applicant in that state, submit

(i) A written confirmation on the letterhead of the resident state agency responsible for regulating prescription drug wholesale distribution in that state that permitting of the applicant establishment is not required by that state and

(ii) A statement signed by the applicant that the applicant will comply with all storage, handling, and recordkeeping requirements of the resident state related to the sale and physical distribution of prescription drugs into Florida, or if none exist in the resident state that the applicant will comply with all storage, handling, and recordkeeping requirements, as set forth in 21 C.F.R. 205.50 (as of 10/1/03 ~~1/1/01~~) which is incorporated by reference herein, for the sale and physical distribution of prescription drugs into Florida.

~~The Out-of-State Prescription Drug wholesaler application will not be approved until the license or permit status in the resident state is verified. The Out-of-State Prescription Drug Wholesaler application will not be approved until the license or permit status in the resident state is verified.~~

7. Identify a person who has been Certified pursuant to s. 499.012(11), F.S., to serve as the certified designated representative. If the prescription drug wholesaler operates in 'shift' schedules, a different person per shift may be designated; however the shift hours for which each person is responsible must be clearly identified. You may use Notification of Designated Representative form DH 2130, effective January 2004, for the initial notification or for changes in the designated representative.

8.~~4.~~ Pay the appropriate fee(s) as required by Rule 64F-12.018, F.A.C.

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

(f) Application requirements for Retail Pharmacy Wholesalers include:

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

3. Submit a photocopy of all permits issued to the applicant's address which authorize the purchase of prescription drugs at that address, regardless of the issuing agency.

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

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

(g) Application requirements for freight forwarders.

1. Contact the department's Bureau of Statewide Pharmaceutical 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 January 2004, which is incorporated by reference herein.

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

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

(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, F.A.C., Medical Oxygen Retailers, and Veterinary Legend Drug Retailers.

(a) Application requirements for Complimentary Drug Distributors include:

1. Contact the department's Bureau of Statewide Pharmaceutical ~~Pharmacy~~ Services for an application form or download the application from the bureau's web site. An out of the state manufacturer or distributor of complimentary or sample prescription drugs may obtain a "Complimentary Drug Distributor permit" for its headquarters or home office in lieu of a permit for each establishment from which complimentary prescription drugs are distributed. A manufacturer or distributor that uses a fulfillment house, shipping and mailing service, or distributes through co-marketing agreements, must notify the department in writing of the contractor's name, address, and responsibilities prior to the distribution of prescription drug samples in or into this state. The headquarters or home office location is responsible for all recordkeeping requirements and for production of such records as required by Sections 499.0121 and 499.028, F.S., this rule

and Rule 64F-12.012, F.A.C. A person located within the state that manufactures or distributes complimentary or sample prescription drugs directly or through its agents, employees, or independent contractors, must obtain a Complimentary Drug Distributor permit for each establishment located in Florida. A manufacturer or distributor that uses a fulfillment house, shipping and mailing service, or distributes through co-marketing agreements, any of which is located in Florida, must obtain a permit in the name of the manufacturer or distributor issued to the address of the fulfillment house, shipping and mailing service, or similar location. The manufacturer or distributor is responsible for all recordkeeping requirements and for production of such records as required by Sections 499.0121 and 499.028, F.S., this rule and Rule 64F-12.012, F.A.C.

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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

3. Submit a copy of the applicant's license or permit which authorizes the possession of prescription drugs. If the issuing agency does not allow photocopying of a license or permit, the applicant may submit a verification of the license or permit from the issuing agency.

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

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

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

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

3. Submit a listing of all the locations under common control that will be receiving distributions under this permit. This listing must include the name and address of the facility and the pharmacy or other permit number which authorizes that location to possess prescription drugs. Additional locations must be communicated to the department in writing prior to the transfer of prescription drugs. Alternatively, depending on the basis for the application, provide a copy of the written contract evidencing the group purchasing organization and a listing of all the locations that will be receiving distributions under this permit because of joint membership in the group purchasing organization.

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

5. Pay the appropriate fee(s) as required by Rule 64F-12.018, F.A.C.

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

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

3. Submit proof of the charitable organization designation under section 501(c)(3) of the Internal Revenue Code.

4. If the FDA has initiated the enrollment program, submit the FDA central file number of the applicant.

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

6. Pay the appropriate fee(s) as required by Rule 64F-12.018, F.A.C.

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

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

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

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

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

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

3. Submit a detailed plan justifying the necessity for this permit in accordance with subsection 64F-12.023(5), F.A.C.

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 Section 499.012(1)(a)1.d., F.S.

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

6. Pay the appropriate fee(s) as required by Rule 64F-12.018, F.A.C.

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

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

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

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

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

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

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

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

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

1. Contact the department's Bureau of Statewide Pharmaceutical ~~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 January 2004 ~~March 2001~~, which is incorporated by reference herein.

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

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) DESIGNATED REPRESENTATIVE.

(a) In order to provide a method for drug wholesalers to comply with s. 499.012(11), F.S., the department will issue a provisional permit to designated representative prior to full implementation of the testing requirements.

(b) Each designated representative provisionally certified has one year from dissemination of the test results for the first test administered to have attained a passing score of at least 75% correct on the test required by s. 499.012(11)(b)4., F.S. Upon passing the test, the provisional designation for the certification will be deleted. If a person provisionally certified has not attained a passing score of at least 75% correct on the test required by s. 499.012(11)(b)4., F.S., within this time frame, the provisionally certified person will be notified of the department's intent to revoke the provisional certification for failure to meet the requirements to be certified as a designated representative. The person will have to reapply to the department for certification as a designated representative and meet all requirements in effect at that time.

(c) For purposes of the work experience required to be certified as a designated representative:

1. Serving in a managerial capacity does not require actual supervisory responsibilities over employees, but requires a level of responsibility consistent with a managerial employee, including but not limited to decision-making authority, responsibility for developing and implementing policies and procedures related to purchasing, sales, or inventory management for prescription drugs.

2. Responsibilities related to recordkeeping for prescription drugs by a person who worked in a pharmacy may include such activities as, practicing pharmacy pursuant to a valid pharmacy license, routinely purchasing or ordering prescription drugs where cognitive functions were involved and the order is not the result of an automated reorder system, routinely receiving prescription drugs and verifying the accuracy of the order, routinely taking a physical inventory of prescription drugs, routinely assessing the pharmacy shelves for outdated prescription drugs, and routinely completing an inventory for the transfer of adulterated prescription drugs for appropriate disposal.

(d) Application requirements for Certification as a Designated Representative include:

1. Contact the department's Bureau of Statewide Pharmaceutical Service to request an application and fingerprint cards or download the application from the bureau's web site.

2. File with the department a completed application for certification using Form DH 2126 "Application for Certification as a Designated Representative," effective January 2004, which is incorporated by reference herein.

3. Submit a legible fingerprint card and $47.00 per fingerprint card. The fingerprint card must have been obtained from the department so that the card will have the proper coding for processing and reporting.

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

5. Comply with all requirements for certification provided in Chapter 499, F.S., and these rules.

(10) PERMIT RENEWALS FOR ALL PERMITS OTHER THAN A PRESCRIPTION DRUG WHOLESALER, PRESCRIPTION DRUG WHOLESALER – BROKER ONLY, OR OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER. Submission of a renewal application

represents to the department that conditions have not changed with the permitted person which would make the permitted person ineligible to renew the permit.

(a) A permit renewed during the grace period will expire 24 months after the last day of the anniversary month in which the previous permit expired.

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

1. File with the department a completed application for a permit using an "Application for Permit Renewal Under Chapter 499, F.S.," DOH-Form 1034, effective January 2004 ~~March 2001~~, 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. Pay the appropriate fee pursuant to this section and Rule 64F-12.018, F.A.C.

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

~~4. Applicants renewing an Out-of-State Prescription Drug Wholesalers permit must also submit a legible photocopy of a valid (current) prescription drug wholesaler permit granted by the resident state.~~

4.~~5.~~ Applicants renewing a Retail Pharmacy Wholesaler's permit must also submit a legible photocopy of the current community pharmacy permit.

(c) If a permit is not renewed prior to the expiration date or within the grace period, the person will be placed out-of-business for purposes of Chapter 499, F.S. In order to be permitted after the expiration of the 60-day grace period, a person must submit a new application and proceed according to the requirements for submission of a new application.

(11) PERMIT RENEWALS FOR PRESCRIPTION DRUG WHOLESALER, PRESCRIPTION DRUG WHOLESALER – BROKER ONLY, OR OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER.

(a) The bureau will mail an application for renewal of the prescription drug wholesaler, prescription drug wholesaler – broker only, or out-of-state prescription drug wholesaler permit at least 90 days prior to the expiration date of the permit.

(b) A renewal application that is postmarked within 45 days prior to the expiration date of the permit must include submission of a $100 delinquent fee in addition to the annual permit fee, fingerprint fees, and bond.

(c) File with the department a completed application for a permit using an original form DH 2124, "Prescription Drug Wholesaler / Out-of-State Prescription Drug Wholesaler Application" effective January 2004, which is incorporated by reference herein.

(d) File with the department an original form DH 2125, "Personal Information Statement" effective January 2004, which is incorporated by reference herein for the applicant's manager, next four highest ranking employees that are responsible for prescription drug operations, and all affiliated parties.

(e) Submit a legible fingerprint card for any person for whom a Personal Information Statement is submitted who has not previously submitted a fingerprint card on behalf of the applicant company. These fingerprint cards must have been obtained from the department so that the cards will have the proper coding for processing and reporting.

(f) Submit $47.00 for each person for whom a personal information statement was submitted; i.e., the manager of the establishment, the next four highest ranking employees responsible for prescription drug wholesaler operations for the establishment, all affiliated parties, and the designated representative.

(g) Submit a $100,000 bond or security as specified in s. 499.012(2)(a) and (c), F.S., and paragraph (7)(b) above. If you are using a surety bond, the required bond form is DH 2128, "Surety Bond Form," effective January 2004, which is incorporated by reference herein.

(h) If the applicant is located outside of Florida, submit a photocopy of the resident state's current license or permit that authorizes the wholesale distribution of prescription drugs. If the resident state does not allow photocopying of the license or permit, the applicant may submit a verification of the license or permit from the issuing agency. If the resident state does not require a license or permit for the wholesale distribution activities of the applicant in that state, submit:

1. A written confirmation on the letterhead of the resident state agency responsible for regulating prescription drug wholesale distribution in that state that permitting of the applicant establishment is not required by that state; and

2. A statement signed by the applicant that the applicant will comply with all storage, handling, and recordkeeping requirements of the resident state related to the sale and physical distribution of prescription drugs into Florida, or if none exist in the resident state that the applicant will comply with all storage, handling, and recordkeeping requirements, as set forth in 21 C.F.R. 205.50 (as of 10/1/03) which is incorporated by reference herein, for the sale and physical distribution of prescription drugs into Florida.

(i) Pay the appropriate fee(s) as required by Rule 64F-12.018, F.A.C.

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

PROPOSED EFFECTIVE DATE: January 1, 2004.

Specific Authority 499.01, 499.012, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 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, 499.028, 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, 4-17-01, 10-29-02, 7-6-03, 1-1-04.

64F-12.016 Product Registration.

(1) No change.

(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 January 1999; or DOH-Form 1037, "Application for Product Registration– Cosmetics," effective January 1999; 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 and all labeling associated with the product that provides information in addition to or other than what is on the product label 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, or a product category identifier if the product is a cosmetic); and

4. Pay the appropriate fee pursuant to Rule 64F-12.018, F.A.C.

(b) An applicant must amend its product registration list for new products prior to any sales by following the procedures for an initial product registration, listing only those products to be added. Registration for these products will expire concurrently with the biennial cycle for that establishment's other registered products. Fees will be prorated as provided for in subsection 64F-12.018(4), F.A. C.

(3) PRODUCT REGISTRATION RENEWAL.

(a) Applicants applying for renewal of a product registration must:

1. Submit the Application for Product Registration Renewal Under Chapter 499, F.S., DOH-Form 1041, effective January 1999, which is incorporated by reference herein. The permittee should contact the department if the renewal application has not been received at least 30 days prior to the product registration's expiration date.

2. Submit a product label or copy thereof and all labeling associated with the product if the label or labeling has changed in any respect from the initial or previous renewal registration; and

3. Pay the appropriate fee pursuant to Rule 64F-12.018, F.A.C.

(b) Registrations issued by the department within the grace period will automatically expire 24 months after the last day of the month in which the previous registration expired.

PROPOSED EFFECTIVE DATE: January 1, 2004.

Specific Authority 499.01, 499.015, 499.04, 499.05 FS. Law Implemented 499.01, 499.015, 499.04 FS. History–New 7-1-96, Formerly 10D-45.0542, Amended 1-26-99, 4-17-01, 1-1-04.

64F-12.018 Fees.

(1) Biennial fees for a manufacturer's permit are as follows:

Permit	Biennial Fee
Prescription Drug Manufacturer	$1300 ~~1100~~
Prescription Drug Repackager	$1300
Device Manufacturer	$1000
Cosmetic Manufacturer	$600
Over-the Counter Drug Manufacturer	$600
Compressed Medical Gas Manufacturer	$900
Non-resident Prescription Drug Manufacturer	$850

No manufacturer shall be required to pay more than one fee per establishment to obtain an additional manufacturing permit; but the manufacturer must pay the highest fee applicable to the operations in each establishment.

(2)(a) Biennial fees for a wholesaler's permit that is issued on a biennial basis are as follows:

Permit	Biennial Fee
~~Prescription Drug Wholesaler~~	~~$700~~
Compressed Medical Gas Wholesaler	$500
~~Out-of-State Prescription Drug Wholesaler~~	~~$600~~
Retail Pharmacy Wholesaler	$100
Freight Forwarder	$250

(e) Annual fees for a wholesaler's permit that is issued on an annual basis are as follows:

Permit	Annual Fee
Prescription Drug Wholesaler (including Broker Only)	$800
Out-of-State Prescription Drug Wholesaler	$700

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

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

(4) Miscellaneous other fees are as follows:

Description of other service fees	Fee
Certification as Designated Representative	$150
Initial Application/On-site Inspection	$150

(The initial application/on-site inspection fee is non-refundable.)

Prescription Drug Wholesaler Bond/Security or Out-of-State Prescription Drug
Wholesaler Bond/Security ~~if applicable~~, as
set forth in Section 499.012(2), F.S. $100,000
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 drug or cosmetic product registered) $20*
* The registration fee for a drug or cosmetic 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

(5) The department shall assess other fees as provided in Sections 499.001-499.081, F.S.

PROPOSED EFFECTIVE DATE: January 1, 2004.

Specific Authority 499.01, 499.012, 499.015, 499.04, 499.041, 499.05 FS. Law Implemented 499.01, 499.012, 499.015, 499.04, 499.041 FS. History–New 7-1-96, Formerly 10D-45.0544, Amended 4-17-01, 7-6-03, 1-1-04.

64F-12.020 Forms.

All forms referenced in this rule may be obtained without cost from the Department of Health, Bureau of Statewide Pharmaceutical ~~Pharmacy~~ Services, 2818-A Mahan Drive, Tallahassee, Florida 32308, (850) 922-5190. Application forms are also available at the department's web site: www.doh.state.fl.us/pharmacy/drugs.

PROPOSED EFFECTIVE DATE: January 1, 2004.

Specific Authority 499.01, 499.012, 499.0122, 499.013, 499.015, 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, 499.0122, 499.013, 499.015, 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, Formerly 10D-45.56, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.056, Amended 1-26-99, 1-1-04.

64F-12.024 Administrative Enforcement.

(1) through (3) No change.

(4) The following codes outline department policy under Section 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.

CITE	VIOLATION	GENERAL SEVERITY
499 refers to Chapter 499, F.S.		
12 refers to Rule 64F-12, F.A.C.		
FACILITY, STORAGE:		
499.0121(a);		
12.014(4)	Inadequate facility	3
499.0121(b)	Inadequate security	3
499.0121(a)	Unrestricted access to prescription drugs	3*
12.022(4)	Unrestricted access to ether	3
499.0121(3)	Inadequate storage	3*
12.013(3) & 12.014(1)	Improper temperature conditions	2
499.0121(1)(b)	Improper ventilation/physical access	3*
499.0121(1)(c); 12.013(4) & 499.05355(2)	No quarantine area	3
MISCELLANEOUS:		
499.005(4)	Activity in violation of law or rules	3
499.005(20)	Importing a prescription drug	2-1
499.005(21)	Wholesaling by health care entity	2-1
499.0122(2)(d)	Returning dispensed drug to inventory	2
12.023(5)	Failure to monitor	3-1
499.005(7)	Using currency for Rx drug transaction	2-1
OPERATING:		
499.005(6) & 499.67(5)	Refusing entry, inspection, taking evidence	2-1
499.005(6)	Inaccessible during business hours	3-2
12.015(2)(c)		
499.005(22); 499.62 & 12.015	Failure to obtain proper permit (cost of permit plus fine)	3-1
499.015 & 12.016	Failure to register products ($50 per product per year)	3
499.01(4)(a) & 12.016(4)	Failure to notify dept. of address change	3

RECORDKEEPING:		
499.005(18);	Failing to maintain records, inventories	3-1
499.0121(6);	Failing to make records available	3-1
499.028; 499.052; 499.66; 499.67; 12.012 & 12.022(3); 499.66; 499.67 & 12.012		
499.005(28)		
~~499.0121(6)~~	Absence of/not providing pedigree papers	2-1
12.012(1)	Not maintaining a complete audit trail	3
12.012(12)	Separate records, multiple businesses	3
12.007(2)	No written procedures for medical oxygen	3
SAMPLES:		
499.005(17)	Sample drug distribution – activity with	1
499.005(25)	Charging a dispensing fee for a prescription sample	2-1
ADULTERATED & MISBRANDED:		
499.005(1)	Activity with adulterated or misbranded product	3-1
499.005(2)	Adulterating or misbranding a product	3-1
499.005(3)	Receiving adulterated/misbranded product	3-2
499.005(9)	Making a product misbranded	3-1
12.007(3)	Improper labeling on medical oxygen	3
499.013(2)(a)	Prescription Drug Manufacturer not following GMP	3-1
499.013(2)(b)	OTC Drug Manufacturer not following GMP	3-1
499.013(2)(c) & 12.007(1)	Comp. Med. Gas Manufacturer not following GMP	3-1
499.013(2)(d)	Device Manufacturer not following GMP	3-1
12.010	Cosmetic Manufacturer not following GMP/guidelines	3-1
499.005(1)	Activity with drug which left regulatory control, GMP	2-1 ~~3-1~~
499.005(26)	Removing pharmacy dispensing label	1
499.005(27)	Distributing previously dispensed Rx drug	1
499.005(29)	Receipt of Rx drug without pedigree paper	2-1
COUNTERFEIT:		
499.005(8)	Making/dealing in a counterfeit product	1
FALSE & MISLEADING:		
499.005(5) & 12.002	Disseminating false/misleading ad	3
~~499.005(7)~~	~~Giving a false guaranty or undertaking~~	~~2~~
499.005(10)	Forging, counterfeiting, falsely representing a product	2-1
499.005(11)	Labeling or advertisement of effectiveness when not	3
499.005(19); 499.005(23); 499.66 & 499.67	Making false or fraudulent statements	2-1
499.005(19), 499.64(4), & 499.67	Providing department with false/fraudulent records/statements	2-1
499.0054	Advertising Violations	3
499.005(23)	Obtaining/attempting to obtain by fraud, deceit, misrepresentation, subterfuge	2-1
499.005(13)	Activity w/self-testing HIV/AIDS products	2
UNAUTHORIZED SOURCE OR RECIPIENT:		
499.005(14)	Purchase or receipt of prescription drug from unauthorized source	2-1 ~~3*~~
499.005(16)	Purchase or receipt of Comp. Med. Gas from unauthorized source	3*
499.005(15)	Sale or transfer of prescription drug to unauthorized person	3*-1
499.005(24)	Sale or transfer of legend device to unauthorized person	3
499.0122(1)(d) & 12.012(4)	Improper sale of veterinary Rx drug	3
12.012(4)	Distribution of medical oxygen by medical oxygen retailer without a prescription (order)	3
499.66	Sale or transfer of ether to unauthorized person	3-2
POSSESSION:		
499.0122(1)(d)	Activity relating to human Rx drug by Vet. Retailer	3
499.013(2)(b)	Possession of prescription drug by OTC Mfgr	3
499.013(2)(c)	Possession of other Rx drug by Comp. Med. Gas Manufacturer	3

499.0122(1)	Possession of other Rx drugs by medical oxygen retailer	3
499.023	Activity with unapproved new drug	2-1
499.03(1)	Illegal possession, etc. of habit forming toxic, etc. new drug	3-1
499.005(12)	Possession in violation of 499.001-499.081	3*
499.028(15)	Illegal possession of a sample drug	3-1
499.65	Illegal possession of ether >2.5 gallons	3-1
499.69	Possession of ether within 500′ of residence ~~residents~~	2

(5) Administrative fines due the department may be paid by cashier's check, certified check, money order, or other guaranteed funds, payable to the Florida Drugs, Devices and Cosmetics Trust Fund, at 2818-A Mahan Drive, Tallahassee, Florida 32308.

(6) If a prescription drug wholesaler, including a broker only, or out-of-state prescription drug wholesaler fails to pay an administrative fine or costs within 30 days after the fine or costs become final, the department may make a claim against the bond or other security as provided in s. 499.012(2)(a) and (c), F.S.

PROPOSED EFFECTIVE DATE: January 1, 2004.

Specific Authority 499.05 FS. Law Implemented 499.0121, 499.066 FS. History–New 7-1-96, Formerly 10D-45.0595, Amended 1-26-99, 4-17-01, 1-1-04.

NAME OF PERSON ORIGINATING PROPOSED RULE: Jerry Hill, Chief of Statewide Pharmaceutical Services

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Phil E. Williams, Director, Division of Health Awareness and Tobacco

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 24, 2004

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 22, 2003

Section III
Notices of Changes, Corrections and Withdrawals

BOARD OF TRUSTEES OF THE INTERNAL IMPROVEMENT TRUST FUND

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

DEPARTMENT OF CITRUS

RULE CHAPTER NO.: RULE CHAPTER TITLE:
20-36 Certification For "Tree Run" Grade
RULE NOS.: RULE TITLES:
20-36.002 Inspection Required
20-36.006 Determination of Quantity

NOTICE OF WITHDRAWAL

Notice is hereby given that the above proposed rules published in the Florida Administrative Weekly, Vol. 29, No. 33, August 15, 2003 has been withdrawn.

DEPARTMENT OF CORRECTIONS

RULE NO.: RULE TITLE:
33-601.504 Transition Assistance Program

NOTICE OF PUBLIC HEARING

Notice is hereby given that a public hearing on the above referenced proposed rule, as noticed in the Florida Administrative Weekly, Vol. 29, No. 37, September 12, 2003, will be held at 10:00 a.m. on Tuesday, October 14, 2003, at the Department of Corrections Central Office located at 2601 Blair Stone Road, Tallahassee, Florida 32399-2500.

AGENCY FOR HEALTH CARE ADMINISTRATION

Medicaid

RULE NO.: RULE TITLE:
59G-4.165 Inpatient Mental Health and Tuberculosis Hospital Services

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the Notice of Rule Development in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 29, No. 38, September 19, 2003 of the Florida Administrative Weekly.

The date of the workshop for proposed rule development was erroneous. The correct date for the workshop will be as follows:

TIME AND DATE: 10:00 a.m., Tuesday, October 21, 2003

PLACE: 2727 Mahan Drive, Building #3, Conference Room A, Tallahassee, FL

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT IS: Kris Russell, Medicaid Services, 2727 Mahan Drive, Building 3, Mail Stop 20, Tallahassee, Florida 32308-5407, (850)922-7353

AGENCY FOR HEALTH CARE ADMINISTRATION

Medicaid

RULE NO.: RULE TITLE:
59G-8.200 Home and Community-Based Services Waivers