Section I

Notice of Development of Proposed Rules and Negotiated Rulemaking

DEPARTMENT OF HEALTH

Division of Emergency Preparedness and Community Support

RULE NO.: RULE TITLE: 64J-2.001 Definitions

64J-2.002 Prehospital Requirements for Trauma Care 64J-2.003 Trauma Transport Protocols Approval and

Denial Process

64J-2.004 Adult Trauma Scorecard Methodology 64J-2.005 Pediatric Trauma Scorecard Methodology

PURPOSE AND EFFECT: Review these rules and amend rule language as necessary to ensure that all rules conform to statutory requirements and delete unnecessary and obsolete language. The department intends to update trauma rule definitions and prehospital requirements for trauma care and adult and pediatric trauma scoring methodologies. The Department is considering repealing Rules 64J-2.003, 64J-2.004, and 64J-2.005, F.A.C. and adopting the Guidelines for Field Triage of Injured Patients, Recommendation of the National Expert Panel on Field Triage, 2011, as the trauma scoring system.

SUBJECT AREA TO BE ADDRESSED: Definitions, prehospital requirements for trauma care, trauma transport protocols approval and denial process, adult and pediatric trauma scorecard methodologies.

RULEMAKING AUTHORITY: 381.0011(13), 395.401(2), 395.4025(13), 395.4036, 395.4045, 395.405, 395.405(8), 401.35, 401.45(5) FS.

LAW IMPLEMENTED: 381.0205, 395.1031, 395.3025(4)(f), 395.401, 395.4015, 395.402, 395.4025, 395.403, 395.4036, 395.404, 395.4045, 395.405, 401.30, 401.35, 401.45, 765.401 FS.

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

DATE AND TIME: Wednesday, March 9, 2016 at 9:00 a.m.

PLACE: 4052 Bald Cypress Way, 3rd Floor, Conference Room 301, Tallahassee, Florida, Conference Call Number: 1-(888)670-3525, Participant Code: 1043560135

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT IS: Melia Jenkins, 4052 Bald Cypress Way, Bin A-22, Tallahassee, Florida 32399; (850)245-4440, ext. 2773; Melia.Jenkins@flhealth.gov.

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

Section II Proposed Rules

WATER MANAGEMENT DISTRICTS

Suwannee River Water Management District

RULE NO.: RULE TITLE:

40B-21.221 Evaluating Hydrologic Conditions.

PURPOSE AND EFFECT: The Suwannee River Water Management District (District) gives notice that it is amending Rule 40B-21.221, F.A.C., for the purpose of removing subsection 40B-21.221(1), F.A.C., which restates the requirements of Rule 40B-21.211, F.A.C. The effect will be to reduce duplicative regulation and achieve other streamlining benefits for the regulated public.

SUMMARY: Rule amendment – 40B-21.221, F.A.C.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: The District has completed for the Governor's Office of Fiscal Accountability and Regulatory Reform (OFARR) the "Is a SERC Required?" form and prepared a summary of the proposed rule amendment, which are both available upon request. Based on the completed "Is a SERC Required?" form and summary and the analysis performed by the District, the proposed rule amendment is not expected to require legislative ratification pursuant to subsection 120.541(3), F.S.

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

RULEMAKING AUTHORITY: 373.044, 373.113 FS. LAW IMPLEMENTED: 373.175, 373.246 FS.

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Warren Zwanka, Senior Hydrogeologist, Suwannee River Water Management District, 9225 CR 49, Live Oak, Florida 32060, (386)362-1001 or 1(800)226-1066 (FL only)

THE FULL TEXT OF THE PROPOSED RULE IS:

40B-21.221 Evaluating Hydrologic Conditions.

(1) The District shall monitor the condition of the water resources in the District as provided in Rule 40B-21.211, F.A.C.

(1)(2) Current data shall be compared to historical data to determine whether serious harm to the water resources can be expected.

(2)(3) Evaluations under this rule shall consider established minimum flows and levels and associated rules regarding implementation of water shortage provisions contained in Chapter 40B-8, F.A.C.

Rulemaking Authority 373.044, 373.113 FS. Law Implemented 373.175, 373.246 FS. History–New 7-30-06, Amended

NAME OF PERSON ORIGINATING PROPOSED RULE: Warren Zwanka, Senior Hydrogeologist

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Suwannee River Water Management District Governing Board

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: January 12, 2016

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: January 22, 2016

AGENCY FOR HEALTH CARE ADMINISTRATION Medicaid

RULE NO.: RULE TITLE:

59G-4.171 Intermediate Care Facilities for the Mentally

Retarded/Developmentally Disabled;

Recipient Eligibility Criteria

PURPOSE AND EFFECT: Rule 59G-4.171, Florida Administrative Code (F.A.C.), is being repealed. Requirements contained within this rule have been updated and moved to Rule 59G-4.170 F.A.C.

SUMMARY: This rule establishes the criteria for recipients to qualify for Florida Medicaid coverage of ICF/IID services under the Florida Medicaid Institutional Care Program.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely

increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: A checklist was prepared by the Agency to determine the need for a SERC. Based on this information at the time of the analysis and pursuant to section 120.541, Florida Statutes, the rule will not require legislative ratification.

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

RULEMAKING AUTHORITY: 409.919 FS.

LAW IMPLEMENTED: 409.906, 409.908 FS.

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Tracy Thompson, Bureau of Medicaid Policy, 2727 Mahan Drive, Mail Stop 20, Tallahassee, Florida 32308-5407, telephone: (850)412-4270, e-mail: Tracy.Thompson@ahca.myflorida.com

THE FULL TEXT OF THE PROPOSED RULE IS:

59G-4.171 Intermediate Care Facilities for the Mentally Retarded/Developmentally Disabled; Recipient Eligibility Criteria

Rulemaking Authority 409.919 FS. Law Implemented 409.906(13), 409.908, 409.913(5)(e) FS. History—New 1-1-77, Amended 3-10-83, Formerly 10C-7.34, Amended 12-28-93, Formerly 10C-7.034, Repealed

NAME OF PERSON ORIGINATING PROPOSED RULE: Tracy Thompson

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Elizabeth Dudek

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: January 25, 2016

AGENCY FOR HEALTH CARE ADMINISTRATION Medicaid

RULE NO.: RULE TITLE:

59G-6.010 Payment Methodology for Nursing Home

Services

PURPOSE AND EFFECT: The purpose of the amendment to Rule 59G-6.010, Florida Administrative Code, is to incorporate by reference Florida Title XIX Long-term Care

Reimbursement Plan (the Plan), Version XLIII, effective July 1, 2015.

SUMMARY: The amendment specifies the rule is applicable to all nursing facility providers, and updates existing language; and will update the Plan to reflect changes to the payment methodology for nursing home services as authorized in Senate Bill 2500- A, 2015-16 General Appropriations Act, Specific Appropriation 225 and 226, as follows:

- 1. \$1,036,721,006 is provided to buy back nursing facility rate reductions effective on or after January 1, 2008.
- 2. Editorial and technical changes to remove obsolete language and reorganize existing language.
- 3. The amendment will also update the Rule to reflect changes to the due dates for the Nursing Facility

Quality Assessment payment as authorized in 409.9082, Florida Statutes as follows:

- Due date changed to the 20th day of the month
- Penalty date changed to the 25th day of the month.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: A checklist was prepared by the Agency to determine the need for a SERC. Based on this information at the time of the analysis and pursuant to section 120.541, Florida Statutes, the rule will not require legislative ratification.

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

RULEMAKING AUTHORITY: 409.919 FS.

LAW IMPLEMENTED: 409.908, 409.9082, 409.913 FS.

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

DATE AND TIME: March 9, 2016, 10:00 a.m. - 11:00 a.m.

PLACE: Agency for Health Care Administration, 2727 Mahan Drive, Building 3, Conference Room D, Tallahassee, Florida 32308-5407

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 48 hours before the workshop/meeting by contacting: Lisa Smith. If you are hearing or speech impaired,

please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Lisa Smith, Bureau of Medicaid Program Finance, 2727 Mahan Drive, Mail Stop 23, Tallahassee, Florida 32308-5407, telephone: (850)412-4114, e-mail: Lisa.Smith@ahca.myflorida.com

THE FULL TEXT OF THE PROPOSED RULE IS:

59G-6.010 Payment Methodology for Nursing Home Services.

- (1) Reimbursement to participating nursing homes for services provided shall be in accordance with the Florida Title XIX Long-Term Care Reimbursement Plan (the Plan), Version XLIII, effective date July 1, 2015, available at [DOS] 2014, place holder Ref-1 available http://www.flrules.org/Gateway/reference.asp?No=Ref 05167 incorporated by reference. A copy of the Plan, as revised, may be obtained by writing to the Office of the Deputy Secretary for Medicaid, Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop #8, Tallahassee, Florida 32308. The Plan incorporates Provider Reimbursement Manual (CMS Pub. 15-1). The Plan is applicable to all providers of Florida Medicaid nursing facility services who are enrolled in or registered with the Florida Medicaid program.
- (2) Participating nursing homes shall use the Nursing Facility Quality Assessment form (only accepted electronically), AHCA Form 5000-3549, Revised October 2013, incorporated by reference, for the submission of its monthly quality assessment. This form can be accessed at http://ahca.myflorida.com/QAF/index.shtml.
- (3) Each facility shall report monthly to the Agency for Health Care Administration (AHCA) its total number of resident days and remit an amount equal to the assessment rate times the reported number of days. Facilities are required to submit their full quality assessment payment no later than 20 45 days from the next succeeding calendar month.
- (4) Providers are subject to the following monetary fines pursuant to Section 409.9082(7), F.S., for failure to timely pay a quality assessment:
- (a) For a facility's first offense, a fine of \$500 per day shall be imposed until the quality assessment is paid in full, but in no event shall the fine exceed the amount of the quality assessment.
- (b) For any offense subsequent to a first offense, a fine of \$1,000 per day shall be imposed until the quality assessment is paid in full, but in no event shall the fine exceed the amount of the quality assessment. A subsequent offense is defined as any offense within a period of five years preceding the most recent quality assessment due date.

- (c) An offense is defined as one month's quality assessment payment not received by the $2\underline{5}\theta$ th day of the next succeeding calendar month.
- (d) In the event that a provider fails to report their total number of resident days as defined in Section 409.9082(1)(c), F.S., by the 250th day of the next succeeding calendar month, the fines in paragraphs (a)-(c) apply and the maximum amount of the fines shall be equal to their last submitted quality assessment amount but in no event shall the total fine exceed the amount of the quality assessment.
- (5) In addition to the aforementioned fines, providers are also subject to the non-monetary remedies enumerated in Section 409.908<u>2</u>3(7), F.S. Imposition of the non-monetary remedies by AHCA will be as follows:
- (a) For a third subsequent offense, AHCA will withhold any medical assistance reimbursement payments until the assessment is recovered.
- (b) For a fourth or greater subsequent offense, AHCA will seek suspension or revocation of the facility's license.
- (6) Sanctions for failure to timely submit a quality assessment are non-allowable costs for reimbursement purposes and shall not be included in the provider's Medicaid per diem rate.
- (7) The facility may amend any previously submitted quality assessment data, but in no event may an amendment occur more than twelve months after the due date of the assessment. The deadline for submitting an amended assessment shall not relieve the facility from their obligation to pay any amount previously underpaid and shall not waive AHCA's right to recoup any underpaid assessments.

Rulemaking Authority 409.919, 409.9082 FS. Law Implemented 409.908, 409.9082, 409.913 FS. History—New 7-1-85, Amended 10-1-85, Formerly 10C-7.482, Amended 7-1-86, 1-1-88, 3-26-90, 9-30-90, 12-17-90, 9-15-91, 3-26-92, 10-22-92, 4-13-93, 6-27-93, Formerly 10C-7.0482, Amended 4-10-94, 9-22-94, 5-22-95, 11-27-95, 11-6-97, 2-14-99, 10-17-99, 1-11-00, 4-24-00, 9-20-00, 11-20-01, 2-20-02, 7-14-02, 1-8-03, 6-11-03, 12-3-03, 2-16-04, 7-21-04, 10-12-04, 4-19-06, 7-1-06, 8-26-07, 2-12-08, 9-22-08, 3-3-10, 2-23-11, 5-3-12, 2-13-14, 1-19-15, 5-3-15.

NAME OF PERSON ORIGINATING PROPOSED RULE: Lisa Smith

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Elizabeth Dudek

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 8, 2016

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: November 19, 2015

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Division of Drugs, Devices and Cosmetics

RULE NO.: RULE TITLE:

61N-1.028 Product Tracking and Tracing – Definitions. PURPOSE AND EFFECT: The Division proposes the rule amendment to define terms used in the Division's product tracking and tracing rules which implement federal requirements.

SUMMARY: The proposed rule amends several definitions within Chapter 61N-1, F.A.C., to implement the requirements of the federal tracking and tracing law.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE

RATIFICATION: The agency has determined that this rule will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: the economic review conducted by the agency.

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.

RULEMAKING AUTHORITY: 499.0121, 499.05 FS LAW IMPLEMENTED: 499.002, 499.0121, 499.05, 499.052 FS

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Dinah Greene, Operations Review Specialist, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 North Monroe Street Suite 26A, Tallahassee, Florida 32399-1047; 850-717-1802; Dinah.Greene@myfloridalicense.com.

THE FULL TEXT OF THE PROPOSED RULE IS:

- 61N-1.028 Product Tracking and Tracing Definitions. The following definitions apply to the product tracking and tracing requirements set forth in rules 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.
- (1) "AFFILIATE" means a business entity that has a relationship with a second business entity if, directly or indirectly:
- (a) One business entity controls, or has the power to control, the other business entity; or
- (b) A third party controls, or has the power to control, both of the business entities.
 - (2) "AUTHORIZED" means:

- (a) A manufacturer or repackager, registered as a drug establishment with the FDA;
- (b) A wholesale distributor, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. s. 353(e), (as of 12/1/15) which is incorporated by reference herein;
- (c) A third-party logistics provider, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. s. 360eee-3(b) (as of 12/1/15) which is incorporated by reference herein; and
 - (d) A dispenser, having a valid license under Florida law.
- (3) "DISPENSER" means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor. Dispenser does not include a person who dispenses only products to be used in animals when the product is dispensed on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship.
- (4) "DISPOSITION" means, with respect to a product within the possession or control of an entity, the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other handling or actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.
- (5) "DISTRIBUTE" or "DISTRIBUTION" means to sell, purchase, trade, deliver, handle, store, or receive a product; The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.
- (6) "EXCLUSIVE DISTRIBUTOR" means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.
- (7) "GRANDFATHERED" means, with respect to a product, a product that is not labeled with a product identifier and that entered the pharmaceutical distribution supply chain on or before January 1, 2015.
- (8) "HOMOGENOUS CASE" means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.
 - (9) "ILLEGITIMATE PRODUCT" means a product that:
 (a) Is counterfeit, diverted, or stolen;
- (b) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
 - (c) Is the subject of a fraudulent transaction; or

- (d) Appears unfit for distribution such that the product would likely result in serious adverse health consequences or death to humans.
- (10) "LICENSED" means having a valid license in accordance with Florida law. For the purposes of 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C., a dispenser is considered "licensed" if the dispenser has a valid license under Florida law.
 - (11) "MANUFACTURER" means:
- (a) A person that holds an application approved under 21 U.S.C. 355 (as of 12/1/15) which is incorporated by reference herein or a license issued under section 351 of the Public Health Service Act (42 U.S.C. s. 262) (as of 12/1/15) which is incorporated by reference herein for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;
- (b) A co-licensed partner or affiliate of a person described in 61N-1.028(11)(a) that obtains the product directly from a person described in this paragraph or 61N-1.028(11)(a) or 61N-1.028(11)(c); or
- (c) An affiliate of a person described in 61N-1.028(11)(a) or 61N-1.028(11)(b) that receives the product directly from a person described in this paragraph or 61N-1.028(11)(a) or 61N-1.028(11)(b).
- (12) "MEDICAL CONVENIENCE KIT" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2) (as of 12/1/15) which is incorporated by reference herein. A "medical convenience kit" is considered an "exempt medical convenience kit" if it is a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, and:
- (a) The kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with 21 U.S.C. s. 360(b)(2) (as of 12/1/15) which is incorporated by reference herein;
- (b) The kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. s. 801 et seq.) (as of 12/1/15) which is incorporated by reference herein or chapter 893, Florida Statutes;
 - (c) If the kit includes a product:
- 1. The person that manufacturers the kit purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer and did not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and
 - 2. The product is:
- a. An intravenous solution intended for the replenishment of fluids and electrolytes;
- <u>b.</u> A product intended to maintain the equilibrium of water and minerals in the body;
 - c. A product intended for irrigation or reconstitution;
 - d. An anesthetic;
 - e. An anticoagulant;

- f. A vasopressor; or
- g. A sympathomimetic.
- (13) "PACKAGE" means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. For purposes of this paragraph, an "individual saleable unit" is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.
- (14) "PRODUCT" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) (as of 12/1/15) which is incorporated by reference herein that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. s. 2021) (as of 12/1/15) which is incorporated by reference herein, imaging drugs, an intravenous product described in clause 14., 15. or 16. of suparagraph (25)(b) below, any medical gas (as defined in 21 U.S.C. s. 360ddd) (as of 12/1/15) which is incorporated by reference herein, homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with 21 U.S.C. s. 353a (as of 12/1/15) which is incorporated by reference herein or 21 U.S.C. s. 353b (as of 12/1/15) which is incorporated by reference herein.
- (15) "PRODUCT IDENTIFIER" means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier, the standardized numerical identifier, lot number, and expiration date of the product. Unless authorized by the department, the applicable data shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon a package and homogeneous case.
- (16) "QUARANTINE" means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use.
- (17) "REPACKAGER" means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction.
- (18) "RETURN" means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.
- (19) "RETURN PROCESSOR or REVERSE
 LOGISTICS PROVIDER" means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be

- processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.
- (20) "SPECIFIC PATIENT NEED" refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.
- (21) "STANDARDIZED NUMERICAL IDENTIFIER" means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.
- (22) "SUSPECT PRODUCT" means a product for which there is reason to believe that such product:
 - (a) Is potentially counterfeit, diverted, or stolen;
- (b) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- (c) Is potentially the subject of a fraudulent transaction; or (d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.
- (23) "THIRD PARTY LOGISTICS PROVIDER" means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.
 - (24) "TRADING PARTNER" means:
- (a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or
- (b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.
 - (25) "TRANSACTION".
- (a) The term "transaction" means the transfer of product between persons in which a change of ownership occurs.
- (b) EXEMPTIONS. The term "transaction" does not include:
- 1. Intracompany distribution of any product between members of an affiliate or within a manufacturer;
- 2. The distribution of a product among hospitals or other health care entities that are under common control;
- 3. The distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. s. 247d) (as of 12/1/15) which is incorporated by

- reference herein, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
- 4. The dispensing of a product pursuant to a prescription executed in accordance with 21 U.S.C. s. 353(b)(1) (as of 12/1/15) which is incorporated by reference herein;
- 5. The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with 21 U.S.C. s. 353(d) (as of 12/1/15) which is incorporated by reference herein;
- <u>6. The distribution of blood or blood components</u> intended for transfusion;
- 7. The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;
- 8. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. s. 501(c)(3) (Internal Revenue Code) (as of 12/1/15) which is incorporated by reference herein, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- 9. The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;
- 10. The dispensing of a product approved under 21 U.S.C. s. 360b(c) (as of 12/1/15) which is incorporated by reference herein;
- 11. Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. s. 2021) (as of 12/1/15) which is incorporated by reference herein;
- 12. A combination product that is not subject to approval under 21 U.S.C. s. 355 (as of 12/1/15) which is incorporated by reference herein ,or licensure under 42 U.S.C. s. 262 (section 351 of the Public Health Service Act) (as of 12/1/15) which is incorporated by reference herein, and that is:
- a. A product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- b. 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or
- c. 2 or more finished medical devices plus one or more drug or biological products that are packaged together in a "medical convenience kit";
- 13. The distribution of an "exempt medical convenice kit" as set forth in 61N-1.028(12), F.A.C.;
- 14. The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

- 15. The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
- 16. The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
- 17. The distribution of a medical gas (as defined in 21 U.S.C. s. 360ddd) (as of 12/1/15) which is incorporated by reference herein; or
- 18. The distribution or sale of any licensed product under 42 U.S.C. s. 262 (section 351 of the Public Health Service Act) (as of 12/1/15) which is incorporated by reference herein, that meets the definition of a device under 21 U.S.C. s. 321(h) (as of 12/1/15) which is incorporated by reference herein.
- (26) "TRANSACTION HISTORY" means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. The transaction history for a grandfathered product begins with the owner of the product on January 1, 2015.
 - (27) "TRANSACTION INFORMATION" means:
- (a) The proprietary or established name or names of the product;
 - (b) The strength and dosage form of the product;
 - (c) The National Drug Code number of the product;
 - (d) The container size;
 - (e) The number of containers;
 - (f) The lot number of the product;
 - (g) The date of the transaction;
- (h) The date of the shipment, if more than 24 hours after the date of the transaction;
- (i) The business name and address of the person from whom ownership is being transferred; and
- (j) The business name and address of the person to whom ownership is being transferred.
- (28) "TRANSACTION STATEMENT" means a statement, in paper or electronic form, that the entity transferring ownership in a transaction:
 - (a) Is authorized as required under this chapter;
- (b) Received the product from a person that is authorized as defined in paragraph 61N-1.028(2);
- (c) Received transaction information and a transaction statement from the prior owner of the product, as required under 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;
- (d) Did not knowingly ship a suspect or illegitimate product:
- (e) Had systems and processes in place to comply with verification requirements under 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;
- (f) Did not knowingly provide false transaction information; and
 - (g) Did not knowingly alter the transaction history.
- The owner of a grandfathered product is exempt from asserting receipt of transaction information and transaction statement from the prior owner.

- (29) "VERIFICATION" or "VERIFY" means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager.
- (30) "WHOLESALE DISTRIBUTION" means the distribution of a drug subject to 21 U.S.C. s. 353(b) (as of 12/1/15) which is incorporated by reference herein, to a person other than a consumer or patient, or receipt of a drug subject to 21 U.S.C. s. 353(b) (as of 12/1/15) which is incorporated by reference herein, by a person other than the consumer or patient, but does not include:
- (a) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;
- (b) The distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;
- (c) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to 42 U.S.C. s. 247d (section 319 of the Public Health Service Act) (as of 12/1/15) which is incorporated by reference herein, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
- (d) The dispensing of a drug pursuant to a prescription executed in accordance with 21 U.S.C. s. 353(b)(1) (as of 12/1/15) which is incorporated by reference herein;
- (e) The distribution of minimal quantities of drug by a licensed community pharmacy that is a retail pharmacy to a licensed practitioner for office use;
- (f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (g) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;
- (h) The distribution of a drug by the manufacturer of such drug;
- (i) The receipt or transfer of a drug by an authorized thirdparty logistics provider provided that such third-party logistics provider does not take ownership of the drug:
- (j) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;
- (k) The distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with 21 U.S.C. s. 360eee-1(e) (as of 12/1/15) which is incorporated by reference herein;
- (l) Saleable drug returns when conducted by a dispenser; (m) The distribution of an "exempt medical convenience kit" as set forth in 61N-1.028(12), F.A.C.;
- (n) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

- (o) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
- (p) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
- (q) The distribution of medical gas, as defined in 21 U.S.C. s. 360ddd (as of 12/1/15) which is incorporated by reference herein;
- (r) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or
- (s) The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in 21 U.S.C. s. 360eee(16)(B) (as of 12/1/15) which is incorporated by reference herein, and registered under 21 U.S.C. s. 360 (as of 12/1/15) which is incorporated by reference herein, for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.
- (31) "WHOLESALE DISTRIBUTOR" means a person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager, engaged in wholesale distribution.

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NAME OF PERSON ORIGINATING PROPOSED RULE: Reginald D. Dixon, Director

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 9, 2016 DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 30, 2015

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

RULE NO.: RULE TITLE:

61N-1.029 Product Tracking and Tracing –

Manufacturer Requirements

PURPOSE AND EFFECT: The Division proposes the rule amendment to set forth the requirements that permitted manufacturers must follow for tracking and tracing certain prescription drug products through the distribution supply chain.

SUMMARY: The proposed rule implements the manufacturer requirements of the federal tracking and tracing law.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: the economic review conducted by the agency.

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

RULEMAKING AUTHORITY: 499.0121, 499.05 FS.

LAW IMPLEMENTED: 499.002, 499.0121, 499.05, 499.052 FS.

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Dinah Greene, Operations Review Specialist, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 North Monroe Street Suite 26A, Tallahassee, Florida 32399-1047, (850)717-1802, Dinah.Greene@myfloridalicense.com

THE FULL TEXT OF THE PROPOSED RULE IS:

<u>61N-1.029 Product Tracking and Tracing – Manufacturer Requirements.</u>

The following tracking and tracing requirements shall apply to manufacturers:

(1) PRODUCT TRACING.

- (a) A manufacturer shall, prior to or at the time of each transaction in which such manufacturer transfers ownership of a product:
- 1. Provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in a paper or electronic format;
- 2. Capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction; and
- 3. Maintain such information, history, and statement for not less than 6 years after the date of the transaction.
- (b) Requests For Information. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a

- manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction history, and transaction statement for the product.
- (c) Electronic Format. Effective December 1, 2017, a manufacturer shall provide the transaction information, transaction history, and transaction statement required under 61N-1.029(1)(a), F.A.C., in an electronic format. A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under 61N-1.029(1)(a), F.A.C., in a paper format to a licensed health care practitioner authorized to prescribe medication under Florida law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.
- (d) Product Identifier. Effective December 1, 2017, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction. A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.
- (2) AUTHORIZED TRADING PARTNERS. The trading partners of a manufacturer may only be authorized trading partners.
- (3) VERIFICATION. The department adopts and incorporates by reference the manufacturer verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(b)(4) (as of 12/1/15). A manufacturer must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the manufacturer will meet the federal verification requirements as adopted by the department.

<u>Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New</u>.

NAME OF PERSON ORIGINATING PROPOSED RULE: Reginald D. Dixon, Director

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 9, 2016

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 30, 2015

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

RULE NO.: RULE TITLE:

61N-1.030 Product Tracking and Tracing – Wholesale

Distributor Requirements

PURPOSE AND EFFECT: The Division proposes the rule amendment to set forth the requirements that permitted wholesale distributors must follow for tracking and tracing certain prescription drug products through the distribution supply chain.

SUMMARY: The proposed rule implements the wholesale distributor requirements of the federal tracking and tracing law.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: the economic review conducted by the agency.

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

RULEMAKING AUTHORITY: 499.0121, 499.05 FS.

LAW IMPLEMENTED: 499.002, 499.0121, 499.05, 499.052 FS.

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Dinah Greene, Operations Review Specialist, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 North Monroe Street Suite 26A, Tallahassee, Florida 32399-1047, (850)717-1802, Dinah.Greene@myfloridalicense.com

THE FULL TEXT OF THE PROPOSED RULE IS:

<u>61N-1.030 Product Tracking and Tracing – Wholesale Distributor Requirements.</u>

The following tracking and tracing requirements shall apply to wholesale distributors:

(1) PRODUCT TRACING.

- (a) A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this paragraph.
- (b) A wholesale distributor that purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, shall prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, provide to the subsequent purchaser:
- 1. A transaction statement, which shall state that the wholesale distributor, or a member of the affiliate of the wholesale distributor, purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased the product directly from the manufacturer; and
 - 2. The transaction history and transaction information.
- 3. If provided to a dispenser, the transaction history, transaction information, and transaction statement shall be on a single document in a paper or electronic format.
- 4. If provided to a wholesale distributor, the transaction history, transaction information, and transaction statement shall be through any combination of self-generated paper, electronic data, or manufacturer provided information on the product package.
- 5. The lot number of the product, the initial transaction date and the initial shipment date from the manufacturer are not required to be included in the transaction history and information for transactions falling under 61N-1.030(1)(b).
- (c) A wholesale distributor that did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, shall prior to, or at the time of, each transaction or subsequent transaction, provide to the subsequent purchaser, a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the requirements set forth in the departmental rules.
- 1. The transaction history supplied shall begin only with the wholesale distributor that purchased the product directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer.
- 2. The wholesale distributor that did not purchase directly from the manufacturer, the exclusive distributor of the manufacturer or a repackager that purchased directly from the manufacturer, shall inform the subsequent purchaser that the wholesale distributor received a direct purchase statement from a wholesale distributor that purchased the product directly from the manufacturer, the exclusive distributor of the

manufacturer or a repackager that purchased directly from the manufacturer.

(d) A wholesale distributor shall capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction described in this rule and maintain such information, history, and statement for not less than 6 years after the date of the transaction; and maintain the confidentiality of the transaction information, including any lot level information, transaction history, and transaction statement for a product and prohibit disclosure to any person other than state or federal officials, except to comply with the provisions of 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032 F.A.C.

(2) RETURNS.

- (a) Saleable Returns. Notwithstanding 61N-1.030(1)(a), F.A.C., the following shall apply:
- 1. Requirements. Until December 1, 2019, a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and notwithstanding 61N-1.030(1)(b), F.A.C., may distribute the returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of the product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this rule.
- 2. Enhanced Requirements. Beginning December 1, 2019, a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate the returned product with the transaction information and transaction statement associated with that product. For all transactions after December 1, 2019, the transaction history, as applicable, of the product shall begin with the wholesale distributor that accepted and verified the returned product.
- (b) Nonsaleable Returns. A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under 61N-1.030(1)(a), F.A.C.
- (3) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction history, and transaction statement for the product.
- (4) TRADING PARTNER AGREEMENTS. Effective December 1, 2019, a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written

- agreement between such wholesale distributor and such subsequent purchaser. Nothing in this subsection shall be construed to limit the applicability of subsections 61N-1.030(1) through 61N-1.030(3), F.A.C.
- (5) PRODUCT IDENTIFIER. Effective December 1, 2019, a wholesale distributor may engage in transactions involving a product only if that product is encoded with a product identifier or grandfathered as defined by 61N-1.028(7), F.A.C., and not required to be encoded with a product identifier.
- (6) AUTHORIZED TRADING PARTNERS. The trading partners of a wholesale distributor may only be authorized trading partners.
- (7) VERIFICATION. The department adopts and incorporates by reference the wholesale distributor verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(c)(4) (as of 12/1/15). A wholesale distributor must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the wholesale distributor will meet the federal verification requirements as adopted by the department.
 - (8) Drop Shipment.
- (a) A wholesale distributor that does not physically handle or store product shall be exempt from the provisions of this rule, except the federal notification requirements adopted under 61N-1.030(7), F.A.C., provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for such wholesale distributor includes on the transaction information and transaction history to the dispenser, the contact information of the wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser.
- (b) Drop shipment by the wholesale distributor to trading partners, other than to a dispenser, is not exempt from the provisions of this rule.

<u>Rulemaking Authority</u> 499.0121, 499.05 FS. <u>Law Implemented</u> 499.002, 499.0121, 499.05, 499.052 FS. <u>History–New</u>.

NAME OF PERSON ORIGINATING PROPOSED RULE: Reginald D. Dixon, Director

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 9, 2016

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 30, 2015

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

RULE NO.: RULE TITLE:

61N-1.031 Product Tracking and Tracing – Dispenser

Requirements

PURPOSE AND EFFECT: The Division proposes the rule amendment to set forth the requirements that dispensers must follow for tracking and tracing certain prescription drug products through the distribution supply chain.

SUMMARY: The proposed rule implements the dispenser requirements of the federal tracking and tracing law.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: the economic review conducted by the agency.

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

RULEMAKING AUTHORITY: 499.0121, 499.05 FS.

LAW IMPLEMENTED: 499.002, 499.0121, 499.05, 499.052 FS.

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Dinah Greene, Operations Review Specialist, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 North Monroe Street Suite 26A, Tallahassee, Florida 32399-1047, (850)717-1802, Dinah.Greene@myfloridalicense.com

THE FULL TEXT OF THE PROPOSED RULE IS:

<u>61N-1.031 Product Tracking and Tracing – Dispenser</u> Requirements.

The following tracking and tracing requirements shall apply to dispensers:

(1) PRODUCT TRACING.

(a) A dispenser shall not accept ownership of a product, unless the previous owner prior to or at the time of the

- <u>transaction</u>, <u>provides transaction history</u>, <u>transaction</u> <u>information</u>, and a transaction statement;
- (b) A dispenser shall, prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product, excluding dispensing to a patient or returns, provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this rule shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and
- (c) A dispenser shall capture transaction information, including lot level information, if provided, transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.
- (2) AGREEMENTS WITH THIRD PARTIES.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements, required to be maintained under this rule, on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of a dispenser under this rule.

(3) RETURNS.

- (a) Saleable Returns. A dispenser may return a product to the trading partner from which the dispenser obtained the product without providing the information required under 61N-1.031(1)(b), F.A.C.
- (b) Nonsaleable Returns. A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under 61N-1.031(1), F.A.C.
- (4) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request, provide the applicable transaction information, transaction statement, and transaction history that the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or the wholesale distributor to the dispenser. The dispenser may respond to the request by providing the applicable information in either paper or electronic format.

- (5) PRODUCT IDENTIFIER. Effective December 1, 2020, a dispenser may engage in transactions involving a product only if the product is encoded with a product identifier or grandfathered, as defined by 61N-1.028(7), F.A.C., and is not required to be encoded with a product identifier.
- (6) AUTHORIZED TRADING PARTNERS. The trading partners of a dispenser may be only authorized trading partners.
- (7) VERIFICATION. The department adopts and incorporates by reference the dispenser verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(d)(4) (as of 12/1/15). A dispenser must establish, maintain, and adhere to written polices and procedures setting forth the manner in which the dispenser will meet the federal requirements as adopted by the department.
- (8) EXCEPTION. Notwithstanding any other provision of law, the requirements under 61N-1.031(1) through (4), and (7), F.A.C., shall not apply to licensed health care practitioners authorized to prescribe or administer medication under Florida law or other licensed individuals under the supervision or direction of practitioners who dispense or administer products in the usual course of professional practice.

<u>Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New _____.</u>

NAME OF PERSON ORIGINATING PROPOSED RULE: Reginald D. Dixon, Director

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 9, 2016

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 30, 2015

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

RULE NO.: RULE TITLE:

61N-1.032 Product Tracking and Tracing – Repackager Requirements

PURPOSE AND EFFECT: The Division proposes the rule amendment to set forth the requirements that permitted repackagers must follow for tracking and tracing certain prescription drug products through the distribution supply

SUMMARY: The proposed rule implements the repackager requirements of the federal tracking and tracing law.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of

\$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: the economic review conducted by the agency.

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

RULEMAKING AUTHORITY: 499.0121, 499.05 FS.

LAW IMPLEMENTED: 499.002, 499.0121, 499.05, 499.052 FS.

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

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Dinah Greene, Operations Review Specialist, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 North Monroe Street Suite 26A, Tallahassee, Florida 32399-1047, (850)717-1802, Dinah.Greene@myfloridalicense.com

THE FULL TEXT OF THE PROPOSED RULE IS:

<u>61N-1.032 Product Tracking and Tracing – Repackager</u> Requirements.

The following tracking and tracing requirements shall apply to repackagers:

(1) PRODUCT TRACING.

- (a) A repackager shall not accept ownership of a product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement for the product.
- (b) A repackager, prior to, or at the time of, each transaction in which the repackager transfers ownership of a product, shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product.
- (c) A repackager shall capture the transaction information, including lot level information, transaction history, and transaction statement for each transaction described in 61N-1.032(1)(a) and (1)(b), F.A.C., and shall maintain such information, history, and statement for not less than 6 years after the transaction.

(2) RETURNS.

(a) Nonsaleable Product. A repackager may return a nonsaleable product to the manufacturer or repackager, or to the wholesale distributor from whom such product was

purchased, or to a person acting on behalf of such manufacturer, repackager or wholesale distributor, including a returns processor, without providing the information required under 61N-1.032 (1)(b), F.A.C..

- (b) Saleable or Nonsaleable Product. A repackager may return a saleable or nonsaleable product to the manufacturer, repackager, or to the wholesale distributor from whom the product was received without providing the information required under 61N-1.032(1)(b), F.A.C., on behalf of the hospital or other health care entity that took ownership of such product pursuant to the terms and conditions of any agreement between such repackager and the entity that owns the product.
- (3) REQUESTS FOR INFORMATION. Upon a request by the department, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a repackager shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, provide the applicable transaction information, transaction history, and transaction statement for the product.
- (4) PRODUCT IDENTIFIER. Beginning December 1, 2018, a repackager shall:
- (a) Affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction in commerce;
- (b) Maintain the product identifier information for such product for not less than 6 years after the date of the transaction;
- (c) Engage in transactions involving a product only if such product is encoded with a product identifier or grandfathered as defined by 61N-1.028(7), F.A.C., and is not required to be encoded with a product identifier; and
 - (d) Maintain records for not less than 6 years.

A repackager is not required to affix or imprint a unique device identifier on a package that is required to have a standardized numerical identifier.

- (5) AUTHORIZED TRADING PARTNERS. The trading partners of a repackager may only be authorized trading partners.
- (6) VERIFICATION. The department adopts and incorporates by reference the repackager verification requirements as set forth in the federal act at 21 U.S.C. s. 360eee-1(e)(4) (as of 12/1/15). A repackager must establish, maintain, and adhere to written policies and procedures setting forth the manner in which the repackager will meet the federal verification requirements as adopted by the department.

<u>Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History–New</u>.

NAME OF PERSON ORIGINATING PROPOSED RULE: Reginald D. Dixon, Director

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 9, 2016

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 30, 2015

Section III Notice of Changes, Corrections and Withdrawals

DEPARTMENT OF HEALTH

Board of Dentistry

RULE NO.: RULE TITLE: 64B5-15.004 Reexamination Fees

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 41 No. 174, September 8, 2015 issue of the Florida Administrative Register has been withdrawn.

Section IV Emergency Rules

NONE

Section V Petitions and Dispositions Regarding Rule Variance or Waiver

DEPARTMENT OF LAW ENFORCEMENT

Criminal Justice Standards and Training Commission

RULE NO.: RULE TITLE:

11B-27.00212 Maintenance of Officer Certification

The Criminal Justice Standards and Training Commission hereby gives notice:

On January 28, 2016, pursuant to notice, at a meeting held in Lake Mary, Florida the Commission considered a petition for a temporary 60-day waiver of subsection 11B-27.002(4), F.A.C., by Deputy Chief Sean Brammer of the Florida Atlantic University Police Department on Behalf of Howard Jenkins. After careful consideration of the facts in this matter, the Commission found that Petitioner had demonstrated an economic, technological, legal, or other type of hardship resulting from a strict application of subsection 11B-27.002(4), F.A.C., that was particular to petitioner, significantly different from the way the rule affects other similarly situated persons and issued an order granting Petitioner's petition for a temporary 60-day waiver of subsection 11B-27.002(4), F.A.C.

A copy of the Order or additional information may be obtained by contacting: Linton B. Eason, Assistant General Counsel, Florida Department of Law Enforcement, P.O. Box 1489, Tallahassee, FL 32302, (850)410-7676.

DEPARTMENT OF LAW ENFORCEMENT

Criminal Justice Standards and Training Commission

RULE NO.: RULE TITLE:

11B-35.002 Basic Recruit Training Programs for Law Enforcement, Correctional, and Correctional Probation

The Criminal Justice Standards and Training Commission hereby gives notice:

On January 28, 2016, pursuant to notice, at a meeting held in Lake Mary, Florida the Commission considered a petition for a permanent waiver of subparagraph 11B-35.002(5)(f)15., F.A.C., by William Looper Director, Northwest Florida State College Criminal Justice Training Center on behalf of Joseph Riggins and Phillip Lundy, and subparagraph 11B-35.002(5)(h)10., F.A.C., on behalf of James Pepper. After careful consideration of the facts in this matter, the Commission found that Petitioner had demonstrated an economic, technological, legal, or other type of hardship resulting from a strict application of subparagraphs 11B-35.002(5)(f)15. and 11B-35.002(5)(h)10., F.A.C., that was particular to petitioner, significantly different from the way the rule affects other similarly situated persons and issued an

order granting Petitioner's petition for a permanent waiver of subparagraphs 11B-35.002(5)(f)15. and 11B-35.002(5)(h)10., F A C

A copy of the Order or additional information may be obtained by contacting: Linton B. Eason, Assistant General Counsel, Florida Department of Law Enforcement, P.O. Box 1489, Tallahassee, FL 32302, (850)410-7676.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Division of Hotels and Restaurants

RULE NO.: RULE TITLE:

61C-5.001 Safety Standards

The Department of Business and Professional Regulation, Division of Hotels and Restaurants, Bureau of Elevator Safety hereby gives notice:

On February 11, 2016, the Division issued an order. The Final Order was in response to a Petition for an emergency Variance from Regency Palms Condominium, filed January 20, 2016, and advertised on January 22, 2016 in Vol. 42, No. 14, of the Florida Administrative Register. No comments were received in response to the petition. The Final Order on the Petition for Variance grants the Petitioner a variance from Rule 2.2.2.5, and 3.27.4 ASME A17.1b, 2009 edition, as adopted by paragraph 61C-5.001(1)(a), F.A.C., that requires upgrading the elevators sump pump and emergency in-car operation because the Petitioner has demonstrated that the purpose of the underlying statute has been met and that Petitioner would suffer a substantial hardship if required to comply with this rule (VW2016-011).

A copy of the Order or additional information may be obtained by contacting: Michelle Comingore, Bureau of Elevator Safety, 1940 North Monroe Street, Tallahassee, Florida 32399-1013.

Section VI Notice of Meetings, Workshops and Public Hearings

DEPARTMENT OF STATE

Division of Historical Resources

The Bureau of Historic Preservation, Friends of Florida Main Street announces a telephone conference call to which all persons are invited.

DATE AND TIME: February 26, 2016, 11:00 a.m. to conclusion

PLACE: R.A. Gray Building, Room 306B, 500 South Bronough Street, Tallahassee, Florida 32399-0250

GENERAL SUBJECT MATTER TO BE CONSIDERED: Disposition of Friends of Florida Main Street, Inc. and

overview of new Citizen Support Organization. Dissolution of Friends of Florida Main Street, Inc.

A copy of the agenda may be obtained by contacting: Ronni Wood, (850)245-6345, Ronni.Wood@dos.myflorida.com.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 48 hours before the workshop/meeting by contacting: Ronni Wood, (850)245-6345, Ronni.Wood@dos.myflorida.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Ronni Wood, (850)245-6345, Ronni.Wood@dos.myflorida.com.

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Division of Consumer Services

The Board of Professional Surveyors and Mappers announces a public meeting to which all persons are invited.

DATE AND TIME: February 25, 2016, 10:00 a.m.

PLACE: Hilton Ocala, Belmont Room, 3600 S.W. 36th Avenue, Ocala, Florida 34474

GENERAL SUBJECT MATTER TO BE CONSIDERED: This will be a meeting of the Board of Professional Surveyors and Mappers, Rules Workgroup. The Board has charged the Workgroup to review Rule Chapter 5J-17, F.A.C., discuss potential improvements to the rules, and prepare recommendations for the Board. Any recommendations by the Workgroup will be reviewed and discussed by the full Board in a separate meeting or rule workshop.

A copy of the agenda may be obtained by contacting: Jenna Harper, Executive Director, Board of Professional Surveyors and Mappers, 2005 Apalachee Parkway, Tallahassee, Florida 32399-6500, (850)410-3674. One week prior to the meeting date, the agenda will also be available online at: www.freshfromflorida.com/Public-Notices/.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 48 hours before the workshop/meeting by contacting: Jenna Harper at (850)410-3674. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Jenna Harper, Executive Director, Board of Professional Surveyors and Mappers, 2005 Apalachee Parkway, Tallahassee, Florida 32399-6500, (850)410-3674.

DEPARTMENT OF TRANSPORTATION

The Florida Department of Transportation announces a public meeting to which all persons are invited.

DATE AND TIME: March 4, 2016, 12:00 Noon, ET

PLACE: Webinar

https://attendee.gotowebinar.com/register/2983630727599396 609; to join conference call without visual aids call United States: (562)247-8422, access code: 619-517-964. After registering, you will receive a confirmation email containing information about joining the webinar or participating by conference call.

GENERAL SUBJECT MATTER TO BE CONSIDERED: The purpose of the webinar is to gather input on the Florida Shared-Use Non-motorized (SUN) Trail Network. The meeting will begin with an overview presentation of the SUN Trail program, followed by an opportunity for participants to provide input on the prioritization criteria and process for selecting individual trails to be funded by the SUN Trail program.

A copy of the agenda may be obtained by contacting: Robin Birdsong, (850)414-4922 or www.FloridaSunTrail.com.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: Anita Thomas, (850)414-4934. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Robin Birdsong, (850)414-4922.

PUBLIC SERVICE COMMISSION

The Public Service Commission announces a public meeting to which all persons are invited.

DATE AND TIME: March 1, 2016, 9:30 a.m.

PLACE: Betty Easley Conference Center, 4075 Esplanade Way, Room 148, Tallahassee, Florida

GENERAL SUBJECT MATTER TO BE CONSIDERED: To consider those matters ready for decision.

LEGAL AUTHORITY AND JURISDICTION: Chapters 120, 350, 364, 366, and 367, F.S.

Persons who may be affected by Commission action on certain items on the conference agenda may be allowed to address the Commission, either informally or by oral argument, when those items are taken up for discussion at the conference, pursuant to Rules 25 22.0021 and 25 22.0022, F.A.C.

A copy of the agenda may be obtained at the Commission website: www.floridapsc.com.

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

EXECUTIVE OFFICE OF THE GOVERNOR

The Florida Children and Youth Cabinet Technology Workgroup announces a telephone conference call to which all persons are invited.

DATE AND TIME: February 26, 2016, 3:00 p.m. – 4:00 p.m. PLACE: 1(888)670-3525; passcode: 450-816-1561#

GENERAL SUBJECT MATTER TO BE CONSIDERED: Members of the Technology Workgroup will meet to conduct regular business of the workgroup.

A copy of the agenda may be obtained by contacting: Tim Parson, Executive Director, Florida Children and Youth Cabinet, (850)717-4575 or tim.parson@myflfamilies.com.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 3 days before the workshop/meeting by contacting: Tim Parson, Executive Director, Florida Children and Youth Cabinet, (850)717-4575 or tim.parson@myflfamilies.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Tim Parson, Executive Director, Florida Children and Youth Cabinet, (850)717-4575 or tim.parson@myflfamilies.com.

REGIONAL UTILITY AUTHORITIES

Peace River/Manasota Regional Water Supply Authority
The Peace River Manasota Regional Water Supply Authority
announces a public meeting to which all persons are invited.
DATE AND TIME: Thursday, February 25, 2016, 4:00 p.m.
PLACE: Southwest Florida Water Management District,

Sarasota Service Office, 6750 Fruitville Road, Sarasota, Florida

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Board of Directors will convene to take action on the Regional Integrated Loop System Phase 1 Interconnect.

A copy of the agenda may be obtained by contacting: Linda Stewart at (941)316-1776 or lstewart@regionalwater.org.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: (941)316-1776. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: (941)316-1776.

DEPARTMENT OF MANAGEMENT SERVICES

Commission on Human Relations

The Florida Commission on Human Relations announces a public meeting to which all persons are invited.

DATE AND TIME: Thursday, March 17, 2016, 10:00 a.m., ET

PLACE: Call 1(888)670-3525; when prompted, enter pass code: 1760507820, then # key

GENERAL SUBJECT MATTER TO BE CONSIDERED: The purpose of the meeting is for the Commission to vote on the disposition of cases pending before it for decision.

A copy of the agenda may be obtained by contacting: Jim Mallue, (850)907-6805, Jim.Mallue@fchr.myflorida.com.

ACCESS POINT: The FCHR office at 4075 Esplanade Way, Room 110, Tallahassee, FL 32399, will serve as an access point for this meeting. Interested persons wishing to attend this meeting may also do so by appearing in person at this designated access point, at which location telephonic access to the meeting will be provided.

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Jim Mallue at (850)907-6805, Jim.Mallue@fchr.myflorida.com.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Florida Building Commission

The Florida Building Commission, "THE COMMISSION", Structural Technical Advisory Committee, concurrently with the Roofing Technical Advisory Committee, announces a public meeting to which all persons are invited.

DATE AND TIME: March 2, 2016, 1:00 p.m. until completion

PLACE: Teleconference and webinar: teleconference for audio, webinar for visual. Access is now provided by GoToMeeting® Online Meetings Made Easy® at https://global.gotomeeting.com/join/796205213. Join the conference call (United States toll-free) at 1(866)899-4679, access code: 796-205-213; audio PIN shown after joining meeting; meeting ID 796-205-213; public point of access: Florida Building Commission, Department of Business and Professional Regulation, Northwood Centre, Suite 90A, 1940 North Monroe Street, Tallahassee, Florida.

GENERAL SUBJECT MATTER TO BE CONSIDERED: To review and accept the interim reports for the following two research projects: Concurrently- (1) Corrosion of Roofing Fasteners, and; Roofing TAC Only - (2) Field Study and Analytical Assessment of Sealed Attics Conducted for the State of Florida.

A copy of the agenda may be obtained by contacting: Robert Benbow or Joe Bigelow, Building Codes and Standards Office, Department of Business and Professional Regulation, Suite 90, 1940 N. Monroe Street, Tallahassee, Florida 32399, at (850)487-1824 or by visiting the calendar on our website at http://floridabuilding.org/c/default.aspx.

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Robert Benbow or Joe Bigelow, Building Codes and Standards Office, Department of Business and Professional Regulation, Suite 90, 1940 N. Monroe Street, Tallahassee, Florida 32399, (850)487-1824 or visit the calendar on our website at http://floridabuilding.org/c/default.aspx.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Board of Accountancy

The Board of Accountancy announces a telephone conference call to which all persons are invited.

DATES AND TIMES: Friday, February 26, 2016, 9:30 a.m., agenda discussion until all business is concluded; Friday, February 26, 2016, 10:00 a.m., Legislative Committee meeting until all business is concluded

PLACE: 1(888)670-3525, pass code: 1368986679#

GENERAL SUBJECT MATTER TO BE CONSIDERED: To discuss Legislative matters affecting the Board of Accountancy and other issues.

A copy of the agenda may be obtained by contacting: Denise Graves, (352)333-2505.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: Denise Graves. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Denise Graves, (352)333-2505.

DEPARTMENT OF ENVIRONMENTAL PROTECTION

The Department of Environmental Protection announces a public meeting to which all persons are invited.

DATE AND TIME: February 25, 2016, 9:30 a.m.

PLACE: Florida Coastal School of Law, Room 585, 8787 Baypine Road, Jacksonville, FL 32256

GENERAL SUBJECT MATTER TO BE CONSIDERED: The DEP is announcing a meeting for the Lower St. Johns River Main Stem Basin Management Action Plan (BMAP). Items to be discussed include the seventh annual progress report, water quality information, and project updates. The BMAP is the means for implementation of the adopted total maximum daily loads (TMDLs) for total phosphorus and total nitrogen in the freshwater and marine sections of the Lower St. Johns River. Meeting discussion will include an overview of the seventh progress report, describing projects and activities that occurred from January through December 2015. A copy of the agenda may be obtained by contacting: Kevin Coyne, Watershed Planning and Coordination Section, Florida Department of Environmental Protection, 2600 Blair Stone Road, Florida MS 3565, Tallahassee, 32399-2400, Kevin.Coyne@dep.state.fl.us.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 48 hours before the workshop/meeting by contacting: Kevin Coyne, Watershed Planning and Coordination Section, Florida Department of Environmental Protection, 2600 Blair Stone Road, MS 3565, Tallahassee, Florida 32399-2400, Kevin.Coyne@dep.state.fl.us. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Kevin Coyne, Watershed Planning and Coordination Section, Florida Department of Environmental Protection, 2600 Blair Stone Road, MS 3565, Tallahassee, Florida 32399-2400, Kevin.Coyne@dep.state.fl.us.

DEPARTMENT OF HEALTH

Board of Osteopathic Medicine

The Board of Osteopathic Medicine announces a public meeting to which all persons are invited.

DATE AND TIME: February 26, 2016, 8:00 a.m., ET

PLACE: Safety Harbor Resort & Spa, 105 North Bayshore Drive, Safety Harbor, Florida 34695, (727)724-7710

GENERAL SUBJECT MATTER TO BE CONSIDERED: General business of the board. Meetings may be cancelled. Please check the Board website at http://floridasosteopathicmedicine.gov/ for cancellations or changes to meeting dates or times.

A copy of the agenda may be obtained by contacting: Alexandra Alday at Alexandra.Alday@flhealth.gov.

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

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

DEPARTMENT OF HEALTH

Division of Emergency Preparedness and Community Support RULE NO.: RULE TITLE:

64J-2.010 Apportionment of Trauma Centers Among the Trauma Service Areas (TSA)

The Bureau of Emergency Medical Oversight announces a hearing to which all persons are invited.

DATE AND TIME: Thursday, March 10, 2016, 9:00 a.m.

PLACE: Department of Health, Room 301, 4052 Bald Cypress Way, Tallahassee, Florida

Audio of the hearing is available by calling: 1(888)670-3525 and entering: 1043560135, then #

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Bureau of Emergency Medical Oversight will hold a public hearing to discuss proposed rule changes related to the allocation of trauma centers for each trauma service area as published in the FAR on February 4, 2016.

A copy of the agenda may be obtained by contacting: Bethany Lowe, bethany.lowe@flhealth.gov or (850)245-4055.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by

contacting: Bethany Lowe, bethany.lowe@flhealth.gov or (850)245-4055. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

DEPARTMENT OF CHILDREN AND FAMILIES

Substance Abuse Program

The substance Abuse & Mental Health Program announces a public meeting to which all persons are invited.

DATE AND TIME: February 18, 2016, 1:30 p.m.

PLACE: Lifestream Behavioral Center, 2020 Tally Road, Leesburg, FL

GENERAL SUBJECT MATTER TO BE CONSIDERED: Lifestream Behavioral Center wishes to move its Children's Crisis Stabilization Unit from 2020 Tally Road, Leesburg, FL to 2018 Tally Road, Leesburg, FL. In addition, the number of beds will be increased from 6 to 20 due to demand for services.

A copy of the agenda may be obtained by contacting: Ingrid Figueroa, (407)317-7512, 400 W. Robinson St., Orlando, FL 32801 or Philip Scarbelli at (352)442-3709.

For more information, you may contact: Ingrid Figueroa, (407)317-7512, 400 W. Robinson St., Orlando, FL 32801.

DEPARTMENT OF CHILDREN AND FAMILIES

Refugee Services

The Tallahassee Area Refugee Task Force announces a public meeting to which all persons are invited.

DATE AND TIME: Thursday, March 8, 2016, 10:00 a.m. – 12:00 Noon

PLACE: Early Learning Coalition, 1940 N. Monroe Street, Suite 70, Tallahassee, FL 32303

GENERAL SUBJECT MATTER TO BE CONSIDERED: The purpose of the Tallahassee Area Refugee Task Force meeting is to increase awareness of the refugee populations, share best practices, spot trends in refugee populations, build collaborations between agencies, help create good communication among service providers, get informed about upcoming community events, and discuss refugee program service needs and possible solutions to meeting those needs.

A copy of the agenda may be obtained by contacting: Theresa Leslie at (850)778-4065 or Taddese Fessehaye at (407)317-7335

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Theresa Leslie at (850)778-4065 or Taddese Fessehaye at (407)317-7335. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Theresa Leslie at (850)778-4065 or Taddese Fessehaye at (407)317-7335.

DEPARTMENT OF CHILDREN AND FAMILIES

Refugee Services

The Tallahassee Area Refugee Task Force announces a public meeting to which all persons are invited.

DATE AND TIME: Tuesday, March 8, 2016, 10:00 a.m. – 12:00 Noon

PLACE: Early Learning Coalition, 1940 N. Monroe Street, Suite 70, Tallahassee, FL 32303

GENERAL SUBJECT MATTER TO BE CONSIDERED: The purpose of the Tallahassee Area Refugee Task Force meeting is to increase awareness of the refugee populations, share best practices, spot trends in refugee populations, build collaborations between agencies, help create good communication among service providers, get informed about upcoming community events, and discuss refugee program service needs and possible solutions to meeting those needs.

A copy of the agenda may be obtained by contacting: Theresa Leslie at (850) 778-4065 or Taddese Fessehaye at (407)317-7335.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Theresa Leslie at (850)778-4065 or Taddese Fessehaye at (407)317-7335. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Theresa Leslie at (850)778-4065 or Taddese Fessehaye at (407)317-7335.

DEPARTMENT OF CHILDREN AND FAMILIES

Office on Homelessness

The Office on Homelessness announces a telephone conference call to which all persons are invited.

DATE AND TIME: February 18, 2016, 2:00 p.m.

PLACE: Dial toll-free: 1(888)670-3525, enter participant code: 701-539-8451, then #

GENERAL SUBJECT MATTER TO BE CONSIDERED: Affordable Housing Committee call. This conference call will address the committees' continued development of policy recommendations and work tasks to address the Council's Annual Report on recommendations regarding affordable housing to end homelessness in Florida.

A copy of the agenda may be obtained by contacting: Erik Braun, Director, Office on Homelessness, (850)922-9850, erik.braun@myflfamilies.com.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the

agency at least 24 hours before the workshop/meeting by contacting: Erik Braun, Director, Office on Homelessness, (850)922-9850, erik.braun@myflfamilies.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Erik Braun, Director, Office on Homelessness, (850)922-9850, erik.braun@myflfamilies.com.

FISH AND WILDLIFE CONSERVATION COMMISSION Division of Law Enforcement

The Wildlife Alert Reward Association, Inc. announces a public meeting to which all persons are invited.

DATE AND TIME: March 4, 2016, 1:00 p.m. – 4:00 p.m.

PLACE: FWC Headquarters, Bryant Building Room G72, 620 S Meridian Street, Tallahassee, FL 32399

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Board of Directors of the Wildlife Alert Reward Association will conduct administrative business of the Association including the Director update, Marketing update and Financial update.

A copy of the agenda may be obtained by contacting: Ms. Sara Burke, 620 S Meridian Street, Tallahassee, Florida 32399, (850)617-9595.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: the ADA Coordinator at (850)488-6411. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Ms. Sara Burke, 620 S Meridian St, Tallahassee, Florida 32399, (850)617-9595.

BOARD OF GOVERNORS

The Board of Governors of the State University System of Florida announces a public meeting to which all persons are invited.

DATE AND TIME: Wednesday, March 2, 2016, 1:00 p.m.

PLACE: University of Central Florida, Fairwinds Alumni Center, Grand Ballroom, 12676 Gemini Boulevard North, Orlando, Florida 32816

GENERAL SUBJECT MATTER TO BE CONSIDERED: To conduct the regular business of the Board and its committees.

A copy of the agenda may be obtained by contacting: Vikki Shirley, Corporate Secretary, Board of Governors, 1614 Turlington Bldg., 325 W. Gaines St., Tallahassee, FL 32399-0466 and will be available at www.flbog.edu.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to

participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Vikki Shirley, Corporate Secretary, Board of Governors, 1614 Turlington Bldg., 325 W. Gaines St., Tallahassee, FL 32399-0466, (850)245-0466. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Vikki Shirley, Corporate Secretary, Board of Governors, 1614 Turlington Bldg., 325 W. Gaines St., Tallahassee, FL 32399-0466.

DEPARTMENT OF ECONOMIC OPPORTUNITY

Division of Workforce Services

The Reemployment Assistance Appeals Commission announces a public meeting to which all persons are invited.

DATE AND TIME: February 24, 2016, 9:00 a.m.

PLACE: Reemployment Assistance Appeals Commission, 101 Rhyne Building, 2740 Centerview Drive, Tallahassee, Florida 32399-4151

GENERAL SUBJECT MATTER TO BE CONSIDERED: Deliberation for cases pending before the Reemployment Assistance Appeals Commission that are ready for final review and the Chairman's report. No public testimony will be taken.

A copy of the agenda may be obtained by contacting: Reemployment Assistance Appeals Commission, 101 Rhyne Building, 2740 Centerview Drive, Tallahassee, Florida 32399-4151. (850)487-2685.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 24 hours before the workshop/meeting by contacting: the Reemployment Assistance Appeals Commission, 101 Rhyne Building, 2740 Centerview Drive, Tallahassee, Florida 32399-4151, (850)487-2685. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Reemployment Assistance Appeals Commission, 101 Rhyne Building, 2740 Centerview Drive, Tallahassee, Florida 32399-4151, (850)487-2685.

FLORIDA WORKERS' COMPENSATION INSURANCE GUARANTY ASSOC., INC.

The Board of the Florida Workers' Compensation Insurance Guaranty Association announces a public meeting to which all persons are invited.

DATE AND TIME: March 1, 2016, 2:00 p.m.

PLACE: Tallahassee, FL

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Board will meet to discuss general business of the Association. The agenda will include, but not be limited to: Minutes, Receiver's Report, Legal, Financial, Claims and Operations Reports.

A copy of the agenda may be obtained by contacting: Cathy Irvin at (850)386-9200.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 24 hours before the workshop/meeting by contacting: Cathy Irvin at (850)386-9200. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

FLORIDA WORKERS' COMPENSATION INSURANCE GUARANTY ASSOC., INC.

The Investment Committee of the Florida Workers' Compensation Insurance Guaranty Association announces a public meeting to which all persons are invited.

DATE AND TIME: February 25, 2016, 1:00 p.m.

PLACE: Tallahassee, FL

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Investment Committee will meet to discuss the general business of the Committee. The agenda will include, but not be limited to: Minutes, Investment Report and Investment Policy Review.

A copy of the agenda may be obtained by contacting: Cathy Irvin at (850)386-9200.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: Cathy Irvin at (850)386-9200. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

INFINITE SOURCE COMMUNICATIONS GROUP, LLC

The Florida Department of Transportation announces a hearing to which all persons are invited.

DATE AND TIME: March 3, 2016, 6:00 p.m.

PLACE: Coral Gables War Memorial Youth Center – Theater Room, 405 University Drive, Coral Gables, FL 33134

GENERAL SUBJECT MATTER TO BE CONSIDERED: The Florida Department of Transportation (FDOT) District Six will hold a Public Hearing for a safety enhancement project along State Road (SR) 976/SW 40 Street/Bird Road from SW 58 Avenue to Alhambra Circle, in Miami-Dade County, to discuss the project's design and scope of work. The project identification number is 434771-1-52-01. The hearing will begin as an open house, from 6 p.m. to 8 p.m., with a formal presentation starting at 6:30 p.m. Graphic displays will be shown and FDOT representatives will be available to discuss the project and answer questions.

A copy of the agenda may be obtained by contacting: Public Information Specialist, Jeannette Lazo at (786)269-4146, email: Jeannette@iscprgroup.com.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: Ivette Ruiz-Paz at (305)470-5349 or in writing: FDOT, 1000 N.W. 111 Avenue, Miami, FL 33172, email: Ivette.ruiz-paz@dot.state.fl.us. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice). For more information, you may contact: Public Information Specialist, Jeannette Lazo at (786)269-4146, email:

VHB

Jeannette@iscprgroup.com.

The Florida Department of Transportation (FDOT) announces a public meeting to which all persons are invited.

DATE AND TIME: Thursday; February 25, 2016, 5:30 p.m. – 7:30 p.m., open house

PLACE: Titusville City Hall, Council Chambers, 555 South Washington Avenue, Titusville, FL 32796

GENERAL SUBJECT MATTER TO BE CONSIDERED: Financial Management No.: 435627-1-12-01 (US 1); 436187-1-12-01 (SR 406); 436187-1-12-02 (C2C).

Project Description: Corridor planning studies: US 1 and State Road (SR) 406, and the Coast-to-Coast Titusville Connector Study.

This is the second public meeting to be held as part of a community-based evaluation to determine how best to meet the needs of the traveling public. The purpose of this public meeting is to present and explain the potential improvement strategies, seek public and agencies input, and provide interested persons an opportunity to provide feedback and comments to the study team.

A copy of the agenda may be obtained by contacting: Judy Pizzo, MS, GISP, Planning Project Manager for FDOT at 719 S. Woodland Boulevard, DeLand, FL 32720, (386)943-5167, Judy.Pizzo@dot.state.fl.us.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before it by contacting: Melissa Gross, at Vanasse Hangen Brustlin Inc., (407)839-4006, mgross@vhb.com. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

For more information, you may contact: Judy Pizzo, MS, GISP, FDOT Planning Project Manager at (386)943-5167 or Judy.Pizzo@dot.state.fl.us

Section VII Notice of Petitions and Dispositions Regarding Declaratory Statements

DEPARTMENT OF FINANCIAL SERVICES

Division of State Fire Marshal

NOTICE IS HEREBY GIVEN that the Department of Financial Services (Department) has issued an order disposing of the petition for declaratory statement filed by Phillip Green (Petitioner) on November 18, 2015. The following is a summary of the agency's disposition of the petition:

The Notice of Petition for Declaratory Statement was published November 20, 2015 in Vol. 41, No. 227 of the Florida Administrative Register. The Petition asks whether it is the intent of the Legislature to require fire sprinklers in one-and two-family dwellings as outlined in §§633.208(8) and 633.208(9), F.S., to be an independent and separate process from the local amendment to the fire code process as outlined in §633.208(3), F.S. The Petition was answered: Based on statutes and case law, Section 633.208(8) and (9), F.S., is independent and separate from the process for a local amendment to the fire code outlined in section 633.208(3), F.S.

A copy of the Order Disposing of the Petition for Declaratory Statement may be obtained by contacting: Melissa E. Dembicer, Assistant General Counsel, Department of Financial Services, 200 E. Gaines Street, Tallahassee, Florida 32399-0333 or by email: Melissa.Dembicer@myfloridacfo.com.

DEPARTMENT OF FINANCIAL SERVICES

Division of Worker's Compensation

NOTICE IS HEREBY GIVEN that the Department of Financial Services, Division of Workers' Compensation, has received the petition for declaratory statement from KNN Trucking, Corp. The petition seeks the agency's opinion as to the applicability of stop-work order and order of penalty assessment number 15-174-D7 as it applies to the petitioner.

The petition requests the Department to amend the employment classification codes applied to petitioner's employees in Division of Workers' Compensation case number 15-174-D7.

A copy of the Petition for Declaratory Statement may be obtained by contacting: Dustin William Metz, Assistant General Counsel, Division of Legal Services, 200 E. Gaines Street, Tallahassee, Florida 32399-0333, (850)413-3110, email: dustin.metz@myfloridacfo.com.

Please refer all comments to: Dustin William Metz.

Section VIII Notice of Petitions and Dispositions Regarding the Validity of Rules

Notice of Petition for Administrative Determination has been filled with the Division of Administrative Hearings on the following rules:

NONE

Notice of Disposition of Petition for Administrative Determination has been filled with the Division of Administrative Hearings on the following rules:

NONE

Section IX

Notice of Petitions and Dispositions Regarding Non-rule Policy Challenges

NONE

Section X

Announcements and Objection Reports of the Joint Adminstrative Procedures Committee

NONE

Section XI Notices Regarding Bids, Proposals and Purchasing

DEPARTMENT OF EDUCATION

Miami Dade College - 2016-6-25A - A/E Svcs - Parking Garages Structural Repairs and Deferred Maintenance Projects DISTRICT BOARD OF TRUSTEES MIAMI DADE COLLEGE

11011 S.W. 104th STREET MIAMI, FL 33176-3393

The Request for Qualifications (RFQ) listed below will be accepted in the PURCHASING DEPARTMENT, Room 9254, by 3:00 p.m. on THURSDAY, MARCH 24, 2016.

Prospective proposers may obtain RFQ SOLICITATION by calling (305)237-2402 or the RFP may be downloaded from the College's website at www.mdc.edu/purchasing.

RFQ NUMBER RFQ TITLE

2016-6-25A

Architectural/Engineering Services –
Parking Garages Structural Repairs and
Deferred Maintenance Projects

Pre-Proposal Meeting

March 2, 2016 11:00 a.m. - 1:00 p.m.

MDC Kendall Campus

Building R; Room R402

11011 SW 104 Street

Miami, FL 33176

If a person decides to appeal any decision with respect to any matter considered at the above cited meeting, that person will need a record of the proceedings, and for such purpose may need to ensure that a verbatim record of the proceedings is made, which record includes the testimony and evidence upon which the appeal is to be based. A copy of the agenda may be obtained by writing to: Miami Dade College, Office of the Purchasing Director, 11011 S.W. 104 Street, Miami, FL 33176 or by calling (305) 237-2402.

If you should have any questions, please contact:

Ramon Bristol

Assistant Director, Purchasing Department

Phone: (305)237-0011 Fax: (305)237-0737 Email: Rbristol@mdc.edu

DEPARTMENT OF EDUCATION

Miami Dade College - 2016-6-25B - CM Svcs - Parking Garages Structural Repairs and Deferred Maintenance Projects DISTRICT BOARD OF TRUSTEES

MIAMI DADE COLLEGE

11011 S.W. 104th STREET MIAMI, FL 33176-3393

The Request for Qualifications (RFQ) listed below will be accepted in the PURCHASING DEPARTMENT, Room 9254, by 3:00 p.m. on FRIDAY, MARCH 25, 2016.

Prospective proposers may obtain RFQ SOLICITATION by calling (305)237-2402 or the RFP may be downloaded from the College's website at www.mdc.edu/purchasing.

RFQ NUMBER RFQ TITLE

2016-6-25B

Construction Management Services – Parking Garages Structural Repairs and Deferred Maintenance Projects Pre-Proposal Meeting

March 2, 2016 11:00 a.m. - 1:00 p.m.

MDC Kendall Campus Building R; Room R402 11011 SW 104 Street Miami, FL 33176

If a person decides to appeal any decision with respect to any matter considered at the above cited meeting, that person will need a record of the proceedings, and for such purpose may need to ensure that a verbatim record of the proceedings is made, which record includes the testimony and evidence upon which the appeal is to be based. A copy of the agenda may be obtained by writing to: Miami Dade College, Office of the Purchasing Director, 11011 S.W. 104 Street, Miami, FL 33176 or by calling (305)237-2402.

If you should have any questions, please contact:

Ramon Bristol

Assistant Director, Purchasing Department

Phone: (305)237-0011 Fax: (305)237-0737 Email: Rbristol@mdc.edu

DEPARTMENT OF EDUCATION

Miami Dade College - 2016-6-26 - Mechanical and Electrical Shades and Installation for IAP Building

DISTRICT BOARD OF TRUSTEES MIAMI DADE COLLEGE 11011 S.W. 104th STREET MIAMI, FL 33176-3393

The Invitation to Bid (ITB) listed below will be accepted in the PURCHASING DEPARTMENT, Room 9254, by 3:00 p.m. on TUESDAY, MARCH 22, 2016.

Prospective proposers may obtain ITB SOLICITATION by calling (305)237-2402 or the ITB may be downloaded from the College's website at www.mdc.edu/purchasing.

ITB NUMBER ITB TITLE

2016-6-26 Mechanical and Electrical Shades and Installation for IAP Building

Pre-Bid Meeting

March 8, 2016, 11:00 a.m.

MDC InterAmerican Campus

InterAmerican Plaza Building Ground Floor

627 SW 27 Avenue

Miami, FL 33125

If a person decides to appeal any decision with respect to any matter considered at the above cited meeting, that person will need a record of the proceedings, and for such purpose may need to ensure that a verbatim record of the proceedings is made, which record includes the testimony and evidence upon which the appeal is to be based. A copy of the agenda may be obtained by writing to: Miami Dade College, Office of the

Purchasing Director, 11011 S.W. 104 Street, Miami, FL 33176 or by calling (305)237-2402.

If you should have any questions, please contact:

Ramon Bristol

Assistant Director, Purchasing Department

Phone: (305)237-0011 Fax: (305)237-0737 Email: Rbristol@mdc.edu

DEPARTMENT OF EDUCATION

Florida International University

Rule No.6C8-5.009 - Use of University Facilities

RULE NO.: RULE TITLE:

6C8-5.009 Use of University Facilities (Repealed)

NOTICE TO PROFESSIONAL CONSULTANTS

The Florida International University Board of Trustees announces that Professional Services in the discipline of Mechanical/Electrical Engineering will be required for Continuing Services projects at FIU.

Project Location: Modesto A. Maidique Campus (MMC), Biscayne Bay Campus (BBC), Engineering Center (EC), and other properties in South Florida managed by FIU.

Project Description: Continuing Services Contracts are specific projects for Mechanical, Electrical and Plumbing for renovations, alterations, and additions that have a basic construction budget estimated to be \$2,000,000 or less, or studies for which the fee for professional services is \$200,000 or less.

Term of Contract: Any contract resulting from the selection of a professional consultant (or consultants) to provide these services shall require the consultant to be available on an asneeded basis for the Fiscal Year, July1 – June 30. One contract will be awarded to one firm. This contract will be awarded for an initial period of one year with Owner's option to renew the contract, at its sole discretion, for additional one-year periods, however, in no event to exceed a total of five successive years. Selection Process: Selection of finalists for interviews will be made on the basis of qualifications, including experience and ability; past experience; administrative ability, quality control capability and qualification of the firm's personnel and staff. The final ranking shall be determined based on oral presentations and references. The Selection Committee may reject all proposals and stop the selection process at any time. Instructions:

Firms desiring to apply for consideration shall submit a letter of application. The letter of application should have attached:

1. A completed "Florida International University Professional Qualifications Supplement (FIUPQS)." The latest version of official FIUPQS forms (FIUPQS_08_2015) must be downloaded from the FIU web site at

http://facilities.fiu.edu/projects/FIUMEPConsultant2016.htm. Applications on any other form will not be considered.

2. A copy of the applicant's current Professional Registration Certificate from the appropriate Governing board. An applicant must be properly registered at the time of application to practice its profession in the State of Florida. If the applicant is a corporation, it must be properly chartered by the Florida Department of State to operate in Florida.

Submit Nine (9) bound copies of the required proposal data and one CD copy in Adobe Acrobat PDF format of the requested qualifications to: Selection Committee, Florida International University, Facilities Planning, Campus Support Complex, 11555 S.W. 17th St., Room CSC142, Modesto A. Maidique Campus, Miami, Florida 33199. Applications that do not comply with the above instructions will not be considered. Application material will not be returned. The University reserves the right to suspend or discontinue the selection process at any time and to return or reject any or all submissions of qualifications without obligation to the respondent. The award of this contract is subject to availability of funds.

GENERAL REQUIREMENTS: The plans and specifications prepared by the Design Professional are subject to reuse in accordance with the provisions of Section 287.055, Florida Statutes. As required by Section 287.133, Florida Statutes, a consultant may not submit a proposal for this project if it is on the convicted vendor list for a public entity crime committed within the past 36 months. The selected consultant must warrant that it will neither utilize the services of, nor contract with, any supplier, subcontractor, or consultant in excess of \$15,000.00 in connection with this project for a period of 36 months from the date of their being placed on the convicted vendor list.

FIU HAS CREATED STANDARD CONTRACT FORMS AND STANDARD INSURANCE REQUIREMENTS APPLICABLE TO A/E'S FOR A/E SERVICES TO PROVIDE FOR AN EFFICIENT AND EFFECTIVE PROCESS. THESE FORMS ARE AVAILABLE FOR REVIEW AND CAN BE FOUND AT http://facilities.fiu.edu/formsandstandards.htm.

ALL APPLICANTS SHOULD REVIEW THE APPLICABLE FIU CONTRACT FORM AND STANDARD INSURANCE REQUIREMENTS CAREFULLY PRIOR TO MAKING A DECISION AS TO WHETHER OR NOT TO RESPOND TO THIS ADVERTISEMENT.

The Project Fact Sheet, describes the selection process schedule for this Project and additional information regarding the Project scope, and may be obtained from the project web site

http://facilities.fiu.edu/projects/FIUMEPConsultant2016.htm.

In order to minimize the possibility of unethical pressures or influences on the recommendations of the Selection Committee, direct contact with the committee members is not permitted. Requests for meetings by individual firms will not be granted. Committee members and selection schedule milestone dates can be found in the Project Fact Sheet.

Once the firm acquires and reviews the required forms including instructions, any question or explanation desired by an applicant regarding the project or any part of the process must be requested in writing to griffith@fiu.edu. Responses to questions and requests for information will be posted on the project web site. An effort will be made to respond to all applicant questions; however, the University is not obligated to and may choose not to answer every question. The last day questions or inquiries will be considered prior to final interviews for this project is Thursday, March 10, 2016 at 12:00 p.m.

Should a change in schedule become necessary, updated information will be posted on the project website http://facilities.fiu.edu/projects/FIUMEPConsultant2016.htm. All future notices will be posted on the website. Applicants should check the web site daily.

Submittals must be received between 8:30 a.m. and 12:30 p.m. or 1:30 p.m. and 4:00 p.m. local time, Thursday, March 17, 2016. Submittals will not be accepted before or after the times and date stated above. Facsimile (FAX) submittals are not acceptable and will not be considered.

DEPARTMENT OF ENVIRONMENTAL PROTECTION 2016035C Hydrological Restoration at Jonathan Dickinson State Park

Notice of Invitation to Bid: On behalf of the Florida Department of Environmental Protection the Procurement Office is soliciting formal, competitive, sealed bids from contractors for bid number 2016035C, Hydrological Restoration at Jonathan Dickinson State Park. The Department will post notice of any changes or additional meeting(s) on the Vendor Bid System (VBS) in accordance with Section 287.042(3), Florida Statutes, and will not re-advertise any notice in the Florida Administrative Register (FAR). Access the

http://www.myflorida.com/apps/vbs/vbs www.main menu.

Section XII Miscellaneous

NONE

Section XIII Index to Rules Filed During Preceeding Week

NOTE: The above section will be published on Tuesday beginning October 2, 2012, unless Monday is a holiday, then it will be published on Wednesday of that week.