RULEMAKING AUTHORITY: 210.10, FS.
LAW IMPLEMENTED: 210.01, 210.05, 210.085, 210.15, 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: Renita Walton-Hayes, Division of Alcoholic Beverages and Tobacco, Department of Business and Professional Regulation, 1940 North Monroe Street, Suite 26, Tallahassee, Florida 32399, (850)717-1118, renita.walton-hayes@myfloridalicense.com

THE FULL TEXT OF THE PROPOSED RULE IS:

61A-10.0022 Cigarette Distributing Agent – Requirements

Rulemaking ~~Specific~~ Authority 210.10 FS. Law Implemented 210.01, 210.05, 210.085, 210.15 FS. History–New 9-2-08, Repealed _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Anthony Glover, Deputy Director, Division of Alcoholic Beverages and Tobacco, Department of Business and Professional Regulation.
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary, Department of Business and Professional Regulation.
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 4, 2015

DEPARTMENT OF ENVIRONMENTAL PROTECTION

RULE NO.: RULE TITLE:
62-730.186 Universal Pharmaceutical Waste

PURPOSE AND EFFECT: The purpose and effect of the proposed rule development is to provide an opportunity for public input and to clarify, in response to an August 17, 2015, Notice of Unadopted Rule from Zenith Environmental Services, LLC, that the Department's Universal Pharmaceutical Waste rule does not relieve handlers of pharmaceutical waste, that is determined to be hazardous by the generator, from handling all such waste in accordance with state and federal hazardous waste requirements pursuant to Chapter 62-730, F.A.C.

SUMMARY: The United States Resource Conservation and Recovery Act (RCRA) sets out a comprehensive regulatory system governing the treatment, storage, and disposal of hazardous wastes. The United States Environmental Protection Agency (EPA) is the federal agency responsible for administering RCRA. In 1985, Florida received authorization from EPA to administer its own hazardous waste management and regulatory program under RCRA. One of the conditions of the authorization is that Florida's program be no less stringent than the Federal program. EPA maintains oversight of Florida's program and must approve any amendments thereto. In 2007, Florida adopted the Universal Pharmaceutical Waste rule to provide specific alternative handling requirements for pharmaceuticals that are determined to be hazardous waste pharmaceuticals by the generator.

When a generator of pharmaceutical wastes determines it to be "hazardous waste," Florida's RCRA regulations require that the hazardous waste pharmaceuticals be managed as a universal pharmaceutical waste in accordance with Rule 62 730.186, F.A.C., or as a hazardous waste in accordance with Chapter 62 730, F.A.C. Accordingly, subsequent handlers or transporters of the hazardous waste pharmaceuticals are not permitted to change the waste determination, and the waste must ultimately be sent to either a destination facility or a hazardous waste treatment, storage or disposal facility except as expressly provided in Rule 62-730.186, F.A.C. That rule expressly allows subsequent handlers of the universal pharmaceutical waste to sort, disassemble and remove hazardous waste pharmaceuticals from packing when (1) the innermost container of each individual pharmaceutical remains intact and closed or (2) the innermost container is placed into another individual sealed container. See Rule 62-730.186(7)(c), F.A.C. In the event the solid waste – i.e., the packages from which the pharmaceuticals were removed – is not hazardous, it can be managed as non-hazardous waste. See Rule 62-730.186(7)(d), F.A.C. Other than the removal of packaging, Florida's regulations do not provide for handlers to otherwise treat or dispose of pharmaceutical waste that was determined to be hazardous by the generator of such waste.

On August 17, 2015, Zenith Environmental Services, LLC, notified the Department that it perceived this above requirement – that all pharmaceuticals determined to be hazardous by the generator to be managed as hazardous waste in accordance with the Department's Universal Pharmaceutical Waste rule – to be an unadopted rule. In the spirit of cooperation and in an effort to promote regulatory certainty, the Department is amending its Universal Pharmaceutical Waste rule to further clarify that it does not relieve handlers of waste that is marked as hazardous by the generator from managing all such waste in accordance with the requirements of Chapter 62 730, 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: amendment of this rule is merely clarifying the current state of hazardous waste regulations and therefore will not have an adverse impact or increase regulatory costs on any entity.

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: 403.061, 403.151, 403.704, 403.72, 403.721 FS.

LAW IMPLEMENTED: 120.52, 120.54, 403.061, 403.151, 403.704, 403.72, 403.721 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: Tim Bahr, Program Administrator, Permitting & Compliance Assistance Program, 2600 Blair Stone Road, MS 4560, Tallahassee, Florida 32399-2400, Tim.Bahr@dep.state.fl.us, (850)245-8790.

THE FULL TEXT OF THE PROPOSED RULE IS:

62-730.186 Universal Pharmaceutical Waste.

(1) The requirements of this section apply to:

(a) "Hazardous waste pharmaceuticals" [as defined in paragraph 62-730.186(4)(e), F.A.C.] while they are managed in Florida; and

(b) Large and small quantity handlers of universal pharmaceutical waste as defined in paragraphs 62-730.186(4)(f) and (l), F.A.C., including persons who handle universal pharmaceutical waste on an infrequent or episodic basis, as well as those who handle such waste routinely or periodically.

(2) The requirements of this section do not apply to:

(a) Pharmaceuticals that are a solid waste, but that are not determined to be hazardous waste by the generator pursuant to 40 CFR 262.11 [as adopted in subsection 62-730.160(1), F.A.C.];

(b) Pharmaceuticals that have not been discarded and that are:

1. Returned with a reasonable expectation of credit through the pharmaceutical reverse distribution system to a manufacturer, wholesaler or reverse distributor, in accordance with an agreement or policy of the manufacturer, due to an oversupply, expiration of the recommended shelf life, a manufacturer recall, a shipping error or damage to the exterior packaging;

2. Donated to a charitable organization as described in the Internal Revenue Code and permitted pursuant to the requirements of Chapter 64F-12, F.A.C.; or

3. Sold to persons who resell and do not discard the pharmaceuticals;

(c) Pharmaceuticals that are biomedical waste as defined in Section 403.703, Florida Statutes (F.S.);

(d) Spill residues, cleanup materials, and media that are contaminated with pharmaceuticals as the result of a spill or discharge; ~~and~~

(e) Raw materials or ingredients used in the manufacture of pharmaceuticals; and~~.~~

(f) Solid waste which is handled as hazardous waste, but not as universal waste.

(3) Hazardous waste pharmaceuticals as determined by the generator pursuant to 40 CFR 262.11 [as adopted in subsection 62-730.160(1), F.A.C.] are considered to be universal waste, referred to hereinafter as "universal pharmaceutical waste," in Florida when managed in accordance with this section. Hazardous waste pharmaceuticals not managed as universal waste in accordance with this section shall be managed as a hazardous waste in accordance with Chapter 62-730, F.A.C., and shall be disposed of at a permitted hazardous waste treatment, storage or disposal facility.

(4) Definitions. As used in this section:

(a) "Consumer packaging" means the packaging that surrounds or encloses a container, in a form intended or suitable for a healthcare or retail venue, or rejected during the manufacturing process as long as it is enclosed in its bottle, jar, tube, ampule, or package for final distribution to a healthcare or retail venue.

(b) "Container" means the receptacle, such as a bottle, jar, tube, or ampule, into which a pharmaceutical is placed, packaged for transport and/or transported and intended for distribution or dispensing to an ultimate user, and does not include any element of a pharmaceutical that is intended to be absorbed, inhaled or ingested.

(c) "Distribute" means to deliver a pharmaceutical by means other than by administering or dispensing.

(d) "Distributor" means a person who distributes.

(e) "Hazardous waste pharmaceutical" means any waste determined by the generator to be a "non-viable" "pharmaceutical" [as defined in paragraphs 62-730.186(4)(i) and 62-730.186(4)(h), F.A.C., respectively] that exhibits a characteristic as described in 40 CFR Part 261, Subpart C, or any ~~is~~ listed hazardous waste pursuant to 40 CFR Part 261, Subpart D. If the waste formulation includes a commercial chemical product listed in Subpart D as the sole active ingredient, then the entire formulation is considered a hazardous waste pharmaceutical, unless excluded by 40 CFR 261.3(g). A pharmaceutical becomes a waste when it is no longer "viable" [as defined in paragraph 62-730.186(4)(n), F.A.C.]; when a decision is made to discard the pharmaceutical; or when the pharmaceutical is abandoned as described in 40 CFR 261.2(b). A pharmaceutical does not meet the definition of a "solid waste" under 40 CFR 261.2 and is considered product as long as it is viable, a decision to discard it has not been made, and it is not abandoned as described in 40 CFR 261.2(b). Pharmaceuticals that are produced by a pharmaceutical manufacturer without reasonable expectation of sale, returned or delivered without a reasonable expectation of credit to a manufacturer, wholesaler, reverse distributor or any type of waste broker, are non-viable and are discarded. Once a decision has been made to discard a viable pharmaceutical, it becomes non-viable. Non-viable pharmaceuticals that are hazardous waste may be handled as universal waste under this rule. 40 CFR Part 261 and all sections thereof as cited in this paragraph have been adopted by reference as state regulations in subsection 62-730.030(1), F.A.C. Once a generator has determined solid waste to be a hazardous waste pharmaceutical, all of the solid waste so determined is a hazardous waste and shall be managed as a hazardous waste according to Chapter 62-730, F.A.C., or it may be managed as a universal waste in accordance with this section, including the requirements for sorting and removing packaging as provided below in subsection 62-730.186(7), F.A.C.

(f) "Large quantity handler of universal pharmaceutical waste" means a "universal waste handler" [as defined in 40 CFR 273.9 (as adopted in subsection 62-730.185(1), F.A.C.)] that, at any time:

1. Accumulates 5,000 kilograms or more total of universal pharmaceutical waste (batteries, pesticides, thermostats, lamps, or pharmaceuticals, calculated collectively) which includes some amount of universal pharmaceutical waste, or

2. Accumulates universal pharmaceutical waste consisting of more than one kilogram total of pharmaceuticals listed in 40 CFR 261.33(e) [as adopted in subsection 62-730.030(1), F.A.C.] as acute hazardous waste ("p-listed wastes"). The designation as a large quantity handler of universal waste is retained through the end of the calendar year in which the universal waste, identified in subparagraphs 1. and 2. of paragraph 62-730.186(4)(f), F.A.C., is accumulated.

(g) "Manufacturer" means a person who prepares, derives, manufactures, or produces a pharmaceutical.

(h) "Pharmaceutical" means a manufactured chemical product that is intended to be inhaled, ingested, injected, or topically applied for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease or injury in humans or other animals.

(i) "Non-viable" means a pharmaceutical that cannot be sold, returned to the manufacturer, wholesaler or reverse distributor with a reasonable expectation of credit, or donated to a charitable organization. Pharmaceuticals that are obviously "waste-like", such as partial intravenous formulations; partial vials used in the preparation of intravenous (IV) formulations; outdated samples; other outdated items repackaged at the pharmacy; partial vials or vials used on the unit and not emptied (such as insulin and epinephrine dispensing devices); partial ointments, creams and lotions; partial inhalants; partial containers that are not empty as defined in 40 CFR 261.7 [as adopted in subsection 62-730.030(1), F.A.C.]; patient's personal medications that have been left at the hospital; filled finished products that are rejected during the manufacturing process, so long as they are in their consumer package (such as bottle, jar, tube, or ampule), do not support a reasonable expectation of credit and therefore are non-viable pharmaceuticals.

(j) "Pharmaceutical reverse distribution system" means the established practice of shipping expired or other unsaleable prescription drugs from pharmacies, medical practitioners, over-the-counter pharmaceutical retailers, and pharmaceutical wholesalers to pharmaceutical reverse distributors and then to manufacturers with the intent of receiving credit. These items may be shipped directly to manufacturers depending on manufacturer return policies.

(k) "Reverse distributor" means a person engaged in the reverse distribution of prescription drugs who:

1. Operates a warehouse licensed by the Florida Department of Business and Professional Regulation under Chapter 499, F.S., as a reverse distributor; and

2. Has management systems in place to ensure compliance with applicable requirements of 40 CFR Parts 260 through 273 [as adopted in Rules 62-730.021 and 62-730.183, and subsections 62-730.020(1), 62-730.030(1), 62-730.160(1), 62-730.170(1), 62-730.180(1) and (2), 62-730.181(1), 62-730.185(1), and 62-730.220(1), F.A.C.] and Chapter 62-730, F.A.C.

NOTE: The Federal Drug Enforcement Administration has registration requirements for persons engaged in the reverse distribution of prescription drugs who handle controlled substances in Schedules II through V promulgated under United States Code, Title 21, Section 812.

(l) "Small quantity handler of universal waste" means a "universal waste handler" [as defined in 40 CFR 273.9 (as adopted in subsection 62-730.185(1), F.A.C.)] that does not:

1. Accumulate 5,000 kilograms or more total of universal waste (batteries, pesticides, thermostats, lamps or pharmaceuticals, calculated collectively) which includes some amount of universal pharmaceutical waste; or

2. Accumulate universal pharmaceutical waste consisting of more than one kilogram total of pharmaceuticals listed in 40 CFR 261.33(e) [as adopted in subsection 62-730.030(1), F.A.C.] as acute hazardous waste ("p-listed wastes").

(m) "Universal waste" means any of the following hazardous wastes that are subject to the universal waste requirements of 40 CFR Part 273 [as adopted in subsection 62-730.185(1), F.A.C.], Chapter 62-730, F.A.C., or Chapter 62-737, F.A.C.: batteries as described in 40 CFR 273.2; pesticides as described in 40 CFR 273.3; thermostats as described in 40 CFR 273.4; lamps as described in 40 CFR 273.5; mercury-containing devices as described in Chapter 62-737, F.A.C.; and pharmaceuticals as defined in paragraph 62-730.186(4)(e), F.A.C.

(n) "Viable" means a pharmaceutical can be sold, returned to the manufacturer, wholesaler or reverse distributor with a reasonable expectation of credit, or donated to a charitable organization meeting the definition in the Internal Revenue Code and permitted in accordance with Chapter 64F-12, F.A.C.

(o) "Wholesaler" means a person who sells or distributes for resale any pharmaceutical as defined in paragraph 62-730.186(4)(e), F.A.C., to any entity other than the ultimate user.

(5) A large or small quantity handler of universal pharmaceutical waste ("handler") is prohibited from:

(a) Disposing of universal pharmaceutical waste; and

(b) Diluting or treating universal pharmaceutical waste, except when responding to releases as described in subsection 62-730.186(10), F.A.C., or when managing waste as described in subsection 62-730.186(7), F.A.C.

(6) A handler, except for generators that are small quantity handlers of universal pharmaceutical waste, or a transporter of universal pharmaceutical waste shall notify the Department in writing and receive an EPA Identification Number before accumulating universal pharmaceutical waste, or offering such waste for transport, or transporting such waste, and shall use Form 62-730.900(1)(b), "8700-12FL, Florida Notification of Regulated Waste Activity," effective date 4-23-13 [as adopted by reference in paragraph 62-730.150(2)(a), F.A.C.] to do so. A handler or transporter of hazardous waste that has already notified the Department of its hazardous waste management activities and obtained an EPA Identification Number is not required to renotify under this section.

(7) A handler shall implement proper universal pharmaceutical waste management activities that include the following:

(a) A handler shall contain any universal pharmaceutical waste that shows evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions. A handler shall manage universal pharmaceutical waste in a way that prevents releases of any universal pharmaceutical waste or component of a universal pharmaceutical waste to the environment. The universal pharmaceutical waste shall be contained in one or more of the following:

1. A container that remains closed (except when adding or removing waste), is structurally sound, and compatible with the pharmaceutical, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions;

2. A container that does not meet the requirements of subparagraph 62-730.186(7)(a)1., F.A.C., provided the unacceptable container is overpacked in a container that does meet the requirements; and

3. A tank that meets the requirements of 40 CFR Part 265 Subpart J [as adopted in subsection 62-730.180(2), F.A.C.], except for 40 CFR 265.197(c), 265.200 and 265.201.

(b) A handler shall clearly label those containers and tanks accumulating waste pharmaceuticals with the phrase "universal pharmaceutical waste" or "universal waste pharmaceuticals," and keep records of what is going into each container sufficient to allow safe handling and proper disposal of the universal pharmaceutical waste.

(c) A handler may conduct the following activities as long as the innermost container of each individual pharmaceutical remains intact and closed, or if the innermost container is placed into another individual sealed container:

1. Sorting or mixing individual pharmaceuticals in one outer container, as long as the pharmaceuticals are compatible;

2. Disassembling packaging ~~packages~~ used for shipping or storage, excluding innermost containers, containing several pharmaceuticals into individual pharmaceuticals; and

3. Removing consumer packaging from pharmaceuticals, except that removing the innermost containers from hazardous waste pharmaceuticals, as determined by the generator, shall be prohibited ~~from consumer packaging~~.

(d) A handler of universal pharmaceutical waste may generate solid waste as a result of removing packaging used for shipping or storage, including consumer packaging, but excluding innermost containers, pursuant to the activities in paragraph 62-730.186(7)(c), F.A.C. A handler of universal pharmaceutical waste that generates solid waste shall determine whether the solid waste is hazardous waste identified in 40 CFR Part 261 Subpart C or D [as adopted in subsection 62-730.030(1), F.A.C.]. If the solid waste is a hazardous waste, it shall be managed in compliance with all applicable requirements of Chapter 62-730, F.A.C. The handler is considered the generator of the hazardous waste and is subject to 40 CFR Part 262 [as adopted in subsection 62-730.160(1), F.A.C.]. If the solid waste is not hazardous waste, the handler may manage the waste in any way that is in compliance with applicable federal, state and local solid waste regulations.

(e)1. A reverse distributor or wholesaler who meets the definition of "universal waste handler" in 40 CFR 273.9 [as adopted in subsection 62-730.185(1), F.A.C.] shall meet the requirements for "handlers" in subsections 62-730.186(6) through (12), F.A.C., of this section.

2. A reverse distributor or wholesaler that makes determinations as to whether pharmaceuticals are viable shall:

a. Begin the process of distinguishing viable pharmaceuticals from universal pharmaceutical waste or hazardous waste within 14 days of receipt of a complete shipment of returns from a handler, and in no event more than 21 days from the receipt of the first installment of a partial shipment;

b. Complete the universal pharmaceutical waste or hazardous waste identification process within 21 days of receipt of the complete shipment, and in no event more than 30 days from receipt of the first installment of a partial shipment; and

c. Keep a record of each shipment of returns by any method that clearly demonstrates the date on which the shipment was received and the date on which the reverse distributor or wholesaler determined the universal pharmaceutical waste or hazardous waste status of all items in the shipment.

(8) The following are accumulation time limits and verification practices for handlers of universal pharmaceutical waste:

(a) A small quantity handler may accumulate universal pharmaceutical waste for no longer than one year from the date the universal pharmaceutical waste was generated, unless the requirements of paragraph 62-730.186(8)(c), F.A.C., are met.

(b) A large quantity handler may accumulate universal pharmaceutical waste for no longer than 6 months from the date the universal pharmaceutical wastes are generated, unless the requirements of paragraph 62-730.186(8)(c), F.A.C., are met.

(c) A handler may accumulate universal pharmaceutical waste for a longer period of time than specified in paragraphs 62-730.186(8)(a) and (b), F.A.C., if such activity is solely for the purpose of accumulation of such quantities of universal pharmaceutical waste as are necessary to facilitate proper recovery, treatment or disposal. However, the handler bears the burden of proving that the extended accumulation time is solely for these purposes.

(d) A handler shall be able to demonstrate the accumulation time for the universal pharmaceutical waste. The handler may make this demonstration by:

1. Placing the universal pharmaceutical waste in a container and marking or labeling the container with the earliest date that any universal pharmaceutical waste in the container became a waste;

2. Marking or labeling each individual item of universal pharmaceutical waste (e.g., each individual pharmaceutical container or package) with the date it became a waste;

3. Maintaining an inventory system on-site that identifies the date each universal pharmaceutical waste became a waste;

4. Maintaining an inventory system on-site that identifies the earliest date that any universal pharmaceutical waste in a group of universal pharmaceutical wastes, or a group of containers of universal pharmaceutical wastes, became waste; or

5. Using any other method which clearly demonstrates the length of time the universal pharmaceutical wastes have been accumulating from the date they became a waste.

(9) A handler shall ensure that all employees handling or managing universal pharmaceutical waste successfully complete a program of classroom instruction or on-the-job training.

(a) The training shall ensure that all employees are thoroughly familiar with proper waste management procedures relevant to their responsibilities during normal facility operations and emergencies. The training shall include response to releases as required by subsection 62-730.186(10), F.A.C.

(b) Employees working at a handler's facility on April 22, 2007 shall successfully complete the training program required in paragraph 62-730.186(9)(a), F.A.C., within three months after the effective date. Employees hired or assigned after April 22, 2007 shall successfully complete the training program within three months after the date of their employment at or assignment to the handler's facility. These employees shall not manage universal pharmaceutical waste unsupervised until they have completed the training requirements.

(c) Employees shall take part in an annual review of the initial training required in paragraph 62-730.186(9)(a), F.A.C., and the handler shall ensure that the annual review is available to the employees.

(d) A handler shall document the training given to each employee. The documents shall include the employee's name, signature, date of hire or assignment, date of training, and type of training. The training documents shall be kept at the handler's place of business for at least three years.

(10) A handler shall immediately contain all releases of universal pharmaceutical waste (including spills that occur indoors). A handler shall determine whether any material resulting from a release is hazardous waste. A handler shall manage any such hazardous waste in compliance with the requirements of 40 CFR Parts 260 through 272 [as adopted in Rules 62-730.021 and 62-730.183, and subsections 62-730.020(1), 62-730.030(1), 62-730.160(1), 62-730.170(1), 62-730.180(1) and (2), 62-730.181(1) and 62-730.220(1), F.A.C.]. The handler is considered the generator of the material resulting from the release and shall manage the material in compliance with 40 CFR Part 262 [as adopted in subsection 62-730.160(1), F.A.C.]. Material resulting from the release of universal pharmaceutical waste may not be managed as universal pharmaceutical waste.

(11) Off-site shipments of universal pharmaceutical waste shall meet the following requirements:

(a) A handler is prohibited from sending or taking universal pharmaceutical waste to a place other than to a handler or a reverse distributor who has notified the department pursuant to subsection 62-730.186(6), F.A.C.; a destination facility as defined in 40 CFR 273.9 [as adopted in subsection 62-730.185(1), F.A.C.]; or a foreign destination in accordance with the requirements of paragraph 62-730.186(11)(k), F.A.C.

(b) A reverse distributor is prohibited from taking or sending universal pharmaceutical waste to a place other than a destination facility that is permitted pursuant to 40 CFR Parts 264 [as adopted in subsection 62-730.180(1), F.A.C.] and 270 [as adopted in subsection 62-730.220(1), F.A.C.] for treatment, storage or disposal of hazardous waste, or a foreign destination in accordance with the requirements of paragraph 62-730.186(11)(k), F.A.C.

(c) If a handler self-transports universal pharmaceutical waste off-site, the handler becomes a universal waste transporter for those self-transportation activities and shall comply with the transporter requirements of 40 CFR Part 273 Subpart D [as adopted in subsection 62-730.185(1), F.A.C.] while transporting the universal pharmaceutical waste.

(d) A person who transports, at any one time, more than 5000 kilograms of universal pharmaceutical waste or more than one kilogram of p-listed universal pharmaceutical waste shall comply with the financial responsibility requirements of subsection 62-730.170(2), F.A.C.

(e) A handler that intends to transport a universal pharmaceutical waste that meets the definition of hazardous materials in 49 CFR Parts 171 through 180 is advised of its duty to comply with the applicable Department of Transportation regulations in 49 CFR Parts 172 through 180. These regulations address packaging, labeling, marking and placarding the shipment, and preparing proper shipping papers. Handlers are further advised to consult 49 CFR 172.101 for a list of hazardous materials and a table summarizing shipping requirements.

(f) A handler that transports a universal pharmaceutical waste to a reverse distributor or another handler must provide the reverse distributor or handler with written information sufficient to allow the reverse distributor or other handler to make knowledgeable decisions about the safe handling and proper disposal of the universal pharmaceutical waste.

(g) Prior to sending a shipment of universal pharmaceutical waste to a destination facility, the originating handler shall ensure that the destination facility agrees in writing to receive the shipment. One agreement to accept universal waste from a handler can cover more than one shipment.

(h) If a handler sends a shipment of universal pharmaceutical waste to a destination facility and the shipment is rejected by the destination facility, the originating handler shall either:

1. Receive the waste back when notified that the shipment has been rejected; or

2. Agree with the destination facility on an alternate destination facility to which the shipment will be sent.

(i) If a destination facility receives a shipment containing hazardous waste that is labeled universal pharmaceutical waste but is not in fact universal pharmaceutical waste, the destination facility shall immediately notify the Department of the mislabeled shipment and provide the name, address, and telephone number of the originating handler. The destination facility shall handle the hazardous waste in accordance with the requirements of Chapter 62-730, F.A.C.

(j) If a destination facility receives a shipment of non-hazardous, non-universal waste pharmaceuticals, the destination facility may manage the waste pharmaceuticals in any way that is in compliance with applicable federal, state and local solid waste regulations.

(k)1. A handler who sends universal pharmaceutical waste to a foreign destination which is one of the following designated member countries of the Organization for Economic Cooperation and Development (OECD): Australia, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, and United Kingdom, is subject to the requirements of 40 CFR Part 262 Subpart H [as adopted in subsection 62-730.160(1), F.A.C.]

2. A handler who sends universal pharmaceutical waste to a foreign destination other than those listed in subparagraph 62-730.186(11)(k)1., F.A.C., must:

a. Comply with the requirements applicable to a primary exporter in 40 CFR 262.53, 262.56(a)(1) through (4), (6), and (b), and 262.57 [as adopted in subsection 62-730.160(1), F.A.C.];

b. Export such universal pharmaceutical waste only upon consent of the receiving country and in conformance with the EPA Acknowledgement of Consent as defined in 40 CFR 262.51 [as adopted in subsection 62-730.160(1), F.A.C.]; and

c. Provide a copy of the EPA Acknowledgement of Consent for the shipment to the transporter who transports the shipment for export.

(l) This section applies to hazardous waste pharmaceuticals only while they are managed in Florida. Handlers are advised to meet the regulatory requirements of the receiving state when hazardous waste pharmaceuticals are shipped out of state.

(12) A handler shall keep a record of each shipment of universal pharmaceutical waste sent to another handler, a reverse distributor, destination facility, or foreign destination. The record shall consist of a written receipt, manifest, bill of lading or other written documentation. A handler shall retain the records at its place of business for at least three years from the date of shipment. The record for each shipment of universal pharmaceutical waste shall include the following information:

(a) The name and address of the handler, reverse distributor, destination facility or foreign destination to which the universal pharmaceutical wastes were sent;

(b) The quantity of universal pharmaceutical waste sent; and

(c) The date the shipment of universal pharmaceutical waste left the handler's facility.

(13) This section constitutes state authorization for reverse distributors and wholesalers to manage hazardous pharmaceutical waste from conditionally exempt hazardous waste generators (CESQGs) and authorization for CESQGs to ensure delivery of their hazardous waste pharmaceuticals to a reverse distributor or wholesaler, pursuant to 40 CFR 261.5(f)(3)(iii) and 40 CFR 261.5(g)(3)(iii) [as adopted in subsection 62-730.030(1), F.A.C.]. Wholesalers are authorized by this section to manage hazardous pharmaceutical waste only from the CESQGs to whom they distributed the pharmaceutical(s) which became waste.

Rulemaking Authority 403.061, 403.151, 403.704, 403.72, 403.721 FS. Law Implemented 120.52, 120.54, 403.061, 403.151, 403.704, 403.72, 403.721 FS. History–New 4-22-07, Amended 1-4-09, 4-23-13, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Tim Bahr

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Secretary Jonathan P. Steverson

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 11, 2015

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: September 14, 2015

DEPARTMENT OF HEALTH

Board of Medicine

RULE NO.: RULE TITLE:
64B8-2.001 Definitions

PURPOSE AND EFFECT: The proposed rule amendments are intended to delete obsolete definitions from the rule.