STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

HARMONY ENVIRONMENTAL, INC.,

Petitioner,

vs. Case No. 14-5334RU

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION, DRUGS, DEVICES AND COSMETICS PROGRAM,

Respondent.
_____/

FINAL ORDER

A final hearing was held in this matter before Robert S. Cohen, Administrative Law Judge with the Division of Administrative Hearings, on December 8, 2014, in Tallahassee, Florida.

APPEARANCES

For Petitioner: Edwin A. Bayó, Esquire
Grossman, Furlow and Bayó, LLC
2022-2 Raymond Diehl Road
Tallahassee, Florida 32308

For Respondent: Bart O. Moore, Esquire
Beth A. Miller, Esquire
Kathryn E. Price, Esquire
Division of Drugs, Devices, and Cosmetics
Department of Business and
Professional Regulation
1940 North Monroe Street, Suite 26A
Tallahassee, Florida 32399

STATEMENT OF THE ISSUES

Whether Petitioner has been substantially affected by agency statements made by Respondent, and, if so, whether the statements violate section 120.54(1)(a), Florida Statutes?

PRELIMINARY STATEMENT

Petitioner filed a Petition to Determine Invalidity of Agency Statements Defined as Rules on November 13, 2014. An Order of Assignment was entered, notifying the parties that the undersigned was assigned as the administrative law judge (ALJ) on the matter. A Notice of Hearing was issued on November 17, 2014, setting the matter for December 8, 2014. The parties subsequently engaged in and exchanged discovery. On November 25, 2014, Respondent filed a Motion for More Definite Statement. Petitioner filed a response to that motion on December 1, 2014. Thereafter, Respondent filed a Motion to Dismiss or, in the Alternative, Motion for Summary Final Order, as well as a Motion to Take Official Recognition, requesting the ALJ to take official recognition of chapter 499, Florida Statutes; Florida Administrative Code Chapter 61N; and a Notice of Intent to Deny Permit dated August 18, 2014, directed to Petitioner. On December 4, 2014, Petitioner filed a Motion to Take Official Recognition of Florida Administrative Code Rule 62-730.186; 21 C.F.R. pt. 1317; and an October 17, 2014 "Dear Practitioner" letter from the U.S. Drug Enforcement Administration (DEA). On

December 5, 2014, Respondent filed a Motion in Limine to Exclude Evidence and Testimony (Motion in Limine). Petitioner filed a response to that motion on December 5, 2014. The parties subsequently filed unilateral pre-hearing statements.

The matter proceeded to hearing on December 8, 2014. Respondent's Motion for More Definite Statement was denied based upon Petitioner's response. Both Motions to Take Official Recognition were granted. The Motion in Limine was denied, and the ALJ reserved ruling on the Motion for Summary Final Order, notifying the parties that if he was still in doubt at the conclusion of the hearing, he would request a memorandum related to the summary final order. No memorandum was requested at the conclusion of the hearing. The motion is denied.

At the hearing, Petitioner presented the testimony of two witnesses, Reginald Dixon, Division Director and party representative for Respondent; and Michelle Chambers, the unpaid Director of Compliance and Regulatory Affairs and registered agent for Petitioner. Ms. Chambers was accepted as an expert in universal pharmaceutical waste and related state and federal regulations. Petitioner also offered eight exhibits, numbered 2 through 4 and 9 through 13, all of which were admitted into evidence, except for Exhibit 9. Respondent presented the testimony of two witnesses, Dr. Tram Vu, a drug inspector for Respondent, and David Laven, a drug inspector for Respondent.

Both Dr. Vu and Mr. Laven were accepted as experts in pharmacy and in conducting investigations under chapter 499 for Respondent. Respondent offered four exhibits, all of which were admitted into evidence.

A two-volume Transcript of the hearing was filed with the Division on December 22, 2014. The parties noted some errors in the Transcript and requested that the court reporter issue a corrected transcript which was done. A Motion for Enlargement of Time to Submit Proposed Final Order was filed by Respondent on December 23, 2014, and Petitioner did not object. A corrected transcript was filed on December 29, 2014. On December 31, 2014, Respondent's Motion for Enlargement of Time to Submit Proposed Final Order was granted. Petitioner and Respondent filed their proposed findings of fact and conclusions of law on January 8, 2015.

References to statutes are to Florida Statutes (2014) unless otherwise noted.

FINDINGS OF FACT

1. Petitioner, Harmony Environmental (Harmony), is duly-licensed as a Universal Waste Transporter Facility (UWTF) with the Florida Department of Environmental Protection (FDEP), holding EPA ID No. FLR000202424. Additionally, Harmony is registered as a Hazardous Waste Transporter by FDEP as well as the U.S. Department of Transportation (USDOT); a Used Oil Handler

by FDEP; a Biomedical Waste Transporter by the Florida Department of Health; and as a Waste Transporter by Broward and Miami-Dade counties.

2. Respondent is the state department charged with regulating drugs, devices, and cosmetics pursuant to section 20.165 and chapter 499, Florida Statutes. Respondent does not have jurisdiction over the permitting of universal waste transporters or over Florida Administrative Code Chapter 62-730. Respondent has not issued any permits or licenses to Petitioner.

3. On May 20, 2014, Respondent's Inspector Dr. Tram Vu inspected Petitioner. The Entry Notice and On-Site Inspection Report was included as an exhibit to the Petition filed in this matter. It makes reference to the "inspection" by Dr. Vu as one, "conducted under Ch. 499.051, F.S., and Rule 61N-1.019, F.A.C., to assess firm's activities and compliance." Respondent admitted the May 20th inspection was conducted under the authority cited in the report.

4. On July 16 and 17, 2014, Dr. Vu again inspected Petitioner. A number of photographs were taken during the inspection. The photographs depict two large white containers referred to in the Petition and at the hearing as "yard super sacks." Inspector Vu testified that the yard super sacks were sealed and that none of the "prescription drugs" photographed

were found outside of the sealed Universal Pharmaceutical Waste (UPW) containers.

5. Dr. Vu subsequently requested Petitioner to "voluntarily" quarantine the super sacks and a black tote, and a voluntary quarantine form was prepared and executed. The voluntary quarantine form states that it is "an alternative to the Florida Department of Business and Professional Regulation ('DBPR') removing some or all of the products for examination and sampling pursuant to Section 499.065(2), Florida Statutes."

6. Respondent issued a Notice of Intent to Deny (NOID) to Petitioner on August 18, 2014, regarding its application for a restricted drug distributor/destruction permit. The NOID concluded that Petitioner acted as a restricted drug distributor/destruction establishment without a license. The NOID cited rule 61N-1.023(4), which provides that such a permit is required for a person to take possession in Florida of a prescription drug for the purpose of arranging for its destruction.

7. When asked by Petitioner in an interrogatory, "Are there any facts or circumstances that would cause the DDC to consider that a prescription drug has become UPW and no longer subject to its authority? If so, state or identify each and every such fact or circumstance." Respondent answered, "No. The term 'UPW' is a term that is within the jurisdiction of another Florida state

agency, the Department of Environmental Protection (DEP). A prescription drug is no longer a prescription drug when the nature of the prescription drug is altered or changed in a way that the active ingredient which causes the prescription drug to be a prescription drug is no longer active."

8. Reginald Dixon, the Director of the Division of Drugs, Devices, and Cosmetics (DDC), acknowledged that in his two years as Director, Respondent's chapter 61N-1 has not contained any definition that addresses the difference between viable drugs and non-viable drugs and that it contains no reference to UPW.

9. Mr. Dixon further acknowledged that chapter 61N-1 does not contain the statement that "[a] prescription drug is no longer a prescription drug when the nature of the prescription drug is altered or changed in a way that the active ingredient which causes the prescription drug to be a prescription drug is no longer active." He further acknowledged that he is not aware of any federal or Florida law, rule, or regulation that provides the same or similar statement; and that chapter 61N-1 does not contain any definition or explanation as to how the change or alteration that may render the active ingredient inactive takes place.

10. Respondent's policy that a drug continues to be a prescription drug until its nature is altered or changed so that the active ingredient that makes it a prescription drug is no

longer active applies not only to Petitioner. Such policy would apply to other entities engaged in a similar business, as well as to pharmacies, drug wholesalers, and hospitals when considering how to legally dispose of prescription drugs.

11. Respondent takes the position that the UPW rule "is not a rule that belongs to DBPR" (Hr'g Tr. 62); that Respondent "does not have any jurisdiction over the DEP rules" (Hr'g Tr. 75); and that Respondent does "not look at the DEP rules to determine or use their determination of whether or not a drug is viable . . . or nonviable" (Hr'g Tr. 75). "To the extent that [the UPW] rule talks about viable and nonviable pharmaceuticals, that's not something within our jurisdiction and we don't deal with it" (Hr'g Tr. 78).

12. Respondent admitted that it is important for regulated entities to know when the agency considered that a drug is no longer under its jurisdiction. Respondent also admitted that if other regulations exist that do not call prescription drugs "prescription drugs" anymore, but instead call them "solid waste, universal pharmaceutical waste or hazardous waste," those statutes and regulations may "possibly" have a bearing on chapter 499 and chapter 61N-1.

13. In response to Petitioner's Request for Admissions, Respondent claimed to be "without knowledge" of whether the hazardous waste program under the Federal Resource Conservation

Recovery Act (RCRA) established a "cradle to grave" system for controlling hazardous waste; and whether pursuant to 40 C.F.R. § 272.501, the Federal EPA approved the hazardous waste management program administered by the FDEP pursuant to chapter 403, Florida Statutes. Moreover, Respondent was "without knowledge" of whether the U.S. Food and Drug Administration (FDA) does not regulate drugs that have been discarded as hazardous or pharmaceutical waste; and that the FDA does not regulate generators or handlers of hazardous or pharmaceutical waste.

14. Respondent also claimed to be "without knowledge" that some UPW is generated by hospitals during surgical procedures when a vial containing a standard dose of medication is not fully used because of the patient's size or condition, with the unused dose "wasted" by placing it in a sealed, properly labeled UPW container; that hospitals that dispose of non-controlled and non-viable drugs in a properly labeled UPW container pursuant to rule 62-730.186, do not routinely create a list or inventory of the drugs being wasted or placed in the container that includes the name of the manufacturer, the name of the drug, the quantity, lot number, expiration date, or any combination of these elements; and that hospitals wasting non-viable controlled substances maintain a log that identifies the name and quantity of the controlled substance wasted, but not the manufacturer, the lot number, or the expiration date; and that such controlled

substance log complies with DEA regulations as well as chapter 893, Florida Statutes.

15. Mr. Dixon testified that the act of disposing of the unused portion of a prescription drug in a UPW container at a hospital that also contains sharps, broken glass, tissue, and bloody gauzes could constitute the adulteration of that prescription drug. Further, Mr. Dixon testified that when hospitals dispose of drugs in UPW containers they are "possibly" adulterating drugs, and when Petitioner picks up the UPW container, Petitioner may likewise "possibly" be holding adulterated drugs.

16. Petitioner's witness, Michelle Chambers, was accepted as an expert witness on UPW and related regulations, both state and federal. Although unpaid for her work due to being the spouse of Petitioner's owner, she is the compliance coordinator, bookkeeper, and registered agent for Petitioner. Mrs. Chambers trains drug wholesalers how to manage their UPW by directing them to "utilize a return if they can get credit for the drug, but that once a drug becomes waste it falls under the guidelines of UPW and those drug wholesalers need to create a separate area that can handle UPW containers." When discussing the process of sending UPW to a reverse distributor regulated by Respondent, Mrs. Chambers referred to the FDEP's pharmaceutical waste guidelines, which state:

> Only pharmaceuticals with a reasonable expectation of credit can be sent to a reverse distributor. Drop pills, non-credible items, formulated mixtures, items with patient's names, and raw chemicals cannot be sent to a reverse distributor for credit; thereafter, a waste determination is required and the decision must be made to manage this waste as hazardous waste or UPW waste.

Mrs. Chambers stated she had knowledge of unexpired drugs, still in the original packaging that were declared waste by the wholesaler. She asserted that drug wholesalers abandoned or discarded the unexpired drugs in their original packaging because "they couldn't send it back to a reverse distributor to get credit. There was just no value to it, whatsoever, so they decided to make that waste determination that this is waste, UPW."

17. Mrs. Chambers stated that UPW labels are attached to UPW containers in Petitioner's facility, according to the FDEP rule regarding UPW. These labels represent the characteristics of the hazardous waste and other waste inside those containers. Some of the notations on the label refer to a substance, material, or a chemical product that is a prescription drug. She also testified that several documents may be created in the UPW process, such as a hazardous-waste manifest and a bill of lading. In records that a UPW handler is expected to maintain under FDEP rules, a UPW handler is not required to have those records

contain the name of the drugs that are in the UPW containers, the manufacturer's information, or the expiration date of the drugs in the UPW container. She asserted that Petitioner could not reasonably create inventories of all the drugs inside a UPW container because "some of the labels have been poured on by other elements within the container; some are unidentifiable; some are broken . . . it would be very difficult to create an inventory." Based upon her audits of more than 200 hospitals, Mrs. Chambers stated that if a hospital has a procedure to put non-viable drugs in a UPW container, it is because they are trained to do so. She testified that no hospital she has ever audited has ever kept records that include drug names, manufacturers, or expiration dates for anything they have placed in the UPW containers. Petitioner picks up these containers and brings them to its facility. A UPW handler can add waste to the container, as well as consolidate those containers.

18. Mrs. Chambers also discussed consumer packaging under rule 62-730.186(4)(a), which states:

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

Further, UPW handlers can conduct activities, including disassembling packages containing several pharmaceuticals into individual pharmaceuticals from consumer packaging.

19. In her experience in the auditing of hospitals for UPW, as well as with Petitioner, Mrs. Chambers stated that controlled substances are put into UPW containers from time to time, yet Petitioner has never been cited or received a notice of violation from the DEA regarding the possession of a controlled substance. To her knowledge, the DEA has never notified any UPW handler in Florida of any violations for possessing controlled substances.

20. Dr. Vu conducts inspections and investigations pursuant to chapter 499, specifically investigating unlicensed activities as well as inspecting facilities that are attempting to obtain a DDC permit. Dr. Vu was tendered and accepted as an expert in pharmacy and conducting inspections for Respondent pursuant to chapter 499. She testified that during her inspection of Petitioner on July 14, 2014, she pulled drugs from UPW containers to inspect them. She admitted there were no prescription drugs outside the UPW containers on Petitioner's premises. She stated that Petitioner's agents or employees volunteered to open the UPW containers for her inspection. The scant evidence Dr. Vu relied upon that Petitioner had any controlled substances on the premises was based upon documents she obtained from a third party

as well as from Petitioner. She admitted there was no evidence of controlled substances on Petitioner's premises.

21. While Dr. Vu stated she is able to recognize prescription drugs when she sees them, she is not able to recognize UPW since she is "not trained in universal pharmaceutical waste." She also stated she is not able to recognize a non-viable drug when she sees it. Dr. Vu has received no training from Respondent on the opening of UPW containers, and even though she has not been trained in UPW rules and definitions, she strongly asserted that Petitioner "[c]learly was in possession of prescription drugs," and that Petitioner had no permit or authorization to possess prescription drugs. When asked about her understanding of when a prescription drug ceases to be a prescription drug, she replied that "a prescription drug is always a prescription drug unless it's inactivated or loses its drug ability -- characteristics." Dr. Vu noted that this understanding is not stated in chapter 61N-1 or chapter 499.

22. David Laven, another drug inspector for Respondent, was tendered and accepted as an expert in pharmacy and issues related to the inspection for Respondent under chapter 499. He testified that Petitioner is not allowed to possess prescription drugs without a DDC permit. On cross-examination, however, he admitted he had not read the rule on UPW, has no knowledge of EPA rules and requirements, and that he is not trained to recognize a

non-viable drug. He testified that he considers a prescription drug that is discarded in a UPW container still to be a prescription drug because "there's still a possibility, depending on how that drug has been disposed of, the container may be partially full -- it can be a full container sometimes. Drugs are thrown in a container for a number of reasons, doesn't necessarily mean that the drug is no longer viable or can be used in any way." Regarding the definition of prescription drugs, Mr. Laven stated that "[a] drug is no longer viable or useable if it's out of date, it's been damaged in some way, compromised, mis-branded, [or] adulterated."

23. On October 6, 2014, Petitioner sent a Notice of Unadopted Rules letter to Respondent, stating that the conduct and statements set forth above constitute unpromulgated rules and that, according to section 120.595(4)(b), Florida Statutes, they have 30 days to begin proposed rulemaking in order to rectify the actions and statements made. Respondent did not begin proposed rulemaking in that 30-day period. Respondent presented no evidence or testimony to establish that rulemaking was not feasible or practicable.

CONCLUSIONS OF LAW

24. The Division of Administrative Hearings has jurisdiction over the subject matter and parties to this action

in accordance with sections 120.56(4), 120.569, and 120.57(1), Florida Statutes.

25. Section 120.56(4)(a) authorizes any person who is substantially affected by an agency statement to seek an administrative determination that the statement is actually a rule whose existence violates section 120.54(1)(a) because the agency has not formally adopted the statement. Section 120.54(1)(a) declares that "[r]ulemaking is not a matter of agency discretion" and directs that "[e]ach agency statement defined as a rule by s. 120.52 shall be adopted by the rulemaking procedure provided by this section as soon as feasible and practicable."

26. The statutory term for an informal rule-by-definition is "unadopted rule," which is defined in section 120.52(20) to mean "an agency statement that meets the definition of the term 'rule,' but that has not been adopted pursuant to the requirements of s. 120.54."

27. Section 120.52(16) defines the term "rule" to mean each agency statement of general applicability that implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute or by an existing rule. The term also includes the amendment or repeal of a rule. The

statutory definition excludes several types of agency statements from its operation, but none of these exclusions is applicable here.

28. To be a rule, a statement of general applicability must operate in the manner of a law. Thus, if the statement's effect is to create stability and predictability within its field of operation; if it treats all those with like cases equally; if it requires affected persons to conform their behavior to a common standard; or if it creates or extinguishes rights, privileges, or entitlements, then the statement is a rule. As the First District Court of Appeal explained, the breadth of the definition in section 120.52(1) indicates that the legislature intended the term to cover a great variety of agency statements regardless of how the agency designates them. Any agency statement is a rule if it "purports in and of itself to create certain rights and adversely affect others," State, Department of Administration v. Stevens, 344 So. 2d 290, 296 (Fla. 1st DCA 1977), or serves "by [its] own effect to create rights, or to require compliance, or otherwise to have the direct and consistent effect of law." McDonald v. Dep't of Banking & Fin., 346 So. 2d 569, 581 (Fla. 1st DCA 1977). State Dep't of Admin. v. Harvey, 356 So. 2d 323, 325 (Fla. 1st DCA 1977); see also Jenkins v. State, 855 So. 2d 1219 (Fla. 1st DCA 2003); Amos v. Dep't of Health & Rehabilitative Servs., 444 So. 2d 43, 46 (Fla. 1st DCA 1983).

29. An agency statement is any declaration, expression, or communication. It does not need to be in writing. See Dep't of High. Saf. & Motor Veh. v. Schluter, 705 So. 2d 81, 84 (Fla. 1st DCA 1997). To be a rule, however, the statement or expression must be an "agency statement," that is, a statement which reflects the agency's position with regard to law or policy. Therefore, the offhand comment of an agency employee, without more, is not an "agency statement"; rather, the statement must be "attributable to [the agency's] collegial head . . . or some duly authorized delegate." Id. at 87 (Benton, J., concurring and dissenting); see also, State, Dep't of Admin. v. Stevens, 344 So. 2d 290, 296 (Fla. 1st DCA 1977) (The procedures at issue were "issued by the agency head for implementation by subordinates with little or no room for discretionary modification."). Further, a statement made in error should not ordinarily constitute a rule, unless the agency has actually enforced or implemented the allegedly mistaken statement (in which case it would cease being an erroneous statement, though it might have been such originally). See Filippi v. Dep't of Educ., Case No. 07-4783RU, 2008 Fla. Div. Adm. Hear. LEXIS 700 (Fla. DOAH June 20, 2008).

30. Because the definition of the term "rule" expressly includes statements of general applicability that implement or interpret law, an agency's interpretation of a statute that gives

the statute a meaning not readily apparent from its literal reading and purports to create rights, require compliance, or otherwise have the direct and consistent effect of law, is a rule, but one which simply reiterates a statutory mandate is not. See State Bd. of Admin. v. Huberty, 46 So. 3d 1144, 1147 (Fla. 1st DCA 2010); Beverly Enterprises-Florida, Inc. v. Dep't of Health & Rehabilitative Servs., 573 So. 2d 19, 22 (Fla. 1st DCA 1990); St. Francis Hosp., Inc. v. Dep't of Health & Rehabilitative Servs., 553 So. 2d 1351, 1354 (Fla. 1st DCA 1989).

31. A statement which, by its terms, is limited to a particular person or singular factual situation is not generally applicable, nor is one whose applicability depends on the circumstances. Such ad hoc directives are orders, not rules. By contrast, "general applicability" requires that the scope of the statement -- its field of operation -- be sufficiently encompassing as to constitute a principle; there must be, in other words, a comprehensiveness to the statement, which distinguishes the statement from the more narrowly focused, individualized orders that agencies routinely issue in determining the substantial interests of individual persons. A generally applicable statement purports to affect, not just a single person or singular situations, but a category or class of persons or activities. See McCarthy v. Dep't of Ins., 479 So. 2d 135 (Fla. 2d DCA 1985) (letter prescribing "categoric

requirements" for certification as a fire safety inspector was a rule).

32. To be generally applicable, a statement need not apply universally to every person or activity within the agency's jurisdiction. It is sufficient, rather, that the statement apply uniformly to a class of persons or activities over which the agency may properly exercise authority. See Schluter, 705 So. 2d at 83 (policies that established procedures pertaining to police officers under investigation were said to apply uniformly to all police officers and thus to constitute statements of general applicability); see also Disability Support Serv., Inc. v. Dep't of Child. & Fams., Case No. 97-5104RU, 1997 Fla. Div. Adm. Hear. LEXIS 5331, *11 (Fla. DOAH June 4, 1997) ("[The agency's] arguments equate generally applicable with universally applicable. It is unnecessary for Petitioner to show that the [statements] apply to all parties contracting with [the agency] for the provision of any sort of service or product subject to Medicaid reimbursement. It is enough to show that the [statements] are generally applicable to classes of providers.").

33. On the other hand, if the class of persons or activities is too narrow, a statement pertaining solely to that category might be considered not "generally applicable." For example, in Agency for Health Care Administration v. Custom Mobility, Inc., 995 So. 2d 984 (Fla. 1st DCA 2008), it was

alleged that AHCA's statistical formula for cluster sampling, which the agency used in some cases to calculate Medicaid overpayments, was an unadopted rule. The court found, however, that the formula was not a statement of general applicability because it did not apply to all Medicaid providers, or even to all providers being audited, but rather only to some of the providers being audited. Id. at 986. The category of "all providers being audited using cluster sampling" -- which comprised about ten percent of all auditees -- was too specific to support a finding of general applicability.

34. If in challenging an alleged unadopted rule the petitioner proves at hearing that the agency statement is a rule, the agency then has the burden of overcoming the presumptions that rulemaking was both feasible and practicable.

35. Section 120.54(1)(a)1. provides as follows:

> Rulemaking shall be presumed feasible unless the agency proves that:
> a. The agency has not had sufficient time to acquire the knowledge and experience reasonably necessary to address a statement by rulemaking; or
> b. Related matters are not sufficiently resolved to enable the agency to address a statement by rulemaking.

In this context, therefore, "feasibility" is essentially a ripeness concern. What the agency must show is that the time to make a rule has not yet come.

36. Section 120.54(1)(a)2. provides as follows:

> Rulemaking shall be presumed practicable to the extent necessary to provide fair notice to affected persons of relevant agency procedures and applicable principles, criteria, or standards for agency decisions unless the agency proves that:
> a. Detail or precision in the establishment of principles, criteria, or standards for agency decisions is not reasonable under the circumstances; or
> b. The particular questions addressed are of such a narrow scope that more specific resolution of the matter is impractical outside of an adjudication to determine the substantial interests of a party based on individual circumstances.

37. Section 120.56(4)(c) authorizes the ALJ to enter a final order determining that all or part of a challenged statement violates section 120.54(1)(a). The ALJ is not authorized to decide, however, whether the statement is an invalid exercise of delegated legislative authority as defined in section 120.52(8)(b) through (f). Thus, in a section 120.56(4) proceeding, it is not necessary or even appropriate for the ALJ to decide whether the unadopted rule exceeds the agency's grant of rulemaking authority, for example, or whether it enlarges, modifies, or contravenes the specific provisions of law implemented, or is otherwise "substantively" an invalid exercise of delegated legislative authority.

38. Section 120.56(4) is forward-looking in its approach. It is designed to prevent future or recurring agency action based

on an unadopted rule, not to provide relief from final agency action that has already occurred. Thus, if a violation of section 120.54(1)(a) is found, the agency must, pursuant to section 120.56(4)(d), "immediately discontinue all reliance upon the statement or any substantially similar statement as a basis for agency action." See, e.g., Agency for Health Care Admin. v. HHCI Ltd., 865 So. 2d 593, 596 (Fla. 1st DCA 2004).

39. In order for Petitioner to bring a rule challenge, Petitioner must have standing. In administrative proceedings, standing is a matter of subject matter jurisdiction. Abbott Labs. v. Mylan Pharms., Inc., 15 So. 3d 642, 651 n.2 (Fla. 1st DCA 2009). In order to have standing to challenge an agency statement defined as a rule in a proceeding before an administrative law judge, a person must be "substantially affected" by the statement in question. § 120.56(4)(a), Fla. Stat. ("Any person substantially affected by an agency statement may seek an administrative determination that the statement violates s. 120.54(1)(a).").

40. Generally speaking, the petitioner must show that he or she will suffer an immediate "injury in fact" within the "zone of interest" protected by the statute the challenged unadopted rule is implementing or by other related statutes. See, e.g., Fla. Medical Ass'n, Inc. v. Dep't of Prof'l Reg., 426 So. 2d 1112, 1114 (Fla. 1st DCA 1983). In NAACP, Inc. v. Florida Board of

Regents, 863 So. 2d 294, 300 (Fla. 2003), however, the Florida Supreme Court held that student members of the NAACP who were genuine prospective candidates for admission to a state university were substantially affected by rules which eliminated certain affirmative action policies; thus, they had standing to challenge these rules without showing "immediate and actual harm," such as the rejection of an application for admission.

41. There is "a difference between the concept of 'substantially affected' under section 120.56(1), and 'substantial interests' under section 120.57(1)." Dep't of Prof'l Reg., Bd. of Dentistry v. Fla. Dental Hygienist Ass'n, 612 So. 2d 646, 651 (Fla. 1st DCA 1993). Thus, for example, "decisions in licensing and permitting cases[, which] have made it clear that a claim of standing by third parties based solely upon economic interests is not sufficient unless the permitting or licensing statute itself contemplates consideration of such interests, or unless standing is conferred by rule, statute, or based on constitutional grounds[,]" are not controlling in actions brought under section 120.56. Id.; see also Cole Vision Corp. v. Dep't of Bus. & Prof'l Reg., 688 So. 2d 404, 407 (Fla. 1st DCA 1997) ("[T]his court has recognized that a less demanding standard applies in a rule challenge proceeding than in an action at law, and that the standard differs from the 'substantial interest' standard of a licensure proceeding.").

42. Petitioner has the burden of proving, by a preponderance of the evidence, that the challenged statement or policy has the effect of a rule. Goodman v. Dep't of Banking & Fin., Case No. 00-4920RU (Fla. DOAH Jan. 17, 2001). Under section 120.56(4)(b), once Petitioner has met its burden of proof, the burden shifts to the agency to prove that the rulemaking is not feasible or practicable under section 120.54(1)(a). For the reasons set forth below, Petitioner has proved its standing to bring this challenge to what it describes as unpromulgated rules by Respondent, and has proved that the agency statements complained of herein constitute unpromulgated rules. Finally, Respondent has failed to prove that rulemaking was neither feasible nor practical.

43. As part of its broad jurisdiction, FDEP regulates the activities of generators and transporters of hazardous waste under chapter 62-730. These rules incorporate by reference federal regulations promulgated by the U.S. Department of Environmental Protection (USDEP), found at 40 C.F.R. pt. 260. The federal rules provide requirements for hazardous waste identification, classification, generation, management, and disposal. 40 C.F.R. § 261(2)(b) provides that materials are solid waste if they are abandoned by being: 1) disposed of; 2) burned or incinerated; or 3) accumulated, stored, or treated

(but not recycled) before, or in lieu of, being abandoned by being disposed of, burned, or incinerated.

44. FDEP rule 62-730.186 is entitled "Universal Pharmaceutical Waste" (UPW). The UPW rule provides comprehensive regulations for UPW handlers, including training of personnel. UPW must be contained in appropriately labeled closed containers. Records must be created and maintained which allow other UPW handlers to make knowledgeable decisions about the safe handling or proper disposal of the UPW. Petitioner is prohibited from sending or taking UPW to a place other than to another UPW handler or an approved reverse distributor; a destination facility as defined in 40 C.F.R. § 273.9; or a foreign destination in accordance with the requirements of the rule.

45. Petitioner and other UPW handlers must retain records of any shipment of UPW at their place of business for at least three years from the date of shipment. The record can be a written receipt, manifest, bill of lading, or other written documentation, which must include: a) The name and address of the handler, reverse distributor, destination facility, or foreign destination to which the UPW was sent; b) The quantity of UPW sent; and c) The date the shipment of UPW left the handler's facility.

46. Rule 62-730.186 cites extensively to the applicable federal rules and is intended to ensure that Petitioner and other UPW handlers comply with both the FDEP and USDEP requirements.

47. The UPW rule defines "viable" and "non-viable" pharmaceuticals. A "viable" pharmaceutical is one that 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 61N-1.

48. A non-viable pharmaceutical is defined by rule 62-730.186(4)(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.

49. Rule 62-730.186(4)(e) provides:

> "Hazardous waste pharmaceutical" means 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 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.

50. Rule 62-730.186(4)(j) defines "pharmaceutical reverse distribution system" as the established practice of shipping expired or other unusable 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. Reverse distributors are regulated by Respondent. They must obtain a permit and are subject to "audit trail" documentation requirements under chapter 61N-1. As a part of the audit trail, their records must identify at a minimum the name of the prescription drug product and whether it is a prescription drug sample, the manufacturer, and the quantity for each prescription drug removed from the establishment. Petitioner does not handle any viable drugs for credit or destruction. Petitioner only handles UPW and arranges for UPW's disposal.

51. Petitioner has established with particularity statements and conduct by Respondent that constitute an unpromulgated rule. Respondent asserts, through its expert inspectors, that it has jurisdiction over prescription drugs that have been abandoned and meet the definitions of "solid waste" and "non-viable pharmaceuticals," and have been legally committed to the UPW process in compliance with state and federal rules and regulations. Respondent has accomplished this by deeming all

prescription drugs to continue to be prescription drugs under its jurisdiction until "the nature of the prescription drug is altered or changed in a way that the active ingredient which causes the prescription drug to be a prescription drug is no longer active." Respondent admits that its rules do not contain any similar statement, nor do they contain any definition that addresses how the change or alteration that renders the active ingredient inactive takes place. Respondent's rules do not address the difference between viable and non-viable drugs, nor contain any reference to UPW.

52. Respondent has applied its unpromulgated rule to interpret the definition of "prescription drug" in section 499.003(43) and, by doing so, applies every requirement and definition applicable under chapter 499 to Petitioner. Based upon the unpromulgated rule, Respondent inspected Petitioner, requested "audit trail" documentation applicable to drug wholesalers, and forced the quarantine of non-viable pharmaceuticals that had been legally discarded and committed to the UPW process in compliance with FDEP and USDEP rules and regulations that govern the process. Respondent acknowledged this unpromulgated rule applies not only to Petitioner, but to other UPW handlers, pharmacies, drug wholesalers, and hospitals when considering how to legally dispose of prescription drugs.

Petitioner has proven it is substantially affected by the unpromulgated rule and has standing to initiate this challenge.

53. Section 499.002 provides, in part:

> (1) This part is intended to:
> (a) Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.
> (b) Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.
> (c) Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

54. Respondent admits it is unaware of any federal or Florida law, rule, or regulation similar to its unpromulgated rule, and admits it is without knowledge as to state and federal hazardous waste regulations. Respondent admits it is without knowledge as to how hospitals generate UPW or how partially used drugs are "wasted" during surgical procedures by being discarded into a sealed and properly labeled UPW container. Respondent's unpromulgated rule requires the creation of audit trail documents that are not required to be created during the UPW process and

that could not be reasonably created after the fact by Petitioner.

55. Respondent agrees it is important for regulated entities to know when it considers a drug is no longer under its jurisdiction, and that rules and regulations from other state and federal agencies that address solid waste and UPW may "possibly" have a bearing on chapter 499 and chapter 61N-1. The application of the UPW rule is more than "possibly" relevant here. Respondent has been aware of the UPW rule for years, yet considers it a rule they need not "look at" or "deal with." Respondent's inspectors, experts in pharmaceuticals, should at least have a working knowledge of the UPW rule in order to know in what circumstances and to which entities it applies. Not being trained in UPW or to recognize "non-viable drugs" is not a sufficient excuse for expert investigators to raise when attempting to regulate activity not within their agency's jurisdiction.

56. Section 499.006(2) states that a drug is considered adulterated "[i]f it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health." Respondent's unpromulgated rule produces the illogical result of considering hospitals discarding wasted or non-viable drugs in a sealed and properly labeled UPW container as "possibly" adulterating drugs,

and that licensed UPW handlers may "possibly" be holding adulterated drugs, thereby subjecting them to possible criminal penalties under section 499.0051(12).

57. By the statements it made which have been deemed by the undersigned to be unpromulgated rules, Respondent mistakenly attempted to expand its jurisdiction to include UPW that is regulated by both the FDEP and the USDEP. It did this by determining that drugs contained in UPW might still be considered viable drugs for purposes of its agency regulation under chapter 499. Its attempt to expand its jurisdiction to include UPW in its definitions of "prescription drugs" or "adulterated drugs" was misplaced.

58. Petitioner has met its burden of proof in this proceeding. The statements by Respondent violate section 120.54(1)(a) and constitute an unpromulgated rule. Respondent relies on the unpromulgated rule to assert jurisdiction and control over UPW in a manner that confers standing on Petitioner in this proceeding.

59. In a proceeding brought pursuant to section 120.56(4) to determine a violation of section 120.54(1)(a), if the ALJ issues a final order determining that all or part of an agency statement constitutes an unadopted rule, the agency must "immediately discontinue all reliance upon the statement or any

substantially similar statement as a basis for agency action." § 120.56(4)(d), Fla. Stat.

60. Pursuant to section 120.595(4)(a), when an:

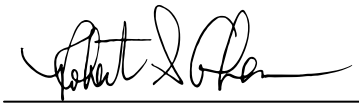
> [A]dministrative law judge determines that . . . an agency statement violates s. 120.54(1)(a) . . . a[n] . . . order shall be entered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that the statement is required by the Federal Government to implement or retain a delegated or approved program or to meet a condition to receipt of federal funds.

Respondent has not made the demonstration required to avoid an order of attorney's fees and costs. Reasonable attorney's fees and costs, to be determined, therefore are hereby entered against Respondent.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED that the conduct and statements by Respondent constitute unpromulgated rules and Respondent shall pay Petitioner's reasonable attorney's fees and costs.

DONE AND ORDERED this 26th day of February, 2015, in Tallahassee, Leon County, Florida.



ROBERT S. COHEN
Administrative Law Judge
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-3060
(850) 488-9675
Fax Filing (850) 921-6847
www.doah.state.fl.us

Filed with the Clerk of the
Division of Administrative Hearings
this 26th day of February, 2015.

COPIES FURNISHED:

Edwin A. Bayó, Esquire
Grossman, Furlow and Bayó, LLC
2022-2 Raymond Diehl Road
Tallahassee, Florida 32308
(eServed)

Bart O. Moore, Esquire
Beth A. Miller, Esquire
Kathryn E. Price, Esquire
Division of Drugs, Devices, and Cosmetics
Department of Business and
Professional Regulation
1940 North Monroe Street, Suite 26A
Tallahassee, Florida 32399
(eServed)

Ken Lawson, Secretary
Department of Business and
Professional Regulation
Northwood Centre
1940 North Monroe Street
Tallahassee, Florida 32399
(eServed)

William N. Spicola, General Counsel
Department of Business and
  Professional Regulation
Northwood Centre
1940 North Monroe Street
Tallahassee, Florida 32399
(eServed)

Reginald D. Dixon, Executive Director
Division of Drugs, Devices, and Cosmetics
Department of Business and
  Professional Regulation
Northwood Centre
1940 North Monroe Street
Tallahassee, Florida 32399
(eServed)

Ernest Reddick, Chief
Alexandra Nam
Department of State
R. A. Gray Building
500 South Bronough Street
Tallahassee, Florida 32399-0250
(eServed)

Ken Plante, Coordinator
Joint Administrative Procedures Committee
Room 680, Pepper Building
111 West Madison Street
Tallahassee, Florida 32399-1400
(eServed)

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original notice of administrative appeal with the agency clerk of the Division of Administrative Hearings within 30 days of rendition of the order to be reviewed, and a copy of the notice, accompanied by any filing fees prescribed by law, with the clerk of the District Court of Appeal in the appellate district where the agency maintains its headquarters or where a party resides or as otherwise provided by law.