

**AGENDA**  
**Department of Business and Professional Regulation**  
**Drug Wholesale Distributor Advisory Council**  
**1940 N. Monroe Street, Board Room**  
**Tallahassee, FL 32399**

**Conference Call Number 888-670-3525**  
**Conference Code 9259887749**

**August 15, 2013**  
**9:30 a.m.**

Council Members:

Gary Cacciatore, Pharm.D., J.D., Chair,  
Primary Prescription Drug Wholesalers  
Mike Ayotte, Vice Chair, Retail Pharmacy  
Albert Garcia, Board of Pharmacy  
Joseph Brecko, Primary Prescription Drug Wholesalers  
Scott Brock, Pharmaceutical Manufacturers  
Jenn Ungru, Agency for Health Care Administration  
Dean Ellis, Secondary Prescription Drug Wholesalers  
William Mahoney, Primary Prescription Drug Wholesalers  
Patrick Barnes, Hospital Pharmacist  
Vacant, Physician

DBPR Staff:

Reggie Dixon, Director,  
Division of Drugs, Devices and Cosmetics Program  
Ken Lawson, Secretary  
Tim Vaccaro, Deputy Secretary  
Robert Jernigan, Compliance Manager  
Dinah Greene, Controlled Substance Reporting  
Rebecca Burnett, Regulatory Supervisor  
Amy Bennett, Office Manager

**Call to Order and Introductions: Gary Cacciatore, Chair**

TAB 1: Approval of Minutes –May 16, 2013 Meeting

TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD  
1. Federal Pedigree – Liz Gallenagh

TAB 3: Executive Director's Report – Reginald Dixon  
1. Rules  
    a. Notice of Proposed Rulemaking  
        61N.1.001 Definitions  
        61N-1.012 Records of Drugs, Cosmetics and Devices  
        61N-1.013 Prescription Drugs; Receipt, Storage and Security  
        61N-1.018 Fees  
2. Senate Bill 284-School Emergencies  
3. Senate Bill 50- Public Meetings  
4. Office Update

TAB 4: Other Business  
1. Proposed 2014 Meeting Dates

## Notice of Meeting/Workshop Hearing

### **DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

#### **Drugs, Devices and Cosmetics**

The Drug Wholesale Distributor Advisory Council announces a public meeting to which all persons are invited.

DATE AND TIME: August 15, 2013, 9:30 a.m.

PLACE: 1940 N. Monroe Street, Tallahassee, FL 32399 - Board Room

Please Note: Conference Call Number: 1(888)670-3525, Conference Code: 9259887749

GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business.

A copy of the agenda may be obtained by contacting: Division of Drugs, Devices and Cosmetics Program office at (850)717-1800 or website at: <http://www.myfloridalicense.com/dbpr/ddc/index.html> seven days prior to meeting date.

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 10 days before the workshop/meeting by contacting: Division of Drugs, Devices and Cosmetics Program, 1940 N. Monroe Street, Tallahassee, FL 32399 or (850)717-1800. 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: Division of Drugs, Devices and Cosmetics Program, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047 or (850)717-1800.

**TAB 1: Approval of Minutes – May 16, 2013**

1 **Drug Wholesale Distributor Advisory Council Meeting**  
2 **May 16, 2013**  
3 **Draft Meeting Minutes**  
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5 **9:30 a.m. Call to Order by Gary Cacciatore, Chair**

6 The meeting was called to order by the Chair, Mr. Cacciatore.  
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9 Roll Call taken by Dinah Greene.  
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11 The following council members were present:

12 Mr. Cacciatore, Mr. Brecko, Mr. Ellis, Mr. Barnes, Mr. Brock, Ms. Ungru.  
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14 Mr. Mike Ayotte, Mr. Albert Garcia and Bill Mahoney were absent.  
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16 A quorum was present  
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18 **Tab 1: Approval of February 12, 2013 Meeting Minutes**

19 The minutes were approved.  
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22 **Motion by:** Mr. Barnes and seconded by Mr. Brecko to approve the minutes.

23 Motion Carried.  
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25 **Tab 2: Chair's Report: Gary Cacciatore, Chair**  
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27 Mr. Cacciatore stated there has been a lot of movement in regards to Federal Pedigree.  
28 Mr. Cacciatore suggested that it be monitored very closely. No action was taken.  
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30 **Tab 3: Executive Director's Report- Reginald Dixon**  
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33 **1. Rules Report:**

- 34 \* Mr. Dixon gave a briefing on the Division's current rulemaking efforts.  
35 The Division will be finalizing language and will forward to the council for review.  
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37 **2. Office Use Compounding:**

- 38 \* Mr. Dixon informed the council that this language was put in the agenda material  
39 for informational purposes only. No action was taken.  
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**3. Final Order Allegations:**

- \* Mr. Dixon stated the council asked for a summary of the Division's allegations at the last meeting. The charts provided in the agenda material show what percentage of cases are being processed and the types.  
No action was taken.

**4. 2013 Legislation**

- \* Mr. Dixon gave a legislative update to the council. He informed the council that the Division has been working on SB 284.  
This would authorize a public school to purchase and maintain a supply of epinephrine auto-injectors.

Mr. Dixon informed the council he would keep them informed as the Division moves forward. No action was taken.

**TAB 4: Other Business**

Mr. Barnes stated he saw a notice that the 340B entity would be required to have a Restricted Drug Wholesale permit. Mr. Barnes asked about the pedigree requirements for this.

Mr. Dixon stated this permit excludes you from pedigree.

Mr. Cacciatore asked if there was any other business or comments.

**Motion by:** Mr. Barnes to adjourn the meeting, second by Mr. Brecko.  
Motion Carried.

**TAB 2: CHAIR'S REPORT- GARY CACCIATORE, PharmD, JD**

**1. Federal Pedigree- Liz Gallenagh**

**Discussion Only**

**TAB 3: DIRECTOR'S REPORT- REGINALD DIXON**

**1. Rules**

**a. Notice of Proposed Rulemaking**

61N-1.001 Definitions

61N-1.012 Records of Drugs, Cosmetics and Devices

61N-1.013 Prescription Drugs, Receipt, Storage and Security

61N-1.018 Fees

**Ken Lawson, Secretary**

**Rick Scott, Governor**

**RULES REPORT**

To: Drug Wholesale Distributor Advisory Council

From: Reginald D. Dixon, Director

Date: July 23, 2013

Re: Division Rulemaking (rev. 7/23/13)

The following chart is a summary of the Division's current rulemaking efforts.

Rule #	Title	Purpose	Current Action	Next Actions
61N-1.001	General Regulations; Definitions	Clear up the definitions of certain terms, as well as to define "limited quantities" as used in ss. 499.01(3) & (4), F.S.	Rule Development filed; language provided to DWDAC	1. DWDAC review & approval 2. Notice Rulemaking
61N-1.012	Records of Drugs, Cosmetics and Devices	Set forth recordkeeping requirements for Florida manufacturers engaging in "limited quantities" of Rx drugs obtained from non-Florida licensed entities.	Rule Development filed; language provided to DWDAC	1. DWDAC review & approval 2. Notice Rulemaking
61N-1.013	Prescription Drugs; Receipt, Storage and Security.	Set forth Rx drug storage requirements for Florida manufacturers engaging in "limited quantities" of Rx drugs obtained from non-Florida licensed entities.	Rule Development filed; language provided to DWDAC	1. DWDAC review & approval 2. Notice Rulemaking
61N-1.015	Licensing, Application, Permitting	Rearrange the rule and to incorporate the new DDC application forms	Language is being drafted by staff.	1. Finalize initial draft 2. File Rule Development
61N-1.018	Fees	Specify fee for restricted Rx drug distributor – blood establishment permit; and for device product registration.	Rule Development filed; language provided to DWDAC	1. DWDAC review & approval 2. Notice Rulemaking
61N-1.023	Restricted Prescription Drug Distributor Permits; Special Provisions	Create/set forth the restricted Rx drug distributor permit; identify Rx drugs these permits can distribute per s. 499.01(2)(g)1.c., F.S.	Language is being drafted by staff.	1. Finalize initial draft 2. File Rule Development

\*\* Rule 61N-1.024 – rule is being challenged as an invalid exercise of delegated legislative authority in DOAH Case No. 13-2559RX; Infupharma, LLC v. Department of Business and Professional Regulation, Drugs, Devices and Cosmetics



**Greene, Dinah**

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**From:** Dixon, Reggie  
**Sent:** Thursday, May 30, 2013 8:47 AM  
**To:** Greene, Dinah  
**Subject:** Florida Drugs, Devices & Cosmetics Rules  
**Attachments:** 61N-1 001 Definitions v3 5-10-13.pdf; 61N-1.018 v1 RDD 4-11-13.pdf

**Council Members:**

At the last council meeting, I provided you all with a Rules report summarizing the Division's efforts at rulemaking. At that time, I did not think that we had noticed any of the rules for development. I was my intent that we would provide those rules to the council for consideration, once we had worked the language internally (within the Division) and had preliminary sign-off internally (within the Department). Through an oversight, on my part, the rule developments for several of the rules that we have been working on, have been recently published in the FAR. These rules are:

61N-1.001 General Regulations; Definitions.  
61N-1.018 Fees.

Although the Notices of Development have been filed with FAR, the draft language was not published. I have attached the draft language with this email. Given that the Notices have been filed, I think that it would be prudent to solicit input from the industry on the proposed changes, to collate the comments, and then to schedule a council meeting to discuss. As such, I have copied this communication to our interested parties list.

Dinah will be contacting you regarding a possible date for a council meeting to discuss the draft language.

Respectfully,

Reginald D. Dixon  
Director  
Division of Drugs, Devices & Cosmetics  
Department of Business & Professional Regulation  
1940 North Monroe Street, Suite 26A  
Tallahassee, Florida 32399-1047  
(850) 717.1800 Main Line  
(850) 717.1172 Direct Line  
(850) 414.8240 Facsimile  
[Reggie.Dixon@myfloridalicense.com](mailto:Reggie.Dixon@myfloridalicense.com)

7/22/2013

## NOTICE OF PROPOSED RULEMAKING

**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION****Division of Professions****RULE NOS.: RULE TITLES:**

61N-1.001 General Regulations; Definitions

61N-1.012 Records of Drugs, Cosmetics and Devices

61N-1.013 Prescription Drugs; Receipt, Storage and Security

**PURPOSE AND EFFECT:** To clarify the definitions of terms set forth in Chapter 499, F.S., and the Division's rules; set forth the records which must be created and maintained by entities in Florida engaging in the possession of limited quantities of prescription drugs, obtained from non-Florida licensed sources, for the purpose of research and development; and set forth the storage requirements for those entities.

**SUMMARY:** The Division proposes the rule amendments to clarify the definitions of terms set forth in Chapter 499, F.S., and the Division's rules; set forth the records which must be created and maintained by entities in Florida engaging in the possession of limited quantities of prescription drugs, obtained from non-Florida licensed sources, for the purpose of research and development; and set forth the storage requirements for those entities.

**SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS:** The agency has determined that these rules 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 rules are 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:** 499.003, 499.01(3), (4), (6), 499.012(12), 499.0121, 499.0122, 499.013, 499.014, 499.024, 499.025(5), 499.03(4), 499.05, 499.052 FS.

**LAW IMPLEMENTED:** 499.028 (6), 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS.

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

**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)488-1802

**THE FULL TEXT OF THE PROPOSED RULE IS:**

61N-1.001 General Regulations; Definitions.

(1) No change.

(2) In addition to definitions contained in Sections 499.003, 499.012(1), 499.0121(6), 499.0122(1), 499.028(1), 499.029(3), and 499.61, F.S., the following definitions apply, to Chapter 499, F.S. and to Rule Chapter 61N-1, F.A.C.:

(a) "Administer" or "administration"-- means the direct application or introduction obtaining and giving of a single dose of drugs by a legally authorized person to or into the body of an individual human or animal a patient, for his consumption whether by injection, inhalation, ingestion or any other means.

(b) No change.

(c) "Authorized absence" -- means, for purposes of Section 499.012(11)(d), F.S., ~~the management or owner of a permitted wholesale establishment has approved in writing in a document that is available for inspection under~~

~~Section 499.051, F.S., at the time of the inspection, the physical absence of the designated representative from the permitted establishment, pursuant to the written policy developed and maintained by the owner or management of the permitted establishment, for a cumulative period not to exceed 60 calendar days in any 12-month period for situations such as: the birth of the employee's child and to care for the newborn child; the placement of a child with the employee for adoption or foster care; the care of a family member (child, spouse, or parent) with a serious health condition, where the employee is needed to care for the a-family member (child, spouse or parent) with a serious health condition; or the employee's own serious health condition makes the employee unable to perform the functions of the designated representative.~~

(d) "Authorized recipient" – means a person permitted by or otherwise authorized by Florida law, or by the law of the jurisdiction in which the person receives the prescription drugs, Chapter 499, F.S., to purchase, receive or possess those prescription drugs; ~~The term includes:~~

~~1. Any a pharmacy licensed under by Chapter 465, F.S., and authorized under that chapter to possess non-dispensed prescription drugs; except a Class I Institutional Pharmacy since it is only authorized to possess dispensed prescription drugs and medical oxygen for administration to its patients;~~

~~2. Any a practitioner licensed by Florida law to purchase and receive prescription drugs; or a person who is authorized by the law of the jurisdiction where the delivery occurs to purchase, own, receive, and/or possess those prescription drugs; and~~

~~3. A licensed ship captain, or first officer, or designated medical officer for a vessel engaged in international or interstate trade or for or in trade between ports of the United States and any merchant vessel belonging to the U.S. Government, The is an authorized recipient for prescription drugs must be intended solely for emergency medical purposes, and the wholesale distributor must deliver provided the prescription drugs are delivered by the wholesaler directly to the ship/vessel or transfer possession to the appropriate ship's/vessel's officer as near to the ship/vessel as state and federal laws allow.~~

(e) "Broker" – means a person participating in a prescription drug the wholesale distribution by performing all of the following activities without taking physical possession of the drug:

(i) buying, purchasing, or otherwise taking ownership of or title to the drug;

(ii) selling or transferring, or offering to sell or transfer, ownership of or title to the drug; and

(iii) to a person other than the patient or the patient's agent.

~~of a prescription drug that buys and sells the drug but does not take physical possession such that the drug is "sold to" the broker and "shipped to" a third party.~~

(f) through (m) No change.

(n) "Limited quantities" – pursuant to Section 499.01(3) and(4)(b), F.S., means:

1. Nonclinical/Preclinical – For purposes of nonclinical (not involving the actual use of the product in or on humans or other animals) and preclinical (involving animal use but not human) research and development ("R&D") activities, the number of transactions necessary to advance the program to the clinical stage, provided that the researcher may not acquire or have on hand more than a three-month supply of any product based on forecasts set forth in R&D records created in advance of or contemporaneously with the R&D activities.

2. Clinical – For purposes of clinical trials and biostudies approved by FDA, including filed Investigational New Drug applications (an "IND") and studies exempt from IND regulations under 21 C.F.R. s. 312.2 (effective 01/01/13), the researcher may engage in the number of transactions necessary to obtain (i) clearance to advance to the next clinical phase of FDA's approval process (Phase 1 to Phase 2 or Phase 2 to Phase 3), or (ii) for Phase 3 studies, final FDA approval, provided that the researcher may not acquire or have on hand more than a six-month supply of any product based on forecasts set forth in R&D records created contemporaneously with the R&D activities.

~~(o)(n)~~ "Pedigree" – means a document that satisfies the requirements of Section 499.003(31)(a) or (b), F.S., as applicable, and the applicable rule requirements of subsection 61N-1.012(3), F.A.C., and any forms adopted therein.

~~(p)(e)~~ "Point of origin" – means the location from which the manufacturer transfers title, and the location from which the manufacturer transfers possession, if different, of the specific unit of the prescription drug being transferred or sold.

~~(q)(p)~~ "Practitioner" means a person who is duly licensed and authorized by laws of the state to administer, prescribe, or dispense, as appropriate, a drug or device for medical purposes.

(r) "Principal address" – means, as used in Section 499.0121(6), F.S. and any permit application submitted to the department under Chapter 499, F.S., the person's primary place of business.

(s)(a) "Product" – anything produced or made either naturally or artificially.

(t)(e) "Propagation" of a drug – means, as used under the definition of "manufacture" at Section 499.003(27), F.S., for purposes of permitting under Section 499.013, F.S., the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA) or a New Animal Drug Application (NADA), provided that such application has become effective or is otherwise approved consistent with Section 499.023, F.S.; a private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distribution point for the manufacturer, contract manufacturer or private label distributor whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site.

(u)(e) "Provides prescription services to the public" – means, for the purposes of the retail pharmacy wholesaler permit, holding the pharmacy out to the public through prominently displayed pharmacy signs on the exterior of the building and adequate inventory on hand to fill a variety of prescriptions for a variety of medical conditions that would be required by the public generally.

(v)(e) "Readily available" and "readily retrievable" mean that records, either hard copy or computerized, are organized in such a manner that they can be quickly and easily retrieved during an inspection; individual records can be produced within minutes of the request (unless the permitted address is not within the state in which case a 48 hour timeframe is available for producing records). Required records that are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems are kept in such a manner so that they can be separated out from all other records in a reasonable time.

(w)(u) "Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution" means:

1. Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1000 to bottles of 100.

2. Altering a manufacturer's package for sale under a label different from the manufacturer. For example, a medical convenience kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D packaged together and marketed as an immunization kit under a label of manufacturer Z.

3. Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product. This does not include:

a. Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in multiple units, or

b. Selling or transferring a fully labeled individual unit, by adding the package insert, by a person authorized to distribute prescription drugs to an institutional pharmacy permit, health care practitioner or emergency medical service provider for the purpose of administration and not for dispensing or further distribution.

(x)(v) "Rx" – means prescription.

(y)(w) "Sale" – includes any transfer of title or ownership whether by barter, exchange or gift.

(z)(e) "Separate and distinct cosmetic product" – means a cosmetic product for that establishment which is, or will be sold, distributed, or given away. The adding of color, flavor, or scents does not make a separate and distinct cosmetic product for each variation.

(aa)(y) "Separate and distinct device product" – means a device product in its finished form for that manufacturer which is, or will be sold, distributed, or given away. The function or use of the device determines whether a device is separate and distinct.

(bb)(z) "Separate and distinct drug product" – means a drug product in the finished form and strength for that manufacturer which is, or will be sold, distributed or given away.

(cc)(aa) "Specific unit of a prescription drug" – means the individual saleable unit of a specific prescription drug being transferred or sold, which is capable of being serialized to contain its own serial number, which drug is identified by name, strength, dosage form, container size, and lot number.

(bb) "Specified drug" – means all dosage forms, strengths and container sizes of the following prescription drugs:

1. Bextra (valdecoxib);
2. Celebrex (celecoxib);
3. Combivir (lamivudine/zidovudine);
4. Crivivan (indinavir sulfate);
5. Diflucan (fluconazole);
6. Epivir (lamivudine);
7. Epogen (epoetin alfa);
8. Gamimune (globulin, immune);
9. Gamagard (globulin, immune);
10. Immune globulin;
11. Lamisil (terbinafine);
12. Lipitor (atorvastatin calcium);
13. Lupron (leuprolide acetate);
14. Neupogen (filgrastim);
15. Nutropin AQ (somatropin, e-coli derived);
16. Panglobulin (globulin, immune);
17. Procrit (epoetin alfa);
18. Retrovir (zidovudine);
19. Risperdal (risperidone);
20. Rocephin (ceftriaxone sodium);
21. Serostim (somatropin, mammalian derived);
22. Sustiva (efavirenz);
23. Trizivir (abacavir sulfate/lamivudine/zidovudine);
24. Venoglobulin (globulin, immune);
25. Viagra (sildenafil citrate);
26. Videx (didanosine);
27. Viracept (nelfinavir mesylate);
28. Viramune (nevirapine);
29. Zerit (stavudine);
30. Ziagen (abacavir sulfate);
31. Zocor (simvastatin);
32. Zofran (ondansetron);
33. Zoladex (goserelin acetate); and
34. Zyprexa (olanzapine).

~~(dd)~~(ee) "State Current Good Manufacturing Practices" means current good manufacturing practices and quality system regulations as prescribed as of 1/1/01 in Title 21 Code of Federal Regulations, Parts 210, 211, 600-610, and 820, and the federal guidelines which are incorporated by reference herein and made a part of this rule, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the guidelines for manufacturing cosmetics as set forth in Rule 61N-1.010, F.A.C.

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

~~(ff)~~(ee) "Usual course of business as carriers" – means for purposes of commercial airlines, the purchase, receipt, distribution and storage of prescription drugs for emergency medical reasons, which includes:

1. The transportation of a prescription drug aboard a commercial aircraft where the drug is required by 14 CFR Section 121.803 (and appendix A to 14 CFR part 121), to be on board the aircraft as part of an approved emergency medical kit; and,

2. The purchase of the prescription drug by the commercial airline, and receipt of the prescription drug by the commercial airline at an establishment operated by the airline, provided that, the prescription drug is sold and provided to the commercial airline by a person and establishment that is licensed to engage in wholesale distribution of prescription drugs. The recordkeeping requirements of subsections 61N-1.012(1), (2), F.A.C., apply to all

distributions of prescription drugs under this sub-sub paragraph. In all such distributions to commercial airlines, the recipient's license number shall be the registration number assigned to the carrier by the Federal Aviation Administration.

~~(gg)(ff)~~ "Valid client-veterinarian relationship" – means one in which (1) a veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client (the owner or other caretaker of the animal or animals) has agreed to follow the instructions of the veterinarian; (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

~~(hh)(gg)~~ "Verifiable account" – means a number issued by the manufacturer to a wholesaler when the wholesaler sets up an account with the manufacturer for the purchase of a prescription drug from that manufacturer that uniquely identifies the wholesaler and that is to be used on a recurring basis.

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

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

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

*Rulemaking Authority 499.003(31), 499.024, 499.025(5), 499.01(6), 499.0121(6), 499.0122(2), 499.012(12), 499.013(3), 499.014(5), 499.03(4), 499.05 FS. Law Implemented 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS. History—New 1-1-77, Amended 12-12-82, 1-30-85, Formerly 10D-45.31, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.031, Amended 1-26-99, 4-17-01, 6-30-03, 10-7-03, 1-1-04, 1-29-04, 5-29-05, 1-19-06, 2-14-06, 8-6-06, 12-27-07, Formerly 64F-12.001, Amended \_\_\_\_\_.*

#### 61N-1.012 Records of Drugs, Cosmetics and Devices.

(1) through (16) No change.

(17) For purposes of prescription drugs obtained in "limited quantities" for research and development ("R&D") purposes under Section 499.01(3) and (4)(b), F.S. and paragraph 61N-1.001(2)(n), F.A.C., the required records must forecast, identify and schedule the acquisition and use of each such drug relative to anticipated and ongoing R&D activities. These records must be created in advance of or contemporaneously with the particular R&D activities, and are subject to inspection under Section 499.051, F.S. Nonclinical/preclinical R&D quantity forecasts must be updated at least monthly, and clinical R&D quantity forecasts must be updated at least quarterly. These records must account for all product acquired and consumed in R&D activities, and the researcher must ensure that none of the product acquired for R&D is used in any clinical (for use on or in humans) context or setting. The researcher must maintain all other records required under Chapter 499, including, without limitation, Section 499.01(3) or (4)(b), and applicable federal laws.

*Rulemaking Authority 499.003, 499.01(2)(g), 499.05, 499.0121 FS. Law Implemented 499.01, 499.003, 499.012, 499.0121, 499.01212, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 FS. History—New 1-1-77, Amended 12-12-82, 7-8-84, 1-30-85, Formerly 10D-45.53, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.053, Amended 1-26-99, 4-17-01, 10-7-03, 1-1-04, 6-15-04, 8-2-04, 1-19-06, 8-6-06, Formerly 64F-12.012, Amended 3-4-13, \_\_\_\_\_.*

#### 61N-1.013 Prescription Drugs; Receipt, Storage and Security.

(1) through (2) No change.

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

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

1. through 2. No change.

3. Prescription drugs obtained in "limited quantities" for research and development ("R&D") purposes under Section 499.01(3) and(4)(b), F.S. and paragraph 61N-1.001(2)(n), F.A.C., must be physically segregated from all other products intended for manufacturing, compounding, dispensing or administration. In a manufacturer's establishment, these drugs must also be stored and maintained in a separate and clearly designated area.

(4) through (7) No change.

*Rulemaking Authority 499.0121(1), 499.05 FS. Law Implemented 499.004, 499.006, 499.007, 499.0121, 499.028(6), 499.052 FS. History--New 7-8-84, Amended 1-30-85, Formerly 10D-45.535, Amended 11-26-86, 7-1-96, Formerly 10D-45.0535, Amended 1-26-99, 4-17-01, 1-1-04, 1-19-06, 11-18-07, Formerly 64F-12.013, Amended \_\_\_\_\_.*

NAME OF PERSON ORIGINATING PROPOSED RULE: 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)488-1802

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary, Department of Business and Professional Regulation

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 28, 2013

DATE THE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: May 20, 2013

**61N-1.018 Fees.**

(1) Biennial fees for a MANUFACTURER or REPACKAGER permit are as follows:

	Biennial Fee
Prescription Drug Manufacturer	\$1500
Prescription Drug Repackager	\$1500
Device Manufacturer	\$1200
Cosmetic Manufacturer	\$800
Over-the Counter Drug Manufacturer	\$800
Compressed Medical Gas Manufacturer	\$1000
Non-resident Prescription Drug Manufacturer	\$1000

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

(2)(a) Biennial fees for a WHOLESALE DISTRIBUTOR or FREIGHT FORWARDER permit that is issued on a BIENNIAL basis are as follows:

	Biennial Fee
Compressed Medical Gas Wholesale Distributor	\$600
Retail Pharmacy Drug Wholesale Distributor	\$100
Freight Forwarder	\$600
Veterinary Prescription Drug Wholesale Distributor	\$1000
Limited Prescription Drug Veterinary Wholesale Distributor	\$1000

(b) Annual fees for a WHOLESALE DISTRIBUTOR permit that is issued on an ANNUAL basis are as follows:

	Annual Fee
Prescription Drug Wholesale Distributor (including Broker Only)	\$800
Out-of-State Prescription Drug Wholesale Distributor	\$800

(3) Biennial fees for OTHER permits are as follows:

	Biennial Fee
Complimentary Drug Distributor	\$500
Veterinary Prescription Drug Retail Establishment	\$600
Medical Oxygen Retail Establishment	\$600
<u>Restricted Prescription Drug Distributor – Blood Establishment</u>	<u>\$600</u>
Restricted Prescription Drug Distributor – Health Care Entity	\$600
Restricted Prescription Drug Distributor – Charitable Organization	\$600
Restricted Prescription Drug Distributor – Reverse Distributor	\$600
Restricted Prescription Drug Distributor – Destruction	\$600
Restricted Prescription Drug Distributor – Government Programs	\$600
Restricted Prescription Drug Distributor – Institutional Research	\$600
Third Party Logistics Provider	\$600
Health Care Clinic Establishment	\$255

(4) Miscellaneous OTHER fees are as follows:

	Fee
(a) Certification as Designated Representative	\$150
(b) Initial Application/On-site Inspection	\$150 Non-Refundable

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



If the department determines it must re-inspect for an initial application because the applicant does not have security, climate control, a quarantine area, or written policies and procedures, as required by the particular permit for which the applicant is applying; fails to appear for a scheduled inspection; or is otherwise not ready or available for inspection or available to schedule an inspection on or after the date indicated on the application form, an additional on-site inspection fee of \$150 is required for each re-inspection.

(c) Bond/Security: Prescription Drug Wholesale Distributor \$100,000  
or Out-of-State Prescription Drug Wholesale Distributor,  
as set forth in Section 499.01(2)(d), (e), F.S.

(d) Bond/Security: Limited Prescription Drug Veterinary Wholesale, as set forth in Section 499.01(2)(l), F.S. \$20,000

(e) Change of Address:

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

(f) Product Registration (for each drug, device or cosmetic product registered) \$30\*

\* The registration fee for a prescription drug, device or cosmetic product being amended to an existing product registration that has 12 months or less until it expires is \$15.

(g) Listed Identical Products \$15

(h) Free Sale Certificate \$25

Signature of Free Sale Certificate copy (requested concurrently) \$2

(i) Delinquent Establishment Permit Renewal (per permit) \$100

(5) The department shall assess other fees as provided in Chapter 499, Part I, F.S.

*Rulemaking Authority 499.01, 499.04, 499.05 FS. Law Implemented 499.01, 499.012, 499.015, 499.04, 499.041, 499.05, 499.028 FS. History—New 7-1-96, Formerly 10D-45.0544, Amended 4-17-01, 7-6-03, 1-1-04, 9-13-04, 2-14-06, 9-5-07, 3-10-09, Formerly 64F-12.018, \_\_\_\_\_.*

**TAB 3: DIRECTOR'S REPORT- REGINALD DIXON**

**Industry Comments**

Dinah, I am not sure if this is correct forum but I wanted to raise an issue with the definition related to Good manufacturing practice. The definition as written uses a 1/1/01 date for the GMP's. The FDA is constantly review these and from time to time publishing changes to the GMP's.

The language per the proposed Florida rule is

(ddcc) —State Current Good Manufacturing Practices□ means current good manufacturing practices and quality system regulations as prescribed as of 1/1/01 in Title 21 Code of Federal Regulations, Parts 210, 211, 600-610, and 820, and the federal guidelines which are incorporated by reference herein and made a part of this rule, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the guidelines for manufacturing cosmetics as set forth in Rule 61N-1.010, F.A.C.

I would like to ask that the definition be modified from "as prescribed as of 1/1/01" to "as CURRENTLY prescribed" then delete "as of 1/1/01".

Thanks

Steve Miller  
Air Liquide USA

850-577-6954

TIM.CERIO@GRAY-ROBINSON.COM

June 28, 2013

**TRANSMITTAL VIA E-MAIL AND HAND-DELIVERY**

Ms. Dinah Greene, C.P.N.  
Division of Drugs, Devices and Cosmetics  
Department of Business and Professional Regulation  
1940 North Monroe Street, Ste. 26A  
Tallahassee, FL 32399-1047

Re: Comments to Notice of Proposed Rulemaking Regarding Rules 61N-1.001  
and 61N-1.012

Dear Ms. Greene:

Thank you for the opportunity to comment on the proposed amendments to Rules 61N-1.001 and 61N-1.012. Our law firm represents Watson Laboratories, Inc.-Florida ("Watson"). Watson's ultimate parent, Actavis, Inc., operates in 62+ countries, serves over 5 billion customers, and is the third-largest generic manufacturer in the world. Actavis has publicly announced plans to invest over \$40 million to expand its manufacturing and warehousing operations in Florida. Indeed, R&D and manufacturing operations critical to the continued success of Actavis, Inc. are housed under Watson, which employs approximately 1,250 Floridians in three facilities in Broward County.

Over the last several years Actavis, Inc. and Watson have worked hard to establish strong relationships with Florida stakeholders, as well as its regulator, the Drugs, Devices and Cosmetics ("DDC") Program. Watson was actively involved in passing legislation creating the limited permit and pedigree exemptions at issue in this rule development. These exemptions were meant to enhance and facilitate research and development of generic pharmaceuticals in Florida, while still protecting the public from harmful or adulterated drug product. They are found in Florida Statute Sections 499.01(3) and 499.01(4)(b), and provide license and pedigree exemptions for the distribution of "limited quantities" of active pharmaceutical ingredient ("API") and finished product, respectively, for R&D purposes.

Ms. Dinah Greene, C.P.N.  
June 28, 2013  
Page 2

## I. Amendments to Rule 61N-1.001

The Department proposes to define limited quantities in Rule 61N-1.001 as follows:

(n) "Limited quantities" – pursuant to Section 499.01(3) and(4)(b), F.S., means:

1. Nonclinical/Preclinical – For purposes of nonclinical (not involving the actual use of the product in or on humans or other animals) and preclinical (involving animal use but not human) research and development ("R&D") activities, the number of transactions necessary to advance the program to the clinical stage, provided that the researcher may not acquire or have on hand more than a three-month supply of any product based on forecasts set forth in R&D records created in advance of or contemporaneously with the R&D activities.

2. Clinical – For purposes of clinical trials and biostudies approved by FDA, including filed Investigational New Drug applications (an "IND") and studies exempt from IND regulations under 21 C.F.R. s. 312.2 (effective 01/01/13), the researcher may engage in the number of transactions necessary to obtain (i) clearance to advance to the next clinical phase of FDA's approval process (Phase 1 to Phase 2 or Phase 2 to Phase 3), or (ii) for Phase 3 studies, final FDA approval, provided that the researcher may not acquire or have on hand more than a six-month supply of any product based on forecasts set forth in R&D records created contemporaneously with the R&D activities.

**It is critical the DDC Program understand that the proposed definition of limited quantities will inhibit the ability of Watson, and other drug manufacturers with operations in Florida, to compete against similar companies located in other states and around the world.** Although it appears the DDC Program intended to allow flexibility in the importation of drug product for R&D purposes by limiting quantities purchased to that needed for a particular timeframe, the rule as drafted will serve as an impediment.

For nonclinical and preclinical research and development, a manufacturer may only import a 3-month supply of drug product. For the clinical phase of research and development, a manufacturer may only import a 6-month supply. By necessity, companies engaging in research and development of generic drugs must move quickly

Ms. Dinah Greene, C.P.N.  
June 28, 2013  
Page 3

and aggressively in order to compete in the marketplace. Oftentimes this race results in drug manufacturers filing an Abbreviated New Drug Application the very day that a name brand product is launched.

Importantly, at the beginning of the R&D process, generic manufacturers will almost always order the entire amount of drug substance/product needed for all phases of R&D. This happens for two reasons: (1) if only part of the needed drug substance/product is purchased, a subsequent shortage in product would bring the entire R&D process to a halt; and (2) if drug substance/product is ordered in batches, and a competing generic manufacturer learns of the orders, the competitor will often attempt to buy up the remaining available volume – this is a well-known tactic in the industry. Accordingly, the rule as drafted would have the unintended effect of codifying a competitive disadvantage in the marketplace for generic manufacturers engaging in R&D in the State of Florida.

We suggest that the proposed rule be amended to allow manufacturers to import the entire amount of drug substance/product needed to engage in specific R&D for a particular generic product. Accordingly, we respectfully offer the following alternative:

(n) “Limited quantities” – pursuant to Section 499.01(3) and (4)(b), F.S., means the number of transactions necessary for R&D purposes and/or to obtain a final FDA approval and/or approval from an equivalent foreign regulatory authority, based on requirements set forth in R&D records created contemporaneously with the R&D activities.

This proposed alternative definition of “limited quantities” will ensure Florida manufacturers engaging in R&D remain vibrant and competitive in the marketplace. Furthermore, the DDC Program remains empowered to police the integrity of the drug supply and maintain the safety of the public because these same manufacturers must still adhere to, recordkeeping, and product segregation requirements set forth in Florida Statutes Chapter 499 and Rule Chapter 61N-1.

## **II. Amendments to Rule 61N-1.012**

The Department proposes to add a paragraph (17) to Rule 61N-1.012, which reads as follows:

61N-1.012 Records of Drugs, Cosmetics and Devices.

Ms. Dinah Greene, C.P.N.

June 28, 2013

Page 4

(1) through (16) No change.

(17) For purposes of prescription drugs obtained in “limited quantities” for research and development (“R&D”) purposes under Section 499.01(3) and (4)(b), F.S. and paragraph 61N-1.001(2)(n), F.A.C., the required records must forecast, identify and schedule the acquisition and use of each such drug relative to anticipated and ongoing R&D activities. These records must be created in advance of or contemporaneously with the particular R&D activities, and are subject to inspection under Section 499.051, F.S. Nonclinical/preclinical R&D quantity forecasts must be updated at least monthly, and clinical R&D quantity forecasts must be updated at least quarterly. These records must account for all product acquired and consumed in R&D activities, and the researcher must ensure that none of the product acquired for R&D is used in any clinical (for use on or in humans) context or setting. The researcher must maintain all other records required under Chapter 499, including, without limitation, Section 499.01(3) or (4)(b), and applicable federal laws.

We respectfully offer the following alternative:

(17) For purposes of prescription drugs obtained in “limited quantities” for research and development (“R&D”) purposes under Section 499.01(3) and (4)(b), F.S. and paragraph 61N-1.001(2)(n), F.A.C., the required records must identify the requirements and schedule the acquisition and use of each such drug relative to anticipated and ongoing R&D activities. These records must be created in advance of or contemporaneously with the particular R&D activities, and are subject to inspection under Section 499.051, F.S. R&D quantities for all phases must be updated at least annually. The researcher must maintain all other records required under Chapter 499, including, without limitation, Section 499.01(3) or (4)(b), and applicable federal laws.

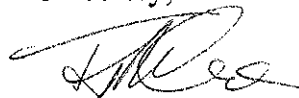
It is critically important that any confidential R&D documents obtained by the DDC Program pursuant to its inspection authority under Florida Statute Section 499.051 remain confidential and exempt from disclosure under Chapter 119 as trade secret information. We believe Section 499.051 clearly provides such protection but its importance cannot be stressed enough, and we urge the DDC Program to ensure that its inspectors and attorneys are adequately trained on this subject matter. The inadvertent,

Ms. Dinah Greene, C.P.N.  
June 28, 2013  
Page 5

improper disclosure of confidential, trade secret R&D-related information could cost a Florida company millions of dollars.

Thank you for the opportunity to provide comments to the proposed rule amendments. We look forward to continuing to participate in this important process.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. Cerio', with a stylized flourish at the end.

Timothy M. Cerio

TMC/jfl



**TAB 3: DIRECTOR'S REPORT- REGINALD DIXON**

2. Senate Bill 284- School Emergencies

## CHAPTER 2013-63

### Committee Substitute for Senate Bill No. 284

An act relating to school emergencies; amending s. 1006.07, F.S.; requiring district school board policies to list the emergency response agencies that are responsible for notifying the school district of emergencies; amending s. 1002.20, F.S.; authorizing a public school to purchase and maintain a supply of epinephrine auto-injectors; requiring that the school district adopt a protocol developed by a licensed physician for the administration of epinephrine auto-injectors for emergency use when a student is having an anaphylactic reaction; providing that the supply of epinephrine auto-injectors may be provided to and used by a student authorized to self-administer epinephrine by auto-injector or trained school personnel; providing that a school district and its employees and agents, including a physician providing a standing protocol for school epinephrine auto-injectors, are not liable for an injury to a student arising from the use of an epinephrine auto-injector under certain circumstances; amending s. 1002.42, F.S.; requiring the emergency response agencies to notify private schools in the school district of emergencies under certain circumstances; authorizing a private school to purchase and maintain a supply of epinephrine auto-injectors; requiring that the private school adopt a protocol developed by a licensed physician for the administration of epinephrine auto-injectors for emergency use when a student is having an anaphylactic reaction; providing that the supply of epinephrine auto-injectors may be provided to and used by a student authorized to self-administer epinephrine by auto-injector or trained school personnel; providing that a private school and its employees and agents, including a physician providing a standing protocol for school epinephrine auto-injectors, are not liable for an injury to a student arising from the use of an epinephrine auto-injector under certain circumstances; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (4) of section 1006.07, Florida Statutes, is amended to read:

1006.07 District school board duties relating to student discipline and school safety.—The district school board shall provide for the proper accounting for all students, for the attendance and control of students at school, and for proper attention to health, safety, and other matters relating to the welfare of students, including:

(4) **EMERGENCY DRILLS; EMERGENCY PROCEDURES.—**

(a) Formulate and prescribe policies and procedures for emergency drills and for actual emergencies, including, but not limited to, fires, natural disasters, and bomb threats, for all the public schools of the district which

comprise grades K-12. District school board policies shall include commonly used alarm system responses for specific types of emergencies and verification by each school that drills have been provided as required by law and fire protection codes. The emergency response agency that is responsible for notifying the school district for each type of emergency must be listed in the district's emergency response policy.

(b) ~~The district school board shall~~ Establish model emergency management and emergency preparedness procedures, including emergency notification procedures pursuant to paragraph (a), for the following life-threatening emergencies:

1. Weapon-use and hostage situations.
2. Hazardous materials or toxic chemical spills.
3. Weather emergencies, including hurricanes, tornadoes, and severe storms.
4. Exposure as a result of a manmade emergency.

Section 2. Paragraph (i) of subsection (3) of section 1002.20, Florida Statutes, is amended to read:

1002.20 K-12 student and parent rights.—Parents of public school students must receive accurate and timely information regarding their child's academic progress and must be informed of ways they can help their child to succeed in school. K-12 students and their parents are afforded numerous statutory rights including, but not limited to, the following:

(3) HEALTH ISSUES.—

(i) *Epinephrine use and supply.*—

1. A student who has experienced or is at risk for life-threatening allergic reactions may carry an epinephrine auto-injector and self-administer epinephrine by auto-injector while in school, participating in school-sponsored activities, or in transit to or from school or school-sponsored activities if the school has been provided with parental and physician authorization. The State Board of Education, in cooperation with the Department of Health, shall adopt rules for such use of epinephrine auto-injectors that shall include provisions to protect the safety of all students from the misuse or abuse of auto-injectors. A school district, county health department, public-private partner, and their employees and volunteers shall be indemnified by the parent of a student authorized to carry an epinephrine auto-injector for any and all liability with respect to the student's use of an epinephrine auto-injector pursuant to this paragraph.

2. A public school may purchase from a wholesale distributor as defined in s. 499.003 and maintain in a locked, secure location on its premises a supply of epinephrine auto-injectors for use if a student is having an

anaphylactic reaction. The participating school district shall adopt a protocol developed by a licensed physician for the administration by school personnel who are trained to recognize an anaphylactic reaction and to administer an epinephrine auto-injection. The supply of epinephrine auto-injectors may be provided to and used by a student authorized to self-administer epinephrine by auto-injector under subparagraph 1. or trained school personnel.

3. The school district and its employees and agents, including the physician who provides the standing protocol for school epinephrine auto-injectors, are not liable for any injury arising from the use of an epinephrine auto-injector administered by trained school personnel who follow the adopted protocol and whose professional opinion is that the student is having an anaphylactic reaction:

a. Unless the trained school personnel's action is willful and wanton;

b. Notwithstanding that the parents or guardians of the student to whom the epinephrine is administered have not been provided notice or have not signed a statement acknowledging that the school district is not liable; and

c. Regardless of whether authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced registered nurse practitioner.

Section 3. Subsections (16) and (17) are added to section 1002.42, Florida Statutes, to read:

1002.42 Private schools.—

(16) EMERGENCY PROCEDURES.—The emergency response agencies identified in a district school board's emergency response policy pursuant to s. 1006.07(4) which are responsible for notifying the school district of an occurrence that threatens student safety shall also notify private schools in the district that request such notification by opting into the district school board's emergency notification procedures.

(17) EPINEPHRINE SUPPLY.—

(a) A private school may purchase from a wholesale distributor as defined in s. 499.003 and maintain in a locked, secure location on its premises a supply of epinephrine auto-injectors for use if a student is having an anaphylactic reaction. The participating private school shall adopt a protocol developed by a licensed physician for the administration by private school personnel who are trained to recognize an anaphylactic reaction and to administer an epinephrine auto-injection. The supply of epinephrine auto-injectors may be provided to and used by a student authorized to self-administer epinephrine by auto-injector under s. 1002.20(3)(i) or trained school personnel.

(b) The private school and its employees and agents, including the physician who provides the standing protocol for school epinephrine auto-

injectors, are not liable for any injury arising from the use of an epinephrine auto-injector administered by trained school personnel who follow the adopted protocol and whose professional opinion is that the student is having an anaphylactic reaction:

1. Unless the trained school personnel's action is willful and wanton;

2. Notwithstanding that the parents or guardians of the student to whom the epinephrine is administered have not been provided notice or have not signed a statement acknowledging that the school district is not liable; and

3. Regardless of whether authorization has been given by the student's parents or guardians or by the student's physician, physician's assistant, or advanced registered nurse practitioner.

Section 4. This act shall take effect July 1, 2013.

Approved by the Governor May 30, 2013.

Filed in Office Secretary of State May 30, 2013.

**TAB 3: DIRECTOR'S REPORT- REGINALD DIXON**

3. Senate Bill 50 – Public Meetings

CHAPTER 2013-227

Committee Substitute for  
Committee Substitute for Senate Bill No. 50

An act relating to public meetings; creating s. 286.0114, F.S.; defining "board or commission"; requiring that a member of the public be given a reasonable opportunity to be heard by a board or commission before it takes official action on a proposition; providing exceptions; establishing requirements for rules or policies adopted by the board or commission; providing that compliance with the requirements of this section is deemed to have occurred under certain circumstances; providing that a circuit court has jurisdiction to issue an injunction under certain circumstances; authorizing a court to assess reasonable attorney fees in actions filed against a board or commission; providing that an action taken by a board or commission which is found in violation of this section is not void; providing that the act fulfills an important state interest; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 286.0114, Florida Statutes, is created to read:

286.0114 Public meetings; reasonable opportunity to be heard; attorney fees.—

(1) For purposes of this section, "board or commission" means a board or commission of any state agency or authority or of any agency or authority of a county, municipal corporation, or political subdivision.

(2) Members of the public shall be given a reasonable opportunity to be heard on a proposition before a board or commission. The opportunity to be heard need not occur at the same meeting at which the board or commission takes official action on the proposition if the opportunity occurs at a meeting that is during the decisionmaking process and is within reasonable proximity in time before the meeting at which the board or commission takes the official action. This section does not prohibit a board or commission from maintaining orderly conduct or proper decorum in a public meeting. The opportunity to be heard is subject to rules or policies adopted by the board or commission, as provided in subsection (4).

(3) The requirements in subsection (2) do not apply to:

(a) An official act that must be taken to deal with an emergency situation affecting the public health, welfare, or safety, if compliance with the requirements would cause an unreasonable delay in the ability of the board or commission to act;

(b) An official act involving no more than a ministerial act, including, but not limited to, approval of minutes and ceremonial proclamations;

(c) A meeting that is exempt from s. 286.011; or

(d) A meeting during which the board or commission is acting in a quasi-judicial capacity. This paragraph does not affect the right of a person to be heard as otherwise provided by law.

(4) Rules or policies of a board or commission which govern the opportunity to be heard are limited to those that:

(a) Provide guidelines regarding the amount of time an individual has to address the board or commission;

(b) Prescribe procedures for allowing representatives of groups or factions on a proposition to address the board or commission, rather than all members of such groups or factions, at meetings in which a large number of individuals wish to be heard;

(c) Prescribe procedures or forms for an individual to use in order to inform the board or commission of a desire to be heard; to indicate his or her support, opposition, or neutrality on a proposition; and to indicate his or her designation of a representative to speak for him or her or his or her group on a proposition if he or she so chooses; or

(d) Designate a specified period of time for public comment.

(5) If a board or commission adopts rules or policies in compliance with this section and follows such rules or policies when providing an opportunity for members of the public to be heard, the board or commission is deemed to be acting in compliance with this section.

(6) A circuit court has jurisdiction to issue an injunction for the purpose of enforcing this section upon the filing of an application for such injunction by a citizen of this state.

(7)(a) Whenever an action is filed against a board or commission to enforce this section, the court shall assess reasonable attorney fees against such board or commission if the court determines that the defendant to such action acted in violation of this section. The court may assess reasonable attorney fees against the individual filing such an action if the court finds that the action was filed in bad faith or was frivolous. This paragraph does not apply to a state attorney or his or her duly authorized assistants or an officer charged with enforcing this section.

(b) Whenever a board or commission appeals a court order that has found the board or commission to have violated this section, and such order is affirmed, the court shall assess reasonable attorney fees for the appeal against such board or commission.



(8) An action taken by a board or commission which is found to be in violation of this section is not void as a result of that violation.

Section 2. The Legislature finds that a proper and legitimate state purpose is served when members of the public have been given a reasonable opportunity to be heard on a proposition before a board or commission of a state agency or authority, or of an agency or authority of a county, municipal corporation, or political subdivision. Therefore, the Legislature determines and declares that this act fulfills an important state interest.

Section 3. This act shall take effect October 1, 2013.

Approved by the Governor June 28, 2013.

Filed in Office Secretary of State June 28, 2013.

**TAB 3: DIRECTOR'S REPORT- REGINALD DIXON**

4. Office Update- Discussion only

**TAB 4: OTHER BUSINESS**

1. Proposed 2014 Meeting Dates

**Proposed 2014 Council Meeting Dates**

**February 20, 2014- Face to Face**

**May 15, 2014- Conference Call**

**August 14, 2014 Face to Face**

**December 11, 2014- Conference Call**