

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Bean, Chair
Senator Sobel, Vice Chair

MEETING DATE: Tuesday, September 24, 2013
TIME: 2:00 —3:00 p.m.
PLACE: *Pat Thomas Committee Room, 412 Knott Building*

MEMBERS: Senator Bean, Chair; Senator Sobel, Vice Chair; Senators Brandes, Braynon, Flores, Galvano, Garcia, Grimsley, and Joyner

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	Discussion on Sterile Compounding and Manufacturing of Prescription Drugs: Michele Weizer, Chair, Compounding Rules Committee, Board of Pharmacy. Reginald Dixon, Executive Director, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation.		Discussed
2	Demonstration and Discussion of Data Security in the Prescription Drug Monitoring Database (PDMP): Rebecca Poston, Program Manager, Prescription Drug Monitoring Program, Department of Health.		Discussed
3	Other Related Meeting Documents		



Sterile Compounding Update

**Michele Weizer, Pharm.D., BCPS
Member, Florida Board of Pharmacy**



Background

- We are here today discussing sterile compounding due to the NECC tragedy resulting in four deaths and 25 cases of meningitis in Florida and this highlighted potential vulnerabilities in public safety for Florida
- The role of Board of Pharmacy is to protect the health and safety of the public.... Not the licenses of pharmacists or pharmacy permits



Background

- In November 2012, the board had an emergency meeting with an outcome- that based on the permitting process in Florida, there was no way to ascertain who or how many pharmacies currently engaged in sterile compounding
- An emergency rule was created and required all permitted pharmacies to answer a compounding survey (including non-resident pharmacies)



Compounding Survey Results

- 8193 permitted pharmacies returned the survey and 946 answered that they compound sterile products
- 301 (32%) are permitted as non-resident pharmacies – these are the pharmacies that the National Legislation targets
- 220 (23%) are permitted as Institutional II (hospitals)
- 139 (15%) – community special parenteral/enteral permit



Compounding Survey Results

- 111 (12%)- modified class II permit (surgical centers)
- The only permits not allowed to sterile compound include: animal shelter, ESRD, institutional I nursing home and assisted living facilities
- Large variability existed with regard to hood/safety cabinet inspections, air quality inspections, and compounding of bulk products



Special Sterile Compounding Permit

- 64B16-28.800 requires ALL resident pharmacy permits compounding sterile products to obtain the special sterile compounding permit
- Exception: Special Parenteral/Enteral and Special Limited P/E since these are already limited sterile compounding permits
- Additional application process for the new permit



Special Sterile Compounding Permit

- If pharmacy already permitted, first application grace period is 180 days and free
- All inspections of current permitted resident pharmacies who compound sterile products are completed
- Non-resident pharmacies require legislative change for a new permit
- The board currently reviews every new pharmacy permit application



Current Rule 64B16-27.797

- Sterile compounding advisory committee assisted the board of pharmacy in creating the rule
- Original rule adopted in 2008 and amended in 2010
- US Pharmacopeia 797 guidelines used as reference
- Original rule had a phased in implementation process due to room re-design requirements



Current Rule and Inspections

- USP was revised in 2012 and is now considered a standard rather than a guideline
- Our rule has not been revised since 2010
- Pharmacists, inspectors and board members have identified that the rule requires clarity and updating
- Neither inspectors nor board members feel it is appropriate to penalize for following current USP 797 standards



Compounding Committee Established

- Board of Pharmacy sterile compounding committee established in 2013
- Conference calls and live workshops
- Current recommendation is to adopt USP 797 and related chapters for sterile compounding and list exemptions to standards



USP 797 verses GMP

- The US Pharmacopeia 797 and related chapters is a compounding guide designed for the practitioner (never designed for mass manufacturing)
- Good Manufacturing Process (GMP) is what the FDA regulates and what manufacturers are required to follow
- Compounding pharmacies who compound patient specific should not be required to follow GMP



64B16-27.797

- Sterile compounding pharmacists are expected to be familiar with the USP 797 standards
- It would be impossible to be compliant today with 64B16-27.797 and not have read the USP guidelines that created the rule in 2008 and the revisions for 2010
- The USP 797 standards were last revised in December 2012 and for a period of time, were offered free
- Annual practitioner access to entire sterile and nonsterile compendium costs \$99



Responsibility

- Sterile compounding falls under the Prescription Department Manager or consultant of record for that permit
 - May be a different person than the primary permit
- Be FAMILIAR with sterile compounding and USP 797 standards
- Specialized experience +/- or training is NOT required, but encouraged
- Additional or specialized CE is not required



PDM or Consultant of Record

- Ensure Compounded Sterile Products are accurately identified, measured, diluted, mixed and are correctly purified, sterilized, packaged, sealed, stored, dispensed and distributed.
- Oversee the maintenance of appropriate cleanliness conditions and provide labeling and supplementary instructions for proper administration of the CSPs.
- Documents a written quality assurance program
- Deems competence of all compounding personnel



Product Examples

- Low Risk
 - Single patient admixture
 - Single patient ophthalmic, preserved
 - Single-patient syringe without preservative used within 28 hours
 - Batch-filled syringes with preservatives
 - TPN solution made by GRAVITY transfer of carbohydrate and AA into an empty container with the addition of sterile additives via one adaptor (entering the bag no more than twice)



Medium Risk examples

- Injections for use in portable pump or reservoir over several days utilizing sterile ingredient
- Batch-reconstituted antibiotics without preservatives
- Batch-prefilled syringes without preservatives
- TPN solutions mixed with an automatic compounding device



Single and Multi-dose Containers

- Conditions LESS than ISO Class 5, opened or needle-punctured SINGLE use containers= use within 1 hour
- ISO Class 5- use within 6 hours
- Open AMPULES should not be stored regardless
- Open Multi-dose containers, unless written documentation exists, have a 28 day BUD after needle-puncture



High Risk- ISO 5

- Non-sterile ingredient(s) including routes not usually intended for sterile administration or using non-sterile device prior to sterilization
- High risk for contamination
 - Sterile product exposed in non-ISO 5 environment greater than 1 hour
 - CSPs lacking preservatives
 - Nonsterile water-containing products which sit longer than 6 hours before being sterilized
 - Lack of appropriate gowning and garbing



Immediate Use

- Not defined in our rule yet
- Emergency need or immediate patient administration of CSP
- Not for storage or bulk products of any kind
 - No more than 3 sterile ingredients into one container; no more than 2 entries into single one
 - Compounding procedure is less than 1 hour
 - Aseptic technique followed during preparation
 - Constant surveillance until administered
 - Start of administration less than 1 hr from start of prep
 - Clear labeling with date/time expiration



Expiration Dating

Risk Category	Room Temp	Refrigeration	Frozen ($\leq 10^{\circ}\text{C}$)
Immediate-Use	1 hour	1 hour	N/A
Low-Risk	48 hours	14 days	45 days
Low-risk/ 12 hr BUD	12 hours	12 hours	N/A
Medium-Risk	30 hours	9 days	45 days
High-Risk	24 hours	3 days	45 days



BUD Sterility Testing

- If want to exceed USP expiration dating
- Cannot release any medication from batch until results are returned
- Must send enough samples to meet indicator for batch
- Must conduct sterility test for EVERY batch
- USP approved tests – sterility (71)



Hazardous Drugs

- ISO Class 7 buffer area must be separated from other areas; if ante area is adjacent, it must also be ISO Class 7
- 100% vented to outside air through HEPA filtration
- ISO Class 5 compounding aseptic containment isolators (CACIs)- if cannot be located in ISO 7 environment, it must still adhere to the pressure specifications and the compounding area must have at least 12 air changes per hour (ACPH)



Personnel Training/Evaluation

- Applies to ALL compounding personnel
- Didactic review required
- Pass written and media fill testing of skills annually for low and medium risk compounding
- High-risk personnel must complete every six months



Finished Product Release Checks

- Physical inspection for integrity (absence of particulate matter, phase changes, and discoloration)
- Verification of compounding accuracy conducted by someone other than the compounder, ensuring proper measurement, reconstitution, and component measurement
- Accurate labeling and determination of correct fill volumes or quantities are outlined in written procedures



Quality Assurance

- Required to have clear policy and procedures describing sterile IV compounding program
- Available for inspection by Department of Health
- Address routine cleaning and disinfection program, compounding personnel competency training/evaluation, risk level compounded and final product check, air quality sampling, product packing, storage and transportation instructions for determining beyond use dating and/or how to find facility beyond use date



Inspections

- Sterile Compounding permits inspected at least annually
- Combination record review and observation review
- Standard operating procedures found in USP 797 provides list of items that should be addressed in policy as well as safe compounding practices to be implemented
- List of appendices at the end are also helpful



Board of Pharmacy

- Rule 64B16-27.797 Standards of Practice for CSPs
- Has NOT (yet) been revised to meet the 2012 USP 797 standard revisions, so does NOT address any “new” items from the current guidelines
- Rule revision in process and rules workshops ongoing
- Was originally similar to USP797 guidelines, but Less strict--- terminology in rule allows for USP797 compliance (following more strict guidelines than the Board rule)



Summary

- All resident pharmacy permits who compound sterile products (except Special P and E and Limited P/E) will need to apply for the new Special Sterile Compounding Permit
- This means pharmacies who compound sterile products will have 2 pharmacy permits
- Non-resident pharmacy permits require legislative change



Summary

- Proposed change to 64B16-27.797 is to implement adoption of USP 797 and related chapters (version 2012)
- Annual subscription to practitioner version of US Pharmacopeia sterile and non-sterile compendium is \$99
- National legislation if passed would impact those pharmacies who ship into or out of state (non-resident status)



Questions





Florida Department of Health
Division of Medical Quality Assurance

Florida Board of Pharmacy Compounding Survey
Report

January 23, 2013



Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary of Health

Albert Garcia, BPharm, MHL
Chair, Board of Pharmacy

Cynthia R. Griffin, PharmD
Immediate Past Chair, Board of Pharmacy

Lucy C. Gee, MS
Director, Division of Medical Quality Assurance

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Executive Summary

In September 2012, the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) began working closely with the Centers for Disease Control and Prevention (CDC) and state partners to investigate an outbreak of meningitis among patients who received an epidural steroid injection. The product in question was preservative-free methylprednisolone acetate (MPA), an injectable steroid compounded and distributed by the New England Compounding Center (NECC) in Framingham, Massachusetts. NECC was also licensed at the time as a non-resident pharmacy in Florida. In addition to the Department of Health's (DOH) immediate public health response to the meningitis outbreak, the Board of Pharmacy identified the need for short and long-term regulatory action to ensure the safety of compounded products in Florida, for which the data in this report will provide important policy guidance.

Prescription drug compounding is defined by Board of Pharmacy rule, [Section 64B16-27.700, Florida Administrative Code](#), and includes incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent. Several types of Florida pharmacy permits allow [sterile](#) and [non-sterile](#) compounding. There are risks associated with either type of compounding and they include contaminated products or products that do not possess the strength, quality, and purity required to achieve the intended health outcome.

Compounding includes preparation of drugs or devices:

- in anticipation of prescriptions based on prescribing patterns;
- which are not commercially available;
- which are commercially available from bulk but patient specific; and
- for office use by a practitioner in a treatment setting (allowed under amended board rule, effective Oct. 7, 2008).

As of Nov. 27, 2012, 8,981 pharmacies held Florida permits, 774 of which were non-resident. Compounding was authorized in 8,011 of these pharmacies, including community, certain class II institutional, special parenteral and enteral, special limited community, non-resident, and nuclear pharmacies. Although permitted as pharmacies, animal shelters, assisted living facilities, special ESRD (End Stage Renal Disease), and class I institutional pharmacies cannot compound. (See [Appendix C](#) for more information about each pharmacy permit type.)

The definition of "manufacture" is set forth in [Chapter 499, F.S.](#), and means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic. The term "manufacturer" specifically does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in [Chapter 465, F.S.](#), and rules adopted under that chapter. Furthermore, the federal government exempts drug products compounded by a pharmacist or a physician from key provisions of the Federal Food, Drug and Cosmetic Act that governs pharmaceutical manufacturing.

Detailed information on current compounding practices in Florida licensed pharmacies has been limited. To understand fully the scope of compounding and potential patient safety concerns, information was needed on whether compounded products are shipped to other states; whether compounding is performed pursuant to a patient-specific prescription or from bulk (compounding multiple doses from a single source or batch); and what types and quantities of products are being compounded.

A meeting devoted solely to the subject of pharmacy compounding was called by the Board of Pharmacy Chair, Cynthia R. Griffin, PharmD, on Nov. 20, 2012. It was at this meeting that the board approved an [emergency rule](#) requiring immediate notification, via survey, by pharmacies of their compounding activities and inspections. The emergency rule also set forth the specific reasons for finding an immediate danger to the public health, safety or welfare. The compounding [survey](#) was required to be completed by Dec. 11, 2012. Additionally, non-resident pharmacies were required to provide a copy of their last two inspection reports from the state in which the pharmacy is physically located and licensed. Failure to comply with these requirements constitutes the basis for disciplinary action by the Board of Pharmacy.

This report contains a summary of the responses to the compounding survey submitted through Jan. 8, 2013. Of the 8,981 permitted pharmacies, responses were received from 8,294, resulting in an overall response rate of 92 percent. Of the 774 non-resident pharmacies, 712 responded, resulting in a 92 percent response rate. The required inspection reports were submitted by 502 non-resident pharmacies for a response rate of 65 percent. Incorrectly completed surveys (101) were excluded from this analysis, resulting in 8,193 analyzed responses.

Key Results

Of the 8,193 permitted pharmacy (in-state and non-resident) responses analyzed:

Compounding Practices

Non-sterile Compounding

- 55% (4,494) compound non-sterile products
 - 382 of the 4,494 (9%) respondents who compound non-sterile products are non-resident pharmacies
- 54% (4,380) compound non-sterile products pursuant to a patient specific prescription
 - 373 of the 4,380 (9%) respondents who compound non-sterile products pursuant to a patient specific prescription are non-resident pharmacies
- 6% (459) compound non-sterile products in bulk
 - 373 of the 459 (81%) respondents who compound non-sterile products in bulk are non-resident pharmacies
- 1% (119) compound non-sterile products in bulk for office use
 - 59 of the 119 (50%) respondents who compound non-sterile products in bulk for office use are non-resident pharmacies
- 5% (382) ship compounded non-sterile products to other states
 - 307 of the 382 (80%) respondents who ship compounded non-sterile products are non-resident pharmacies

Sterile Compounding

- 12% (946) compound sterile products (such as injectables, irrigation fluids, ophthalmics, and aqueous inhalant solutions for respiratory treatments)
 - 301 of the 946 (32%) respondents who perform sterile compounding are permitted as non-resident pharmacies

- 220 of the 946 (23%) respondents who perform sterile compounding are permitted as class II institutional pharmacies (e.g., hospitals)
- 139 of the 946 (15%) respondents who perform sterile compounding are permitted as community special parenteral/enteral pharmacies
- 111 of the 946 (12%) respondents who perform sterile compounding are permitted as modified class II institutional pharmacies (e.g., nursing homes)
- 7% (613) compound parenteral antibiotics
 - 48 of the 613 (8%) respondents who compound parenteral antibiotics are non-resident pharmacies
- 6% (454) compound parenteral electrolytes
 - 40 of the 454 (9%) respondents who compound parenteral electrolytes are non-resident pharmacies
- 5% (430) compound parenteral analgesic drugs
 - 59 of the 430 (14%) respondents who compound parenteral analgesic drugs are non-resident pharmacies
- 11% (913) compound sterile products pursuant to a patient specific prescription
 - 289 of the 913 (32%) respondents who compound sterile products pursuant to a patient specific prescription are non-resident pharmacies
- 4% (314) compound sterile products in bulk
 - 120 of the 314 (38%) respondents who compound sterile products in bulk are non-resident pharmacies
- 1% (95) compound sterile products in bulk for office use
 - 79 of the 95 (83%) respondents who compound sterile products in bulk for office use are non-resident pharmacies
- 4% (348) compound sterile products in bulk and/or in bulk for office use:
 - 174 of the 348 (50%) respondents who compound sterile products in bulk compound 24 or less doses from a single batch; 44 of the 174 (25%) are non-resident pharmacies
 - 42 of the 348 (12%) respondents who compound sterile products in bulk compound 25 to 49 doses from a single batch; 19 of the 42 (45%) are non-resident pharmacies
 - 47 of the 348 (14%) respondents who compound sterile products in bulk compound 50 to 100 doses from a single batch; 31 of the 47 (66%) are non-resident pharmacies
 - 83 of the 348 (24%) respondent who compound sterile products in bulk compound greater than 100 doses from a single batch; 61 of the 83 (73%) are non-resident pharmacies
- 4% (307) ship compounded sterile products to other states
 - 250 of the 307 (81%) respondents who ship compounded sterile products to other states are non-resident pharmacies; 177 of the 250 (71%) who ship sterile compounded products to other states ship sterile products to Florida
 - 57 of the 307 (19%) respondents who ship compounded sterile products to other states are physically located in Florida

This survey will remain open as staff continues to contact non-respondents and those who completed the survey incorrectly to achieve 100 percent compliance. Full compliance is important because the results of this survey will be used in a number of ways. The DOH investigative team is using the information to prioritize inspections based upon risk associated with the type of compounding practice. The Board of Pharmacy will review the findings to guide rulemaking and determine whether legislative changes are needed to establish appropriate guardrails that protect patients without creating unduly burdensome regulation. Finally, this information will be shared with federal and state policy makers to inform ongoing discussions about compounding practices and how to reduce the risk of patient harm.

Background

The FDA in September 2012 began working closely with the CDC and state partners to investigate an outbreak of meningitis among patients who received an epidural steroid injection. The product in question was preservative-free methylprednisolone acetate (MPA), an injectable steroid produced and distributed by NECC in Framingham, Massachusetts. As of Oct. 3, 2012, NECC voluntarily ceased producing and distributing drug products. According to the FDA, fungal contamination was observed under direct microscopic examination of foreign matter taken from a sealed vial of MPA collected from NECC. On Oct. 6, 2012, NECC announced a voluntary recall of all products in circulation compounded at and distributed by its facility in Framingham, MA.

On Oct. 15, 2012, the FDA advised practitioners to not use any NECC products. Two new products were identified as potentially associated with meningitis-triamcinolone acetonide and cardioplegic solution. The FDA reiterated their previous guidance for medical professionals that all products distributed by NECC should be retained, secured, and withheld from use. The FDA further advised health care practitioners that, in an abundance of caution, they should follow up with patients if they had administered an NECC injectable product to a patient after May 21, 2012, including an ophthalmic drug that is injectable or used in conjunction with eye surgery or a cardioplegic solution.

At the time, NECC also held a non-resident Florida pharmacy permit. On Oct. 25, 2012, DOH obtained a disciplinary voluntary relinquishment from NECC which prohibits the pharmacy from re-applying for a permit in Florida. Tragically, 25 patients in Florida were diagnosed with fungal meningitis after receiving injections from contaminated NECC injectable steroids; 3 died. This tragedy exposed not only the risks associated with improper pharmacy compounding practices, it showed where the need for more information about current compounding practices exists, so that well informed policy discussions and regulatory changes, where needed, can occur. Pharmacy compounding and pharmaceutical manufacturing are governed by different regulatory bodies. A brief look at this regulatory structure helps provide context for this report and its findings.

The regulation of compounding by pharmacies in Florida is under the purview of DOH and the Florida Board of Pharmacy. [Chapter 465, Florida Statutes](#) (F.S.), regulates the practice of pharmacy, and the Florida Board of Pharmacy sets the standards of practice for pharmacy compounding by administrative rule.

Prescription drug compounding is defined by Board of Pharmacy rule, [Section 64B16-27.700, Florida Administrative Code](#), and includes incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent.

Compounding includes preparation of drugs or devices:

- in anticipation of prescriptions based on prescribing patterns;
- which are not commercially available;
- which are commercially available from bulk but patient specific; and
- for office use by a practitioner in a treatment setting (allowed under amended board rule, effective Oct. 7, 2008).

The definition of manufacture is set forth in [Chapter 499, F.S.](#), and means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic. The term "manufacturer" does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in [Chapter 465, F.S.](#), and rules adopted under that chapter. The regulation of pharmaceutical manufacturing in Florida is under the purview of the Department of Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics.

Manufacturing is also regulated at the federal level by the FDA, under the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 360(g)(1), exempts retail pharmacies from registering under the Federal Food, Drug and Cosmetics Act if they operate in accordance with state law and dispense drugs "upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail."

As of Nov. 27, 2012 [sterile](#) and [non-sterile](#) compounding was authorized in 8,011 pharmacies and included community, certain class II institutional, special parenteral and enteral, special limited community, non-resident, and nuclear pharmacies. Except for nuclear pharmacy compounding, a special permit is not **required** to compound. Animal shelters, class I institutional, special ESRD (End Stage Renal Disease), and assisted living facility pharmacy permittees are not authorized to compound; a total of 970 permittees. A special parenteral/enteral permit is available and allows the compounding of sterile products without some of the additional mandates included in a community pharmacy permit (e.g. the requirement to be open 40 hours/week.) (See [Appendix C](#) for more information about each pharmacy permit type.) There are risks associated with either sterile or non-sterile compounding and they include contaminated products or products that do not possess the strength, quality, and purity required to achieve the intended health outcome.

DOH is authorized to enter and inspect, unannounced, the prescription department compounding room or any other place where prescriptions are compounded, filled, processed, accepted, dispensed, or stored in each pharmacy. The board rules require a minimum of one inspection per year except under certain circumstances such as having passed inspections for the most current three years and no discipline. Non-resident pharmacies are inspected by the governing body in the state in which they are physically located. Non-resident pharmacy applicants are required to submit a copy of their last inspection form with their initial application. Non-resident pharmacy applicants with prior out-of-state discipline due to a failed inspection are reviewed by the Board of Pharmacy for final determination of licensure.

The Board of Pharmacy establishes by rule standards of practice for compounding sterile preparations such as injectables, irrigation fluids, ophthalmics, and aqueous inhalant solutions for respiratory treatments.

The Board of Pharmacy chair, Cynthia Griffin, PharmD, called a meeting of the Board of Pharmacy on Nov. 20, 2012 dedicated to the topic of compounding pharmacy regulation. With input from stakeholders, the board began formulating ideas for strengthening regulation to provide further public protection. They voted to approve adoption of an emergency rule, Rule No. 64B-16ER12-1, Immediate Notification of Compounding Status and Inspections, which went into effect, Nov. 26, 2012. (See [Appendix D](#) for full text.) In addition to requiring that all permitted pharmacies complete the survey within 14 days, it further required that all non-resident pharmacies provide a copy of their last two inspection reports conducted by the state in which the pharmacy is physically located and licensed.

Methodology

A first class mailing was sent to 8,981 permitted pharmacies (in-state and non-resident) on [Nov. 27, 2012](#). (The letter notification was also sent to pharmacies not authorized to compound, i.e., institutional class I pharmacies, ESRD, and animal shelter pharmacies.) Concurrently, [emails](#) were sent to 2,713 pharmacies, for which the board had email addresses. The Florida Pharmacy Association, Independent Pharmacy Network, and Florida Society of Health System Pharmacists also sent email notifications to their members, more than 8,000.

To maximize the response rate, another first class mailing was sent to non-respondents on [Dec. 4, 2012](#), and email reminders including the survey link and phone calls were made to non-respondents and those respondents who submitted incorrect responses through Jan. 8, 2013. The survey remains open as more respondents are reached.

Results

Of the 8,981 permitted pharmacies, responses have been received from 8,294, resulting in a response rate of 92 percent. This report includes analysis of 8,193 responses submitted through 2:00 p.m. Tuesday, Jan. 8, 2013. The responses received from the remaining 101 permitted pharmacies have been excluded from the analysis because the surveys were incorrectly completed.

For the 8,193 analyzed survey responses, 956 of the respondents (12 percent) indicated that they also hold a permit in a state other than Florida. The following is a list of the number and percentage of respondents who hold another permit by state:

Alabama – 575 (60%)	Maine – 351 (37%)	Ohio – 522 (55%)
Alaska – 327 (34%)	Maryland – 443 (46%)	Oklahoma – 476 (50%)
Arizona – 411 (43%)	Massachusetts – 174 (18%)	Oregon – 342 (36%)
Arkansas – 329 (34%)	Michigan – 508 (53%)	Pennsylvania – 215 (22%)
California – 396 (41%)	Minnesota – 466 (49%)	Rhode Island – 417 (44%)
Colorado – 484 (51%)	Mississippi – 434 (45%)	South Carolina – 504 (53%)
Connecticut – 483 (51%)	Missouri – 474 (50%)	South Dakota – 385 (40%)
Delaware – 420 (44%)	Montana – 327 (34%)	Tennessee – 431 (45%)
District of Columbia – 285 (30%)	Nebraska – 303 (32%)	Texas – 596 (62%)
Georgia – 199 (21%)	Nevada – 424 (44%)	Utah – 401 (42%)
Hawaii – 333 (35%)	New Hampshire – 402 (42%)	Vermont – 372 (39%)
Idaho – 400 (42%)	New Jersey – 533 (56%)	Virginia – 414 (43%)
Illinois – 528 (55%)	New Mexico – 418 (44%)	Washington – 448 (47%)
Indiana – 519 (54%)	New York – 502 (53%)	West Virginia – 448 (47%)
Iowa – 441 (46%)	North Carolina – 419 (44%)	Wisconsin – 478 (50%)
Kansas – 489 (51%)	North Dakota – 357 (37%)	Wyoming – 412 (43%)
Kentucky – 378 (40%)		
Louisiana – 350 (37%)		

The top five states where respondents hold another permit are Texas (596), Alabama (575), New Jersey (533), Illinois (528) and Ohio (522).

For the 8,193 analyzed survey responses, the following response rates are attributed to each pharmacy permit type:

Pharmacy Type:	Number of Respondents	Percent of Total Respondents
Community	4,493	54.84%
Modified Class II Institutional	1,504	18.36%
All Other Permit Types*	813	9.92%
Non-Resident	712	8.69%
Class II Institutional	262	3.20%
Community/Special PE	180	2.20%
Special Closed System	95	1.16%
Special Parenteral/Enteral	36	0.44%
Nuclear	30	0.37%
Special Limited Community	24	0.29%
Special Closed/Special PE	24	0.29%
Special Parenteral/Enteral Extended Scope	13	0.16%
Community/Central Fill	5	0.06%
Internet	2	0.02%
Total:	8,193	100.00%

*Note: All other permit types are Animal Control Shelters, Institutional Class I Nursing Homes, Special ESRD, and Assisted Living Facilities, which are not authorized to compound.

For the 8,193 analyzed survey responses, 40 of the respondents (0.5 percent) indicated that they are currently registered, licensed, or permitted as a **pharmaceutical manufacturer** in any state. The following is a list of the number and percentage of respondents who are registered, licensed, or permitted as a pharmaceutical manufacturer by state:

Alabama – 6 (15%)	Illinois – 3 (8%)	Nebraska – 2 (5%)
Alaska – 3 (8%)	Indiana – 2 (5%)	Nevada – 2 (5%)
Arizona – 2 (5%)	Iowa – 3 (8%)	New Hampshire – 4 (10%)
Arkansas – 4 (10%)	Kansas – 2 (5%)	New Jersey – 3 (8%)
California – 2 (5%)	Kentucky – 2 (5%)	New Mexico – 2 (5%)
Colorado – 2 (5%)	Louisiana – 2 (5%)	New York – 4 (10%)
Connecticut – 3 (8%)	Maine – 3 (8%)	North Carolina – 2 (5%)
Delaware – 3 (8%)	Maryland – 3 (8%)	North Dakota – 2 (5%)
District of Columbia – 2 (5%)	Massachusetts – 2 (5%)	Ohio – 2 (5%)
Florida – 23 (58%)	Michigan – 3 (7.5%)	Oklahoma – 2 (5%)
Georgia – 3 (8%)	Minnesota – 4 (10%)	Oregon – 4 (10%)
Hawaii – 2 (5%)	Mississippi – 2 (5%)	Pennsylvania – 5 (13%)
Idaho – 2 (5%)	Missouri – 2 (5%)	Rhode Island – 3 (8%)
	Montana – 2 (5%)	South Carolina – 2 (5%)

South Dakota – 2 (5%)	Vermont – 2 (5%)	Wisconsin – 2 (5%)
Tennessee – 6 (15%)	Virginia – 2 (5%)	Wyoming – 2 (5%)
Texas – 5 (13%)	Washington – 2 (5%)	
Utah – 2 (5%)	West Virginia – 2 (5%)	

The top four states where respondents are currently registered, licensed, or permitted as a pharmaceutical manufacturer are Florida (23), Alabama (6), Arkansas (4), and Minnesota (4).

Additionally, 161 respondents (two percent) indicated that they are currently registered, licensed, or permitted as a **wholesale distributor** in any state. The following is a list of the number and percentage of respondents who are registered, licensed, or permitted as a wholesale distributor by state:

Alabama – 26 (16%)	Kentucky – 19 (12%)	North Dakota – 10 (6%)
Alaska – 14 (9%)	Louisiana – 29 (18%)	Ohio – 24 (15%)
Arizona – 17 (11%)	Maine – 14 (9%)	Oklahoma – 20 (12%)
Arkansas – 22 (14%)	Maryland – 12 (7%)	Oregon – 13 (8%)
California – 18 (11%)	Massachusetts – 7 (4%)	Pennsylvania – 25 (16%)
Colorado – 0 (0%)	Michigan – 20 (12%)	Rhode Island – 17 (11%)
Connecticut – 18 (11%)	Minnesota – 20 (12%)	South Carolina – 17 (11%)
Delaware – 10 (6%)	Mississippi – 27 (17%)	South Dakota – 14 (9%)
District of Columbia – 14 (9%)	Missouri – 17 (11%)	Tennessee – 29 (18%)
Florida – 65 (40%)	Montana – 14 (9%)	Texas – 33 (20%)
Georgia – 26 (16%)	Nebraska – 14 (9%)	Utah – 8 (5%)
Hawaii – 7 (4%)	Nevada – 13 (8%)	Vermont – 13 (8%)
Idaho – 18 (11%)	New Hampshire – 20 (12%)	Virginia – 18 (11%)
Illinois – 20 (12%)	New Jersey – 18 (11%)	Washington – 18 (11%)
Indiana – 9 (6%)	New Mexico – 18 (11%)	West Virginia – 17 (11%)
Iowa – 15 (9%)	New York – 33 (20%)	Wisconsin – 14 (9%)
Kansas – 20 (12%)	North Carolina – 20 (12%)	Wyoming – 11 (7%)

The top five states where respondents are currently registered, licensed, or permitted as a wholesale distributor are Florida (65), New York (33), Texas (33), Louisiana (29), and Tennessee (29).

COMPOUNDING PRACTICES

Non-Sterile Compounding

For the 8,193 analyzed survey responses, 4,494 of the respondents (55 percent) indicated that they compound **non-sterile** products. The following table reflects the number and percentage of respondents that compound sterile products by pharmacy type:

Pharmacy Type:	Number of Respondents	Percent of Total Respondents
Community	3,624	80.64%
Non-Resident	382	8.50%
Class II Institutional	217	4.83%
Community/Special PE	127	2.83%
Modified Class II Institutional	39	0.87%
Special Closed System	28	0.62%
Nuclear	23	0.51%
Special Closed/Special PE	18	0.40%
Special Parenteral/Enteral	15	0.33%
Special Limited Community	11	0.24%
Special Parenteral/Enteral Extended Scope	4	0.09%
Class I Institutional	2	0.04%
Animal Shelter	2	0.04%
Special ESRD	1	0.02%
Internet	1	0.02%
Total:	4,494	99.98%

- Of the 4,494 respondents that indicated that they compound **non-sterile** products, the following response rates are attributed to the percentage of business related to non-sterile compounding:

Less than 10% of their business - 4,103 (91%)

11% to 25% of their business - 99 (2%)

26% to 50% of their business - 57 (1%)

51% to 75% of their business - 73 (2%)

Greater than 75% of their business - 140 (3%)

No Response - 22 (1%)

- Of the 4,494 respondents that indicated they compound **non-sterile** products, the following response rates are attributed to each product type:

Mouthwash – 3,790 (84%)
Creams – 3,252 (72%)
Ointments – 2,792 (62%)
Liquids – 2,771 (62%)
Lotions – 2,278 (51%)
Gels - 801 (18%)
Capsules - 733 (16%)
Suppositories - 609 (14%)
Drops - 556 (12%)
Troches - 467 (10%)
Tablets - 269 (6%)
Other non-sterile products - 170 (4%)

- Of the 4,494 respondents that indicated that they compound **non-sterile** products, the following indicated that they compound pursuant to:

A patient specific prescription *ONLY* - 3,932 (87.5%)
In bulk (compounding multiple doses from a single source or batch) *ONLY* - 44 (1%)
In bulk for office use *ONLY* - 10 (0.2%)
A patient specific prescription *AND* in bulk for office use - 33 (0.7%)
A patient specific prescription *AND* in bulk (compounding multiple doses from a single source or batch) - 339 (7.5%)
In bulk (compounding multiple doses from a single source or batch) *AND* In bulk for office use - 3 (0.05%)
ALL THREE methods - 76 (2%)
No Response – 57 (1%)

- Of the 505 pharmacies that responded affirmatively to **compounding non-sterile products in bulk**, their largest single batch sizes include:

24 or less doses from a single batch - 233 (46%)
25 to 49 doses from a single batch - 58 (12%)
50 to 100 doses from a single batch - 100 (20%)
Greater than 100 doses from a single batch - 107 (21%)
No Response – 7 (1%)

For the 8,193 analyzed survey responses, 382 of the respondents (five percent) indicated that they ship **non-sterile** products to other states. The following is a list of the number and percentage of respondents that ship by state:

Alabama – 191 (50%)	Louisiana – 106 (28%)	North Dakota – 107 (28%)
Alaska – 103 (27%)	Maine – 104 (27%)	Ohio – 172 (45%)
Arizona – 137 (36%)	Maryland – 144 (38%)	Oklahoma – 159 (42%)
Arkansas – 92 (24%)	Massachusetts – 134 (35%)	Oregon – 111 (29%)
California – 151 (40%)	Michigan – 170 (45%)	Pennsylvania – 169 (44%)
Colorado – 181 (47%)	Minnesota – 151 (40%)	Rhode Island – 131 (34%)
Connecticut – 158 (41%)	Mississippi – 147 (38%)	South Carolina – 163 (43%)
Delaware – 133 (35%)	Missouri – 158 (41%)	South Dakota – 120 (31%)
District of Columbia – 94 (25%)	Montana – 101 (26%)	Tennessee – 151 (40%)
Florida* – 216 (57%)	Nebraska – 99 (26%)	Texas – 214 (56%)
Georgia – 181 (47%)	Nevada – 144 (38%)	Utah – 121 (32%)
Hawaii – 105 (27%)	New Hampshire – 127 (33%)	Vermont – 114 (30%)
Idaho – 128 (34%)	New Jersey – 188 (49%)	Virginia – 149 (39%)
Illinois – 183 (48%)	New Mexico – 135 (35%)	Washington – 153 (40%)
Indiana – 175 (46%)	New York – 191 (50%)	West Virginia – 138 (36%)
Iowa – 134 (35%)	North Carolina – 123 (32%)	Wisconsin – 168 (44%)
Kansas – 161 (42%)		Wyoming – 118 (31%)
Kentucky – 131 (34%)		

***Note:** Only those responses received from Non-Resident pharmacies were used to calculate the number and percentage of respondents shipping **non-sterile** products to Florida.

The top six states where respondents ship **non-sterile** products are Florida (216), Texas (214), Alabama (191), New York (191), New Jersey (188), and Illinois (183).

For the 8,193 analyzed survey responses, 27 of the respondents (0.3 percent) indicated that they have recalled a **non-sterile** compounded product due to a compounding error. Of the 27 respondents that indicated they have recalled **non-sterile** products, the following response rates are attributed to the timeframe of when the recall occurred:

Less than six months – 9 (33%)
Six months to one year – 5 (19%)
Greater than one year – 12 (44%)
No response – 1 (4%)

Sterile Compounding

For the 8,193 analyzed survey responses, 946 of the respondents (12 percent) indicated that they compound **sterile** products. The following table reflects the number and percentage of respondents that compound sterile products by pharmacy type:

Pharmacy Type:	Number of Respondents	Percent of Total Respondents
Non-Resident	301	31.82%
Class II Institutional	220	23.26%
Community/SpecPE	139	14.69%
Modified Class II Institutional	111	11.73%
Community	68	7.19%
Special Parenteral/Enteral	31	3.28%
Nuclear	28	2.96%
Special Closed/SpPE	14	1.48%
Special Parenteral/Enteral Extended Scope	12	1.27%
Special Closed System	11	1.16%
Special Limited Community	9	0.95%
Class I Institutional	2	0.21%
Total:	946	100.00%

- Of the 946 respondents that indicated that they compound **sterile** products, the following response rates are attributed to the percentage of business related to non-sterile compounding:
 - Less than 10% of their business - 411 (43%)
 - 11% to 25% of their business - 182 (19%)
 - 26% to 50% of their business - 115 (12%)
 - 51% to 75% of their business - 48 (5%)
 - Greater than 75% of their business - 178 (19%)
 - No response - 12 (1%)
- Of the 946 respondents that indicated they compound **sterile** products, the following response rates are attributed to each product type:
 - Parenteral antibiotics – 613 (65%)
 - Parenteral electrolytes – 454 (48%)
 - Parenteral analgesic drugs – 430 (45%)

- Parenteral vitamins – 403 (43%)
- Irrigating fluids – 358 (38%)
- Ophthalmic preparations – 323 (35%)
- Total Parenteral Nutrition (RPN) solutions – 312 (33%)
- Parenteral antineoplastic agents – 291 (31%)
- Other – 251 (27%)
- Aqueous inhalant solutions for respiratory treatments – 168 (18%)

- Of the 946 respondents that indicated that they compound **sterile** products, the following indicated that they compound pursuant to:
 - A patient specific prescription **ONLY** - 584 (62%)
 - In bulk (compounding multiple doses from a single source or batch) **ONLY** - 11 (1%)
 - In bulk for office use **ONLY** - 4 (0.4%)
 - A patient specific prescription **AND** in bulk for office use - 30 (3%)
 - A patient specific prescription **AND** in bulk (compounding multiple doses from a single source or batch) - 212 (22%)
 - In bulk (compounding multiple doses from a single source or batch) **AND** In bulk for office use - 4 (0.4%)
 - ALL THREE** methods - 87 (9%)
 - No Response – 14 (1.5%)
- Of the 348 pharmacies that responded affirmatively to **compounding sterile products in bulk**, their largest single batch sizes include:
 - 24 or less doses from a single batch - 174 (50%)
 - 25 to 49 doses from a single batch - 42 (12%)
 - 50 to 100 doses from a single batch - 47 (13.5%)
 - Greater than 100 doses from a single batch - 83 (24%)
 - No Response - 2 (0.6%)

For the 8,193 analyzed survey responses, 307 of the respondents (four percent) indicated that they ship **sterile** products to other states. The following is a list of the number and percentage of respondents that ship by state:

- | | | |
|------------------------|---------------------------------|----------------------|
| Alabama – 147 (48%) | Connecticut – 128 (42%) | Hawaii – 75 (24%) |
| Alaska – 72 (23%) | Delaware – 102 (33%) | Idaho – 96 (31%) |
| Arizona – 102 (33%) | District of Columbia – 72 (23%) | Illinois – 135 (44%) |
| Arkansas – 67 (22%) | Florida – 177 (58%) | Indiana – 134 (44%) |
| California – 116 (38%) | Georgia – 123 (40%) | Iowa – 104 (34%) |
| Colorado – 129 (42%) | | Kansas – 127 (41%) |

Kentucky – 94 (31%)	New Hampshire – 91 (30%)	South Carolina – 127 (41%)
Louisiana – 82 (27%)	New Jersey – 147 (48%)	South Dakota – 88 (29%)
Maine – 76 (25%)	New Mexico – 99 (32%)	Tennessee – 108 (35%)
Maryland – 110 (36%)	New York – 133 (43%)	Texas – 165 (54%)
Massachusetts – 91 (30%)	North Carolina – 101 (33%)	Utah – 96 (31%)
Michigan – 128 (42%)	North Dakota – 78 (25%)	Vermont – 87 (28%)
Minnesota – 110 (36%)	Ohio – 135 (44%)	Virginia – 102 (33%)
Mississippi – 107 (35%)	Oklahoma – 125 (41%)	Washington – 111 (36%)
Missouri – 120 (39%)	Oregon – 81 (26%)	West Virginia – 102 (33%)
Montana – 78 (25%)	Pennsylvania – 126 (41%)	Wisconsin – 121 (39%)
Nebraska – 73 (24%)	Rhode Island – 99 (32%)	Wyoming – 90 (29%)
Nevada – 114 (37%)		

Note: Only those responses received from Non-Resident pharmacies were used to calculate the number and percentage of respondents shipping **sterile** products to Florida.

The top four states where respondents ship **sterile** products are Florida (177), Texas (165), Alabama (147), and New Jersey (147).

Note: The survey responses to questions 10-13 related to sterile compounding: number of staff type, number of clean rooms, and number of laminar flow hoods are not included in this report. More in-depth data analytics will be applied to evaluate staffing ratios for in-state and non-resident pharmacies, stratified across other variables such as volume of compounding, etc., for reporting at a future Board of Pharmacy meeting. The text responses to questions 14a and 15a, the names and addresses of independent contractors certifying clean rooms and laminar flow hoods, also is not included in this report, but will be used for cross-comparison by inspectors with the Investigative Services Unit when conducting compounding inspections.

- Of the 946 respondents that indicated that they compound **sterile** products, the following response rates are attributed to the timeframe of the last time their clean room was certified by an independent contractor for [National Sanitation Foundation Standard 49](#):
 - Less than six months – 719 (76%)
 - Six months to one year – 38 (4%)
 - Greater than one year – 26 (3%)
 - No response – 163 (17%)
- Of the 946 respondents that indicated that they compound **sterile** products, the following response rates are attributed to the timeframe of the last time their laminar flow hood was certified by an independent contractor for National Sanitation Foundation Standard 49:
 - Less than six months – 770 (81%)
 - Six months to one year – 44 (5%)
 - Greater than one year – 9 (1%)
 - No response – 123 (13%)

- Of the 946 respondents that indicated that they compound **sterile** products, 35 (4%) indicated that they have recalled a sterile compounded product due to a compounding error.
- Of the 35 respondents that indicated they have recalled **sterile** products, the following response rates are attributed to the timeframe of when the recall occurred:
 - Less than six months – 16 (46%)
 - Six months to one year – 6 (17%)
 - Greater than one year – 9 (26%)
 - No Response – 4 (11%)

NON-RESIDENT PHARMACIES

As of the date of the initial survey, there were 774 permitted non-resident pharmacies in Florida.

- Of the 712 non-resident pharmacies that responded to the survey, 685 (96%) of the respondents indicated that the state in which they are physically located allows compounding.
- Of the 685 non-resident pharmacies that indicated their state permits compounding, the following indicated that their state permits compounding pursuant to:
 - A patient specific prescription *ONLY* - 387 (56%)
 - In bulk (compounding multiple doses from a single source or batch) *ONLY* - 4 (0.6%)
 - In bulk for office use *ONLY* - 1 (0.2%)
 - A patient specific prescription *AND* in bulk for office use - 12 (2%)
 - A patient specific prescription *AND* in bulk (compounding multiple doses from a single source or batch) - 122 (18%)
 - ALL THREE* methods - 145 (21%)
 - No Response* – 14 (2%)
- Of the 712 non-resident pharmacies that responded to the survey, 257 non-resident pharmacies indicated that if they compound products in bulk, their largest single batch size includes:
 - 24 or less doses from a single batch - 87 (12%)
 - 25 to 49 doses from a single batch - 30 (4%)
 - 50 to 100 doses from a single batch - 55 (8%)
 - Greater than 100 doses from a single batch - 85 (12%)
 - No Response* – 455 (64%)
- Of the 712 non-resident pharmacies that responded to the survey, the following response rates are attributed to the timeframe of when the last inspection was conducted by their state regulatory authority:
 - Less than six months – 234 (33%)
 - Six months to one year – 180 (25%)
 - Greater than one year – 269 (38%)
 - No Response* – 30 (4%)

Next Steps

This survey will remain open as staff continues to contact non-respondents and those who completed the survey incorrectly to achieve 100 percent compliance. Full compliance is important because the results of this survey will be used in a number of ways. The DOH investigative team is using the information to prioritize inspections based upon risk associated with the type of compounding practice. The Board of Pharmacy will review the findings to guide rulemaking and determine whether legislative changes are needed to establish appropriate guardrails that protect patients without creating unduly burdensome regulation. Finally, this information will be shared with federal and state policy makers to inform ongoing discussions about compounding practices and how to reduce the risk of patient harm.

Other action steps in which the Department and the Board of Pharmacy are engaging:

1. DOH investigators will obtain nationally accredited training in sterile compounding standards starting in March 2013.
2. Inspection forms have been modified to capture more detailed information about compounding practices in the facilities being inspected.

APPENDIX A Correspondence to Pharmacies

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Email sent on November 27, 2012

Dear Pharmacy Permittee,

With the recent nationwide fungal meningitis outbreak caused by contaminated compounded products, the Florida Board of Pharmacy adopted Emergency Rule 64B16ER12-1, Florida Administrative Code. This Emergency Rule **requires all Florida licensed pharmacy permit holders**, including non-residents, to complete a **mandatory survey** to inform the Board of its compounding activities. The goal of this **mandatory survey** is to determine the scope of sterile and non-sterile compounding within Florida licensed pharmacies --whether physically located in or out-of-state. **Failure to timely complete the mandatory survey is grounds for disciplinary action; however the goal is not to discipline, only to obtain critical data. Your cooperation in this matter is important to the department's public protection mission.**

This Emergency Rule became effective Monday, November 26, 2012 and the survey must be completed by **December 11, 2012**. For your convenience we have created a web-based survey which should take no longer than 10 minutes to complete. To view the Emergency Rule and complete the survey, log onto the following secure website at:
<http://www.doh.state.fl.us/mqa/pharmacy/survey.html>

In addition to completing this survey, all non-resident pharmacy permit holders are required to provide copies of their two most recent inspection reports from the state in which their pharmacy is physically located. The inspection reports must be postmarked by December 11, 2012 and mailed to:

Florida Department of Health
Board of Pharmacy
c/o Mark Whitten, Executive Director
4052 Bald Cypress Way, Bin C04
Tallahassee, Florida 32399-3254

Protecting patient safety and the integrity of the pharmacy compounding industry is critical. This survey is intended to gather data that will allow policymakers to make **informed** decisions, without creating undue regulatory burdens.

Thank you for helping the Department of Health and the Board to protect, promote and improve the health of all people in Florida through integrated state, local and community efforts.

Letter mailed on November 27, 2012

Rick Scott
Governor



John H. Armstrong, MD, FACS
Surgeon General & Secretary

November 27, 2012

Dear Pharmacy Permittee,

This letter is a follow up to the electronic notice that was sent by email on November 27, 2012.

With the recent nationwide fungal meningitis outbreak caused by contaminated compounded products, the Florida Board of Pharmacy adopted Emergency Rule 64B16ER12-1, Florida Administrative Code. This Emergency Rule **requires all Florida licensed pharmacy permit holders**, including non-residents, to complete a **mandatory survey** to inform the Board of its compounding activities. The goal of this **mandatory survey** is to determine the scope of sterile and non-sterile compounding within Florida licensed pharmacies – whether physically located in or out-of-state. **Failure to timely complete the mandatory survey is grounds for disciplinary action; however the goal is not to discipline, only to obtain critical data. Your cooperation in this matter is important to the department's public protection mission.**

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Thank you for helping the Department of Health and the Board to protect, promote and improve the health of all people in Florida through integrated state, local and community efforts.

Sincerely,

Mark Whitten, Executive Director
Florida Department of Health
Board of Pharmacy

Board of Pharmacy
4052 Bald Cypress Way, Bin C04 • Tallahassee, Florida 32399-3254
Phone: (850) 245-4292 • Fax: (850) 413-6982 • <http://www.doh.state.fl.us/mqa/pharmacy>

Letter mailed on December 4, 2012

Rick Scott
Governor



John H. Armstrong, MD, FACS
Surgeon General & Secretary

SECOND NOTICE



December 4, 2012

Dear Pharmacy Permittee,

This is a follow up to the letter mailed to you on November 27, 2012. We have not yet received your response to the mandatory survey. Please be aware that the deadline to complete this mandatory survey is 12:00 midnight, December 11, 2012.

With the recent nationwide fungal meningitis outbreak caused by contaminated compounded products, the Florida Board of Pharmacy adopted Emergency Rule 64B16ER12-1, Florida Administrative Code. This Emergency Rule **requires all Florida licensed pharmacy permit holders**, including non-residents, to complete a **mandatory survey** to inform the Board of its compounding activities. The goal of this **mandatory survey** is to determine the scope of sterile and non-sterile compounding within Florida licensed pharmacies – whether physically located in or out-of-state. **Failure to timely complete the mandatory survey is grounds for disciplinary action; however, the goal is not to discipline, only to obtain critical data. Your cooperation in this matter is important to the department's public protection mission.**

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In addition to completing this survey, all non-resident pharmacy permit holders are required to provide copies of their two most recent inspection reports from the state in which their pharmacy is physically located. The inspection reports must be postmarked by December 11, 2012 and mailed to the attention of Mark Whitten, Executive Director, at the address reflected in the footer below.

Protecting patient safety and the integrity of the pharmacy compounding industry is critical. This survey is intended to gather data that will allow policymakers to make **informed** decisions, without creating undue regulatory burdens.

Thank you for helping the Department of Health and the Board to protect, promote and improve the health of all people in Florida through integrated state, local and community efforts.

Sincerely,

Mark Whitten, Executive Director
Florida Department of Health
Board of Pharmacy

Board of Pharmacy
4052 Bald Cypress Way, Bin C04 • Tallahassee, Florida 32399-3254
Phone: (850) 245-4292 • Fax: (850) 413-6982 • <http://www.doh.state.fl.us/mqa/pharmacy>

APPENDIX B Survey

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Florida Board of Pharmacy Compounding Survey

Pharmacy Name:

Pharmacy Address:

Pharmacy Permit Number:

Email Address:

1. Does your pharmacy hold a permit in any state other than Florida?

- Yes
- No

1a. If yes, in which other state(s) does your pharmacy hold a pharmacy permit (check all that apply)?

- AL AK AZ AR CA CO CT DE DC FL GA HI ID IL IN
 IA KS KY LA ME MD MA MI MN MS MO MT NE
 NV NH NJ NM NY NC ND OH OK OR PA RI SC
 SD TN TX UT VT VA WA WV WI WY

2. Pharmacy permit type (check all that apply):

- Central Fill
- Class II Institutional
- Community
- Internet
- Modified Class II Institutional
- Non-Resident
- Nuclear
- Special Closed System
- Special ESRD
- Special Limited Community
- Special Parenteral/Enteral
- Special Parenteral/Enteral Extended Scope
- None of the above (If you are permitted as an Animal Control Shelter, Institutional Class I Nursing Home, or Assisted Living Facility, you are not authorized to compound. The survey is complete; please submit.)

3. Is your pharmacy currently registered, licensed, or permitted as a pharmaceutical manufacturer in any state?

- Yes
- No

3a. If yes, which state(s) is your pharmacy currently registered, licensed, or permitted as a pharmaceutical manufacturer (check all that apply)?

- AL AK AZ AR CA CO CT DE DC FL GA HI ID IL IN
IA KS KY LA ME MD MA MI MN MS MO MT NE
NV NH NJ NM NY NC ND OH OK OR PA RI SC
SD TN TX UT VT VA WA WV WI WY

4. Is your pharmacy currently registered, licensed, or permitted as a wholesale distributor in any state?

- Yes
 No

4a. If yes, in which state(s) is your pharmacy currently registered, licensed, or permitted as a wholesale distributor (check all that apply)?

- AL AK AZ AR CA CO CT DE DC FL GA HI ID IL IN
IA KS KY LA ME MD MA MI MN MS MO MT NE
NV NH NJ NM NY NC ND OH OK OR PA RI SC
SD TN TX UT VT VA WA WV WI WY

Non-Sterile Compounding

5. Does your pharmacy compound non-sterile products?

- Yes
 No

5a. If yes, what percentage of your business is related to non-sterile compounding?

- Less than 10%
 11% to 25%
 26% to 50%
 51% to 75%
 Greater than 75%

5b. If yes, what types of non-sterile products do you compound (check all that apply)?

- Creams
 Lotions
 Ointments
 Mouthwash
 Liquids

- Drops
 Capsules
 Troches
 Suppositories
 Tablets
 Gels

Other:

5c. If yes, do you compound (check all that apply)?

- pursuant to a patient-specific prescription
 in bulk (compounding multiple doses from a single source or batch)
 in bulk for office use

5d. If you answered "yes" to compounding in bulk, would your largest single batch include:

- 24 or less doses from a single batch
 25 to 49 doses from a single batch
 50 to 100 doses from a single batch
 Greater than 100 doses from a single batch

6. Does your pharmacy ship non-sterile compounded products to other states?

- Yes
 No

6a. If yes, in which state(s) does your pharmacy ship (check all that apply)?

- AL AK AZ AR CA CO CT DE DC FL GA HI ID IL IN
IA KS KY LA ME MD MA MI MN MS MO MT NE
NV NH NJ NM NY NC ND OH OK OR PA RI SC
SD TN TX UT VT VA WA WV WI WY

7. Has your company ever recalled a non-sterile compounded product due to compounding error?

- Yes
 No

7a. If yes, list the name(s) of the drug and the reason for the recall.

7b. If yes, did the recall occur:

- Within the last six months
- Greater than six months and less than one year
- More than one year

Sterile Compounding

8. Does your pharmacy compound sterile products?

- Yes
- No

8a. If yes, what percentage of your business is related to sterile compounding?

- Less than 10%
- 11% to 25%
- 26% to 50%
- 51% to 75%
- Greater than 75%

8b. If yes, what types of sterile products do you compound (check all that apply)?

- Total Parenteral Nutrition (TPN) solutions
- Parenteral analgesic drugs
- Parenteral antibiotics
- Parenteral antineoplastic agents
- Parenteral electrolytes
- Parenteral vitamins
- Irrigating fluids
- Ophthalmic preparations
- Aqueous inhalant solutions for respiratory treatments

Other:

8c. If yes, do you compound (check all that apply)?

- pursuant to a patient-specific prescription
- in bulk (compounding multiple doses from a single source or batch)
- in bulk for office use

8d. If you answered "yes" to compounding in bulk, would your largest single batch include:

- 24 or less doses from a single batch
- 25 to 49 doses from a single batch
- 50 to 100 doses from a single batch
- Greater than 100 doses from a single batch

9. Does your pharmacy ship sterile compounded products to other states?

- Yes
- No

9a. If yes, to which state(s) does your pharmacy ship (check all that apply)?

- AL AK AZ AR CA CO CT DE DC FL GA HI ID IL IN
- IA KS KY LA ME MD MA MI MN MS MO MT NE
- NV NH NJ NM NY NC ND OH OK OR PA RI SC
- SD TN TX UT VT VA WA WV WI WY

10. Total number of pharmacy staff:

Pharmacists:

Technicians:

Interns:

11. Total number of pharmacy staff preparing sterile products:

Pharmacists:

Technicians:

Interns:

12. How many clean rooms are in your pharmacy?

Number of clean rooms:

13. How many laminar flow hoods are in your pharmacy?

Number of laminar flow hoods:

14. When was the last time your clean room was certified by an independent contractor for National Sanitation Foundation Standard 49?

- Less than six months
- Six months to one year
- Greater than one year

14a. What is the name and address of the independent contractor certifying your clean room?

15. When was the last time your laminar flow hood was certified by an independent contractor for National Sanitation Foundation Standard 49?

- Less than six months
- Six months to one year

- Greater than one year

15a. What is the name and address of the independent contractor certifying your laminar flow hood?

16. Has your company ever recalled a sterile compounded product due to compounding error?

- Yes
- No

16a. If yes, list the name(s) of the drug and the reason for the recall.

16b. If yes, did the recall occur:

- Less than six months
- Six months to one year
- Greater than one year

If you are a *Non-Resident Pharmacy* please proceed to the next section. If you are NOT a Non-Resident Pharmacy, the survey is complete; please submit.

Non-Resident Pharmacies

17. Does the state in which you are physically located allow compounding?

- Yes
- No

17a. If yes, does your state permit compounding (check all that apply)?

- pursuant to a patient-specific prescription
- in bulk (compounding multiple doses from a single source or batch)
- in bulk for office use

17b. If you answered "yes" to compounding in bulk, would your largest single batch include:

- 24 or less doses from a single batch
- 25 to 49 doses from a single batch
- 50 to 100 doses from a single batch
- Greater than 100 doses from a single batch

17c. When was your pharmacy last inspected by your state regulatory authority?

- Less than six months
- Six months to one year
- Greater than one year

DH-MQA 1308, 11/12, Rule 64B16ER12-1, FAC

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APPENDIX C Glossary

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Compounding: the incorporation of ingredients to create a finished product for dispensing to a patient or for the administration by a health care practitioner to the patient.

- Non-Sterile: includes creams, lotions, ointments, mouthwash, liquids, tablets, lollipops, etc.
- Sterile: includes parenteral analgesic drugs (e.g., methylprednisolone acetate), parenteral antibiotics, irrigating fluids, ophthalmic preparations, etc. Sterile compounding is classified as high risk, medium risk, low risk, and immediate use. High-Risk Level Compounding Sterile Preparations are products compounded under conditions set forth in rule and includes products compounded using non-sterile ingredients that are incorporated into sterile parenteral administration products. Sterile compounding requirements and practice standards are set in board rule. Key requirements include a laminar flow hood in a clean room or a barrier isolator and non sink or drain in the clean room.
- In Bulk: compounding multiple doses from a single source or batch.

Office Use Compounding: Board of Pharmacy rules allow pharmacies to prepare many doses of a drug without patient-specific prescriptions and to provide those drugs to doctors' offices and clinics based on regularly observed prescribing patterns. "Office use" is defined as the administration of a compounded drug to a patient by a health care practitioner in a treatment setting.

National Sanitation Foundation (NSF) Standard 49: The NSF Biosafety Cabinetry Program was initiated over 25 years ago at the request of the regulatory community, including the Centers for Disease Control (CDC), National Institutes of Health (NIH), and the National Cancer Institute (NCI). The first phase of the program was the development of NSF/ANSI Standard 49 for the evaluation of Class II laminar flow biological safety cabinets. The standard was completed in 1976, followed by the implementation of a testing and certification program to that standard, titled the Biosafety Cabinetry Certification Program. The third and final stage was completed in 1993, titled the Biosafety Cabinet Field Certifier Accreditation Program.

Prescription: Section 465.003(14), F.S., defines a "prescription" to include any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

PERMIT	STATUTE/RULE	PDM/CPH	REQUIREMENTS	SETTINGS
Animal Shelter	465.005 828.055 29.001 29.003	Shelter Manager	<ul style="list-style-type: none"> This permit does not authorize sterile or non-sterile compounding Authorizes the animal shelter to purchase and store specific drugs for animal euthanasia 	<ul style="list-style-type: none"> Animal Shelters
Closed System Pharmacy	465.0196 28.830	PDM	<ul style="list-style-type: none"> This permit authorizes sterile and non-sterile compounding Pharmacist dispenses unit dose prescription drugs pursuant to a prescription to individuals in institutional closed type settings 	<ul style="list-style-type: none"> Nursing Homes Jails Adult Living Facilities Correctional Facilities
Community Pharmacy	465.018 28.404	PDM	<ul style="list-style-type: none"> This permit authorizes sterile and non-sterile compounding Pharmacist dispenses prescription drugs pursuant to a prescription to individuals that live in the community 	<ul style="list-style-type: none"> Regular walk-in pharmacy Mail Order Central Fill Internet
Dispensing Practitioner	465.0276		<ul style="list-style-type: none"> Licensee registers with the Board of Medicine as a dispensing practitioner Physician dispenses prescription drugs pursuant to a prescription Must comply with all laws and rules applicable to pharmacists and pharmacies 	<ul style="list-style-type: none"> Dispensing Practitioner
Institutional Class I	465.019 28.501	CPH	<ul style="list-style-type: none"> This permit does not authorize sterile or non-sterile compounding This permit allows nursing homes to store and administer prescription drugs from an individual prescription containers dispensed by a pharmacist to an individual patient 	<ul style="list-style-type: none"> Nursing Homes
Institutional Class II	465.019 28.501 28.602 28.603	CPH	<ul style="list-style-type: none"> This permit authorizes sterile and non-sterile compounding This permit allows pharmacies to prepare medications to be administered to inpatients of a hospital 	<ul style="list-style-type: none"> Hospital

PERMIT	STATUTE/RULE	PDM/CPH	REQUIREMENTS	SETTINGS
Internet Pharmacy	465.1097	RPH is designated the PDM to dispense into FL.	<ul style="list-style-type: none"> This permit authorizes sterile and non-sterile compounding Pharmacist dispenses prescription drugs pursuant to a prescription If they hold a community, institutional, special or nuclear pharmacy permit they may do internet 	<ul style="list-style-type: none"> Not opened to the general public
Modified Institutional II A or B	465.019 28.702	CPH	<ul style="list-style-type: none"> This permit authorizes sterile and non-sterile compounding Facility where drugs are stored for administration to patients A: formulary limited to 15 drugs B: meds may be stored as stock or patient specific from another permit C: provides pharmacy services in a custodial care facility; meds are stored as patient specific from another permit 	<ul style="list-style-type: none"> Rapid In/Out Surgery Centers Kidney Dialysis Centers Correctional Institutions Methadone Clinics Alcoholic Treatment Centers
Non-Resident Pharmacy Registration	465.0156 28.840	RPH must be licensed in the state of location to dispense into FL.	<ul style="list-style-type: none"> If authorized in the state in which located, the permittee may compound sterile and non-sterile products Facility located outside the State of Florida that dispenses medication based on a prescription to the residents in Florida Not inspected by DOH 	<ul style="list-style-type: none"> Must be licensed in the state where located
Nuclear Pharmacy	465.0193 28.901	NPH	<ul style="list-style-type: none"> This permit authorizes the pharmacy to provide radiopharmaceutical services which includes the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping and disposal of radiopharmaceuticals (radioactive materials) 	
Special ALF (Adult	465.0196	CPH	<ul style="list-style-type: none"> This permit does not authorize sterile or non-sterile compounding 	<ul style="list-style-type: none"> Adult Living Facilities

PERMIT	STATUTE/RULE	PDM/CPH	REQUIREMENTS	SETTINGS
Living Facility)	28.870		<ul style="list-style-type: none"> This is an optional permit for an ALF which allows them to return unused medication to the dispensing pharmacies stock if they are unit dosed Pharmacist is not on-site in the ALF. Pharmacist dispenses prescription drugs pursuant to a prescription. 	
Special ESRD (End Stage Renal Disease)	465.0196 28.850	CPH	<ul style="list-style-type: none"> This permit does not authorize sterile or non-sterile compounding This permit is limited to dialysis products and supplies to persons with chronic kidney failure for self-administration 	<ul style="list-style-type: none"> Dialysis Centers
Special Limited Community	465.0196 28.810	PDM	<ul style="list-style-type: none"> This permit authorizes sterile and non-sterile compounding Issued in conjunction with an Institutional II permit Allows for dispensing up to a three day supply of meds to someone being released from the hospital as well as filling employee prescriptions or emergency room 	<ul style="list-style-type: none"> Hospital
Special P&E Extended Scope	465.0196 28.860	PDM	<ul style="list-style-type: none"> This permit authorizes sterile and non-sterile compounding This permit allows the pharmacy to mix, compound and dispense intravenous therapy for hospitals, in addition to Special P&E functions 	
Sterile Products & Special P&E Compounding Pharmacy	465.0196 28.820	PDM	<ul style="list-style-type: none"> This permit authorizes compounding of sterile products, as well as compounding and mixing for intravenous therapy Can be bundled with an existing community permit Pharmacist dispenses compounded prescription drugs pursuant to a prescription 	<ul style="list-style-type: none"> Compounding Pharmacy

APPENDIX D Emergency Rule

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Notice of Emergency Rule

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.: RULE TITLE:

64B16ER12-1: Immediate Notification of Compounding Status and Inspections

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are currently investigating a multi-state fungal meningitis and other infectious outbreak. The investigation involves collaboration with multiple local and state health departments. The investigation revealed that the outbreak resulted from a compounded drug – a contaminated (adulterated) steroid injection. The New England Compounding Center (NECC) located in Framingham, Massachusetts, compounded and distributed the contaminated, injectable product. As of November 19, 2012, the investigation has confirmed 490 infections and 34 deaths related to the adulterated steroid injection. The CDC has confirmed, in Florida alone, 24 cases of infections and 3 patient deaths. The investigation has further revealed that the NECC compounding facility lacked proper sanitary conditions. As of November 8, 2012, there were 7,879 Florida licensed pharmacies authorized to compound. Pharmacies may compound either sterile or non-sterile products, excluding nuclear pharmaceuticals, without any additional permit or licensure requirements. However, the board has set standards for compounding sterile products. All permitted pharmacies are subject to inspection to determine compliance with the laws and rules regulating pharmacies. A non-resident pharmacy is a pharmacy physically located outside of Florida that is registered with the board which allows the delivery of a dispensed medicinal drug into this state. As of November 8, 2012, Florida had 725 non-resident pharmacies. NECC is an example of a non-resident pharmacy. Non-resident pharmacies are only subject to inspections based on the laws and rules of the state in which they are physically located and in which they are licensed. Non-resident pharmacies are not required to produce inspection reports to the board.

A compounded product that is contaminated or adulterated or a compounding pharmacy which lacks proper sterile and sanitary environments, presents an immediate, clear, present danger to the welfare, health, and safety of the citizens of the state of Florida as manifested by the recent outbreak of infections and resulting deaths. Moreover, The State Surgeon General recently issued the emergency suspension of two Florida compounding pharmacies for improper sanitary and environmental controls. For the protection of the citizens' health, welfare and safety from continued proliferation of unsanitary or contamination compounding environments and distribution of contaminated products into this state, the board is in immediate need of comprehensive data: the specific compounding activities taking place at all permitted pharmacies and non-resident pharmacies. The rule is specifically designed to target, through inspection reporting requirements of non-resident pharmacies, to identify and minimize the immediate threat of contaminated products. The rule is also critical for identifying the high risk compounding activities in Florida pharmacies, so the department and board can prioritize inspections to minimize the immediate health and safety risks associated with unsanitary and unsterile compounding facilities in Florida.

REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: On November 14, the Board provided a public notice that the board would

be holding a public meeting on November 20, 2012, to address compounding pharmacies. The board published the notice in the Florida Administrative Register. The Florida Administrative Register is available worldwide on the web. The agenda included the topic of requiring mandatory compounding reporting. The board placed the notice on the department website and provided a public notice of the agenda on the same website. On November 20, 2012, the board held a publicly noticed meeting for the purposes of addressing pharmacy compounding that included the necessity of this emergency rule. The board gave all interested parties the opportunity to provide input on pharmacy compounding and the rule. The parties present included counsels for pharmacy companies; state and national pharmacy associations; and individual pharmacy company representatives. Accordingly, the board provided all impacted parties sufficient notice of the intended action and provided a fair procedural opportunity for participation. Additionally, the board has directed that all pharmacies impacted by this emergency rule must be given direct notice of the rule through electronic mail or via correspondence at the the address of record on file with the department.

SUMMARY: The rule requires all permitted and registered pharmacies immediately notify the board of its compounding activities. Based on the data, the board requires prioritizing inspections based on the risk level to the citizens of the state of Florida.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Mark Whitten, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254

THE FULL TEXT OF THE EMERGENCY RULE IS:

64B16ER12-1 Immediate Notification of Compounding Status and Inspections.
All permitted and non-resident pharmacies shall, within 14 days of the effective date of this rule, report their compounding activities.

(1) All Pharmacies: The compounding status of all permitted and registered pharmacies shall be reported on form number DH-MQA 1308, Compounding Survey, herein adopted and incorporated by reference. The form is available at <http://survey.doh.state.fl.us/survey/entry.jsp?id=1353086689950>;

(2) Permitted Pharmacies: Based on the compilation of the data reported, inspections of permitted pharmacies required by Rule 64B16-28.101 shall be prioritized as follows: 1) Those pharmacies which only engage in compounding sterile products; 2) Those pharmacies which engage in the compounding of sterile and non-sterile products; 3) Those pharmacies which only engage in non-sterile compounding and those pharmacies which do not engage in compounding;

(3) Registered Non-Resident Pharmacies: All registered pharmacies must immediately provide a copy of their last two inspection reports that were required by the state in which the pharmacy is physically located and licensed. The board must receive the report within 14 days of the effective date of this rule.

(4) A failure to timely comply with this section shall constitute the basis for disciplinary action.

Rule Making Authority: 465.005; 465.0155; 465.022, F.S. Law Implemented: 465.0155; 465.0156(1)(c) and (2); 465.017; 465.022; 465.023, F.S. History – New.

THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.

EFFECTIVE DATE: November 26, 2012

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APPENDIX E Pharmacy Compounding in Florida

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Pharmacy Compounding in Florida

November 16, 2012

Lucy C. Gee, M.S.
Director, Division of Medical Quality Assurance

**COMPOUNDING
VERSUS
MANUFACTURING**

Pharmacy Compounding

- The Florida Board of Pharmacy regulates pharmacy compounding and promulgates compounding rules.
- Compounding is the incorporation of ingredients to create a finished drug product for dispensing to a patient or for the administration by a health care practitioner to the patient.
- Excluding nuclear pharmaceuticals, any pharmacy permittee can perform compounding except for animal shelters, assisted living facilities (ALF) or nursing homes.
- A special parenteral/enteral permit, a type of pharmacy permit, allows the compounding of sterile products without some of the additional mandates included in a community pharmacy permit (e.g. the mandate to be open 40 hours a week). A special parenteral/enteral permit is not required, however, to perform sterile compounding in Florida. As of November 8, 2012, there were 285 special parenteral/enteral pharmacy permittees in Florida.
- A nuclear pharmacy permit is required to compound sterile nuclear pharmaceuticals. As of November 8, 2012, there were 33 nuclear pharmacy permittees in Florida.
- As of November 8, 2012, there were 7,879 Florida licensed pharmacies authorized to compound.
- Board of Pharmacy rules allow compounding of drugs or devices in anticipation of prescriptions and for drugs that are not commercially available (e.g. no manufacturer is producing the drug or the patient needs modified ingredients). Additionally, the rules allow compounding from bulk, commercially available drugs, based on a patient specific prescription. Compounding for office use is also permitted.
- The Board of Pharmacy has defined "office use" to mean the administration of a compounded drug to a patient by a health care practitioner in a treatment setting.
- Board rules allow pharmacies to prepare many doses of a drug without patient-specific prescriptions and to provide those drugs to doctors' offices and clinics based on regularly observed prescribing patterns.
- According to the International Academy of Compounding Pharmacists, 42 states allow office use compounding in some form. Six states specifically prohibit this type of compounding, and two states are silent.
- Board rules on record keeping require a pharmacy to record date of compounding, control number for each batch/sub-batch, and patient name when dispensed directly to the patient. The control number may be the manufacturer's lot number or a new number assigned by the pharmacist. The rules do not require a compounding pharmacy to maintain a record of lot numbers for products sold for office use.

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- According to a November 5, 2012 Washington Post article, "Previous Fungal Meningitis Outbreak a Decade Ago Resulted in no Oversight Changes," compounding pharmacies in most states must follow the less strict standards of USP 797, set by the United States Pharmacopeia than the workplace standards and sterility requirements of pharmaceutical plants. According to the Pharmacy Compounding Accreditation Board, 17 states have adopted USP 797 in its entirety.
- Florida laws and rules governing compounding pharmacies are less strict than the standards in USP 797 and the requirements for manufacturers, which are regulated by the United States Food and Drug Administration and the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics.
- A non-resident pharmacy is a pharmacy located outside of Florida delivering a dispensed medicinal drug in any manner into this state. As of November 8, 2012, Florida had 725 non-resident pharmacy permittees.
- Non-resident pharmacies licensed by Florida must be compliant with the laws of the state in which they are physically located, must operate six days per week for at least 40 hours, and must have a toll free telephone number.
- A pharmacy that is operating in compliance with the pharmacy practice standards of the Board of Pharmacy does not fall within the term "manufacturer" set forth in Chapter 499, Florida Statutes, Florida's Drugs, Cosmetics and Household Products Act.
- Compounding in Florida falls into two categories, sterile and non-sterile. Neither requires a special permit.
- Non-sterile compounding includes creams, lotions, ointments, mouthwash, liquids, tablets, lollipops, etc.
- Sterile compounding includes parenteral analgesic drugs (e.g. methylprednisolone acetate), parenteral antibiotics, irrigating fluids, ophthalmic preparations, etc.
- Sterile compounding is classified as high risk, medium risk, low risk and immediate use. High-Risk Level Compounding Sterile Preparations (CSPs) are products compounded under conditions set forth in rule and includes products compounded using non-sterile ingredients that are incorporated into sterile parenteral administration products.
- Sterile compounding requirements and practice standards are set in board rule. Key requirements include a laminar flow hood in a clean room or a barrier isolator and no sink or drain in the clean room.
- Sterility testing is required if high risk compounding of batches larger than 25 units is performed and if sterile compounded preparations are stored longer than specified in board rule.
- All compounding personnel are required to demonstrate competency by completing a commercially available sterile fluid culture media. Media-filled vials are incubated at 25-35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days.

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- The laminar flow hood and clean room must meet air quality requirements that are certified by an independent contractor hired by the pharmacy.
- Compounding pharmacies engaged in high risk sterile preparation require semi-annual certification of air quality. Medium and low risk compounding require annual certification of air quality.

Pharmacy Manufacturing

- Drugs, devices and cosmetics manufacturing in Florida are governed under Chapter 499, F.S., which is under the Department of Business and Professional Regulation. "Manufacturing" means the preparation, deriving, compounding, propagation, processing, producing or fabrication of any drug, device or cosmetic. The term "manufacturer" under Chapter 499, F.S., specifically excludes a pharmacy that is operating in compliance with pharmacy practice standards.
- The Federal government exempts drug products compounded by a pharmacist or a physician from three key provisions of the Federal Food, Drug and Cosmetic Act that governs pharmaceutical manufacturing. Drug products compounded by a pharmacist or physician for an individualized patient are exempt from the Federal adulteration provision concerning good manufacturing requirements; the misbranding provision concerning the labeling of drugs with adequate directions of use; and the new drug provision concerning the approval of drugs under new or abbreviated drug applications.

COMPOUNDING INSPECTIONS

- Pharmacies in Florida are inspected by 18 DOH investigators hired specifically for pharmacy inspections, five of whom are licensed pharmacists.
- The frequency of inspections is established in board rule. New pharmacies are inspected twice during their first year. The frequency of other pharmacy inspections is based on prior inspection history or disciplinary action taken by the board, but should be no less than every other year.
- Non-resident pharmacies are inspected by the regulatory body in the state in which they are physically located according to the standards in that state. No proof of inspection is required for license renewal.
- Florida pharmacies that perform sterile and non-sterile compounding must meet additional inspection criteria.
- Pharmacies that perform sterile compounding are inspected according to specifications in board rule that include review of sterility documentation, performance of a visual check of the compounding area, a review of policies and procedures, verification that there are no sinks or drains in the clean room, verification of adequate supplies and equipment, etc.

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- DOH investigators do not test the air quality of clean rooms and laminar flow hoods, or the sterility of compounded products.
- DOH investigators check for documentation of certification of clean rooms and laminar flow hoods that has been performed by an outside entity hired by the pharmacy. There are no board approval requirements for these outside entities.
- DOH investigators also check for documentation that the compounding pharmacy is performing sterility testing for high risk level sterile preparations compounded in batches greater than 25 units. Sterility testing is also required if products are stored longer than authorized by rule based on risk level, for which investigators also check documentation.

COMPOUNDING VIOLATIONS AND DISCIPLINE

- A violation identified during an inspection is handled in one of two ways: 1) the pharmacy is given an opportunity to correct minor violations, (e.g. policies and procedures out of date) and provide proof of correction by mail; or 2) for more serious violations, a complaint is opened for investigation and possible emergency action based upon an immediate risk to public health and safety.
- When an investigation is opened based upon an inspection violation complaint, during the course of the investigation, an inspector will re-inspect the pharmacy to determine what actions have been taken to correct the violation. The results of the re-inspection are considered by the Board.
- No penalty guidelines exist for violations specifically related to the Standards of Practice for Compounding Sterile Preparations. General penalty guidelines for the practice of pharmacy apply.
- A compounding error, including contamination, can be charged as a violation of Florida Law, and the guidelines are a \$250 fine and an eight-hour misfill continuing education course, up to revocation.
- At the October 2012 Board meeting for a case involving violations of the compounding standards (no known patient harm was involved), the Board imposed probation on both the pharmacy and pharmacist for 1-2 years with quarterly inspections at the licensee's cost to determine and ensure compliance with compounding standards and additional continuing education for the pharmacist involved.
- Two pharmacists and three pharmacies have been disciplined by the Board of Pharmacy related to the practice of compounding from January 1, 2009 through November 9, 2012.
- Of the six pharmacies in Florida currently on Emergency Suspension Order, two are related to compounding.

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- Rejuvi Pharmaceuticals, Inc PH 23297 E.S.O. issued on October 24, 2012: Not clean and safe for sterile compounding.
- People's Choice Pharmacy, LLC PH24693 E.S.O. issued November 6, 2012: A complete disregard for quality assurance in high-risk sterile compounding and the use of unlicensed personnel for high-risk sterile compounding makes the pharmacy unsafe and the public at risk

**RECOMMENDATIONS
FOR CONSIDERATION
BY THE BOARD**

Compounding General

Permitting

- Require all pharmacies, excluding hospitals and surgery centers, to obtain a special license or special license designation modifier in order to compound sterile drug products.

- Establish inspection fees to cover costs of mandatory inspections.
- Allow accreditation of compounding pharmacies by a national accrediting body or, in lieu of accreditation, require annual inspections at the cost of the permittee, according to USP 797 guidelines.

Practice Standards

- Require compounding pharmacies to meet or exceed USP 797 guidelines, including a mandatory audit trail of all compounded drug products.
- Expand record keeping requirements to capture lot numbers from compounding pharmacy to administration or dispensing to patient (possibly Boards of Medicine, Osteopathic Medicine, Dentistry, Nursing and Podiatry practice act modification).
- Establish mandatory adverse event reporting, including compounding errors, to the purchaser and the department.
- Establish clearer definitions and practice standards for non patient-specific compounding.
- Only allow the compounding of non-commercially available drugs based on a patient specific prescription. This provision should make exception for compounding drugs not available due to drug shortages.

Enforcement/Discipline

- Establish minimum mandatory disciplinary guidelines for compounding violations for pharmacy owners, pharmacy managers, pharmacy permits, pharmacists and pharmacy technicians.
- If the compounding pharmacy's permit is revoked, any person named in the permit documents of the compounding pharmacy, including persons owning or operating it may not, as an individual or as part of a group, apply to operate a compounding pharmacy for 5 years after the date the permit is revoked.
- The relinquishment of a license in anticipation of a compounding violation constitutes the permanent revocation of the license.
- Establish grounds for discipline for the pharmacy manager and pharmacy owner if a compounding error occurs.

Non-Resident Permits

- Require mandatory accreditation and periodic reaccreditation by the Pharmacy Compounding Accreditation Board (PCAB), its successor organization, or an equivalent accredited organization approved by the Florida Board of Pharmacy for all non-resident permits with a compounding permit.
- At initial licensure of non-resident pharmacies, require notification to the Board of Pharmacy of the scope of compounding permitted in their home state and require updates of any change in their state's laws.
- Establish increased renewal requirements for existing non-resident pharmacies, including proof of inspection by the state regulatory authority in which the pharmacy is located, within the last year, until accredited.
- Require criminal background screening of all owners, officers and affiliated persons of non-resident pharmacies.

Florida Department of Business & Professional Regulation

License efficiently. Regulate fairly.

Ken Lawson
Secretary

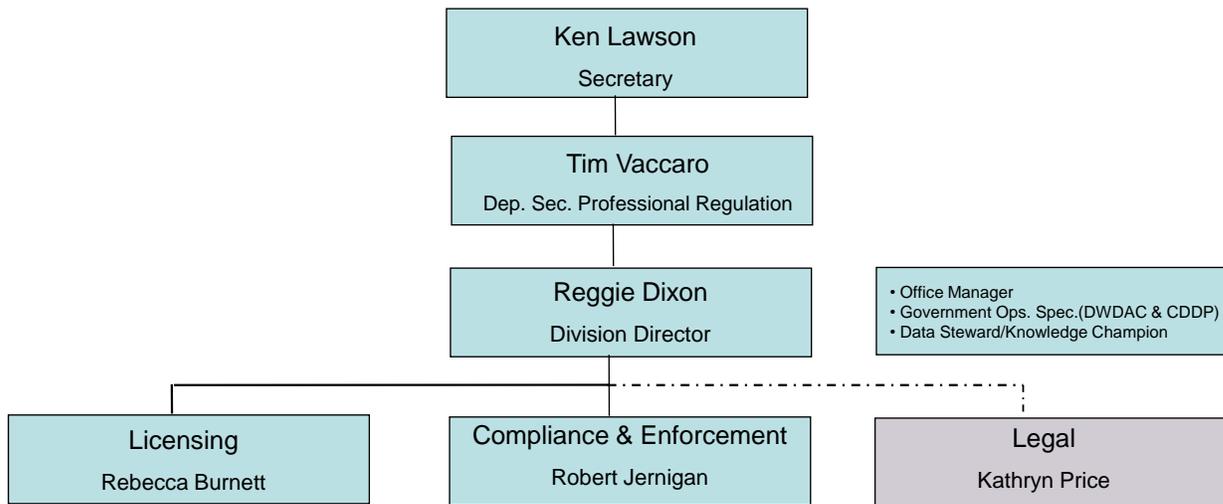
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Drugs, Devices, and Cosmetics

- Mission – safeguard Florida citizenry from injury by the use of adulterated or contaminated drugs, drug ingredients and cosmetics, by administering the Florida Drug and Cosmetic Act (Chapter 499, F.S.)
- 30.5 Positions – (including 10 drug inspectors (pharmacists)) in the division
- 4 Units
 - Director's Office
 - Compliance & Enforcement
 - Legal (supervised by DBPR's Office of General Counsel)
 - Licensing
- Approximately 9,353 licensed establishments
- Drug Wholesaler Distribution Advisory Council – provides input to the department for the administration of Chapter 499, F.S., including rules.
- Cancer Drug Donation Program – allows for donation of cancer drugs to uninsured patients.

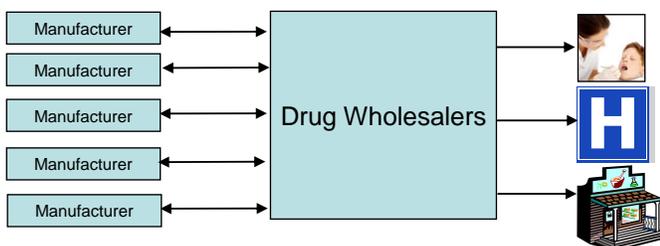
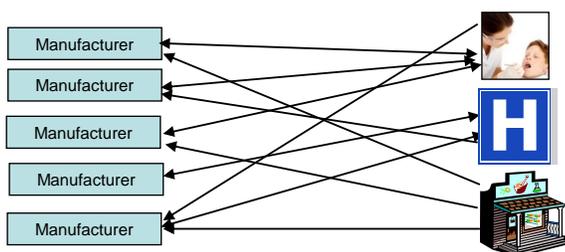
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Drugs, Devices, and Cosmetics



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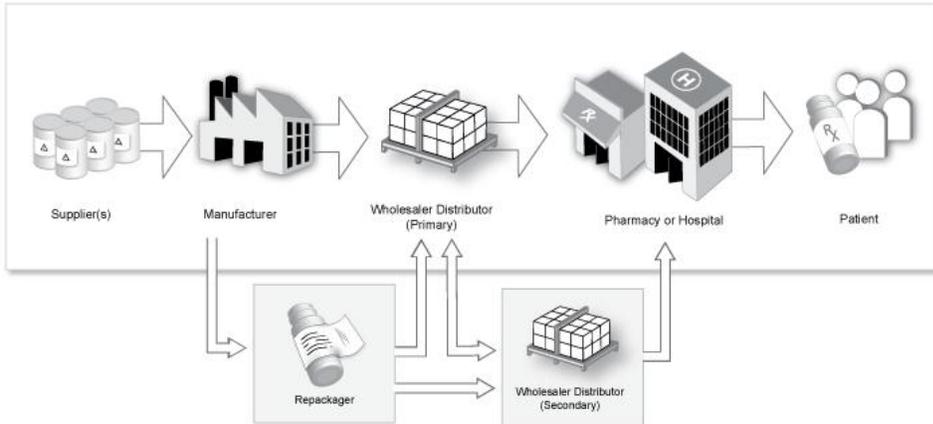
Drugs, Devices, and Cosmetics



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Drugs, Devices, and Cosmetics

Example of Typical Drug Supply Chain Today



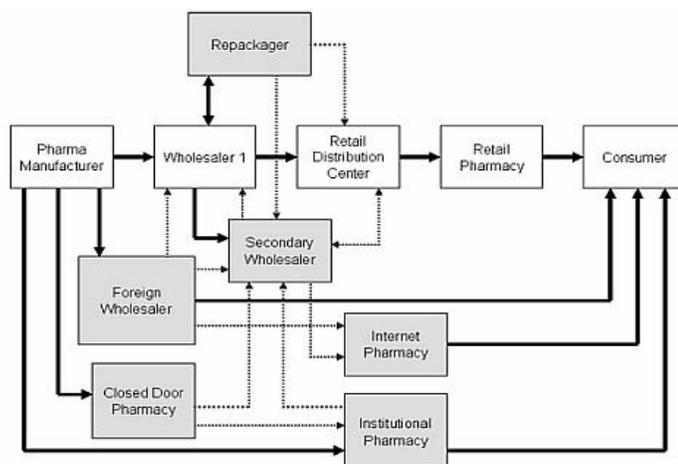
In Florida:

- Manufacturers, Distributors, Repackagers and Health Care Entities have to be permitted under Chapter 499, F.S., before distributing Rx drugs into or within the state.
- Distributors, other than manufacturers, will have to deliver and/or receive some form of a pedigree.

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Drugs, Devices, and Cosmetics

Typical Drug Supply Chain Today



- As more entities become involved in the supply chain, concerns regarding the security and the integrity of the drug supply increase.
- Importance of education, licensure, inspections, pedigree, and documentation.

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Drugs, Devices, and Cosmetics

Traditional Compounding

- Compounding - art and science of preparing customized medication that are not otherwise commercially available.
- Performed by or under the supervision of a pharmacist pursuant to an order from a licensed prescriber for an individual patient.
- Compounding is an essential element of pharmacy practice.
- Regulated by individual state Boards of Pharmacy.
- No formal approval prior to dispensing to the patient.



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Drugs, Devices, and Cosmetics

Manufacturing

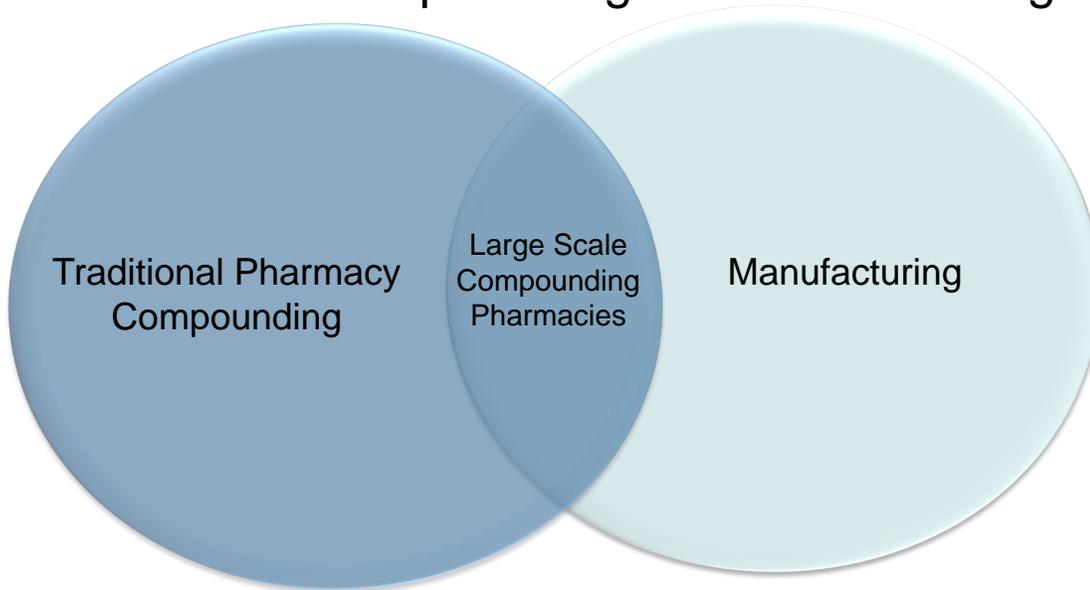
- Manufacturing is the process of industrial-scale synthesis of pharmaceutical drugs by pharmaceutical companies.
- Regulated by the federal Food and Drug Administration (FDA) and individual states.
- Extensive testing and pre-market approval required.



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Drugs, Devices, and Cosmetics

Traditional Compounding vs. Manufacturing



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Drugs, Devices, and Cosmetics

Traditional Compounding vs. Manufacturing

Characteristic	Traditional Compounding	Manufacturing
Quantity, duration, and distribution of medication	Small, short, and local to individual patients	Large, long, and nationally to wholesalers and pharmacies
Main legal regulation	State Boards of Pharmacy	Food and Drug Administration
Quality/Performance testing	Florida Pharmacy Rules 64B16-27, F.A.C.	Current Good Manufacturing Practices
Patient – Physician – Pharmacist Triad	Critical to success	Almost non-existent
Patient Specific Prescription for medication	Yes	No

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Drugs, Devices, and Cosmetics

Business Factors Leading to Pharmacy Service Outsourcing

Organizational/Operational Factors

- Re-engineering and downsizing
- Consolidation and integration of health services or departments
- Implementation of automatic pharmacy systems

Staffing Factors

- Shortage of pharmacists with specific experience and capabilities

Cost Factors

- Restricted budgets (lowers costs, reduces risk exposure, labor costs)
- Increased drug costs (purchase bulk drugs using group purchasing contracts)

Quality

- Focus on quality of patient care by expanding or increasing other services

Competition

- Increased competition among health care organizations
- Increased competition among suppliers of pharmaceuticals and related services

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Drugs, Devices, and Cosmetics

Concurrent Jurisdiction of DBPR and DOH

DBPR - DDC

- Drug Manufacturers and Wholesale Distributors – in and out-of-state that distribute within FL.
- Repackagers – repackage/re-label and distribute drugs in FL.
- Health Care Clinic Establishments – place of business with a qualifying physician that purchases Rx drugs.
- Other establishments where drugs are made, held, sold, e.g., retail stores, pharmacies, hospitals, etc.

DOH

- Contaminated compounded drugs
- Pharmacies where drugs are compounded
- Use of non-sterile equipment by practitioner or business
- Use of known contaminated drugs or equipment
- Possession of adulterated drugs by Health Care practitioner or facility
- Manufacturing drugs under the guise of “compounding”
- Pharmacy – FL licensed pharmacies / pharmacists and practice of pharmacy, including compounding.
- Individual Health Care Practitioner practice, including failures to comply with Ch. 499 F.S.
- Any establishment where the licensee is authorized to prescribe Controlled Substances operates.
- Hospitals, clinics, physician's offices, etc., in FL.
- Coordination of state efforts to prevent diseases, illnesses, and hazards to human health.
- Enforce state health laws.

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Drugs, Devices, and Cosmetics

Federal Legislation (bill similarities)

	House Bill (H.R. 1919)	Senate Bill (S. 957)
Patient-specific compounded drugs	Exempted from federal requirements (Current Good Manufacturing Practices (cGMPs), new drug approval, directions for use)	
Restricted compounding of certain drugs	Complex formulations that are difficult to compound safely (as identified by FDA rule); drugs removed from market for safety reasons; copies of FDA-approved drugs that are not under shortage that do not differ significantly from the approved version	
FDA Inspection Authority	Specific authority to enter and inspect pharmacies that compound non-patient specific drugs	
FDA Registration	Pharmacies that compound non-patient specific drugs must register as drug establishments with the FDA	
FDA Labeling Requirements	Compounded drugs must be identified on the label as compounded	
Fees for pharmacies compounding non-patient specific drugs	Registration (\$15,000 per year, per establishment) Inspection (\$15,000 per inspection and re-inspection)	

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Drugs, Devices, and Cosmetics

Federal Legislation (bill differences)

	House Bill (H.R. 1919)	Senate Bill (S. 957)
FDA Authority	FDA given exclusive authority over compounding pharmacies that place high risk sterile products in interstate commerce.	Distinguishes between traditional compounding (state regulated) and compounding manufacturers (FDA regulated)
Wholesale Distribution	Not addressed	Prohibits wholesale distribution of compounded drugs; drugs may only be distributed by compounding entity and drugs must be labeled "not for resale."
Current Good Manufacturing Practices (cGMPs)	Not addressed	Compounding manufacturers must comply with cGMPs

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Contact Information

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THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

9/24/2013

Meeting Date

Topic Sterile Compounding Update

Bill Number N/A
(if applicable)

Name Michele Weizer, PharmD, BCPS

Amendment Barcode N/A
(if applicable)

Job Title Member, BOARD OF PHARMACY

Address 10194 BOCA VISTA DR

Phone 561 703 5992

Street
Boca Raton

E-mail weizer@comcast.net

City FL State 33498 Zip

Speaking: For Against Information

Representing FLORIDA BOARD OF PHARMACY

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

9/24/13
Meeting Date

Topic Drugs, Devices and Cosmetics, Compounding

Bill Number N/A
(if applicable)

Name Reggie Dixon

Amendment Barcode N/A
(if applicable)

Job Title Director, DDC

Address 1940 N. Monroe St.
Street

Phone (850) 717.1172

Tall. FL 32399
City State Zip

E-mail reggie.dixon@myflorida
license.com

Speaking: For Against Information

Representing DBPR

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

Demonstration & Discussion of Data Security in the PDMP



Senate Health Policy Committee
September 24, 2013
Rebecca Poston, BPharm, MHL

1

Objectives



- Provide reporting requirements, registration, statistics, and query process overview
- Review security and privacy measures
- Discuss enhanced privacy

Dispenser Reporting Requirements



- Controlled substances must be reported within 7 days of dispensing
- Mandatory reporting began September 1, 2011
- Dispensers retroactively reported from December 1, 2010

3

PDMP Statistics



- 85 million dispensing records
- 11,188 prescribers and 11,497 pharmacists have registered
- 5.8 million queries

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PDMP Statistics



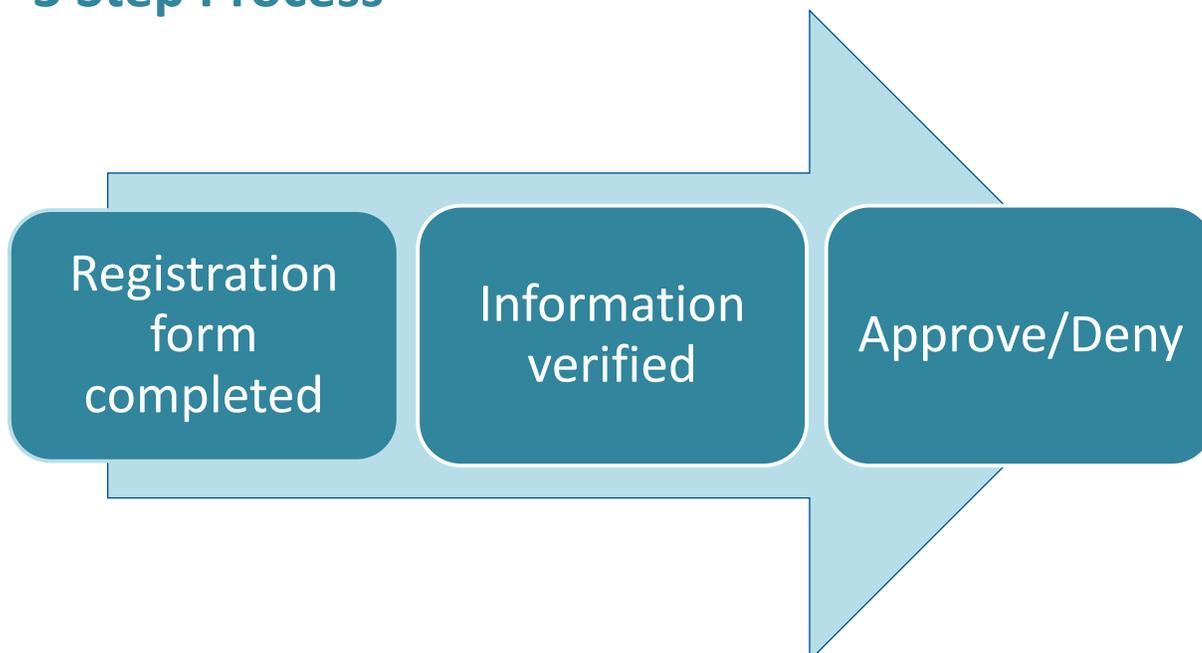
- Highest registration rate
 - Pharmacists- 42.1%
 - Osteopathic physicians- 22.3%
- Highest utilization rate
 - Pharmacists- 87.4%
 - Osteopathic physicians- 75%

5

Database Registration for Health Care Practitioners



3 Step Process



6

Law Enforcement Statistics



- E-FORCSE staff approved:
 - 234 agency administrators
 - 870 law enforcement authorized users
 - 32,000 law enforcement requests

7

Law Enforcement Statistics



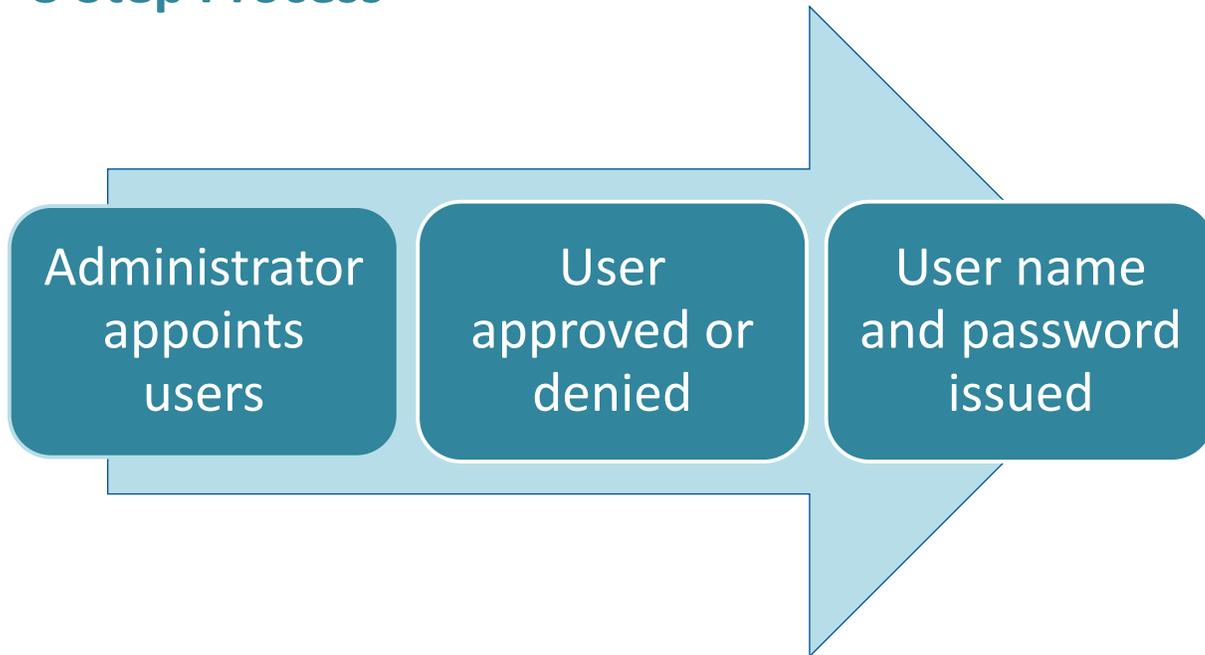
- 17,024 requests by 765 authorized users at 105 agencies
 - 5,331 cases
 - 11,683 duplicates
 - 2,061 no results
 - 148 denied
 - 48% still active

8

Database Registration for Investigative Agencies



3 Step Process



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Recipient Request by Practitioner



- Required fields: name, date of birth
- Optional fields: sounds like, alias, county
- Select report format

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Recipient Request by Law Enforcement



- Active investigation certification
- Required fields: agency case number, subject name, date of birth, address, time frame
- Select report format

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Prescriber Request by Law Enforcement



- Active investigation certification
- Required fields: case number, prescriber DEA number and/or prescriber last name, timeframe
- Select report format

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Dispenser Request by Law Enforcement



- Active investigation certification
- Required fields: case number, pharmacy DEA number and/or pharmacy name, timeframe
- Select report format

13

Report Formats



- PDF
- CSV
- Web (with Mapping)

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Public Record Exemption



- Authorizes release of confidential and exempt information
- Authorizes disclosure of confidential exempt information to a criminal justice agency
- Creates a penalty

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Security of Information



- Background screens completed
- Three-step security approach
- All user activity digitally recorded and archived

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Security of Information



- All users certify reason for request
- Search fields include last name, first name, date of birth, and address
- Law enforcement search fields include the purpose for search and a case number

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Allegation of Disclosure of Confidential Information



- Active criminal investigation by DEA
- Reports requested and approved by E-FORCSE
- Law Enforcement worked with local physicians to uncover prescription fraud ring
- 7 arrests; State Attorney charged 6 individuals

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Allegation of Disclosure of Confidential Information



- Discs containing PDMP information were produced in discovery
- Discs marked confidential
- Defense attorney shared confidential disc with a colleague not associated with criminal case

Allegation of Disclosure of Confidential Information



- Suit filed against State Attorney
- Disc with patient records under seal and plaintiff ordered to relinquish
- Hearing on 9/4/13 on State Attorney's Motion to Dismiss
- DOH not a party

Rule 64K-1.003 through 1.004 Workshops



- Initial workshop on July 8, 2013
- Second workshop on August 27, 2013
- Next steps:
 - Publish the language
 - Implement enhancements to strengthen the privacy of information

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Presentation Summary



- Reviewed reporting requirements, registration, statistics, and query process
- Reviewed security and privacy measures
- Discussed enhanced privacy

Contact Information



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Demonstration & Discussion of Data Security in the PDMP



Handouts

Senate Health Policy Committee
September 24, 2013

Rebecca Poston, BPharm, MHL

Handout 1

Report Format:	Recipient Query		
Name Selection	Demographic Focus	County Selection	Zipcode Selection (blank for all)
Recipient: Begins with Sounds like Fastest: Last Name = and First Name Begins *Last Name: <input type="text"/> *First Name: <input type="text"/>	Gender All <input type="text"/> *Target DOB <input type="text"/> mm/dd/yyyy Within Exact Match <input type="text"/>	Statewide Alachua Baker Bay Select statewide for best results	<input type="text"/>
Alias #1 Name:	Last: <input type="text"/>	First:	DOB:
Alias #2 Name:	Last: <input type="text"/>	First:	DOB:
Alias #3 Name:	Last: <input type="text"/>	First:	DOB:
Primary Address:		City:	
Other Address 1:		City:	
Other Address 2:		City:	
*Dispensed Timeframe From: 08/13/2012 mm/dd/yyyy		*Dispensed Timeframe To: 08/13/2013 mm/dd/yyyy	
Preset Timeframe Ranges			
<input checked="" type="radio"/> Custom Timeframe <input type="radio"/> Past Month <input type="radio"/> Past Three Months <input type="radio"/> Past Six Months <input type="radio"/> Past Year			
*Required Field All required fields must be filled in. However, for the best search results, fill in as many fields as possible.			

Submit

Handout 2



Law Enforcement Report Request

Search for Prescriber Search for Pharmacy

Requestor Agency Information		
PDMP Account Id: becki.le	Agency: FL DOH	*Your Case #: 2013-0810
Requesting Officer: Becki Test	Request Date: 08/13/13	Return Report by: Web Site
*Telephone: 850	Fax:	Email: Rebecca_Poson@doh.state.fl.us

Information about the Subject that we MUST have to fulfill your report request			
<input checked="" type="radio"/> Subject Name Begins with <input type="radio"/> or Name Sounds like	*Last: Dume	*First: Data	*Born on: 10/09/1977 mm/dd/yyyy Within: Exact Match Sex: All/Any
Alias #1 Name:	Last: <input type="text"/>	First:	Born: mm/dd/yyyy
Alias #2 Name:	Last: <input type="text"/>	First:	Born: mm/dd/yyyy
Alias #3 Name:	Last: <input type="text"/>	First:	Born: mm/dd/yyyy
*Dispensed Timeframe From: 03/01/12 mm/dd/yyyy		*Dispensed Timeframe To: 04/30/12 mm/dd/yyyy	
Purpose: Forged Prescription Investigation			

Optional Information that helps to qualify your report request (if DOB is blank or has wide range you MUST provide County or Zipcode and Address to help narrow down search results.)			
SSN: <input type="text"/>	Statewide Alachua Baker Bay Select statewide for best results	Zipcode: <input type="text"/>	(blank for any)
DL# (with State Abbrev): <input type="text"/>	Country Selection:		
Health Insurance Card Id: <input type="text"/>	*Primary Address: 1234 Bald Cypress Way	*City: Tallahassee	
	Other Address 1:	City:	
	Other Address 2:	City:	
*Required Field All required fields must be filled in. However, for the best search results, fill in as many fields as possible.			

Choose Report Type: PDF CSV Web (with mapping)

Submit

Handout 3

Law Enforcement Report Request



Search for Prescriber Search for Pharmacy

Requestor Agency Information

PDMP Account Id: becki.le	Agency: FL DOH	*Your Case #: 2013-0810
Requesting Officer: Becki Test	Request Date: 08/13/13	Return Report by: Web Site
*Telephone: 850	Fax:	Email: Rebecca_Poston@doh.state.fl.us

Information about the Subject that we MUST have to fulfill your report request

<input checked="" type="radio"/> Subject Name Begins with: *Last: Dume <input type="radio"/> or Name Sounds like:	*First: Data	*Born on: 10/09/1977 mm/dd/yyyy Within: Exact Match Sex: All/Any
Alias #1 Name: Last:	First:	Born: mm/dd/yyyy
Alias #2 Name: Last:	First:	Born: mm/dd/yyyy
Alias #3 Name: Last:	First:	Born: mm/dd/yyyy
*Dispensed Timeframe From: 03/01/12 mm/dd/yyyy	*Dispensed Timeframe To: 04/30/12 mm/dd/yyyy	
Purpose: Forged Prescription Investigation		

Optional Information that helps to qualify your report request (if DOB is blank or has wide range you MUST provide County or Zipcode and Address to help narrow down search results.)

SSN:	County Selection: Statewide, Alachua, Baker, Bay	Zipcode: (blank for any)
DL# (with State Abbrev):	Select statewide for best results	
Health Insurance Card Id:	*Primary Address: 1234 Bald Cypress Way	*City: Tallahassee
	Other Address 1:	City:
	Other Address 2:	City:

*Required Field
All required fields must be filled in.
However, for the best search results, fill in as many fields as possible.

Choose Report Type: PDF CSV Web (with mapping)

Submit

Handout 4

Law Enforcement Query

Report Format:	Prescriber Query		
	Prescriber ID	County Selection	Zipcode Selection (blank for all)
**Prescriber DEA: **Prescriber Last Name Begins With (smith, jane):	AM2681350 Mill, Phill	Statewide Alachua Baker Bay Select statewide for best results	
	*Dispensed Timeframe From: 03/01/2012 mm/dd/yyyy	*Dispensed Timeframe To: 04/30/12 mm/dd/yyyy	
*Your Case #: 13-0616			
**Either last name or DEA number is required. *Required Field All required fields must be filled in. However, for the best search results, fill in as many fields as possible.			

Choose Report Type: PDF CSV Web (with mapping)

Submit

Handout 5

Law Enforcement Query

Report Format:	Prescriber Report
Prescriber Name Begins <i>Mill, Phill</i> For Zip codes beginning	MILL, PHILL, AM2681350 FT LAUDERDALE 33301
Dispensed Timeframe From: 03/01/2012	Dispensed Timeframe To: 04/30/2012
*Your Case #: 13-0616	

Request

Handout 6

Law Enforcement Report Request



Search for Prescriber Search for Pharmacy

Requestor Agency Information		
PDMP Account Id: beckle	Agency: FL DOH	*Your Case #: 2013-0610
Requesting Officer: Becki Test	Request Date: 08/13/13	Return Report by: Web Site
*Telephone: 850	Fax:	Email: Rebecca_Poston@doh.state.fl.us

Information about the Subject that we MUST have to fulfill your report request			
<input checked="" type="radio"/> Subject Name Begins with:	*Last: Dume	*First: Data	*Born on: 10/09/1977 mm/dd/yyyy
<input type="radio"/> or Name Sounds like:			Within: Exact Match
			Sex: All/Any
Alias #1 Name: Last:		First:	Born: mm/dd/yyyy
Alias #2 Name: Last:		First:	Born: mm/dd/yyyy
Alias #3 Name: Last:		First:	Born: mm/dd/yyyy
*Dispensed Timeframe From: 03/01/12 mm/dd/yyyy		*Dispensed Timeframe To: 04/30/12 mm/dd/yyyy	
Purpose: Forged Prescription Investigation			

Optional Information that helps to qualify your report request (if DOB is blank or has wide range you MUST provide County or Zipcode and Address to help narrow down search results.)

SSN: _____	County Selection: Statewide Alachua Baker Bay	Zipcode: _____ (blank for any)
DL# (with State Abbrev): _____	Select statewide for best results	
Health Insurance Card Id: _____	*Primary Address: 1234 Bald Cypress Way	*City: Tallahassee
	Other Address 1:	City:
	Other Address 2:	City:

*Required Field
All required fields must be filled in.
However, for the best search results, fill in as many fields as possible.

Choose Report Type: PDF CSV Web (with mapping)

Submit

Handout 7

Law Enforcement Query

Report Format:	Pharmacy Query		
	Pharmacy ID	County Selection	Zipcode Selection (blank for all)
**Pharmacy DEA:	AF2468109	Statewide Alachua Baker Bay	
**Pharmacy Name	Florida Pharmacy	Select statewide for best results	
*Dispensed Timeframe From: 03/01/12 mm/dd/yyyy		*Dispensed Timeframe To: 04/30/12 mm/dd/yyyy	
*Your Case #: 2013-0810			
<p>**Either name or DEA number is required. *Required Field All required fields must be filled in. However, for the best search results, fill in as many fields as possible.</p>			

Choose Report Type: PDF CSV Web (with mapping)

Submit

Handout 8

Law Enforcement Query

Report Format:	Pharmacy Report		
Pharmacy	FLORIDA PHARMACY AF2806187 FLORIDA NY 10921 (ORANGE) FLORIDA PHARMACY AF2468109 SUNRISE FL 33326 (BROWARD) FLORIDA PHARMACY # 2 FF2526828 MIAMI GARDENS FL 33055 (MIAMI-DADE) FLORIDA PHARMACY & DISCOUNT BF8659572 MIAMI FL 33126 (MIAMI-DADE) FLORIDA PHARMACY & DISCOUNT CORP FF3685736 MIAMI FL 33135 (MIAMI-DADE)		
Name Begins Florida Pharmacy			
For Zip codes beginning			
Dispensed Timeframe From: 03/01/2012	Dispensed Timeframe To: 04/30/2012		
*Your Case #: 2013-0810			

Request

Handout 9

Health Information Designs Inc.		Florida Query Report		Date: 02/02/12 Page#: 1	
Patient Rx History Report					
DOE, JANE Search Criteria: Last Name 'doe' and First Name 'jane' and D.O.B. = '01/01/83' and Address = '123 Main' and Request Period = '12/01/10' to '02/01/12' - 1 out of 1 Recipient(s) Selected.					
Fill Date	Product, Str, Form	Qty	Days	Pt ID	Prescriber Written RX# N/R* Pharm
03/03/2011	DIAZEPAM 5 MG TABLET	30.000	7	00000000001	BS8292651 03/02/2011 4028684 N BP8575461
02/09/2011	OXYCODONE HCL 30 MG TABLET	180.000	30	00000000001	FG1128443 02/09/2011 620807 N BW7758759
02/09/2011	HYDROMORPHONE 8 MG TABLET	60.000	30	00000000001	FG1128443 02/09/2011 620806 N BW7758759
02/03/2011	ALPRAZOLAM 1 MG TABLET	60.000	30	00000000001	BS8292651 02/03/2011 591314 N BW7852569
01/28/2011	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00000000001	BS8292651 12/03/2010 120205 R BG9194527
01/12/2011	OXYCODONE HCL 30 MG TABLET	180.000	30	00000000001	FG1128443 01/12/2011 586661 N BW7852569
01/12/2011	HYDROMORPHONE 4 MG TABLET	30.000	30	00000000001	FG1128443 01/12/2011 586658 N BW7852569
12/31/2010	DIAZEPAM 10 MG TABLET	30.000	15	00000000001	BS8292651 12/03/2010 120207 R BG9194527
12/30/2010	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00000000001	BS8292651 12/03/2010 120205 R BG9194527
12/22/2010	DIAZEPAM 10 MG TABLET	30.000	15	00000000001	BS8292651 12/03/2010 120207 R BG9194527
12/15/2010	OXYCODONE HCL 30 MG TABLET	180.000	15	00000000001	FG1128443 12/15/2010 2097679 N AW2058887
12/03/2010	DIAZEPAM 10 MG TABLET	30.000	15	00000000001	BS8292651 12/03/2010 120207 N BG9194527
12/03/2010	ZOLPIDEM TARTRATE 10 MG TABLET	30.000	30	00000000001	BS8292651 12/03/2010 120205 N BG9194527
*N/R N=New R=Refill					
Prescribers for prescriptions listed					
BS8292651	Doctor 1, address, city, state, zip				
FG1128443	Doctor 2, address, city, state, zip				
AS1837383	Doctor 3, address, city, state, zip				
Pharmacies that dispensed prescriptions listed					
BG9194527	Pharmacy 1, address, city, state, zip				
AW2058887	Pharmacy 2, address, city, state, zip				
BW7852569	Pharmacy 3, address, city, state, zip				
BW7758759	Pharmacy 4, address, city, state, zip				
BP8575461	Pharmacy 5, address, city, state, zip				
BW8940923	Pharmacy 6, address, city, state, zip				
BH9131436	Pharmacy 7, address, city, state, zip				
BC7975141	Pharmacy 8, address, city, state, zip				
Patients that match search criteria					
00000001	DOE JANE, DOB 01/01/83; 123 MAIN STREET, ANY CITY FL 33333				

Handout 10

Health Information Designs Inc.		Florida Query Report		Date: 02/02/12 Page#: 1	
Prescriber Rx History Report					
DOE, JOHN MD Dispensed From 01/26/12 to 01/31/12					
Fill Date	Product, Str, Form	Qty	Days	Pt ID	Prescriber Written RX# N/R* Pharm
01/31/2012	CHLORDIAZEPOXIDE 25 MG CAPSULE	60.000	30	0000000000001	BS8292651 11/28/2011 133028 N FS1324122
01/30/2012	TEMAZEPAM 30 MG CAPSULE	30.000	30	0000000000002	BS8292651 11/28/2011 133030 R FS1324122
01/30/2012	DIAZEPAM 5 MG TABLET	90.000	30	0000000000003	BS8292651 11/14/2011 128585 R BG9194527
01/28/2012	LORAZEPAM 2 MG TABLET	30.000	30	0000000000004	BS8292651 01/27/2012 4417300 N BK1779036
01/27/2012	VYVANSE 70 MG CAPSULE	30.000	30	0000000000005	BS8292651 01/11/2012 2210803 N BT6202395
*N/R N=New R=Refill					
Prescribers for prescriptions listed					
BS8292651	DOE, JOHN MD, DR. DOE'S MEDICAL OFFICE, 123 MAIN STREET, ANY CITY, FL 33333				
Pharmacies that dispensed prescriptions listed					
BT6202395	PHARMACY 1, ADDRESS, CITY, STATE, ZIP				
BK1779036	PHARMACY 2, ADDRESS, CITY, STATE, ZIP				
FS1324122	PHARMACY 3, ADDRESS, CITY, STATE, ZIP				
Patients that match search criteria					
0000000000001	PATIENT 1, DOB, CITY, STATE, ZIP				
0000000000002	PATIENT 2, DOB, CITY, STATE, ZIP				
0000000000003	PATIENT 3, DOB, CITY, STATE, ZIP				
0000000000004	PATIENT 4, DOB, CITY, STATE, ZIP				
0000000000005	PATIENT 5, DOB, CITY, STATE, ZIP				
Report Disclaimers:					
The Report is based on the search criteria and the data provided by the dispensing entities. For more information about any prescription, please contact the dispenser or the prescriber.					
This Report contains confidential information, including patient identifiers, and is not a public record. The information should not be provided to any other persons or entity.					

Handout 11

Health Information Designs Inc.	Florida Query Report	Date: 02/02/12 Page#: 1
Dispenser Rx History Report		
PHARMACY NAME Dispensed From 01/25/12 to 01/25/12		
Fill Date	Product, Str, Form	Qty Days Pt ID Prescriber Written RX# N/R* Pharm
01/25/2012	ROXICET 5-325 TABLET	60.000 30 000000000001 BS4319693 01/25/2012 2210795 N BT6202395
01/25/2012	ZOLPIDEM TARTRATE 10 MG TABLET	30.000 30 000000000002 AE1863441 08/16/2011 4442046 R BT6202395
01/25/2012	TEMAZEPAM 15 MG CAPSULE	30.000 30 000000000003 BS8823672 12/26/2011 4443150 R BT6202395
01/25/2012	CLONAZEPAM 1 MG TABLET	90.000 30 000000000004 AK5855044 01/19/2012 4443404 N BT6202395
*N/R N=New R=Refill		
Prescribers for prescriptions listed		
BS4319693	PRESCRIBER 1, ADDRESS, CITY, STATE, ZIP	
AE1863441	PRESCRIBER 2, ADDRESS, CITY, STATE, ZIP	
BS8823672	PRESCRIBER 3, ADDRESS, CITY, STATE, ZIP	
AK5855044	PRESCRIBER 4, CITY, STATE, ZIP	
Pharmacies that dispensed prescriptions listed		
BT6202395	PHARMACY NAME, ADDRESS, CITY, STATE, ZIP	
Patients that match search criteria		
000000000001	PATIENT 1, ADDRESS, CITY, STATE, ZIP	
000000000002	PATIENT 2, ADDRESS, CITY, STATE, ZIP	
000000000003	PATIENT 3, ADDRESS, CITY, STATE, ZIP	
000000000004	PATIENT 4, ADDRESS, CITY, STATE, ZIP	
Report Disclaimers:		
The Report is based on the search criteria and the data provided by the dispensing entities. For more information about any prescription, please contact the dispenser or the prescriber.		
This Report contains confidential information, including patient identifiers, and is not a public record. The information should not be provided to any other persons or entity.		

Handout 12

Fill Date	Product-S	Qty	Days	Written	RX#	N/R	Pt ID	Pt Last Na	Pt First Na	Pt DOB	Pt Street / Pt City	Pt State	Pt Zip	Pt Pharmacy
4/9/2012	HYDROCO	90	30	4/9/2012	456123	N	8087323	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	BG
4/9/2012	CARISOPR	60	30	4/9/2012	456124	N	8087323	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	BG
4/9/2012	ZOLPIDEM	30	30	4/9/2012	456125	N	8087323	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	BG
#####	OXYCODO	60	30	#####	987654	N	8087323	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	MC
#####	LORAZEPA	60	30	#####	987655	N	8087323	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	MC
3/3/2012	HYDROCO	90	30	3/3/2012	123456	N	8087323	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN
3/3/2012	ALPRAZOL	90	30	3/3/2012	123457	N	8087323	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN
3/3/2012	ZOLPIDEM	30	30	3/3/2012	123458	N	8087323	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN
#####	HYDROCO	90	30	3/3/2012	123456	R	8087324	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN
#####	ALPRAZOL	90	30	3/3/2012	123457	R	8087324	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN
#####	ZOLPIDEM	30	30	03/03/12	123458	R	8087324	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN
#####	HYDROCO	60	30	3/3/2012	123456	R	8087325	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN
#####	ALPRAZOL	90	30	3/3/2012	123457	R	8087325	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN
#####	ZOLPIDEM	30	30	3/3/2012	123458	R	8087325	DATA	DUME	#####	77 SUNSET Fort Laude FL	FL	33305	AN

Handout 13

Open in new window

Law Enforcement Report
All Prescribers
All Dispensers
3 out of 3 Recipient Selected From:
Name Begins data, dume; DOB 100977; DOB ?; DOB ?;
DATA, DUME - DOB: 10/09/1977 - 77 Sunset Strip
DATA, DUME - DOB: 10/09/1977 - 77 Sunset Strip Apt 2a
DATA, DUME - DOB: 10/09/1977 - 77 Sunstrip

Date Dispensed	Drug Name	Quantity Dispensed	Days of Supply	Prescriber ID	Prescriber	Date Prescribed	Prescription Number	New/Refill	Dispenser ID	Dispenser	Dispens
04/09/12	HYDROCODON-ACETAMINOPH 7.5- 750	90	30	BG6543210	GATOR IRA	04/09/12	456123	0	AA1927376	AL'S APOTHECARY	HOLLYV
04/09/12	CARISOPRODOL 350 MG TABLET	60	30	BG6543210	GATOR IRA	04/09/12	456124	0	AA1927376	AL'S APOTHECARY	HOLLYV
04/09/12	ZOLPIDEM TARTRATE 10 MG TABLET	30	30	BG6543210	GATOR IRA	04/09/12	456125	0	AA1927376	AL'S APOTHECARY	HOLLYV
03/12/12	LORAZEPAM 1 MG TABLET	60	30	MG1234567	GRASS SAW	03/12/12	987655	0	AF2468109	FLORIDA PHARMACY	SUNRISI
03/12/12	OXYCODONE-ACETAMINOPHEN 10- 325	60	30	MG1234567	GRASS SAW	03/12/12	987654	0	AF2468109	FLORIDA PHARMACY	SUNRISI
	ALPRAZOLAM 1				MILLI					EZ DISCOUNT	ET

Internet | Protected Mode: On 95%

THE FLORIDA SENATE APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

9/24/13

Meeting Date

Topic POMP Update

Bill Number _____
(if applicable)

Name Rebecca Poston

Amendment Barcode _____
(if applicable)

Job Title Program Manager

Address 4057 Bald Cypress Way

Phone 245-4444 x3700

Tallahassee FL 32839
City State Zip

E-mail _____

Speaking: For Against Information

Representing _____

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

9/24/2013
Meeting Date

Topic DOH - PDMP Data Security

Bill Number _____
(if applicable)

Name Pamela Burch FORT

Amendment Barcode _____
(if applicable)

Job Title _____

Address 104 S. Monroe Street

Phone 850/425-1344

Tallahassee FL 32301
City State Zip

E-mail TcgLobby@aol.com

Speaking: For Against Information

Representing ACLU of Florida

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/20/11)



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Transportation, *Chair*
Agriculture
Appropriations Subcommittee on Finance and Tax
Appropriations Subcommittee on Transportation,
Tourism, and Economic Development
Education
Health Policy

SELECT COMMITTEE:
Select Committee on Patient Protection
and Affordable Care Act

SENATOR JEFF BRANDES
22nd District

September 23, 2013

Senator Aaron Bean, Chair
Committee on Health Policy
302 Senator Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Chair Bean:

Please excuse my absence from the Committee on Health Policy, tomorrow, September 24, 2013. My wife recently delivered our youngest son Conor.

Thank you for your consideration in this matter.

Sincerely,

Senator Jeff Brandes
District 22

Cc: Sandra Stovall, Staff Director

REPLY TO:

- 3637 Fourth Street North, Suite 101, St. Petersburg, Florida 33704-1300 (727) 552-2745
- 318 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5022

Senate's Website: www.flsenate.gov

DON GAETZ
President of the Senate

GARRETT RICHTER
President Pro Tempore

CourtSmart Tag Report

Room: KN 412

Caption: Senate Health Policy Committee

Case:

Judge:

Type:

Started: 9/24/2013 2:02:18 PM

Ends: 9/24/2013 2:58:12 PM

Length: 00:55:55

2:02:20 PM Senator Bean calls the meeting to order
 2:02:34 PM roll call
 2:03:08 PM quorum present
 2:03:43 PM Senator Bean opening comments
 2:04:44 PM Michele Weizer, Chair, Compounding Rules Committee, Board of Pharmacy presentation
 2:16:22 PM Reginald Dixon, Executive Director, Division of Drugs, Devices & Cosmetics, DBPR presentation
 2:26:34 PM Senator Bean thanks presenters
 2:27:37 PM Senator Joyner asks a question
 2:27:52 PM Dr. Weizer responds
 2:28:49 PM Senator Sobel with a question
 2:29:51 PM Senator Bean responds
 2:30:24 PM Senator Sobel follows up
 2:30:39 PM Mr. Dixon responds
 2:31:57 PM Senator Bean asks question
 2:32:07 PM Mr. Dixon responds
 2:32:12 PM Senator Bean asks question
 2:32:56 PM Dr. Weizer answers
 2:33:14 PM Senator Bean asks question
 2:33:26 PM Dr. Weizer answers
 2:33:33 PM Senator Bean with a follow-up
 2:34:01 PM Dr. Weizer responds
 2:34:16 PM Senator Bean
 2:34:53 PM Dr. Weizer
 2:35:01 PM Senator Joyner with a question
 2:35:38 PM Dr. Weizer answers
 2:36:02 PM Senator Joyner with a follow-up
 2:36:28 PM Dr. Weizer responds
 2:36:37 PM Senator Joyner
 2:36:48 PM Dr. Weizer responds
 2:37:12 PM Senator Joyner
 2:37:34 PM Mr. Dixon responds
 2:38:29 PM Senator Joyner follows up
 2:39:53 PM Dr. Weizer responds
 2:40:14 PM Senator Bean
 2:41:30 PM Rebecca Poston, Program Manager, PDMP, Dept. of Health presentation
 2:47:30 PM Senator Bean
 2:48:56 PM Ms. Poston responds
 2:49:54 PM Senator Bean
 2:50:14 PM Senator Sobel with a question
 2:50:44 PM Ms. Poston responds
 2:51:43 PM Senator Bean
 2:51:59 PM Ms. Poston answers
 2:52:13 PM Senator Bean thanks Ms. Poston
 2:53:22 PM Pamela Thort, ACLU
 2:55:37 PM Senator Bean
 2:56:38 PM Senator Sobel with a question
 2:57:10 PM Ms. Thort responds
 2:57:16 PM Senator Bean
 2:57:57 PM moves we rise