Florida Department of Health
Division of Medical Quality Assurance

Florida Board of Pharmacy Compounding Survey Report

January 23, 2013

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

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

South Dakota – 2 (5%)
Tennessee – 6 (15%)
Texas – 5 (13%)
Utah – 2 (5%)
Vermont – 2 (5%)
Virginia – 2 (5%)
Washington – 2 (5%)
West Virginia – 2 (5%)
Wisconsin – 2 (5%)
Wyoming – 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%)
Alaska – 14 (9%)
Arizona – 17 (11%)
Arkansas – 22 (14%)
California – 18 (11%)
Colorado – 0 (0%)
Connecticut – 18 (11%)
Delaware – 10 (6%)
District of Columbia – 14 (9%)
Florida – 65 (40%)
Georgia – 26 (16%)
Hawaii – 7 (4%)
Idaho – 18 (11%)
Illinois – 20 (12%)
Indiana – 9 (6%)
Iowa – 15 (9%)
Kansas – 20 (12%)
Kentucky – 19 (12%)
Louisiana – 29 (18%)
Maine – 14 (9%)
Maryland – 12 (7%)
Massachusetts – 7 (4%)
Michigan – 20 (12%)
Minnesota – 20 (12%)
Mississippi – 27 (17%)
Missouri – 17 (11%)
Montana – 14 (9%)
Nebraska – 14 (9%)
Nevada – 13 (8%)
New Hampshire – 20 (12%)
New Jersey – 18 (11%)
New Mexico – 18 (11%)
New York – 33 (20%)
North Carolina – 20 (12%)
North Dakota – 10 (6%)
Ohio – 24 (15%)
Oklahoma – 20 (12%)
Oregon – 13 (8%)
Pennsylvania – 25 (16%)
Rhode Island – 17 (11%)
South Carolina – 17 (11%)
South Dakota – 14 (9%)
Tennessee – 29 (18%)
Texas – 33 (20%)
Utah – 8 (5%)
Vermont – 13 (8%)
Virginia – 18 (11%)
Washington – 18 (11%)
West Virginia – 17 (11%)
Wisconsin – 14 (9%)
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%)
Alaska – 103 (27%)
Arizona – 137 (36%)
Arkansas – 92 (24%)
California – 151 (40%)
Colorado – 181 (47%)
Connecticut – 158 (41%)
Delaware – 133 (35%)
District of Columbia – 94 (25%)
Florida* – 216 (57%)
Georgia – 181 (47%)
Hawaii – 105 (27%)
Idaho – 128 (34%)
Illinois – 183 (48%)
Indiana – 175 (46%)
Iowa – 134 (35%)
Kansas – 161 (42%)
Kentucky – 131 (34%)
Louisiana – 106 (28%)
Maine – 104 (27%)
Maryland – 144 (38%)
Massachusetts – 134 (35%)
Michigan – 170 (45%)
Minnesota – 151 (40%)
Mississippi – 147 (38%)
Missouri – 158 (41%)
Montana – 101 (26%)
Nebraska – 99 (26%)
Nevada – 144 (38%)
New Hampshire – 127 (33%)
New Jersey – 188 (49%)
New Mexico – 135 (35%)
New York – 191 (50%)
North Carolina – 123 (32%)
North Dakota – 107 (28%)
Ohio – 172 (45%)
Oklahoma – 159 (42%)
Oregon – 111 (29%)
Pennsylvania – 169 (44%)
Rhode Island – 131 (34%)
South Carolina – 163 (43%)
South Dakota – 120 (31%)
Tennessee – 151 (40%)
Texas – 214 (56%)
Utah – 121 (32%)
Vermont – 114 (30%)
Virginia – 149 (39%)
Washington – 153 (40%)
West Virginia – 138 (36%)
Wisconsin – 168 (44%)
Wyoming – 118 (31%)

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

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

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

FLORIDA DEPARTMENT OF HEALTH

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

FLORIDA DEPARTMENT OF HEALTH

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

SECOND NOTICE

#4740:T19:B:49 **********MIXED AADC 323

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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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 Department of Health
Division of Medical Quality Assurance

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?

O Yes
O 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):

O Central Fill
O Class II Institutional
O Community
O Internet
O Modified Class II Institutional
O Non-Resident
O Nuclear
O Special Closed System
O Special ESRD
O Special Limited Community
O Special Parenteral/Enteral
O Special Parenteral/Enteral Extended Scope
O 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?

O Yes
O 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?

O Yes
O 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?

O Yes
O No

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

O Less than 10%
O 11% to 25%
O 26% to 50%
O 51% to 75%
O 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:

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

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

O Yes
O 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?

O Yes
O No

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

7b. If yes, did the recall occur:

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

Sterile Compounding

8. Does your pharmacy compound sterile products?

O Yes
O No

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

O Less than 10%
O 11% to 25%
O 26% to 50%
O 51% to 75%
O 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:

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

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

O Yes
O 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?

O Less than six months
O Six months to one year
O 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?

O Less than six months
O Six months to one year

O 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?

O Yes
O No

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

16b. If yes, did the recall occur:

O Less than six months
O Six months to one year
O 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?

O Yes
O 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:

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

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

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

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

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APPENDIX C
Glossary

Top

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 anbiobiotics, 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	• This permit does not authorize sterile or non-sterile compounding • Authorizes the animal shelter to purchase and store specific drugs for animal euthanasia	• Animal Shelters
Closed System Pharmacy	465.0196 28.830	PDM	• 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	• Nursing Homes • Jails • Adult Living Facilities • Correctional Facilities
Community Pharmacy	465.018 28.404	PDM	• This permit authorizes sterile and non-sterile compounding • Pharmacist dispenses prescription drugs pursuant to a prescription to individuals that live in the community	• Regular walk-in pharmacy • Mail Order • Central Fill • Internet
Dispensing Practitioner	465.0276		• 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	• Dispensing Practitioner
Institutional Class I	465.019 28.501	CPH	• 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	• Nursing Homes
Institutional Class II	465.019 28.501 28.602 28.603	CPH	• This permit authorizes sterile and non-sterile compounding • This permit allows pharmacies to prepare medications to be administered to inpatients of a hospital	• Hospital

PERMIT	STATUTE/RULE	PDM/CPH	REQUIREMENTS	SETTINGS
Internet Pharmacy	465.1097	RPH is designated the PDM to dispense into FL.	• 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	• Not opened to the general public
Modified Institutional II A or B	465.019 28.702	CPH	• 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	• 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.	• 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	• Must be licensed in the state where located
Nuclear Pharmacy	465.0193 28.901	NPH	• 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	• This permit does not authorize sterile or non-sterile compounding	• Adult Living Facilities

PERMIT	STATUTE/RULE	PDM/CPH	REQUIREMENTS	SETTINGS
Living Facility)	28.870		• 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	• 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	• Dialysis Centers
Special Limited Community	465.0196 28.810	PDM	• 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	• Hospital
Special P&E Extended Scope	465.0196 28.860	PDM	• 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	• 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	• 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 Top

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.

- 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.

- 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 licensees' 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.

- 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.