



# Louisiana Board of Pharmacy

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September 15, 2014

Senator John A Alario, Jr, President  
Louisiana Senate  
PO Box 94183  
Baton Rouge, LA 70804-9183

Via Email: [APA.SenatePresident@legis.la.gov](mailto:APA.SenatePresident@legis.la.gov)

## Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2014-4 ~ Pharmacy Compounding

Dear Senator Alario:

The Board has initiated the rulemaking process to harmonize its existing rules relative to pharmacy compounding with recently-enacted federal legislation. In connection with this regulatory project, you should find the following documents in this packet:

- Notice of Intent
- Proposed Rule (coded + clean)
- Family Impact Statement
- Poverty Impact Statement
- Provider Impact Statement
- Regulatory Flexibility Analysis
- Solicitation of Comments
- Fiscal & Economic Impact Statement

As indicated in the solicitation, we will convene a public hearing on October 30, 2014 to receive public comments and testimony on this proposal. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information, please contact me directly at [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov) or 225.925.6481.

We sent you the original copy of this report on September 9. Shortly thereafter, the editor of the *Louisiana Register* requested the insertion of some minor clarifying information into §2535.A.2. The Legislative Fiscal Office concurred the insertion of the minor clarifying information did not have any fiscal impact nor did it alter the analysis presented in the fiscal impact statement. In the interest of a complete and accurate file, we now re-send the entire packet with the clarifying information inserted.

For the Board:

Malcolm J Broussard  
Executive Director

cc: Chair, Senate Health & Welfare Committee  
Via Email: [APA.S-H&W@legis.la.gov](mailto:APA.S-H&W@legis.la.gov)  
Speaker, House of Representatives  
Via Email: [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)  
Chair, House Health & Welfare Committee  
Via Email: [APA.H-H&W@legis.la.gov](mailto:APA.H-H&W@legis.la.gov)  
Director, Community Outreach Services, La. Economic Development  
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Editor, *Louisiana Register*  
Via Email: [Catherine.Brindley@la.gov](mailto:Catherine.Brindley@la.gov)

**Notice of Intent**

**Department of Health and Hospitals  
Board of Pharmacy**

Pharmacy Compounding (LAC 46:LIII.2531 through 2537)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend *Chapter 25 - Prescriptions, Drugs and Devices*, and more specifically, *Subchapter C – Compounding of Drugs*, of its rules. The proposed rule changes are intended to harmonize the Board's rules on this topic with recently enacted federal legislation, the Drug Quality & Security Act of 2013.

# Louisiana Administrative Code

## Title 46 – Professional and Occupational Standards

### Part LIII: Pharmacists

#### Chapter 25. Prescriptions, Drugs, and Devices

...

#### Subchapter C. Compounding of Drugs

##### §2531. Purpose and Scope

- A. Purpose. The rules of this Subchapter describe the requirements of minimum current good compounding practices for the preparation of drug formulations by Louisiana-licensed pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates for dispensing and/or administration to patients.
- B. Scope. These requirements are intended to apply to all compounded preparations, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or practitioner's office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR

##### §2533. Definitions

- A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

...

*Preparation* – a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations.

...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR

##### §2535. General Standards

- A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.
  - 1. A pharmacy shall have written procedures as necessary for the compounding of drug preparations to assure that the finished preparations have the identity, strength, quality, and purity they are represented to possess.
  - 2. All compounding activities shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, as well as the Federal Food, Drug & Cosmetic Act of 1938 as subsequently amended, and most recently in November 2013 (FDCA), the 2014 edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the 2014 edition of the United States Pharmacopeia – National Formulary (USP 37 – NF 32).
    - a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503A of the FDCA and USP Chapter 797.
    - b. The compounding of non-sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503A of the FDCA and USP Chapter 795.
    - c. The compounding of preparations for veterinary use shall comply with the

- provisions of Section 530 of Title 21 of the CFR.
- d. The compounding of positron emission tomography (PET) drugs shall comply with the provisions of Section 212 of Title 21 of the CFR.
  3. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.
- B. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the compounding of sterile preparations shall notify the board and shall receive approval from the board prior to beginning that practice.
- C. Training and Education. All individuals compounding sterile preparations shall:
1. Obtain practical and/or academic training in the compounding and dispensing of sterile preparations;
  2. Complete a minimum of one hour of Accreditation Council for Pharmacy Education (ACPE) accredited or board-approved continuing education, on an annual basis, related to sterile drug preparation, dispensing, and utilization;
  3. Use proper aseptic technique in compounding of all sterile preparations, as defined by the pharmacy practice site's policy and procedure manual;
  4. Qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to make and dispense sterile preparations; and
  5. Maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:
    - a. name of the individual receiving the training/evaluation;
    - b. date of the training/evaluation;
    - c. general description of the topics covered;
    - d. signature of the individual receiving the training/evaluation; and
    - e. name and signature of the individual providing the training/evaluation.
- D. Anticipated Use Preparations. The pharmacist shall label any excess compounded preparation so as to reference it to the formula used and the assigned lot number and estimated beyond use date based on the pharmacist's professional judgment and/or other appropriate testing or published data.
- E. Compounding Commercial Products Not Available  
A pharmacy may prepare a copy of a commercial product when that product is not available as evidenced by either of the following:
- a. Products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP).
  - b. Products temporarily unavailable from manufacturers, as documented by invoice or other communication from the distributor or manufacturer.
- F. Labeling of Compounded Preparations.
- a. The labeling requirements of R.S. 37:1225, or its successor, as well as this Chapter, shall apply.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR

### **§2537. Requirements for Compounding Sterile Products**

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2106 (October 2003), effective January 1, 2004, repealed LR

1 Louisiana Administrative Code

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3 Title 46 – Professional and Occupational Standards

4  
5 Part LIII: Pharmacists

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7 Chapter 25. Prescriptions, Drugs, and Devices

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9 ...  
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11 Subchapter C. Compounding of Drugs

12  
13 §2531. Purpose and Scope

- 14 A. Purpose. The rules of this Subchapter describe the requirements of minimum current good  
15 compounding practices for the preparation of drug ~~products~~ formulations by Louisiana-licensed  
16 pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates for  
17 dispensing and/or administration to patients.  
18 B. Scope. These requirements are intended to apply to all compounded ~~products~~ preparations and  
19 pharmacy generated drugs, sterile and non-sterile, regardless of the location of the patient, e.g., home,  
20 hospital, nursing home, hospice, or physician's practitioner's office.

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22 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

23 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708  
24 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004,  
25 amended LR

26  
27 §2533. Definitions

- 28 A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this  
29 Section:

30 ...

31 ~~Manufacturing means the production, preparation, propagation, conversion, or processing of a drug~~  
32 ~~or device, either directly or indirectly, by extraction from substances of natural origin or independently~~  
33 ~~by means of chemical or biological synthesis, and includes any packaging or repackaging of the~~  
34 ~~substance or labeling or relabeling of its container, and the promotion and marketing of such drugs or~~  
35 ~~devices. Manufacturing also includes the preparation and promotion of commercially available~~  
36 ~~products from bulk compounds for resale by pharmacies, practitioners, or other persons.~~

37 ~~Pharmacy generated Drug—a drug made by a pharmacy.~~

38 ~~Practitioner Administered Compounds—products compounded by a licensed pharmacist, upon the~~  
39 ~~medical order of a licensed prescriber for administration by a prescriber for diagnostic or therapeutic~~  
40 ~~purposes.~~

41 ~~Preparation – a compounded drug dosage form or dietary supplement or a device to which a~~  
42 ~~compounder has introduced a drug. This term will be used to describe compounded formulations; ~~the~~~~  
43 ~~term product will be used to describe manufactured pharmaceutical dosage forms.~~

44 ...

45  
46 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

47 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708  
48 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004,  
49 amended LR

50  
51 §2535. General Standards

- 52 A. Compounding Practices. Compounded medications may be prepared using prescription medications,  
53 over-the-counter medications, chemicals, compounds, or other components.  
54 1. A pharmacy shall have written procedures as necessary for the compounding of drug ~~products~~  
55 preparations and the making of pharmacy generated drugs to assure that the finished  
56 preparations and products have the identity, strength, quality, and purity they are represented  
57 to possess.

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2. All compounding drug preparation activities shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, as well as the Federal Food, Drug & Cosmetic Act of 1938 as subsequently amended, most recently in November 2013 (FDCA), the 2014 edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the 2014 edition of the United States Pharmacopeia – National Formulary (USP 37 – NF 32).
    - a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503A of the FDCA and USP Chapter 797.
    - b. The compounding of non-sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503A of the FDCA and USP Chapter 795.
    - ~~c. Subject to the allowance provided in Paragraph D of this Section, the making of pharmacy generated drugs pursuant to the receipt of a non patient specific practitioner's order shall comply with the provisions of the *Current Good Manufacturing Practices*, as published in 21 CFR 211 or its successor.~~
    - c. The compounding of preparations for veterinary use shall comply with the provisions of Section 530 of Title 21 of the CFR.
    - d. The compounding of positron emission tomography (PET) drugs shall comply with the provisions of Section 212 of Title 21 of the CFR.
  3. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.
- B. ~~Beyond Use Date. Compounded All medications compounded or generated by a pharmacy shall be labeled with a beyond use date of no more than one hundred eighty (180) days, unless documentation on file supports a longer beyond use date.~~
- Board Notification. An applicant or pharmacy permit holder who wishes to engage in the practice of compounding of sterile preparations or generating sterile products drugs shall notify the board prior to beginning that practice, and shall receive approval from the board prior to beginning that practice.
- C. ~~Records and Reports. Any procedures or other records required to comply with this section shall be maintained for a minimum of two years.~~
- Training and Education. All individuals compounding and preparing sterile preparations and generating sterile products drugs shall:
1. Obtain practical and/or academic training in the compounding-and dispensing preparation of sterile products drugs preparations;
  2. Complete a minimum of one hour of American Council on Pharmaceutical Education Accreditation Council for Pharmacy Education (ACPE) accredited or board-approved continuing education, on an annual basis, related to sterile product drug preparation compounding, dispensing, and utilization;
  3. Use proper aseptic technique in all sterile product preparation compounding compounding of all sterile preparations, as defined by the pharmacy practice site's policy and procedure manual;
  4. Qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to compound make and dispense sterile preparations and products; and
  5. Maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:
    - a. name of the individual receiving the training/evaluation;
    - b. date of the training/evaluation;
    - c. general description of the topics covered;
    - d. signature of the individual receiving the training/evaluation; and
    - e. name and signature of the individual providing the training/evaluation.
- ~~D. Compounding for Prescriber's Use Pharmacy generated Drug. Pharmacists may prepare practitioner administered compounds pharmacy generated drugs for a prescriber's practitioner's use with the following requirements:~~
- ~~1. an order by the prescriber from the practitioner indicating the formula and quantity ordered to be compounded made by the pharmacist pharmacy;~~
  - ~~2. the product is to be administered by the prescriber practitioner and not dispensed to the patient;~~

- 116 3. ~~the pharmacist shall generate a label and sequential identification number for the compounded~~  
117 ~~drug for the product which complies with the requirements of Paragraph G of this Section;~~  
118 ~~and~~  
119 4. ~~a pharmacy may prepare such products drugs in compliance with the compounding standards~~  
120 ~~in USP Chapter 795 for non-sterile preparations or USP Chapter 797 for sterile preparations;~~  
121 ~~provided such drugs made according to these standards shall not to exceed ten percent of the~~  
122 ~~total number of drug dosage units prescriptions dispensed and orders distributed by the~~  
123 ~~pharmacy on an annual basis.~~  
124 ~~a. The purpose of this limitation is to ensure at least ninety percent of the total~~  
125 ~~number of prescriptions and orders released from the pharmacy on an annual basis~~  
126 ~~shall be dispensed pursuant to patient specific prescriptions, and further, no more~~  
127 ~~than ten percent shall be distributed pursuant to non-patient specific orders from a~~  
128 ~~practitioner.~~  
129 ~~b. With respect to Louisiana licensed non-resident pharmacies, the ten percent~~  
130 ~~limitation shall be calculated from the total number of prescriptions and orders~~  
131 ~~sent to Louisiana residents and/or clients.~~  
132 ~~c. No pharmacy shall distribute any pharmacy-generated drug products to a state~~  
133 ~~other than the state within which the pharmacy is located.~~  
134 5. ~~The pharmacy shall label any pharmacy generated drug product held in the pharmacy so as to~~  
135 ~~reference it to the formula used and the assigned lot number and estimated beyond use date~~  
136 ~~based on the pharmacist's professional judgment and/or other appropriate testing or published~~  
137 ~~data.~~  
138 6. ~~The pharmacy shall establish and maintain a record of practitioners receiving pharmacy-~~  
139 ~~generated drugs. Such records shall contain, at a minimum, the name of the practitioner, the~~  
140 ~~name of the drug, the lot number of the drug, and the date of formulation of the drug.~~  
141 E. Anticipated Use ~~Products~~ Preparations. The pharmacist shall label any excess compounded ~~product~~  
142 preparation so as to reference it to the formula used and the assigned lot number and estimated beyond  
143 use date based on the pharmacist's professional judgment and/or other appropriate testing or published  
144 data.  
145 F. Compounding Commercial Products Not Available  
146 A pharmacy may prepare a copy of a commercial product when that product is not available as  
147 evidenced by either of the following:  
148 1. Products appearing on a website maintained by the federal Food and Drug Administration  
149 (FDA) and/or the American Society of Health-System Pharmacists (ASHP).  
150 2. Products temporarily unavailable from ~~distributors~~ manufacturers, as documented by invoice  
151 or other communication from the distributor or manufacturer.  
152 G. Labeling of Compounded ~~Products~~ Preparations and Pharmacy-generated Drugs.  
153 1. ~~For patient-specific compounded products preparations, The labeling requirements of R.S.~~  
154 ~~37:1225, or its successor, as well as this Chapter, shall apply.~~  
155 2. ~~All practitioner administered compounds pharmacy generated drugs shall be packaged in a~~  
156 ~~suitable container with a label containing, at a minimum, the following information:~~  
157 ~~a. pharmacy's name, address, and telephone number;~~  
158 ~~b. practitioner's name;~~  
159 ~~c. name of preparation;~~  
160 ~~d. strength and concentration;~~  
161 ~~e. lot number;~~  
162 ~~f. beyond use date;~~  
163 ~~g. special storage requirements, if applicable;~~  
164 ~~h. assigned identification number; and~~  
165 ~~i. pharmacist's name or initials.~~  
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167 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

168 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708  
169 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October  
170 2003), effective January 1, 2004, amended LR 39: 236 (Emergency Rule effective January 31, 2013), amended LR  
171

172 **§2537. Requirements for Compounding and Generating of Sterile Preparations and**  
173 **Products**

174 ~~A. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the practice of~~  
175 ~~compounding of sterile preparations or generating sterile products, compounding shall notify the board~~  
176 ~~prior to beginning that practice, and shall receive approval from the board prior to beginning that~~  
177 ~~practice.~~

178 ~~B. Personnel.~~

179 ~~1. The pharmacist in charge shall be responsible for the following:~~

- 180 ~~a. procurement, storage, compounding, generating, labeling, dispensing, and~~  
181 ~~distribution of all prescription drugs, devices, and related materials necessary in~~  
182 ~~compounding and dispensing the preparation of sterile products drugs;~~
- 183 ~~b. establishment of policies and procedures for the compounding of sterile~~  
184 ~~preparations and generating and dispensing of sterile products. The policy and~~  
185 ~~procedure manual shall be current, accessible to all staff, and available for~~  
186 ~~inspection by the board upon request. The policy and procedure manual shall, at a~~  
187 ~~minimum, include:~~
  - 188 ~~i. policies and procedures for the compounding and dispensing of sterile~~  
189 ~~products preparations as well as the generation and distribution of~~  
190 ~~sterile products;~~
  - 191 ~~ii. a quality assurance program for the purpose of monitoring patient care,~~  
192 ~~adverse drug reactions, personnel qualifications, training and~~  
193 ~~performance, product integrity, equipment, record keeping, facilities,~~  
194 ~~infection control;~~
  - 195 ~~iii. guidelines regarding patient education; and~~
  - 196 ~~iv. procedures for the handling and disposal of cytotoxic agents, waste,~~  
197 ~~and spills.~~
- 198 ~~c. documentation of competency in aseptic techniques. The aseptic technique of~~  
199 ~~each individual compounding sterile preparations and dispensing generating sterile~~  
200 ~~products shall be observed and evaluated as satisfactory during orientation and~~  
201 ~~training, and at least on an annual basis thereafter.~~

202 ~~2. Training and Education. All individuals compounding and preparing sterile preparations and~~  
203 ~~generating sterile products shall:~~

- 204 ~~a. obtain practical and/or academic training in the compounding and dispensing~~  
205 ~~preparation of sterile products drugs;~~
- 206 ~~b. complete a minimum of one hour of American Council on Pharmaceutical~~  
207 ~~Education Accreditation Council for Pharmacy Education (ACPE) or board-~~  
208 ~~approved continuing education, on an annual basis, related to sterile product drug~~  
209 ~~preparation compounding, dispensing, and utilization;~~
- 210 ~~c. use proper aseptic technique in all sterile product preparation compounding as~~  
211 ~~defined by the pharmacy practice site's policy and procedure manual;~~
- 212 ~~d. qualify through an appropriate combination of specific training and experience to~~  
213 ~~operate or manipulate any item of equipment, apparatus, or device to which such~~  
214 ~~persons will be assigned to use to compound make and dispense sterile~~  
215 ~~preparations and products; and~~
- 216 ~~e. maintain in the pharmacy practice site a written record of initial and subsequent~~  
217 ~~training and competency evaluations. The record shall contain the following~~  
218 ~~minimum information:~~
  - 219 ~~i. name of the individual receiving the training/evaluation;~~
  - 220 ~~ii. date of the training/evaluation;~~
  - 221 ~~iii. general description of the topics covered;~~
  - 222 ~~iv. signature of the individual receiving the training/evaluation; and~~
  - 223 ~~v. name and signature of the individual providing the training/evaluation.~~

224 ~~C. Physical Requirements.~~

225 ~~1. The pharmacy shall have a designated area with entry restricted to designated personnel for~~  
226 ~~preparing compounding sterile products preparations and generating sterile products, and the~~  
227 ~~designated area shall be:~~

- 228 ~~a. structurally isolated from other areas with restricted entry or access and shall be~~  
229 ~~configured in such a manner so as to avoid unnecessary traffic and airflow~~  
230 ~~disturbances from activity within the controlled facility;~~
- 231 ~~b. used only for the preparation of these sterile products drugs; and~~



- 232 e. ~~sufficient in size to accommodate a laminar air flow hood or other device capable~~  
233 ~~of providing a sterile compounding environment and to provide for the proper~~  
234 ~~storage of drugs and supplies under appropriate conditions of temperature, light,~~  
235 ~~moisture, sanitation, ventilation, and security.~~
- 236 2. ~~The pharmacy where sterile preparations and products are prepared made shall have:~~  
237 a. ~~a sink with hot and cold running water that shall be located in, or adjacent to, the~~  
238 ~~area where sterile preparations and products are compounded made;~~  
239 b. ~~appropriate environmental control devices capable of maintaining at least Class~~  
240 ~~100 environment in the workplace where critical objects are exposed and critical~~  
241 ~~operations are performed. These devices, e.g., laminar air flow hoods, and other~~  
242 ~~zonal laminar flow hoods utilizing High Efficiency Particulate Air (HEPA) filters,~~  
243 ~~shall be capable of maintaining Class 100 conditions during normal activity;~~  
244 c. ~~appropriate refrigeration for storing supplies and as well as sterile preparations and~~  
245 ~~products requiring refrigeration subsequent to their preparation and prior to their~~  
246 ~~dispensing, distribution, or administration to patients. The pharmacy shall~~  
247 ~~maintain documentation of refrigeration integrity, in accordance with its policies~~  
248 ~~and procedures.~~  
249 d. ~~appropriate disposal containers for used needles, syringes, and other sharps, and if~~  
250 ~~applicable, for cytotoxic waste from the preparation of chemotherapy agents and~~  
251 ~~infectious wastes from patients' homes; and~~  
252 e. ~~temperature controlled delivery containers, when required.~~
- 253 3. ~~The pharmacy shall maintain supplies adequate to ensure an environment suitable for the~~  
254 ~~aseptic preparation of sterile preparations and products. Within the sterile compounding area,~~  
255 ~~prescription drugs, devices, and related materials shall not be stored in shipping containers~~  
256 ~~constructed of corrugated cardboard or other high particulate producing materials.~~
- 257 4. ~~The pharmacy shall maintain current reference materials related to sterile preparations and~~  
258 ~~products accessible to all personnel.~~
- 259 D. ~~Drug Handling. Any sterile compounded preparation or product shall be shipped or delivered to a~~  
260 ~~patient in appropriate temperature controlled delivery containers as defined by USP standards and~~  
261 ~~appropriately stored.~~
- 262 E. ~~Cytotoxic Drugs. In addition to the minimum standards for a pharmacy established by the board, the~~  
263 ~~following requirements are established for pharmacies that prepare cytotoxic drugs, to insure the~~  
264 ~~protection of the personnel involved.~~
- 265 1. ~~All cytotoxic drugs shall be compounded in a vertical flow, Class II Biological Safety~~  
266 ~~Cabinet. Other products shall not be compounded in this cabinet.~~
- 267 2. ~~Personnel compounding cytotoxic drugs shall wear protective apparel, including disposable~~  
268 ~~masks, gloves, and gowns with tight cuffs.~~
- 269 3. ~~Personnel compounding cytotoxic drugs shall use appropriate safety and containment~~  
270 ~~techniques.~~
- 271 4. ~~Prepared doses of cytotoxic drugs shall:~~
- 272 a. ~~be dispensed and labeled with proper precautions on the inner and outer containers~~  
273 ~~or other device capable of providing a sterile environment; and~~
- 274 b. ~~be shipped in a manner to minimize the risk of accidental rupture of the primary~~  
275 ~~container.~~
- 276 5. ~~Disposal of cytotoxic waste shall comply with all applicable federal, state, and local~~  
277 ~~requirements.~~
- 278 6. ~~A "Chemo Spill Kit" shall be readily available in the work area, and shall consist of~~  
279 ~~appropriate materials needed to clean up spills of hazardous drugs. Personnel shall be trained~~  
280 ~~in its appropriate use for handling both minor and major spills of cytotoxic agents.~~
- 281 F. ~~Quality Control.~~
- 282 1. ~~An ongoing quality control program shall be maintained and documented that monitors~~  
283 ~~personnel performance, equipment, and facilities. Appropriate samples of finished products~~  
284 ~~shall be examined to assure that the pharmacy is capable of consistently preparing sterile~~  
285 ~~preparations and products meeting specifications.~~
- 286 a. ~~All clean rooms and laminar flow hoods shall be certified by an independent~~  
287 ~~contractor according to federal standards for operational efficiency at least every~~  
288 ~~six months. Appropriate certification records shall be maintained.~~
- 289 b. ~~Written procedures shall be developed requiring sampling if/when microbial~~  
290 ~~contamination is suspected.~~

- 291 e. ~~When bulk compounding of sterile solutions is performed using non-sterile~~  
292 ~~chemicals, extensive end-product testing shall be documented prior to the release~~  
293 ~~of the product from quarantine. This process shall include appropriate tests for~~  
294 ~~particulate matter and testing for pyrogens.~~  
295 d. ~~Written justification shall be maintained of the chosen "beyond use" dates for~~  
296 ~~compounded products.~~  
297 e. ~~Documentation shall be maintained of quality control audits at regular, planned~~  
298 ~~intervals, including infection control and sterile technique audits.~~

299 ~~G. Labeling.~~

- 300 1. ~~All practitioner administered sterile compounds shall be packaged in a suitable container, and~~  
301 ~~shall bear a label with the following minimum information:~~  
302 a. ~~pharmacy's name, address, and telephone number;~~  
303 b. ~~preparation name;~~  
304 c. ~~strength and concentration;~~  
305 d. ~~lot number;~~  
306 e. ~~beyond use date;~~  
307 f. ~~practitioner's name;~~  
308 g. ~~assigned identification number;~~  
309 h. ~~special storage requirements, if applicable; and~~  
310 i. ~~pharmacist's name or initials.~~  
311 2. ~~The labeling for all other sterile compounds shall be in accordance with the prescription~~  
312 ~~labeling requirements in §2527 of this Chapter.~~

313 Repealed.

314  
315 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.  
316 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708  
317 (October 1988), effective January 1, 1989, amended LR 29:2106 (October 2003), effective January 1, 2004,  
318 amended repealed LR  
319

FAMILY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

We anticipate no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

We anticipate no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

We anticipate no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

We anticipate no effect on family earnings and the family budget.

V. The effect on the behavior and personal responsibility of children.

We anticipate no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

We anticipate no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.

POVERTY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the rule proposed for adoption, repeal, or amendment.

I. The effect on household income, assets, and financial security.

We anticipate no impact on household income, assets, and financial security.

II. The effect on early childhood development and preschool through postsecondary education development.

We anticipate no impact early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

We anticipate no positive impact on employment and workforce development.

IV. The effect on taxes and tax credits.

We anticipate no impact on taxes or tax credits.

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

We anticipate no effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

PROVIDER IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

I. The effect on the staffing level requirements or qualifications required to provide the same level of service.

We anticipate no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

II. The total direct and indirect effect on the cost to the provider to provide the same level of service.

We anticipate no effect on the cost to the provider to provide the same level of service.

III. The overall effect on the ability of the provider to provide the same level of service.

We anticipate no effect on the ability of the provider to provide the same level of service.

REGULATORY FLEXIBILITY ANALYSIS  
FOR ADMINISTRATIVE RULES

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

There are no reporting requirements in the proposed rule changes. The minimum quality standards for the compounding of drugs are now set by federal law.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no schedules or deadlines or reporting requirements in the proposed rule.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

There are no reporting requirements in the proposed rule.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

There are no design standards in the proposed rule. The pharmacy owner has flexibility on how to achieve the operational standards as long as they comply with the minimum quality standards set by federal law.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

There are no exemptions for small businesses because the proposed rule mirrors the minimum quality standards set by federal law.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed rule. A public hearing on this proposed rule is scheduled for Thursday, October 30, 2014 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard  
Executive Director  
Louisiana Board of Pharmacy

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment:

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)

The proposed rule changes will result in a cost to the Board of Pharmacy of approximately \$2,000 for printing of the proposed and final rules in FY 15. The proposed changes seek to amend the section of Chapter 25 that addresses general standards and practices relevant to the compounding of drugs in order to reflect recently enacted federal legislation, the Drug Quality and Security Act of 2013 (DQSA).

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)

There will be no impact on revenue collections of state or local governmental units from the proposed rule changes.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-  
GOVERNMENTAL GROUPS (Summary)

The proposed rule changes directly affect those pharmacies engaged in the compounding of drugs. Since the Board had already adopted the minimum quality standards now set by federal law, the primary change for the compounding pharmacies is the removal of their authority to prepare medications for 'office use' in response to purchase orders instead of patient-specific prescriptions. The new federal definition of 'compounding' no longer permits pharmacies to perform that type of activity. To the extent a pharmacy has been compounding medications for 'office use', this proposed rule change will result in the loss of any receipts and/or revenue resulting from that activity as required under federal law.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not have any effect on competition or employment.



FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard** Dept.: **Health and Hospitals**  
**Executive Director**  
Phone: **(225) 925-6481** Office: **Board of Pharmacy**  
Return Address: **3388 Brentwood Drive** Title: **Pharmacy Compounding**  
**Baton Rouge, LA 70809** Effective Date of Rule: **January 20, 2014 (est.)**

**SUMMARY**  
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

**I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS**  
(Summary)

The proposed rule changes will result in a cost to the Board of Pharmacy of approximately \$2,000 for printing of the proposed and final rules in FY 15. The proposed changes seek to amend the section of Chapter 25 that addresses general standards and practices relevant to the compounding of drugs in order to reflect recently enacted federal legislation, the Drug Quality and Security Act of 2013 (DQSA).

**II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS**  
(Summary)

There will be no impact on revenue collections of state or local governmental units from the proposed rule changes.

**III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS** (Summary)

The proposed rule changes directly affect those pharmacies engaged in the compounding of drugs. Since the Board had already adopted the minimum quality standards now set by federal law, the primary change for the compounding pharmacies is the removal of their authority to prepare medications for 'office use' in response to purchase orders instead of patient-specific prescriptions. The new federal definition of 'compounding' no longer permits pharmacies to perform that type of activity. To the extent a pharmacy has been compounding medications for 'office use', this proposed rule change will result in the loss of any receipts and/or revenue resulting from that activity as required under federal law.

**IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT** (Summary)

The proposed rule changes will not have any effect on competition or employment.

Malcolm Broussard  
Signature of Agency Head or Designee

**Malcolm J Broussard, Executive Director**  
Typed Name and Title of Agency Head or Designee

John D. Coyne  
Legislative Fiscal Officer of Designee

9/9/14  
Date of Signature

September 8, 2014  
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The Board proposes to amend *Chapter 25 – Prescriptions, Drug and Devices* of its rules, and more specifically, *Subchapter C – Compounding of Drugs*. The proposed rule changes are intended to harmonize the Board's rules with recently enacted federal legislation, the Drug Quality & Security Act of 2013 (DQSA). A copy of the Notice of Intent is appended.

- B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

The U.S. Congress passed the DQSA and the law was effective on November 27, 2013. A copy of the legislation is appended.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session:

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

The Board anticipates an expenditure for the printing of the proposed and final rules of approximately \$2,000 in FY 15.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) \_\_\_\_ Yes. If yes, attach documentation.

(b) \_\_\_\_ No. If no, provide justification as to why this rule change should be published at this time.

The Board operates totally on self-generated funds.

- D. Compliance with Act 820 of the 2008 Regular Session

- (1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of "small businesses", we are unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. To the extent that all of the pharmacies licensed by the Board may meet the statutory definition of a small business, there are 1,872 pharmacies currently licensed by the Board.

- (2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

The recordkeeping required by the proposed rule changes are required by the minimum quality standards set by federal law. There is no change from the existing requirements.

- (3) A statement of the probable effect on impacted small businesses.

The Board anticipates a minimal, if any, impact on small businesses.

- (4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

The proposed rule changes allow a pharmacy to develop its infrastructure as long as it achieves compliance with the minimum quality standards set by federal law.

FISCAL AND ECONOMIC IMPACT STATEMENT  
WORKSHEET

**I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED**

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

<u>COSTS</u>	<u>FY 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 2,000	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 2,000</b>	<b>\$ 0</b>	<b>\$ 0</b>
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The Board has allocated \$2,000 for the printing of the Notice of Intent and the Final Rule in the current fiscal year.

3. Sources of funding for implementing the proposed rule or rule change.

<u>SOURCE</u>	<u>FY 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 2,000	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 2,000</b>	<b>\$ 0</b>	<b>\$ 0</b>

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board has sufficient funds budgeted and available to complete the rulemaking project.

**B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED**

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

The proposed rule change should result in no changes in costs to local governmental units.

**II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS**

A. What increase (decrease) in revenues can be anticipated from the proposed action?

<u>SOURCE</u>	<u>FY 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 0</b>	<b>\$ 0</b>	<b>\$ 0</b>

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

Since the proposed rule does not impact fees, the Board discerns no impact on the revenue collections of state and local governmental units from the proposed rule.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule changes directly affect those pharmacies engaged in the compounding of drug preparations. The Drug Quality & Security Act of 2013 (DQSA) was enacted by the U.S. Congress and signed into law on November 27, 2013. That legislation amended the federal Food, Drug & Cosmetic Act to establish a federal definition of the term 'compounding', then limited compounding to pharmacies performing that activity in response to patient-specific prescriptions. In addition, the federal legislation established the minimum quality standards for pharmacies compounding prescriptions to the relevant chapters of the United States Pharmacopeia (USP) – Chapter 795 for non-sterile preparations and Chapter 797 for sterile preparations.

Since the new federal definition of 'compounding' is consistent with the Board's current statutory definition, and since the Board already requires compliance with the relevant USP chapters, the primary change requiring this harmonization is the issue of pharmacies compounding medications in response to purchase orders for use by practitioners in their offices, instead of patient-specific prescriptions. The Board's rules have permitted that activity; however, DQSA does not allow that activity by compounding pharmacies. Instead, the federal legislation created a new type of entity referred to as outsourcing facilities. These facilities are credentialed and regulated by the federal Food & Drug Administration (FDA) and they are permitted to prepare 'office use' medications in response to purchase orders instead of patient-specific prescriptions. Therefore, the proposed rule changes include the repeal of the allowance for 'office use'.

Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

To the extent a pharmacy has been compounding medications for 'office use', this proposed rule change will result in the loss of any receipts and/or revenue resulting from that activity.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed rule change will not have any effect on competition or employment.

  
\_\_\_\_\_  
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director  
Typed Name and Title of Agency Head or Designee

September 8, 2014  
Date of Signature