Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

November 18, 2014

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

Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for *Regulatory Project 2014-4 ~ Pharmacy Compounding*

Dear Senator Alario:

As we indicated in our first report to you on September 9, 2014, the Board is currently amending its rules relative to pharmacy compounding. Subsequent to our Notice of Intent published in the September 20, 2014 edition of the *Louisiana Register*, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on October 30, 2014.

We received one question for clarification, but no comments or testimony requesting any changes to the original proposal. The Board considered the question, as well as the absence of any comments or testimony requesting changes, during their subsequent meeting on November 13. During that meeting, the Board directed staff how to respond to the question for clarification. The Board then determined it appropriate to move forward with the proposed rule as published.

You should find the following documents appended to this letter:

- Notice of Intent, as published in the September 2014 *Louisiana Register*
- Summary of Comments at October 30, 2014 Public Hearing
- Board Response to Commentator from October 30, 2014 Public Hearing
- Full text of proposed rule

Subject to review by the Joint Legislative Oversight Committee on Health and Welfare, the Board proposes to publish the proposed rule as a Final Rule in the January 20, 2015 edition of the *Louisiana Register*. If you have any questions about the enclosed information or our procedures, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm Broussard

Malcolm J. Broussard
Executive Director

cc: Chair, Senate Committee on Health and Welfare – APA.S-H&W@legis.la.gov
Speaker, House of Representatives – APA.HouseSpeaker@legis.la.gov
Chair, House Committee on Health and Welfare – APA.H-H&W@legis.la.gov
Editor, *Louisiana Register* – Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health and Hospitals
Board of Pharmacy

Pharmacy Compounding
(LAC 46:LIII.Chapter 25)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (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 and Security Act of 2013.

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 40:

§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 40:

§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 and 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. 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:

1. products appearing on a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health-System Pharmacists (ASHP);

2. products temporarily unavailable from manufacturers, as documented by invoice or other communication from the distributor or manufacturer.

F. Labeling of Compounded Preparations

1. 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 40:

§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 40:

Family Impact Statement

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.

1. The effect on the stability of the family. We anticipate no effect on the stability of the family.

2. 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.

3. The effect on the functioning of the family. We anticipate no effect on the functioning of the family.

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

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

6. 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

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.

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

2. The effect on early childhood development and preschool through postsecondary education development. We anticipate no impact on early childhood development or preschool through postsecondary education development.

3. The effect on employment and workforce development. We anticipate no positive impact on employment and workforce development.

4. The effect on taxes and tax credits. We anticipate no impact on taxes or tax credits.

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

Small Business Statement

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.

1. 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.

2. 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.

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no reporting requirements in the proposed Rule.

4. 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.

5. 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.

Provider Impact Statement

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.

1. 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.

2. 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.

3. 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.

Public Comments

Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Thursday, October 30, 2014 at 9 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 noon that same day.

Malcolm J. Broussard
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Pharmacy Compounding

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT 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 NONGOVERNMENTAL 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 J. Broussard
Executive Director
1409#043

John D. Carpenter
Legislative Fiscal Officer
Legislative Fiscal Office

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
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Summary of Testimony & Public Comments
re
Regulatory Project 2014-4 ~ Pharmacy Compounding
at
October 30, 2014 Public Hearing

There were no comments received prior to or during the public hearing. There was one question posed for clarification.

1. [email] Brianna Costales on behalf of Hartley Medical
Commentator noted the proposed revision to §2535.B relative to beyond use date suggested the deletion of the 180 day maximum dating; she asked what would be the replacement standard and questioned whether they should rely on the USP Chapter 797 standards.

From: Malcolm J. Broussard
To: "Compliance "
Subject: FW: Regulatory Project 2014-4 questions
Date: Sunday, November 16, 2014 3:27:00 PM
Attachments: image001.png

Ms. Costales,

During their meeting on November 13, the Board considered your question relative to the Beyond Use Date. The members directed me to respond on their behalf that compounders shall comply with the requirements of the relevant chapter in the United States Pharmacopeia (USP) when determining Beyond Use Dates for their compounded preparations.

Thank you for your interest in the Board's proposed amendment to the rules on pharmacy compounding. We anticipate the proposed rule being published as a Final Rule in the January 20, 2015 edition of the Louisiana Register, effective on the date of publication. In the interim, please remember pharmacists are required to comply with the provisions of the Emergency Rule that became effective on August 6, 2014; that rule is identical to the proposed rule.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
United States of America
Telephone +1.225.925.6481
Telecopier +1.225.923.5669
mbroussard@pharmacy.la.gov

From: Malcolm J. Broussard
Sent: Thursday, October 02, 2014 1:30 PM
To: 'Compliance '
Subject: RE: Regulatory Project 2014-4 questions

Ms. Costales,

Thank you for your interest in the Board's regulatory project relative to pharmacy compounding. Since publishing its *Notice of Intent* in the September 2014 edition of the state register, we are now in the public comment phase of the regulatory project. I will insert your communication into the record of the public hearing scheduled for October 30. The Board will consider the comments and testimony offered at that public hearing during their subsequent meeting on November 13. I will advise you of the Board's response to your question as soon as possible thereafter. In the interim, you should rely on the provisions of the appropriate USP chapter.

Malcolm J Broussard

Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
United States of America
Telephone +1.225.925.6481
Telecopier +1.225.923.5669
mbroussard@pharmacy.la.gov

From: Compliance [mailto:compliance@hartleymedical.com]
Sent: Thursday, October 02, 2014 1:14 PM
To: Malcolm J. Broussard
Subject: Regulatory Project 2014-4 questions

Good afternoon Malcolm,

Regarding the proposed rule change to section 2535, subsection B regarding Beyond Use Date is removed. What is the new proposed BUD? The USP 797 definition?

Best regards,
Brianna Costales
Compliance Officer

113 W. Victoria Street
Long Beach, CA 90805
P: 888.671.2888 Ext. 607
F: 800.648.8550
www.hartleymedical.com

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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

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provisions of Section 530 of Title 21 of the CFR.

c. The compounding of positron emission tomography (PET) drugs shall comply with the provisions of Section 212 of Title 21 of the CFR.

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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.

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1. 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 39: 236 (Emergency Rule effective January 31, 2013), amended LR 40:

§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 40: