Louisiana Board of Pharmacy

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

March 6, 2020

Senator P. Page Cortez, President
Louisiana Senate
Via e-mail: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for *Regulatory Project 2019-16 ~ Pharmacy Compounding*

Dear Senator Cortez:

As we indicated in our first report to your office on November 8, 2019, the Board is amending its rules for pharmacies compounding copies of commercially available products to include recent guidance from the federal food and drug administration.

Subsequent to the publication of our *Notice of Intent* in the November 2019 edition of the *Louisiana Register*, we conducted a public hearing on December 27, 2019 to receive comments and testimony on the proposed amendment. We received no comments or testimony on the proposed rule changes. During their subsequent meeting on February 5, 2020, the Board considered the absence of substantive comments and determined no revisions were necessary. The Occupational Licensing Review Commission approved the continuation of the promulgation process during their February 28, 2020 meeting. In connection with this regulatory project, you should find the following documents in this package:

- *Notice of Intent*, as published in the November 2019 *Louisiana Register* — Page 02
- Record from the December 27, 2019 Public Hearing — Page 04
- Full text of proposed rule — Page 38

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposal without amendment as a *Rule* in the April 20, 2020 edition of the *Louisiana Register* with an immediate effective date. 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-HW@legis.la.gov
Editor, *Louisiana Register* – Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health
Board of Pharmacy

Pharmacy Compounding (LAC 46:LIII.2535)

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 the section of its rules containing standards for pharmacy compounding. The proposed amendment of Paragraph A.2 updates the references to federal law and rule. The proposed amendment of Subsection F updates the standards for compounding copies of commercially available products consistent with recent guidance information from the federal Food and Drug Administration.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 25. Prescriptions, Drugs, and Devices
§2535. General Standards

A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.

1. …

2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, and in compliance with the Federal Food, Drug and Cosmetic Act of 1938 as subsequently amended, the current 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.2.a. - E.4. …

F. Compounding Copies of Commercial Drug Products.

1. Copies of commercial drug products contain the same active pharmaceutical ingredient(s) in the same, similar, or easily substitutable dosage strength which can be used by the same route of administration. Changes in strength of less than 10 percent from the commercial drug product shall not be considered significant enough to warrant the preparation of a copy of a commercial drug product. In the event a prescriber determines a change in the formulation of a commercial drug product is necessary to produce a significant clinical difference for the patient and that determination is documented on the prescription, the pharmacy may prepare a variation of the commercial drug product, provided:

a. the prescriber's determination shall identify both the relevant change requested and the clinically significant difference the change will produce for the patient; and

b. the pharmacy does not prepare copies of commercial drug products regularly or in inordinate amounts.

2. A pharmacy may prepare a copy of a commercial drug product when that product has been discontinued and is no longer marketed, or the product appears on the drug shortage list maintained by the federal Food and Drug Administration, or the product is temporarily unavailable as demonstrated by invoice or other communication from the distributor or manufacturer.

G. - G.2.i. …

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 41:97 (January 2015), amended LR 42:891 (June 2016), LR 46:

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. The proposed Rule amendment will have 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. The proposed Rule amendment will have 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. The proposed Rule amendment will have no effect on the functioning of the family.

4. The Effect on Family Earnings and Family Budget. The proposed Rule amendment will have no effect on family earnings or family budget.

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed Rule amendment will have 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. The proposed Rule amendment will have 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. The proposed Rule amendment will have no effect on household income, assets, or financial security.

2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed Rule amendment will have no effect on early childhood development or preschool through postsecondary education development.

3. The Effect on Employment and Workforce Development. The proposed Rule amendment will have no effect on employment or workforce development.

4. The Effect on Taxes and Tax Credits. The proposed Rule amendment will have no effect on taxes or tax credits.

5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed Rule amendment will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

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 amendment.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. There are no specific schedules for deadlines in the proposed Rule amendment.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. There are no additional compliance or reporting requirements in the proposed Rule amendment.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The standards for the compounding of drugs are federal in origin and apply to all pharmacies.

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.

Public Comments

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to Malcolm J Broussard, Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding the proposed Rule amendment.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule amendment is scheduled for 9 a.m. on Friday, December 27, 2019. During the hearing, 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 p.m. noon that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

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 require the Louisiana Board of Pharmacy to publish the proposed and final rules in the state register, at a cost of $2,000 for FY 20. There are no other costs or savings for other local or state governmental units. The proposed rule changes update standards for compounding copies of commercially available product to align with current guidance from the Food and Drug Administration (FDA).

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

The proposed rule changes will not affect revenue collections for state or local governmental units.

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

The proposed rule changes benefits pharmacists, as they update references to current federal law and rule. The standards for the compounding of commercially available products clarify the current limitation of compounding by stating that the strength of the active ingredient must change by more than 10 percent for the compounded preparation to be recognized as an authorized copy of a commercially available product. The proposed rule changes also remove a private website as a source of information for drugs in shortage, in favor of the website maintained for that purpose by the federal Food and Drug Administration. To the extent a pharmacy compounds copies of commercially available products with changes in strength of the active ingredient of less than 10 percent, the proposed rule changes will require the pharmacy to terminate such activity.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not affect competition or employment.

Malcolm J. Broussard Executive Director 1911#052	Evan Brasseaux Staff Director Legislative Fiscal Office

Louisiana Board of Pharmacy

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Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

Public Hearing Record

December 27, 2019

Louisiana Board of Pharmacy

Public Hearing Attendance Record ~ December 27, 2019

Regulatory Projects 2019-1B through 2019-18

Name	Address	E-mail	Group or Agency Represented
1. TJ Woodard	2450 Cottonwood Ave BR, LA 70808	tj@rxtogeaux.com	Capitol Wellness Solutions / Prescriptions to Geaux
2.			
3.			
4.			
5.			

In The Matter Of:

STATE OF LOUISIANA PARISH OF EAST BATON ROUGE
LOUISIANA BOARD OF PHARMACY

Public Hearing
December 27, 2019

Associated Reporters, Inc.
2431 South Acadian Thruway
Suite 550
Baton Rouge, La. 70808

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Min-U-Script® with Word Index

STATE OF LOUISIANA

PARISH OF EAST BATON ROUGE

LOUISIANA BOARD OF PHARMACY

An Public Hearing was held by the Louisiana Board of Pharmacy, on Friday, December 27, 2019, at their office located at 3388 Brentwood, Baton Rouge, Louisiana 70809 beginning at 9:00 a.m.

BEFORE:

Susan Erkel
Certified Court Reporter
In and For the State of
Louisiana

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P R O C E E D I N G S

MR. FINALET:

Good morning. Today is Friday, December 27, 2019. The time is 9:00 a.m. We're assembled in the Boardroom at the Louisiana Board of Pharmacy located at 3388 Brentwood Drive in Baton Rouge, Louisiana. My name is Carlos Finalet. I serve the Board of Pharmacy as its General Counsel. In his absence, the Board President, Carol Aron, has requested that I moderate this hearing. I now call this Public Hearing to order.

As a courtesy to everyone else in the room, please take time to silence your cell phones or other electronic devices. Further, should you find it necessary to take or make a telephone call, please step outside the meeting room to do so.

For your safety, the emergency exit path from this room is through the door into the lobby and through the front door through which you entered the building. For your comfort, the restrooms are located in the lobby --

ladies on the opposite side of the lobby, just past the receptionist's window, and gentlemen just outside the door to this room.

In addition, we have a water cooler in this room. Please help yourself. For your peace of mind, please ensure that you did not park in one of the three spaces between this building and the back of the building in front of this one, or in front of the building in front of this one. Those parking spaces do not belong to the Board, and tow trucks are regular visitors to that area. Additional parking is available at the rear of the Perlis clothing store on Jefferson Highway, and there is a stairway connecting that parking lot to the Board's parking area in front of our building.

This hearing is held in accordance with Administrative Procedures Act and the Open Meetings Law. As required by these laws, this hearing is convened pursuant to public notice and notice has

been properly posted.

The purpose of today's hearing is to receive public comments and testimony on the 17 regulatory projects listed on the agenda for today's hearing. The Board published its Notices of Intent for all these projects in November 2019 edition of the Louisiana Register. Further, the Board filed its first reports with the legislative oversight committees on November 8 and then distributed electronic Notice of Rulemaking Activity on November 9, 2019 to its electronic List of Interested Parties, as well as all its licensees.

As indicated in the Notices, the Board has convened this public hearing to receive public comments and testimony on all 17 of these regulatory projects. The Board will consider the comments and testimony offered today during their next meeting on February 5, 2020, to determine whether any revisions to the proposed rule amendments are necessary. We will reply to your comments as soon

as possible thereafter.

Prior to making any comments today, we ask that you sign the guest register for this event. Copies of today's agenda and the notices are available at the registration desk or rather, actually right in front of you. The proposed rule amendments are also available in the Public Library section of the Board's website, as well as the website of the Louisiana Register.

While we may answer questions to clarify language or interpretation, it is not our intent to debate any issues today. Again, the purpose of this hearing is to receive your comments and testimony for the Board's consideration. As indicated in the notices, the deadline for all comments and testimony on these proposed rules amendments is 12:00 noon today.

We are now prepared to receive your comments and testimony. As you begin your comments, we ask that you identify yourself and any organization that you

may represent. Please identify which regulatory topic for which you are submitting comments or testimony.

Before we take any oral statements, I do want to enter into the record two written comments that were submitted to the Board Office, one on December 23, 2019 from the National Association of Chain Drug Stores, specifically by its representative Steven C. Anderson, President and its CEO. And then the second written comment was submitted on December 26, 2019 by Albertsons Companies, specifically by its representative, Pharmacist Robert Geddes, Director of Pharmacy, Legislative and Regulatory Affairs.

So if there are any oral statements, comments that the public would like to make, now is would be the time.

MR. WOODARD:

I guess I might as well just to get everything on the record, Carlos. TJ Woodard here representing Capitol Wellness Solutions. I notice the first

item on the agenda, Licensing Marijuana Pharmacies, and I'm not sure exactly how this pertains to us or if I'm even -- if this is the right venue to bring things up, but there's a few things that we've noticed over the first few months of establishing, opening, running, and now we've done it for several months so we kind of have a feel of what's working and what's not working.

And I guess maybe just bullet points to bring up at a future meeting with Board Members to discuss, there are kind of three, well four critical issues that I think we're -- kind of prohibit our growth and the effective running of our marijuana pharmacies. The first I would say, delivery, and I don't know exactly what mechanism, if it's me as the pharmacist in charge of delivery, and if it's a third-party company delivery.

We have several patients that we've seen and we've established a relationship with that are truly bed bound and don't have transportation,

that don't have anyone that can access medication for them, I would be happy to deliver it to their home if that were allowed and legal so maybe just some guidance on even an extreme situations, you know.

I don't think this is a scenario like I deliver in my traditional pharmacy downtown where we deliver everything, but just to have that option would be helpful.

The second and I think it's been discussed is, we, personally speaking for Capitol Wellness, we have two great technicians that are kind of underutilized. They can perform certain duties, data entry, but really beyond that, as far as the filling -- filling of the medication, they can't do now. The pharmacist is the only one in my understanding that can touch the product and you know, essentially stick a label on a box, if you will.

Sometimes that creates a logjam. We spend most of our time counseling

patients so if I'm in the back counseling a patient and we have three additional patients come in, everything is stopped waiting on me, where at a minimum, they could enter it, fill it, label it for me to check and review, as we do in the traditional pharmacy I guess. So in my mind, if they can fill, you know, a Percocet in a traditional pharmacy, I can count behind them and check it and then dispense it.

It would be helpful if they could do that in our world. There just seems to be this firewall between technicians and the product that I don't see any issue whatsoever with it professionally because I'm still checking behind it and the things we traditionally do. So that's another thing.

The -- another big one and I don't know, there's a fine line between we're really -- I don't know all the specifics in the law, but we're really prohibited from advertising. And I don't know that advertising is in a sense of you know,

we need to put up a billboard that we sell medical marijuana here, but it would help one, communicate with doctors and patients kind of what we do and what we can do.

We do that some for education now with physicians. We don't really have a way to reach the patients unless they call us. But the main reason there is a medical marijuana recommending facility adjacent to our location and we're commonly confused with them. So we're on Picardy off of Essen. They're on the corner of Picardy and Essen. You know they have some flag out with some marijuana paraphernalia type things. People regularly think that's us. We would like a way just to let them know that it's not.

I mean, for instance, our location just has on the outside, it just says "Capitol" and our logo. So especially with elderly folks, they're constantly confused with how to get to us, what we do, who we are. So again, I'm not

asking for anything specifically, more so just to start the conversation with how could we do this efficiently and professionally to communicate what we're doing with the general public in a professional way.

I don't think we want to, you know, have the blow up people dancing on the roads saying, you know, medical marijuana here, but it's really been a -- and I think its inhibited the growth statewide for folks. We still have physicians and patients that have literally no idea what it is that we do. In about six months now that we've been open, there have been some lives that have truly been changed so I can honestly say that I think we're going in the right direction.

We're taking it slowly and doing it very controlled and very well. These are just some things that I've seen in practice that I think would help every marijuana pharmacy without hurting the public in any way. Actually, quite the

opposite. But again, I'm not asking for anything specifically. Just maybe at some future meeting we could discuss it.

So I don't even know if this is the right forum for that but just to kind of get that down in the public comment.

MR. FINALET:

And you had a forth point, maybe?

MR. WOODARD:

Well, the fourth point and I'm skipping over, I see at the bottom, number 3, letter Q, Cannabis Metered Dose Inhaler. I don't know remotely what that's about. I will just say, one of the biggest issues we have is getting this product into a patient's system as quickly as possible for various reasons, whether it's acute paid, whether it's an anxiety attack secondary to PTSD. That's still the fastest way to get this medication into someone's body, through the lungs.

So, you know, again, I'm not here saying we should, you know, have flower or vaporization. I don't know. This is

one thing that's come up, metered dose inhaler. I will just say from the clinical perspective, I couldn't support something like this more. I don't know what it looks like. I don't know if it's an ILERA and southern product or it's a GB -- well, it's not GB anymore, Wellcanna, an LSU product, but that's been a real issue with us is we need some mechanism to get instant relief for some patients.

That's one of the biggest complaints we've had is that, you know, we have the tinctures. They're faster than an oral product. They work. They work very well. There's still a 15 to 30 to an hour gap there so if someone's having an acute anxiety attack, I have nothing for them.

MR. FINALET:

And I think that was the purpose of that both legislatively and regulation.

MR. WOODARD:

So just to -- and this is me speaking personally as a pharmacist and on behalf

of Capitol, that's something that we support. There is a need for it.

MR. FINALET:

And to answer your question about if this was the proper forum, I don't think it's improper. You know you definitely addressed that one aspect of the inhaler which was appropriate. The other items are appropriate insofar as they'll be part of the comment review that the Board's going to make at the February meeting.

MR. WOODARD:

Okay.

MR. FINALET:

And my feeling is that the Board President's going to delegate that to Regulation Revision Committee.

MR. WOODARD:

Okay.

MR. FINALET:

And so there should be a very lively chain of meetings thereafter --

MR. WOODARD:

Right.

MR. FINALET:

-- on all these aspects. And as you know, the projects evolving and we expected it to evolve and frankly, want it to evolve to address a lot of the concerns you had about educating appropriately.

MR. WOODARD:

Right, right.

MR. FINALET:

And informing the public and getting the right patients to you.

MR. WOODARD:

And I think we've all -- I will say that speaking with people kind of from other states, speaking with folks at Pennington, speaking with folks at LSU, I think we did it the right way. It's much, you know, much different than in California or Colorado model, but it's well controlled and we can actually use that to our benefit in a lot of ways. I mean we're talking about doing clinical trials now which is kind of groundbreaking.

But, you know, we've got to start and then I think it's, you know, postmortem review of what's working, what's not working and just speaking -- we're in close contact with the other pharmacies in the state and it's kind of the same things that keep coming up. So I don't intend to be the spokesperson for everyone, but I'm happy to answer questions specifically, you know, patient based, what is working and what's not.

MR. FINALET:

And I can tell you that the Board will really want all of your input --

MR. WOODARD:

Okay.

MR. FINALET:

-- as to what you do because y'all are on the front lines.

MR. WOODARD:

Yeah.

MR. FINALET:

Y'all know what is needed and then they could figure out what we can work

with.

MR. WOODARD:

Perfect. So board meeting February at Xavier.

MR. FINALET:

At Xavier and I believe the starting time is 9:00.

MR. WOODARD:

And will the Regulations Committee be before that or after that?

MR. FINALET:

After that.

MR. WOODARD:

So they'll be --

MR. FINALET:

There is a Regulations Committee meeting in January 23rd I think. But that -- nothing marijuana related I don't think is on that agenda. But they wouldn't be discussing this anyway. The Board has to delegate it to the committee.

MR. WOODARD:

Okay.

MR. FINALET:

The committee does take up issues on their own. There's a process for it.

MR. WOODARD:

That's what Malcolm said. I haven't brought it up myself yet to be delegated that because I wasn't quite ready. But maybe at the Board, do I ask for it to be delegated?

MR. FINALET:

Well, what I'm going to suggest to Malcolm when he's preparing the comments, is you know, for the Board's Digest is to itemize your comments and concerns.

MR. WOODARD:

Okay.

MR. FINALET:

And that would give the Board President a vehicle to delegate that at that time.

MR. WOODARD:

Okay. Perfect.

MR. FINALET:

If you want to check before the meeting, you can always just submit a

request for that and then I'm not sure which part of the meeting it would be considered. It might be one of the actual agenda items or it might be part of the Executive Committee report.

MR. WOODARD:

Okay.

MR. FINALET:

I'm not sure. Why don't we do this. Malcolm gets back on the 2nd. You know, between now and then, maybe you shoot him an e-mail just asking that question.

MR. WOODARD:

And it's -- and he has told me that and given me that guidance that the proper procedure like you just said. It's got to go the Regulations Committee. That's where this will be hashed out. And that's really all we want is just to have the discussion. And I'd love for everyone to ask us questions because this was all so new for everyone, what's working.

I will say, professionally speaking, it's worked much more than I thought it

was. You know, we never really knew, you're going to flip the lights on if this is going to be like some, you know, shady, fly-by-night deal and it's just not that at all.

MR. FINALET:

And I've heard that your particular location is doing very well.

MR. WOODARD:

Yeah.

MR. FINALET:

And I've hear good things about it.

MR. WOODARD:

Okay. Thank you, Carlos. I think that's it.

MR. FINALET:

Give Lisa my hello.

MR. WOODARD:

I will.

MR. FINALET:

I might come by soon.

MR. WOODARD:

Thank you again for your help. I've talked to Kerry so I think we have a good plan.

MR. FINALET:

Good deal. Take care. Happy new year.

MR. WOODARD:

You too.

MR. FINALET:

Thank you.

(No public comments were received from 9:17 a.m. until 11:59 a.m.)

MR. FINALET:

The time is now 12:00 noon. This public hearing is adjourned.

(THE HEARING ADJOURNED AT 12:00 P.M.)

C E R T I F I C A T E

This certification is valid only for a transcript accompanied by my original signature and official seal on this page.

I, SUSAN ERKEL, Certified Court Reporter, in and for the State of Louisiana, as the officer before whom this hearing was taken, do hereby certify that the foregoing 6 pages were reported by me in the voice-writing method, and was prepared and transcribed by me or under my personal direction and supervision, and is a true and correct transcript to the best of my ability and understanding;

That the transcript has been prepared in compliance with transcript format guidelines required by statute or by rules of the board, and that I am informed about the complete arrangement, financial or otherwise, with the person or entity making arrangements for deposition services;

That I have acted in compliance with the prohibition on contractual relationships, as defined by Louisiana Code of Civil Procedure Article 1434 and in rules and advisory opinions of the board;

That I have no actual knowledge of any prohibited employment or contractual relationship, direct or indirect, between a court reporting firm and any party litigant in this matter nor is there any such relationship between myself and a party litigant in this matter; and

That I am not related to counsel or to the parties herein, nor am I otherwise interested in the outcome of this matter.

_____

SUSAN ERKEL
CERTIFIED COURT REPORTER
LICENSE NO. 24005

R E P O R T E R ' S P A G E

I, SUSAN ERKEL, Certified Court Reporter in and for the State of Louisiana, before whom this statement was taken, do hereby state on the Record:

That due to the interaction in the spontaneous discourse of this proceeding, dashes (--) have been used to indicate pauses, changes in thought, and/or talkovers;

That same is the proper method for a Court Reporter's transcription of proceedings, and that the dashes (--) do not indicate that words or phrases have been left out of this transcript;

That any words and/or names which could not be verified through reference material have been denoted with the phrase "(spelled phonetically)."

_____

SUSAN ERKEL
CERTIFIED COURT REPORTER
LICENSE NO. 24005

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Louisiana Board of Pharmacy

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

Summary of Testimony & Public Comments
re
Regulatory Project 2019-16 ~ Pharmacy Compounding
at
December 27, 2019 Public Hearing

No comments or testimony received.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

* * *

§2535. General Standards

A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.

1. …
2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, and in compliance with the Federal Food, Drug and Cosmetic Act of 1938 as subsequently amended, the current 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.2.a. – E.4. …

F. Compounding Copies of Commercial Drug Products.

1. Copies of commercial drug products contain the same active pharmaceutical ingredient(s) in the same, similar, or easily substitutable dosage strength which can be used by the same route of administration. Changes in strength of less than 10 percent from the commercial drug product shall not be considered significant enough to warrant the preparation of a copy of a commercial drug product. In the event a prescriber determines a change in the formulation of a commercial drug product is necessary to produce a significant clinical difference for the patient and that determination is documented on the prescription, the pharmacy may prepare a variation of the commercial drug product, provided:
   a. The prescriber's determination shall identify both the relevant change requested and the clinically significant difference the change will produce for the patient; and
   b. The pharmacy does not prepare copies of commercial drug products regularly or in inordinate amounts.
2. A pharmacy may prepare a copy of a commercial drug product when that product has been discontinued and is no longer marketed, or the product appears on the drug shortage list maintained by the federal Food and Drug Administration, or the product is temporarily unavailable as demonstrated by invoice or other communication from the distributor or manufacturer.

G. – G.2.i. …

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 41:97 (January 2015), amended LR 42:891 (June 2016), amended by the Department of Health, Board of Pharmacy, LR