Louisiana Board of Pharmacy

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

June 3, 2024

Senator Cameron Henry
President, Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2023-09 (Summary Report) ~ Product Integrity

Dear Senator Henry:

As we indicated in our first report to your office on November 8, 2023, the Board seeks to amend §1103 and §2501 of its rules relative to prescription department requirements and prescription drugs.

Subsequent to the publication of our *Notice of Intent* in the November 2023 edition of the *Louisiana Register*, we conducted a public hearing on December 28 to receive comments and testimony on the proposed rule changes. We received comments from representatives of five entities objecting to the proposed rule changes, particularly to the drug delivery aspect of the proposal. The comments provided did not express an issue with the drug storage aspect of the proposal. Recognizing the necessity for a regulation in regard to drug storage, the Board decided to remove the delivery component and focus the regulatory project on the storage element. After this project is complete, the Board will reconsider the delivery aspect and may decide to begin another project which will be focused only on the delivery aspect.

The Board then published a *Potpourri Notice* in the April 2024 edition of the *Louisiana Register* and held another public hearing on May 28, 2024 to receive comments and testimony on the substantive changes to the NOI. We received no comments or testimony pursuant to the *Potpourri Notice*. The Board subsequently determined no revisions to the *Potpourri Notice* were warranted. On May 31st we submitted the project to the Department of Justice's Occupational Licensing Review Program (OLRP) and are awaiting their review and approval. In connection with this regulatory project, you should find the following documents in this package:

- *Notice of Intent*, as published in the November 2023 edition of the *Louisiana Register*
- Record from the December 28, 2023 Public Hearing
- *Potpourri Notice*, as published in the April 2024 edition of the *Louisiana Register*
- Record from the May 28, 2024 Public Hearing
- Full text of proposed rule, as intended for publication in the *Louisiana Register*

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare and approval by the OLRP, the Board proposes to publish the rule change as noticed in the Potpourri, without amendment, as a *Rule* in the July 20, 2024 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 jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

M. Joseph Fontenot, Jr. Digitally signed by M. Joseph Fontenot, Jr.
Date: 2024.06.03 10:33:42 -05'00'

M. Joseph Fontenot Jr.
Executive Director

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

NOTICE OF INTENT

Department of Health
Board of Pharmacy

Product Integrity
(LAC 46:LIII.1103 and 2501)

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 Board of Pharmacy hereby gives notice of its intent to amend §1103 and §2501 of its rules relative to prescription department requirements and prescription drugs. The proposed rule change in §1103.A. adds a requirement for a prescription department to be maintained in a clean and orderly condition. The proposed rule changes in §1103.E. and §2501 add environmental condition requirements for all areas where drugs are stored or located prior to the transfer of possession of the drug to the patient or the patient's agent.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII.: Pharmacists

Chapter 11. Pharmacies
Subchapter A. General Requirements
§1103. Prescription Department Requirements

A. A prescription department of a pharmacy shall be maintained in a clean and orderly condition and shall provide sufficient floor space, fixtures, equipment and supplies commensurate with the nature and scope of the pharmacy's practice to ensure that drugs are compounded and dispensed in a dry, well-lighted, climate controlled, and safely enclosed structure.

B. - D. …

E. Drug Inventory

1. Storage. The pharmacy shall provide an adequate prescription inventory in order to compound and dispense prescription orders. All areas where drugs are stored or located shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling, prior to the transfer of possession of the drug to the patient or the patient's agent.

E.2 - J. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, LR 39:315 (February 2013), amended by Department of Health, Board of Pharmacy, LR 46:579 (April 2020), LR 47:1642 (November 2021), LR 48:497 (March 2022), LR 49:1556 (September 2023), amended LR 50:

Chapter 25. Prescriptions, Drugs, and Devices
§2501. Prescription Drugs and Devices

A. - A.2. …

3. Storage.

a. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.

b. All areas where drugs are stored or located shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling, prior to the transfer of possession of the drug to the patient or the patient's agent.

B. - E.3. …

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 29:2101 (October 2003), effective January 1, 2004, amended LR 50:

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 and 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 and 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. The proposed rule amendment will have no effect on reporting requirements for small business.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on schedules or deadlines for compliance or reporting requirements for small business.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule amendment will have no effect on consolidation or simplification of compliance or reporting requirements for small business.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule amendment will have no effect on establishment of performance standards for small businesses to replace design or operational standards for small business.

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 in the proposed rule amendment.

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. The proposed rule amendment will have no effect on the staffing level requirements or qualifications required 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. The proposed rule amendment will have an indeterminate effect on the cost to the provider to provide the same level of service. There may be increased shipping costs for those pharmacies that mail or deliver prescriptions to patients.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule amendment will have no effect on the ability of the provider to provide the same level of service.

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 M. Joseph Fontenot Jr., 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. The deadline for the receipt of all written comments is 12 p.m. on Thursday, December 28, 2023.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for 9 a.m. on Thursday, December 28, 2023 at the board office. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

M. Joseph Fontenot Jr.
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Product Integrity

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

The proposed rule change will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in estimated printing expenses of $1,000 in FY 24. Other than publication costs, which are included in the LBP's annual operating budget, the proposed rule change is not anticipated to result in any additional expenditures or cost savings for LBP.

To the extent a government-operated pharmacy is not currently storing and/or delivering medication in appropriate environmental conditions, there could be additional costs to the pharmacy to ensure appropriate storage conditions prior to transferring possession of the medication to the patient. These costs are indeterminable.

The proposed rule change adds a requirement for the prescription department of a pharmacy to be maintained in a clean and orderly condition. The proposed rule change also adds environmental condition requirements for all areas where drugs are stored or located prior to the transfer of possession of the drug to the patient or the patient's agent.

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

The proposed rule change will not affect revenue collections of state or local governmental units.

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

The proposed rule change will benefit consumers by ensuring that drugs are stored under environmental conditions which ensure the integrity of the drug prior to delivery to the patient.

To the extent a pharmacy is not currently storing and/or delivering medication in appropriate environmental conditions, there could be additional costs to the pharmacy to ensure

appropriate storage conditions prior to transferring possession of the medication to the patient. These costs are indeterminable.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will have no effect on competition or employment.

M. Joseph Fontenot Jr.	Patrice Thomas
Executive Director	Deputy Fiscal Officer
2311#021	Legislative Fiscal Office

Louisiana Board of Pharmacy

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

NOTICE IS HEREBY GIVEN that a Public Hearing has been ordered and called for 9:00 a.m. on Thursday, December 28, 2023 at the Board office, for the purpose to wit:

AGENDA

Revised 11-20-2023

1. Call to Order 9:00 a.m.
2. Appearances
3. Solicitation of Comments & Testimony on Proposed Rule Changes
   A. Regulatory Project 2023-09 ~ Product Integrity
   B. Regulatory Project 2023-10 ~ Prescription Monitoring Program (PMP)
   C. Regulatory Project 2023-11 ~ Pharmacists Application
4. Opportunity for Public Comment
5. Adjourn 12:00 noon

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 M. Joseph Fontenot Jr., Executive Director, at the Board office. He is responsible for responding to inquiries regarding the proposed Rule amendments. The deadline for the receipt of all written comments is 12 p.m. on Thursday, December 28, 2023.

Public Hearing
During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request a disability accommodation, please contact Joe Fontenot, Executive Director, at 225.925.6496 or email at jfontenot@pharmacy.la.gov .

NOTICE: In compliance with Act 256 of the 2019 Louisiana Legislature, the Board gives public notice that any information submitted to the Board may become public record unless specifically exempted by the Public Records Law, R.S. 44:1 *et seq.*
NOTICE: To request a disability accommodation, please contact Joe Fontenot, Executive Director, at 225.925.6496 or email at jfontenot@pharmacy.la.gov

Louisiana Board of Pharmacy

Public Hearing Attendance Record ~ December 28, 2023

Regulatory Project 2023-09 ~ Product Integrity
Regulatory Project 2023-10 ~ Prescription Monitoring Program (PMP)
Regulatory Project 2023-11 ~ Pharmacists Application

Name	Address	E-mail	Group or Agency Represented
1.			
2.			
3. (NONE)			
4.			
5.			

Louisiana Board of Pharmacy

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

December 28, 2023

Public Hearing

Opportunity for Public Comment

1. Name _____ representing _____

   Comments:

2. Name _____ representing _____

   Comments:

(NONE)

3. Name _____ representing _____

   Comments:

4. Name _____ representing _____

   Comments:

Louisiana Board of Pharmacy

3388 Brentwood Drive
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Summary of Testimony & Public Comments

Regulatory Project 2023-09 ~ Product Integrity
at
December 28, 2023 Public Hearing

1. Letter from Scott Clark representing CenterWell Pharmacy

Mr. Clark expressed concerns that the proposed language was vague and ran the risk of creating unintended consequences. Mr. Clark provided substitute language for the Board's consideration and his suggestions were used to develop a subsequent proposal.

2. Letter from Mark Johnston representing CVS Health

Mr. Johnston's concerns were as follows:

- The proposed rules focus only on a portion of the drug distribution cycle, failing to address drug distribution from drug manufacturers to wholesalers and wholesalers to pharmacies.
- The FEIS is incomplete, and the proposed storage rules lack clear visibility to the impact upon delivery, obscuring the impact to pharmacies, the greater drug supply chain, and ultimately patients.
- The construction of the proposed rule is unconventional.
- The proposed rule language does not reflect amenable discussion at 2023 meetings of the Board and its committees.

Additionally, Mr. Johnston provided suggested language which the Board used in developing a subsequent proposal.

3. Letter from Rich Palombo representing Express Scripts.

Mr. Palombo provided the following comments:

- The proposed rule is currently under *Prescription Department Requirements, Drug Inventory, Storage*, and does not clearly distinguish delivery and shipping from storage within facilities.
- The FEIS stating an "undeterminable cost" does not provide a complete assessment of fiscal and economic impact on pharmacies and patients who utilizes delivery of medications.
- The proposed rule focuses only on the pharmacy portion of the drug supply chain, without addressing distribution from drug manufacturers to wholesalers and wholesalers to pharmacies.

Mr. Palombo provided recommendations which were used to develop a subsequent proposal.

4. Letter from Jessica Elliott representing LARP

Ms. Elliott objected to the delivery component of the proposed regulation. She also provided comment that the regulations should include all shipping of prescriptions in the drug supply chain, to include manufacturers and distributors.

5. Letter from Jeenu Philip representing Walgreens

Mr. Philip accused the Board of violating Open Meetings Law by not providing proper notice and comment. Mr. Philip also provided a recommendation which was used to develop a subsequent proposal.

CenterWell Pharmacy

December 27, 2023

Louisiana Board of Pharmacy
Executive Director M. Joseph Fontenot., Jr.
3388 Brentwood Drive
Baton Rouge, LA 70809-1700

Submitted by mail and via email to jfontenot@pharmacy.la.gov

RE: Regulatory Project 2023-09 – Product Integrity

Dear Director Fontenot:

This letter is in response to the notice of public hearing and related documents regarding Regulatory Project 2023-09 – Product Integrity.

CenterWell Pharmacy, Inc. (CenterWell Pharmacy) is a full-service home delivery pharmacy serving patients across all 50 states. CenterWell Pharmacy provides holistic care that is personalized and coordinated with easy-to-use options so our patients can receive the care and prescriptions they need exactly when they need them. This includes retail and specialty pharmacy services, as well as home delivery services. Our pharmacies employ many pharmacists and pharmacy technicians who are critical to ensuring that patients across the country, including those in Louisiana, have access to the medications they need when they need them.

CenterWell Pharmacy appreciates the opportunity to provide comments on this proposed rule. Overall, CenterWell Pharmacy recognizes the Board's efforts to provide greater clarity about its expectations for storing prescription drugs. However, ***the draft language is unclear, and the storage requirements are narrowly directed at pharmacies. Furthermore, the processes in place today ensure the integrity of medications that are shipped or delivered to patients.***

- ***The current language is vague and runs the risk of creating unintended consequences.***

  The draft language creates ambiguity about the meaning of "prior to the transfer of possession of the drug to the patient or the patient's agent." For example, does this mean the point in time when a pharmacy transfers the prescription to a third-party delivery company, or when the patient physically takes possession of the prescription?

  We would appreciate clarification from the Board regarding its intent. If the current language is finalized as is, it will create uncertainty in the regulatory environment and will be difficult for pharmacies to operationalize.

- ***The Board's proposal does not look at the prescription drug supply chain in totality and instead only addresses a small portion. If the state is going***

to act, we encourage the Board to do it in a way that holds all stakeholders to the same level of accountability.

The current proposal is narrowly focused and would only apply these storage standards to pharmacies. These changes would not guarantee end-to-end integrity. If the Board chooses to move forward with the proposed rules as currently drafted, CenterWell Pharmacy requests that the same requirements be applied to the entire supply chain, including manufacturers and wholesalers, to create consistent expectations for all stakeholders.

- ***The processes already in use today ensure the integrity and stability of medications that are shipped or delivered to patients.***

CenterWell Pharmacy ensures medications are reviewed, dispensed, and shipped to the patient in a safe and reliable manner. We undergo rigorous testing of our materials and processes to validate that they maintain the integrity and stability of medications. We utilize a variety of controls and information, which includes manufacturer data and a comprehensive temperature software program.

Recommendation

As previously stated, the proposed rule is vague and narrowly directed at pharmacies. Given these factors, ***CenterWell Pharmacy strongly recommends that the Board amend the language to make clear these storage requirements only apply to areas where drugs are stored or located within a pharmacy.***

We suggest the following modifications to both sections of the proposed rule where this language appears:

> "All areas where drugs are stored or located within the pharmacy shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling., ~~prior to the transfer of possession of the drug to the patient or the patient's agent.~~"

Thank you for the opportunity to provide feedback to the Board on the proposed rules. Please feel free to contact me if you have any questions related to the comments.

Sincerely,

Scott Clark
Vice President, Professional Practice
sclark8@humana.com

Mark Johnston, R.Ph
Executive Director,
Board of Pharmacy Regulatory Affairs
One CVS Drive
Woonsocket, RI 02895
401-601-1968
Mark.Johnston@cvshealth.com

12/28/23

M. Joseph Fontenot Jr., Executive Director,

Louisiana Board of Pharmacy, 3388 Brentwood Drive,

Baton Rouge, LA 70809- 1700

Dear Mr. Fontenot,

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health ("CVS") and its family of pharmacies. CVS, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Louisiana through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to submit comments on the Board of Pharmacy's Notice of Intent entitled Product Integrity (LAC 46:LIII.1103 and 2501).

CVS is supportive and committed to the safe shipping and delivery of prescription medications to patients not only in Louisiana, but across the United States, our territories and to our armed services members deployed across the world. CVS has over forty years' experience in safely distributing medications through the mail and has shipped over one billion medications safely to its patients. Over the years, CVS has utilized its vast experience in shipping medications across the country to design unique packing systems for over 400 individual drugs. These packaging systems were created in conjunction and consultation with drug manufacturers and specialty distribution companies. The packaging systems were created utilizing data, science and vigorous testing protocols. The goal of the packaging systems is to duplicate the methods the drug manufacturers use to distribute their product to licensed pharmacies.

CVS believes the proposed rules attempt to solve a perceived issue that is not grounded in scientific evidence or data, especially as these rules relate to ambient drugs, and we are ultimately concerned that these proposed rules will restrict patient's access to prescription medications causing delays in care. More specifically, our concerns include:

- The proposed rules focus only on a portion of the drug distribution cycle, failing to address drug distribution from drug manufacturers to wholesalers and wholesalers to pharmacies.
- The Fiscal and Economic Impact Statement is incomplete, and the proposed storage rules lack clear visibility to the impact upon delivery, obscuring the impact to pharmacies, the greater drug supply chain, and ultimately patients.
- The construction of the proposed rule is unconventional.
- The proposed rule language does not reflect amenable discussion at 2023 meetings of the Board and its committees.

CVS supports evidence-based rulemaking and is concerned that the Board is proposing a rule to solve a perceived problem before determining, through carefully vetted science and data, that an actual problem

exists. It is our understanding that the Board did not review any scientific data, studies or any other materials necessary to assess the issue. To date, the Board has not released any study or evidence to support these proposed rules for the public and the pharmacy community to digest, scrutinize and independently verify. While CVS objects to these rules pertaining to ambient or "room temperature" drugs without a scientific explanation, CVS does agree that there is a subset of medications that need a specialized packaging system for delivery, and that is why CVS has implemented specialized delivery protocols for these medications.

The State of Louisiana regulates not only pharmacies, but the entire drug supply chain, which includes drug wholesale distributors and drug manufacturers, all of whom distribute and deliver prescription drugs to pharmacies using mail, common carriers, or couriers. If temperature excursions on every medication truly posed a risk to patient health and safety, those risks could just as easily arise from the shipping and delivery practices of all these entities, who are also under the State's jurisdiction. Yet, the proposed rules only address pharmacy delivery to the patient, typically the briefest portion of the distribution cycle. This proposed rule also fails to acknowledge that pharmacies currently ship and deliver drugs in the same manner as they are shipped by the manufacture.

The Fiscal and Economic Impact Statement for Administrative Rules is incomplete. Specifically the Board did not provide Estimated Costs and/or Economic Benefits To Directly Affected Persons, Small Businesses Or Nongovernmental Groups by simply publishing in the Louisiana Register Vol. 49, No. 11 on November 20, 2023: "To the extent a pharmacy is not currently storing and/or delivering medication in appropriate environmental conditions, there could be additional costs to the pharmacy to ensure appropriate storage conditions prior to transferring possession of the medication to the patient. These costs are indeterminable." An "indeterminable cost" does not equate to a summary by the agency as to the estimated costs or economic benefits, or both, to directly affected persons as required in LSA-R.S. 49:961, and at best lacks transparency by the Board.

Additionally, this statement contains the only reference of these storage rules pertaining to delivered medication; The proposed rule language itself does not mention delivery, and thus the proposed amendments are not inherently visible to the public. The economic impact upon pharmacies and patients related to "delivery" as compared to "storage" could be substantial. Therefore, CVS believes that the Board has also not properly published the Notice of Intent, which fails to mention the proposed rule amendment's impact upon delivered medication.

Conventional Board of Pharmacy rule construction does not connect storage requirements as pertaining to delivery requirements, as it typically limits storage requirements to the confines of the licensed space of the pharmacy. At a 2023 meeting of the Board's Regulation Revision Committee, a vague reference to an unnamed statute was identified as the reason for the construction of these proposed storage rules pertaining to delivery. CVS requests that these proposed rules be sent back to committee for a visible discussion of statutory implications and resultant rule construction that does not impose in-pharmacy storage requirements upon entities such as the United States Postal Service.

In conclusion, CVS requests that the Board withdraw this proposed rule and send it back to committee for a complete fiscal and scientific analysis involving all pertinent Louisiana Administrative Agencies and industry experts, including drug manufacturers, wholesalers, and pharmacies to determine if an issue indeed exists before a rule is promulgated. If the Board moves forward with these rules as constructed, at a minimum, we request the following change, which we believe is representative of the Board's Regulation Revision Committee's 2023 discussion involving available manufacture's excursion data and

other information that is not contained within the manufacturer's labeling and best meets the interests of the patients in Louisiana and the pharmacies serving our patients.

"All areas where drugs are stored or located shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP, and/or manufacturer's or distributor's product ~~labeling~~ information, prior to the transfer of possession of the drug to the patient or the 17 patient's agent.

We appreciate the opportunity to submit comments on these proposed rules. CVS is a staunch advocate for the safe dispensing of medications and has adopted multiple packaging systems for the safe delivery of drugs when warranted and supported by science and data. Please don't hesitate to contact me directly

Sincerely,

Mark Johnston, R.Ph

CVS Health,

Executive Director,

Board of Pharmacy Regulatory Affairs

December 28, 2023

Louisiana Board of Pharmacy
Executive Director M. Joseph Fontenot., Jr.
3388 Brentwood Drive
Baton Rouge, LA 70809-1700

Submitted by mail and via email to jfontenot@pharmacy.la.gov

RE: Regulatory Project 2023-09 – Product Integrity

Dear Director Fontenot:

I am writing this letter on behalf of Express Scripts, Inc., and ESI Mail Pharmacy Service Inc. (collectively "Express Scripts", and Accredo Health Group, Inc. ("Accredo") (referred to collectively in this letter as "Express Scripts/Accredo") in response to the notice of public hearing and related documents regarding Regulatory Project 2023-09 – Product Integrity.

Express Scripts/Accredo appreciates the Board's role in protecting the health and welfare of Louisiana residents and the efforts to ensure product integrity is maintained. The proposed rule is currently under *Prescription Department Requirements, Drug Inventory, Storage.* We our concerned that the language has more to do with storage temperatures during the life of a finished drug product and does not clearly distinguish the context of shipping and delivery. We respectfully ask the Board to consider these comments and send the proposed rules back to the Regulations Committee for further review and discussion. At a minimum, we believe revising the rules to distinguish storage from delivery and to allow a pharmacy to consider information provided by the manufacturer, including the way the manufacturer ships or delivers the drug product, will promote patient safety, ensure continued access to medications and help maintain standardization across the supply chain.

Background:

Express Scripts has been delivering mail-service prescriptions for more than 36 years. During that time, Express Scripts has pioneered and employed innovative technology to ensure the integrity of the medications we ship to patients' homes. For every medication shipped in insulated packaging, Express Scripts uses advanced technology that takes into account the acceptable temperature range for each medication, as well as the forecasted weather patterns the medication will pass through on its journey from an Express Scripts/Accredo pharmacy to the patient's hands. Using a forecasting temperature program with a patented algorithm, shipping and destination temperatures are identified and then matched to the medication's temperature profile. Express Scripts uses this information to determine the appropriate shipping time frame and the packaging that should be used in transit. That technology is

used to determine the optimal packaging and delivery methods for temperature sensitive medications, delivered by the Express Scripts and Accredo pharmacies.

Express Scripts/Accredo relies on definitions, standards, and guidelines published in the United States Pharmacopeia (USP), as well as stability data and other manufacturer information, to determine if a medication will require temperature-controlled packaging based on the range of safe temperatures the medication can endure and the current temperature and weather patterns on the delivery route.

Regulatory Project 2023-09 – Product Integrity

Express Scripts/Accredo is concerned that the rule as proposed is unclear and can lead to unintended consequences, including restricting access to medication and/or delays in care. We appreciate the opportunity to provide the following comments related to Regulatory Project 2023-09 – Product Integrity:

- The proposed rule is currently under *Prescription Department Requirements, Drug Inventory, Storage* and does not clearly distinguish delivery and shipping from storage within facilities.

- The Fiscal and Economic Impact Statement stating an "indeterminable cost" does not provide a complete assessment of fiscal and economic impact on pharmacies and patients who utilizes delivery of medications.

- The proposed rule focuses only on the pharmacy portion of the drug supply chain, without addressing distribution from drug manufacturers to wholesalers and wholesalers to pharmacies.

As the draft language does not clearly distinguish shipping and delivery from storage requirements, there is risk of misinterpretation and unintended consequences which may result in delayed access to necessary medications. Additionally, the meaning of "prior to the transfer of possession of the drug to the patient or the patient's agent" is unclear. Express Scripts/Accredo believes further clarification is needed in these areas and requests the Board to provide direction to these sections.

In addition to providing clear distinction between storage and delivery, Express Scripts/Accredo would like the Board to include the entire supply chain, including manufacturers and wholesalers, to ensure consistency for all stakeholders, and to avoid requiring a pharmacy to deliver a medication at a higher standard than they receive the same medication at their pharmacy.

Express Scripts/Accredo believes that including all supply chain participants and providing clear expectations to remove ambiguity and confusion will provide the Board, regulated entities a complete set of expectations and allow for a complete Fiscal and Economic Impact Statement.

Recommendation

Express Scripts/Accredo requests that the Board withdraw the proposed rule and send it back to committee for further review and discussion, including drug manufacturers, wholesalers, pharmacies and industry experts. If the Board does decide to move forward with Regulatory Project 2023-09 Product Integrity, we request the following change, which we believe is representative of the Board's Regulation Revision Committee's 2023-09 intent to ensure patient safety, including continued access to

medications, and help maintain product integrity standardization across the supply chain. We also believe these changes provide clarity to pharmacies and pharmacy personnel to best serve our patients.

> All areas where drugs are stored or located within the pharmacy shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP), and/or manufacturer's or distributor's product labeling, prior to the transfer of possession of the drug to the patient or the patient's agent. A pharmacy shall ensure that all drugs are delivered to the patient in accordance with standards of the manufacturer, United States Pharmacopeia, Federal Food and Drug Administration and/or other recognized standards. A pharmacy shall ensure integrity of any drug requiring temperature control other than room temperature storage that is delivered by mail order and provide a notification to the patient of the timeliness in addressing the proper storage of the drug.

Thank you for the opportunity to comment on Regulatory Project 2023-09 Product Integrity. Please feel free to contact me if you have any questions related to the comments. We look forward to working with the Louisiana Board of Pharmacy on this project.

Sincerely,

Rich Palombo, RPh, DPh
Senior Director, Pharmacy Regulatory Affairs
Richard.Palombo@evernorth.com
609-513-9459

LOUISIANA ALLIANCE OF RETAIL PHARMACIES

December 18, 2023

M. Joseph Fontenot Jr., Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700

Dear Mr. Fontenot:

On behalf of the Louisiana Alliance of Retail Pharmacies (LARP), I am writing to you with great concern over proposed changes to Chapter 11, Subchapter A, §1103 E (1) and Chapter 2501 A (3)(b) regarding the home delivery of prescription drugs approved by the Louisiana Board of Pharmacy now open for public comment. The following language was added: "*All areas where drugs are stored or located shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling, prior to the transfer of possession of the drug to the patient or the patient's agent.*"

It is our understanding the Board interprets the language "All areas…" to include shipping containers used in shipping medications to a patient's home. Therefore, the rule change would require ALL home delivery medications, including room temperature medications, to be sent in temperature-controlled packaging from pharmacies to patients. Not only would these proposed rules be costly, but it is not based on scientific data and could have grave consequences to a patient's access to medication, specifically in rural areas.

Also, the rule only applies to pharmacy shipping to patients – not shipping from manufacturers to drug wholesalers, or at any other point in the supply chain. While we recognize the Board does not have regulatory authority over manufacturers and drug distributors, we believe the shipping of medications falls under the purview of the Board's responsibility of protecting Louisiana patients and patient safety should require **all** shipping of prescriptions, at all points in the supply chain, to adhere to these packaging requirements. There is no manner in which a pharmacy could know that it received a medication that was compromised prior to arriving at the pharmacy.

LARP recommends adding language after "…patient or patient's agent." that says "Room temperature medications" are exempted from this section. "Room temperature medications" are medications that have

a recommended storage range between 68° and 77°F with temporary "excursion" periods ranging as low as 59°F and as high as 86°F."

Pharmacies that offer home delivery of prescriptions already comply with industry shipping standards when delivering medications, and, to our knowledge, no Louisiana-specific, peer reviewed studies exist on this topic. Seeing that pharmacies are already held to benchmarks based on rigorous, national industry standards, implementing a rule based on a Louisiana-specific study that includes manufacturers would seem to make this issue a more objective measure for all of the companies in the supply chain.

All pharmacies work toward the mission of caring for our patients and their safety and well-being are our utmost concern. We would like to continue to work with the Board to find solutions that are fair and objective and not unreasonably costly and burdensome as our current delivery practices are based on industry standards, and a practice or employee that fails to operate on this level are certainly reviewed and handled if they do not meet these standards.

Thank you for the opportunity to provide comments.

Sincerely,

Jessica Elliott

Jessica Elliott
Louisiana Alliance of Retail Pharmacies

From:	Philip, Jeenu
To:	Joe Fontenot
Subject:	Louisiana 2023-09 Comment Letter.docx
Date:	Friday, December 22, 2023 10:55:33 AM
Attachments:	Louisiana 2023-09 Comment Letter.docx

Good morning Mr. Fontenot,

On behalf of all pharmacies owned and operated by Walgreen Co. in the state of Louisiana, we thank the Board for the opportunity to comment and respectfully request an Amendment to Regulatory Project 2023-09 Product Integrity.

Walgreens thanks the Board for the opportunity to provide the request to amend this rule. If the Board would like additional information, please feel free to contact me.

Thank you!

Regards,
Jeenu

Jeenu Philip
Director, Pharmacy Affairs

Walgreen Co.
Telephone 904-386-6776

Member of Walgreens Boots Alliance | MyWalgreens.com

Jeenu Philip, R.Ph.
Director, Pharmacy Affairs
Walgreen Co.
p: 904-386-6776
jeenu.philip@walgreens.com

December 22nd, 2023

Via Email

Louisiana Board of Pharmacy
Attention: Joseph Fontenot, Executive Director
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Email: jfontenot@pharmacy.la.gov

Re: Request for Amendment to Regulatory Project 2023-09

Dear Mr. Fontenot,

On behalf of all pharmacies owned and operated by Walgreen Co. in the state of Louisiana, we thank the Board for the opportunity to comment and respectfully request an Amendment to Regulatory Project 2023-09 Product Integrity.

While we fully support the Board's continued efforts to ensure patient safety through rulemaking, we believe the language added to the drug storage regulation was done so without the proper notice and comment, as required by the Open Meetings Law.

At the July 18 Regulation Revision Committee meeting, the members discussed delivery requirements and incorporated delivery restrictions into the Prescription Drugs and Device Storage requirements. Delivery was not an agenda item, and the Committee did not comply with the Open Meetings Law to add delivery to the agenda and allow public comment. Additionally, at the Full Board meeting, on August 16, 2023, the approved minutes do not mention delivery, and the rule was approved, with no comments.

We ask the board to reconsider this change and make delivery its own agenda item at a future committee meeting to provide the public sufficient notice and allow for public comment.

If the Board declines our request to make delivery its own agenda item, Walgreens asks the Board to strike, "prior to the transfer of possession of the drug to the patient or the patient's agent" from the following chapters:

Chapter 11. Pharmacies
Subchapter A. General Requirements
§1103. Prescription Department Requirements
E. Drug Inventory
1. Storage. The pharmacy shall provide an adequate prescription inventory in order to compound and dispense prescription orders. All areas where drugs are stored or located shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling.~~, prior to the transfer of possession of the drug to the patient or the patient's agent.~~

Chapter 25. Prescription, Drugs, and Devices
§2501. Prescription Drugs and Devices;
3. Storage
b. All areas where drugs are stored or located shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling.~~, prior to the transfer of possession of the drug to the patient or the patient's agent.~~

Rationale:
If it is the Board's intent to include delivery services in its drug storage requirements, we believe it should be clearly referenced as such within the rule to ensure transparency and to allow the public an opportunity to provide comments. Since the Department concluded the costs of such a rule change are indeterminable, public comment would provide insight to the actual cost.

To our knowledge, neither USP nor the Board have shipping standards, e.g., packaging requirements, that ensures the integrity of drugs through the shipping process. Unless there are published standards, each pharmacy will have to bear the cost to perform their own study. These costs will have an impact on both large and small pharmacies and could lead to pharmacies discontinuing delivery services. If that were to happen, this could significantly affect the health and wellbeing of those patients that rely on delivery to get their medications.

Walgreens thanks the Board for the opportunity to provide the request to amend this rule. If the Board would like additional information, please feel free to contact me.

Sincerely,

Jeenu Philip R.Ph.

Responses to Comments Received

From: Emily Reid
To: Joe Fontenot
Cc: Scott Clark
Subject: RE: CenterWell Pharmacy Comments on Regulatory Project 2023-09 – Product Integrity
Date: Tuesday, April 16, 2024 12:59:43 PM

Hello, Director Fontenot –

Thank you for sharing this information on next steps.

Emily Reid
Government Affairs Lead | Corporate Affairs

Humana
Work at Home – Colorado (Mountain Time)

C 850.661.5849
ereid4@humana.com

From: Joe Fontenot <JFontenot@pharmacy.la.gov>
Sent: Monday, April 15, 2024 2:13 PM
To: Emily Reid <ereid4@humana.com>
Cc: Scott Clark <sclark8@Humana.com>
Subject: RE: CenterWell Pharmacy Comments on Regulatory Project 2023-09 – Product Integrity

As a follow up to your public comments submitted in regards to ***Regulatory Project 2023-09 ~ Product Integrity***, on February 21, 2024 the Board approved Draft #2 which was shared with you in my previous email. Draft #2 was considered a substantive change to the proposed rule which requires publication of a *Potpourri Notice* in the *Louisiana Register* and a subsequent Public Hearing to receive comments and testimony. The publication in the *Louisiana Register* is scheduled for April 20, 2024 and the Public Hearing will be held on Tuesday, May 28, 2024. Details regarding the Public Hearing and the public comments will be included in the publication.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

Board may become public record unless specifically exempted by the Public Records Law, R.S. 44:1 et seq.

From: Emily Reid <ereid4@humana.com>
Sent: Tuesday, January 16, 2024 4:21 PM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Cc: Scott Clark <sclark8@Humana.com>
Subject: RE: CenterWell Pharmacy Comments on Regulatory Project 2023-09 – Product Integrity

Hello, Director Fontenot –

Thank you for sharing this draft and information on next steps.

Emily Reid
Government Affairs Lead | Corporate Affairs

Humana
Work at Home – Colorado (Mountain Time)

C 850.661.5849
ereid4@humana.com

From: Joe Fontenot <JFontenot@pharmacy.la.gov>
Sent: Tuesday, January 16, 2024 3:16 PM
To: Emily Reid <ereid4@humana.com>
Cc: Scott Clark <sclark8@Humana.com>
Subject: RE: CenterWell Pharmacy Comments on Regulatory Project 2023-09 – Product Integrity

Dear Ms. Reid,

With respect to the Louisiana Board of Pharmacy's ***Regulatory Project 2023-09 ~ Product Integrity*** and the public comments received in response to the Public Hearing held on December 28, 2023, I've prepared draft #2 (see attached) for consideration by the Board's Regulation Revision Committee during its upcoming meeting scheduled on January 24, 2024. The committee will consider draft #2 as a possible recommendation to the full Board when the Board takes formal notice of the public comments during their upcoming Board meeting on February 21, 2024.

The comments and suggestions received did not appear to have an issue with the product storage component but took issue with the delivery aspect. Based on the comments and suggestions, I prepared draft #2 to focus only on product storage, leaving product delivery for a future discussion and a project of its own, if needed.

If you have any questions, please do not hesitate contacting me.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Joe Fontenot
Sent: Wednesday, December 27, 2023 4:06 PM
To: Emily Reid <ereid4@humana.com>
Cc: sclark8@humana.com
Subject: CenterWell Pharmacy Comments on Regulatory Project 2023-09 – Product Integrity

Dear Ms. Reid,

This email confirms receipt of your public comment provided in response to the Board's *Notice of Intent* published in the November 20, 2023 edition of the Louisiana Register in regards to **Regulatory Project 2023-09 ~ Product Integrity**. Your comments will be provided to the Board for their review and consideration at its next meeting tentatively scheduled for February 21, 2023.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Emily Reid <ereid4@humana.com>
Sent: Wednesday, December 27, 2023 2:40 PM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Subject: CenterWell Pharmacy Comments on Regulatory Project 2023-09 – Product Integrity

Dear Director Fontenot,

On behalf of CenterWell Pharmacy, please see our attached comments regarding Regulatory Project 2023-09 – Product Integrity. A copy of this letter was also mailed to the Board of Pharmacy.

Thank you,

Emily Reid
Government Affairs Lead | Corporate Affairs

Humana
Work at Home – Colorado (Mountain Time)

C 850.661.5849
ereid4@humana.com

From: Joe Fontenot
To: Johnston, Mark D.
Subject: RE: CVS Health comments
Date: Monday, April 15, 2024 3:12:00 PM

Mr. Johnston,

As a follow up to your public comments submitted in regards to ***Regulatory Project 2023-09 ~ Product Integrity***, on February 21, 2024 the Board approved Draft #2 which was shared with you in my previous email. Draft #2 was considered a substantive change to the proposed rule which requires publication of a *Potpourri Notice* in the *Louisiana Register* and a subsequent Public Hearing to receive comments and testimony. The publication in the *Louisiana Register* is scheduled for April 20, 2024 and the Public Hearing will be held on Tuesday, May 28, 2024. Details regarding the Public Hearing and the public comments will be included in the publication.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Johnston, Mark D. <Mark.Johnston@CVSHealth.com>
Sent: Wednesday, January 17, 2024 4:58 PM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Subject: RE: CVS Health comments

Thank you, Joe. I'll see you next week. I appreciate the partnership.

Looking forward to grilled oysters,
Mark

From: Joe Fontenot <JFontenot@pharmacy.la.gov>
Sent: Tuesday, January 16, 2024 3:14 PM
To: Johnston, Mark D. <Mark.Johnston@CVSHealth.com>

Subject: [EXTERNAL] RE: CVS Health comments

****** External Email - Use Caution ******

Mr. Johnston,

With respect to the Louisiana Board of Pharmacy's ***Regulatory Project 2023-09 ~ Product Integrity*** and the public comments received in response to the Public Hearing held on December 28, 2023, I've prepared draft #2 (see attached) for consideration by the Board's Regulation Revision Committee during its upcoming meeting scheduled on January 24, 2024. The committee will consider draft #2 as a possible recommendation to the full Board when the Board takes formal notice of the public comments during their upcoming Board meeting on February 21, 2024.

The comments and suggestions received did not appear to have an issue with the product storage component but took issue with the delivery aspect. Based on the comments and suggestions, I prepared draft #2 to focus only on product storage, leaving product delivery for a future discussion and a project of its own, if needed.

If you have any questions, please do not hesitate contacting me.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Joe Fontenot
Sent: Thursday, December 28, 2023 10:26 AM
To: Johnston, Mark D. <Mark.Johnston@CVSHealth.com>
Subject: RE: CVS Health comments

Mr. Johnston,

This email confirms receipt of your public comment provided in response to the Board's *Notice of Intent* published in the November 20, 2023 edition of the Louisiana Register in regards to **Regulatory Project 2023-09 ~ Product Integrity**. Your comments will be provided to the Board for their review and consideration at its next meeting tentatively scheduled for February 21, 2023.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Johnston, Mark D. <Mark.Johnston@CVSHealth.com>
Sent: Thursday, December 28, 2023 10:14 AM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Subject: CVS Health comments

Joe,

Please accept the attached comments from CVS Health prior to today's comment deadline at Noon CST. I have booked travel for the Jan. Regs Committee meeting and the Feb. full Board meeting. I look forward to seeing you and the Board, as well as grilled oysters!

Happy holidays,
Mark

From: Palombo, Richard A
To: Joe Fontenot
Subject: RE: Regulatory Project 2023-09 – Product Integrity
Date: Tuesday, April 16, 2024 6:52:13 AM

Joe,
Thanks for the updates. I appreciate the Board of Pharmacy willingness to update the public on the proposed regulation. I look forward to the publication on April 20.
Thanks
Rich

Rich Palombo, RPh, DPh
Express Scripts/Cigna State Government Affairs
Please note new email address
Richard.Palombo@evernorth.com
609-513-9459

From: Joe Fontenot <JFontenot@pharmacy.la.gov>
Sent: Monday, April 15, 2024 4:14 PM
To: Palombo, Richard A <Richard.Palombo@evernorth.com>
Subject: [External] RE: Regulatory Project 2023-09 – Product Integrity

Mr. Palombo,

As a follow up to your public comments submitted in regards to ***Regulatory Project 2023-09 ~ Product Integrity***, on February 21, 2024 the Board approved Draft #2 which was shared with you in my previous email. Draft #2 was considered a substantive change to the proposed rule which requires publication of a *Potpourri Notice* in the *Louisiana Register* and a subsequent Public Hearing to receive comments and testimony. The publication in the *Louisiana Register* is scheduled for April 20, 2024 and the Public Hearing will be held on Tuesday, May 28, 2024. Details regarding the Public Hearing and the public comments will be included in the publication.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Joe Fontenot
Sent: Tuesday, January 16, 2024 4:11 PM
To: Palombo, Richard A. (VIR) <Richard.Palombo@evernorth.com>
Subject: RE: Regulatory Project 2023-09 – Product Integrity

Mr. Palombo,

With respect to the Louisiana Board of Pharmacy's ***Regulatory Project 2023-09 ~ Product Integrity*** and the public comments received in response to the Public Hearing held on December 28, 2023, I've prepared draft #2 (see attached) for consideration by the Board's Regulation Revision Committee during its upcoming meeting scheduled on January 24, 2024. The committee will consider draft #2 as a possible recommendation to the full Board when the Board takes formal notice of the public comments during their upcoming Board meeting on February 21, 2024.

The comments and suggestions received did not appear to have an issue with the product storage component but took issue with the delivery aspect. Based on the comments and suggestions, I prepared draft #2 to focus only on product storage, leaving product delivery for a future discussion and a project of its own, if needed.

If you have any questions, please do not hesitate contacting me.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Joe Fontenot
Sent: Thursday, December 28, 2023 12:28 PM
To: Palombo, Richard A. (VIR) <Richard.Palombo@evernorth.com>
Subject: RE: Regulatory Project 2023-09 – Product Integrity

Mr. Palombo,

This email confirms receipt of your public comment provided in response to the Board's *Notice of Intent* published in the November 20, 2023 edition of the Louisiana Register in regards to **Regulatory Project 2023-09 ~ Product Integrity**. Your comments will be provided to the Board for their review and consideration at its next meeting tentatively scheduled for February 21, 2023.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Palombo, Richard A. (VIR) <Richard.Palombo@evernorth.com>
Sent: Thursday, December 28, 2023 11:58 AM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Subject: Regulatory Project 2023-09 – Product Integrity

Joe,
Attached please find my comments to the proposed Rules on Product Integrity.
Thank you
Rich
Richard Palombo
Richard.palombo@evernorth.com

From: Jessica Elliott
To: Joe Fontenot
Subject: RE: Regulatory Project 2023-09 ~ Product Integrity
Date: Wednesday, April 17, 2024 1:32:42 PM

Thank you, Joe!

Jessica Elliott
Louisiana Retailers Association
Louisiana Alliance of Retail Pharmacies
(225) 344-9481

From: Joe Fontenot <JFontenot@pharmacy.la.gov>
Sent: Monday, April 15, 2024 3:13 PM
To: jessica@laretail.org
Subject: RE: Regulatory Project 2023-09 ~ Product Integrity

Ms. Elliott,

As a follow up to your public comments submitted in regards to ***Regulatory Project 2023-09 ~ Product Integrity***, on February 21, 2024 the Board approved Draft #2 which was shared with you in my previous email. Draft #2 was considered a substantive change to the proposed rule which requires publication of a *Potpourri Notice* in the *Louisiana Register* and a subsequent Public Hearing to receive comments and testimony. The publication in the *Louisiana Register* is scheduled for April 20, 2024 and the Public Hearing will be held on Tuesday, May 28, 2024. Details regarding the Public Hearing and the public comments will be included in the publication.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Joe Fontenot
Sent: Tuesday, January 16, 2024 4:18 PM
To: jessica@laretail.org
Subject: RE: Regulatory Project 2023-09 ~ Product Integrity

Dear Ms. Elliott,

With respect to the Louisiana Board of Pharmacy's ***Regulatory Project 2023-09 ~ Product Integrity*** and the public comments received in response to the Public Hearing held on December 28, 2023, I've prepared draft #2 (see attached) for consideration by the Board's Regulation Revision Committee during its upcoming meeting scheduled on January 24, 2024. The committee will consider draft #2 as a possible recommendation to the full Board when the Board takes formal notice of the public comments during their upcoming Board meeting on February 21, 2024.

The comments and suggestions received did not appear to have an issue with the product storage component but took issue with the delivery aspect. Based on the comments and suggestions, I prepared draft #2 to focus only on product storage, leaving product delivery for a future discussion and a project of its own, if needed.

If you have any questions, please do not hesitate contacting me.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Joe Fontenot
Sent: Wednesday, December 27, 2023 8:05 AM
To: jessica@laretail.org
Subject: Regulatory Project 2023-09 ~ Product Integrity

Ms. Elliott,

This email confirms receipt of your public comment provided in response to the Board's *Notice of*

Intent published in the November 20, 2023 edition of the Louisiana Register in regards to **Regulatory Project 2023-09 ~ Product Integrity**. Your comments will be provided to the Board for their review and consideration at its next meeting tentatively scheduled for February 21, 2023.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Joe Fontenot
To: Philip, Jeenu
Subject: RE: Louisiana 2023-09 Comment Letter.docx
Date: Monday, April 15, 2024 3:11:00 PM

Mr. Philip,

As a follow up to your public comments submitted in regards to ***Regulatory Project 2023-09 ~ Product Integrity***, on February 21, 2024 the Board approved Draft #2 which was shared with you in my previous email. Draft #2 was considered a substantive change to the proposed rule which requires publication of a *Potpourri Notice* in the *Louisiana Register* and a subsequent Public Hearing to receive comments and testimony. The publication in the *Louisiana Register* is scheduled for April 20, 2024 and the Public Hearing will be held on Tuesday, May 28, 2024. Details regarding the Public Hearing and the public comments will be included in the publication.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Philip, Jeenu <jeenu.philip@walgreens.com>
Sent: Tuesday, January 16, 2024 5:00 PM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Subject: RE: Louisiana 2023-09 Comment Letter.docx

Thanks for sharing Joe. Much appreciated. I'm planning on being at the meeting next week.

Jeenu Philip
Senior Manager, Pharmacy Affairs
Walgreen Co. ¦ 6800 Southpoint Pkwy, Ste 980, Jacksonville, FL, 32216
Mobile 904 386 6776

Member of Walgreens Boots Alliance

From: Joe Fontenot <JFontenot@pharmacy.la.gov>
Sent: Tuesday, January 16, 2024 5:09 PM
To: Philip, Jeenu <jeenu.philip@walgreens.com>
Subject: RE: Louisiana 2023-09 Comment Letter.docx

Mr. Philip,

With respect to the Louisiana Board of Pharmacy's ***Regulatory Project 2023-09 ~ Product Integrity*** and the public comments received in response to the Public Hearing held on December 28, 2023, I've prepared draft #2 (see attached) for consideration by the Board's Regulation Revision Committee during its upcoming meeting scheduled on January 24, 2024. The committee will consider draft #2 as a possible recommendation to the full Board when the Board takes formal notice of the public comments during their upcoming Board meeting on February 21, 2024.

The comments and suggestions received did not appear to have an issue with the product storage component but took issue with the delivery aspect. Based on the comments and suggestions, I prepared draft #2 to focus only on product storage, leaving product delivery for a future discussion and a project of its own, if needed.

If you have any questions, please do not hesitate contacting me.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Joe Fontenot
Sent: Friday, December 22, 2023 12:44 PM
To: Philip, Jeenu <jeenu.philip@walgreens.com>

Subject: RE: Louisiana 2023-09 Comment Letter.docx

Mr. Philip,

This email confirms receipt of your public comment provided in response to the Board's *Notice of Intent* published in the November 20, 2023 edition of the Louisiana Register in regards to **Regulatory Project 2023-09 ~ Product Integrity**. Your comments will be provided to the Board for their review and consideration at its next meeting tentatively scheduled for February 21, 2024.

Sincerely,

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Office 225.925.6481
jfontenot@pharmacy.la.gov

From: Philip, Jeenu <jeenu.philip@walgreens.com>
Sent: Friday, December 22, 2023 10:54 AM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Subject: Louisiana 2023-09 Comment Letter.docx

Good morning Mr. Fontenot,

On behalf of all pharmacies owned and operated by Walgreen Co. in the state of Louisiana, we thank the Board for the opportunity to comment and respectfully request an Amendment to Regulatory Project 2023-09 Product Integrity.

Walgreens thanks the Board for the opportunity to provide the request to amend this rule. If the Board would like additional information, please feel free to contact me.

Thank you!

Regards,
Jeenu

Jeenu Philip
Director, Pharmacy Affairs

Walgreen Co.
Telephone 904-386-6776

Member of Walgreens Boots Alliance | MyWalgreens.com

2404#062

POTPOURRI

Department of Health
Board of Pharmacy

Public Hearing—Substantive Changes to Proposed Rule:
Product Integrity (LAC 46:LIII.1103 and 2501)

The Board of Pharmacy published a Notice of Intent to amend §1103 and §2501 of its rules relative to prescription department requirements and prescription drugs in the

November 20, 2023 edition of the *Louisiana Register*, volume 49, pages 1969-1971. Pursuant to the board's consideration of comments and testimony received during the December 28, 2023 public hearing, the board proposes to amend the original proposed Rule in order to specifically address drug product storage and remove references to drug product delivery as part of this regulatory project.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 11. Pharmacies
Subchapter A. General Requirements
§1103. Prescription Department Requirements

A. A prescription department of a pharmacy shall be maintained in a clean and orderly condition and shall provide sufficient floor space, fixtures, equipment and supplies commensurate with the nature and scope of the pharmacy's practice to ensure that drugs are compounded and dispensed in a dry, well-lighted, climate controlled, and safely enclosed structure.

B. - D. …

E. Drug Inventory

1. Storage. The pharmacy shall provide an adequate prescription inventory in order to compound and dispense prescription orders. All areas where drugs are stored shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product information or labeling.

E.2. - J. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, LR 39:315 (February 2013), amended by Department of Health, Board of Pharmacy, LR 46:579 (April 2020), LR 47:1642 (November 2021), LR 48:497 (March 2022), LR 49:1556 (September 2023), amended LR 50:

Chapter 25. Prescriptions, Drugs, and Devices
Subchapter A. General Requirements
§2501. Prescription Drugs and Devices

A. - A.2. …

3. Storage

a. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.

b. All areas where drugs are stored shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product information or labeling.

B. - E.3. …

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 29:2101 (October 2003), effective January 1, 2004, amended LR 50:

Public Hearing

A public hearing to solicit comments and testimony on the substantive changes to the proposed Rule is scheduled for 9:00 a.m. on Tuesday, May 28, 2024 at the Board office. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

M. Joseph Fontenot Jr.
Executive Director

Louisiana Board of Pharmacy

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

NOTICE IS HEREBY GIVEN that a Public Hearing has been ordered and called for **9:00 a.m. on Tuesday, May 28, 2024** at the Board office, for the purpose to wit:

AGENDA

Revised 04-20-2024

1. Call to Order 9:01 a.m.
2. Appearances
3. Solicitation of Comments & Testimony on Proposed Rule Changes
   A. Regulatory Project 2023-09 ~ Product Integrity (Pursuant to Potpourri Notice)
   B. Regulatory Project 2024-01 ~ Controlled Dangerous Substances (CDS) Licensing
   C. Regulatory Project 2024-02 ~ Open Meetings via Electronic Means
   D. Regulatory Project 2024-03 ~ Prescription Monitoring Program (PMP) Advisory Council Open Meetings via Electronic Means
4. Opportunity for Public Comment
5. Adjourn 12:00 noon

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 M. Joseph Fontenot Jr., Executive Director, at the Board office. He is responsible for responding to inquiries regarding the proposed Rule amendments. The deadline for the receipt of all written comments is 12 p.m. on Tuesday, May 28, 2024.

Public Hearing
During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request a disability accommodation, please contact Joe Fontenot, Executive Director, at 225.925.6496 or email at jfontenot@pharmacy.la.gov .

Louisiana Board of Pharmacy

Public Hearing Attendance Record ~ May 28, 2024

Regulatory Project 2023-09 ~ Product Integrity (Pursuant to Potpourri Notice)
Regulatory Project 2024-01 ~ Controlled Dangerous Substances (CDS) Licensing
Regulatory Project 2024-02 ~ Open Meetings via Electronic Means
Regulatory Project 2024-03 ~ Prescription Monitoring Program (PMP) Advisory Council Open Meetings via Electronic Means

Name	Address	E-mail	Group or Agency Represented
1.			
2.			
3.			
4.			
5.			

None

Louisiana Board of Pharmacy

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

May 28, 2024

Public Hearing

Opportunity for Public Comment

1. Name _____ representing _____

   Comments:

2. Name _____ representing _____

   Comments:

   None

3. Name _____ representing _____

   Comments:

4. Name _____ representing _____

   Comments:

Louisiana Board of Pharmacy
3388 Brentwood Drive
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Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

Summary of Testimony & Public Comments

Public Hearing

May 28, 2024

Regulatory Project 2023-09 ~ Product Integrity

(Pursuant to Potpourri Notice)

No comments or testimony received.

RULE

Department of Health

Board of Pharmacy

Product Integrity (LAC 46:LIII.1103 and 2501)

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 Board of Pharmacy amended §1103 and §2501 of its rules relative to prescription department requirements and prescription drugs. The rule change in §1103. A. adds a requirement for a prescription department to be maintained in a clean and orderly condition. The rule changes in §1103. E. and §2501 add environmental condition requirements for all areas where drugs are stored. This Rule is hereby adopted on the day of promulgation.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter A. General Requirements

§1103. Prescription Department Requirements

A. A prescription department of a pharmacy shall be maintained in a clean and orderly condition and shall provide sufficient floor space, fixtures, equipment and supplies commensurate with the nature and scope of the pharmacy's practice to ensure that drugs are compounded and dispensed in a dry, well-lighted, climate controlled, and safely enclosed structure.

B. – D. …

E. Drug Inventory

1. Storage. The pharmacy shall provide an adequate prescription inventory in order to compound and dispense prescription orders. All areas where drugs are stored shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product information or labeling.

E.2. – J. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, LR 39:315 (February 2013), amended by Department of Health, Board of Pharmacy, LR 46:579 (April 2020), LR 47:1642 (November 2021), LR 48:497 (March 2022), LR 49:1556 (September 2023), amended LR

* * *

Chapter 25. Prescriptions, Drugs, and Devices

Subchapter A. General Requirements

§2501. Prescription Drugs and Devices

A. – A.2. …

3. Storage.

a. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.

b. All areas where drugs are stored shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product information or labeling.

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M. Joseph Fontenot Jr.
Executive Director