

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



December 6, 2022

Senator P. Page Cortez President, Louisiana Senate

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

### Electronic Mail - Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2022-8 (Summary Report) ~ Transfer of Prescription

Information

Dear Senator Cortez:

As we indicated in our first report to your office on July 7, the Board seeks to amend §2523 of its rules relative to the transfer of prescription information to accommodate the transfer of prescriptions in electronic form.

Subsequent to the publication of our *Notice of Intent* in the July 2022 edition of the <u>Louisiana Register</u>, we conducted a public hearing on August 26 to receive comments and testimony on the proposed rules. We received one letter of support for the proposed amendment. The Board subsequently determined no revisions were warranted. On November 3<sup>rd</sup> the Department of Justice's Occupational Licensing Review Program determined §2523 has no reasonably foreseeable anticompetitive effects and is therefore not an occupational regulation as defined by La R.S. 49:260(G)(4). In connection with this regulatory project, you should find the following documents in this package:

- Notice of Intent, as published in the July 2022 <u>Louisiana Register</u> Page 2
- Record from the August 26, 2022 Public Hearing Page 5
- Full text of proposed rule, as intended for publication in the Louisiana Register Page 12

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rules without amendment as a Rule in the January 20, 2023 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 <a href="mailto:jfontenot@pharmacy.la.gov">jfontenot@pharmacy.la.gov</a> or 225.925.6481.

For the Board:

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: <u>APA.HouseSpeaker@legis.la.gov</u> Chair, House Health & Welfare Committee - Via Email: <u>APA.H-HW@legis.la.gov</u>

Editor, Louisiana Register - Via Email: Reg.Submission@la.gov

Director, Community Competitiveness & Small Business Services, La. Economic Development

Via Email: Witty@la.gov

Reference File

#### NOTICE OF INTENT

### Department of Health Board of Pharmacy

Transfer of Prescription Information (LAC 46:LIII.2523)

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 §2523

of its rules relative to the transfer of prescription information to accommodate the transfer of prescriptions in electronic form. The deletion of language in §2523(A)(1)(a)(i)((b)) removes the reference to the written prescription form thereby making it inclusive of electronic prescriptions. The change of language in §2523(A)(1)(b) replaces the requirement to reduce the transferred prescription information to written form with the word "record" to accommodate electronic prescriptions.

# Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

### Part LIII. Pharmacists

# Chapter 25. Prescriptions, Drugs, and Devices §2523. Transfer of Prescription Information

- A. Prescription Transfer Requirements
  - 1. Prescriptions for Controlled Dangerous Substances
- a. The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements:
- i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
  - (a) invalidation of the prescription;
- (b) record on the invalidated prescription the name, address, and DEA registration of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information;
- (c) record the date of the transfer and the name of the pharmacist transferring the information.
- b. The pharmacist receiving the transferred prescription shall record the following:

A.1.b.i. - B.2. ...

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 29:2104 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007), LR 36:756 (April 2010), amended by the Department of Health, Board of Pharmacy, LR 48:

### **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 changes 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 changes 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 changes will have no effect on the functioning of the family.
- 4. The Effect on Family Earnings and Family Budget. The proposed rule changes will have no effect on family earnings and family budget.
- 5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule changes 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 changes 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 changes 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 changes 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 changes will have no effect on employment or workforce development.
- 4. The Effect on Taxes and Tax Credits. The proposed rule changes 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 changes 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 changes will have no effect on compliance or 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 changes 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 changes will have no effect on 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 changes will have no effect on standards.

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 changes.

### **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 changes will have no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.
- 2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed rule changes will have no effect on the cost to the provider to provide the same level of service.
- 3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule changes will haveno 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 changes.

### **Public Hearing**

A public hearing to solicit comments and testimony on the proposed rule changes is scheduled for 9:00 a.m. on Friday, August 26, 2022 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. noon 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: Transfer of Prescription Information

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

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of \$1,000 in FY 2023. There will be no additional expenditures or cost savings for LBP or other state or local governmental units.

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, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule changes have no costs or economic benefits to directly affected persons, small businesses, or non-governmental groups. The proposed change broadens the language of 'write' to 'record' to account for the electronic transfer of prescriptions. Existing regulation was drafted when only paper prescriptions existed and this rule allows electronic records to simplify recordkeeping requirements in the pharmacy.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

M. Joseph Fontenot Jr. Executive Director 2207#061 Alan M. Boxberger Interim Legislative Fiscal Officer Legislative Fiscal Office



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**NOTICE IS HEREBY GIVEN** that a Public Hearing has been ordered and called for 9:00 a.m. on Friday, August 26, 2022 at the Board office, for the purpose to wit:

AGENDA

Revised 07-07-2022

- Call to Order
- 9:00 Am
- 2. Appearances
- 3. Solicitation of Comments & Testimony on Proposed Rule Changes
  - A. Regulatory Project 2022-06 ~ Nonresident Pharmacies
  - B. Regulatory Project 2022-07 ~ Licensing Dependents of Healthcare Professionals Relocating to Louisiana
  - C. Regulatory Project 2022-08 ~ Transfer of Prescription Information
  - D. Regulatory Project 2022-09 ~ Partial Fills of CDS Prescriptions
  - E. Regulatory Project 2022-10 ~ Compounding
- 4. Opportunity for Public Comment
- 5. Adjourn

12:04pm

Public Hearing Attendance Record ~ August 26, 2022

Project 2022-6 ~ Nonresident Pharmacies

Project 2022-7 ~ Licensing Dependents of Healthcare Professionals Relocating to Louisiana

Project 2022-8 ~ Transfer of Prescription Information

Project 2022-9 ~ Partial Fills of CDS Prescriptions Project 2022-10 ~ Compounding

Name	Address	E-mail	Group or Agency Represented
1.			
2.			
3.	None		
4.			
5.			



# Louisiana Board of Pharmacy 3388 Brentwood Drive

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August 26, 2022

### **Public Hearing**

### **Opportunity for Public Comment**

1.	Name NIA Comments:	representing
2.	NameComments:	representing
3.	NameComments:	representing
4.	NameComments:	representing
5.	Name	representing



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Summary of Testimony & Public Comments

Regulatory Project 2022-8 ~ Transfer of Prescription Information at
August 26, 2022 Public Hearing

1. Letter from Grace Sesi, PharmD on behalf of CVS Health

Ms. Sesi expressed support for the proposed changes to Section 2523 (letter attached).



Grace Sesi, PharmD Executive Director, CVS Health

One CVS Drive Woonsocket, RI 02895

**c** 313-516-6915 **f** 401-652-2213

Grace.Sesi@cvshealth.com

July 28, 2022

Louisiana Board of Pharmacy
Executive Director Joe Fontenot
3388 Brentwood Drive Baton Rouge, LA 70809

Dear Executive Director Joe Fontenot,

I am writing to you in my capacity as Executive Director for CVS Health and its family of pharmacies located across the country. CVS Health appreciates the opportunity to submit comments the Louisiana Board of Pharmacy proposed amendments to current regulations and would like to thank the Board for their continued vigilance to continuously improve the laws and regulations that guide pharmacists serving Louisiana patients.

Re: LAC 46: LIII.2523 Transfer of Prescription Information. CVS Health supports this amendment as it serves to assist pharmacists in their workload and aligns with removing unnecessary steps to be able to ensure the patient receives their medication in a timely manner without any interruptions. CVS Health commends the Board on their efforts removing the requirement for pharmacists to reduce the transferred prescription information to written form to accommodate electronic prescriptions.

Re: LAC 46:LIII. 2307 Nonresident pharmacies CVS Health supports the extended timeline to report the change in Pharmacist-in-Charge (PIC) but ask the Board to consider an extended timeline for the nonresident pharmacy to designate a new pharmacist-in- charge within 10 days of the departure of the prior PIC.

These amendments, specifically I (1), place requirements on a nonresident PIC that while on its face appear to be equivalent to the requirements for an in-state PIC, but in effect put a disproportionate burden on a nonresident pharmacy when compared to the effect of the proposed amendment to an in-state pharmacy.

A nonresident pharmacy, by the nature of being located outside of the state of Louisiana, would have a limited number of Louisiana licensed pharmacists as compared to pharmacies within Louisiana. Therefore, when a nonresident pharmacy experiences the turnover of the Louisiana nonresident PIC, the pharmacy may have to cease dispensing to the residents of the state of Louisiana until the Louisiana nonresident PIC is replaced. The ensuing delay of identifying a



successor could cause an immediate impact to patient safety with the potential resultant lapse in therapy.

We ask the Board to weigh the benefit of non-resident PIC licensure compared to the potential negative effect on the residents of the state of Louisiana. To avoid this impact, we ask that if the proposed amendments of this regulation were to be promulgated, there be additional language added which will allow the pharmacy a reasonable grace period with which to appoint a new Louisiana PIC. This period would ideally be 90 days or longer and allow for extensions if granted by the Board staff after a reasonable extension request is received. This grace period would ensure the continued and timely delivery of medications to patients residing in Louisiana. I have provided an example of language adopted by the Alabama State Board of Pharmacy for your consideration.

Alabama Administrative Code 680-X-2-.07 Mail Order Prescriptions.

(f) Designate a supervising pharmacist who shall be licensed by the Alabama State Board of Pharmacy. The supervising pharmacist shall be responsible for ensuring that the holder of the permit referenced herein complies with the requirements of this rule and all applicable statutory provisions and rules. If there is a change of the designated Supervising Pharmacist, the permit holder shall notify the Board by filing the "Notice of Change of Supervising Pharmacist" form provided by the Board. If the permit holder is unable to maintain a designated supervising pharmacist, the permit holder shall notify the Board within ten (10) days with an action plan to designate another pharmacist as supervising pharmacist. A permit holder without a designated supervising pharmacist after the ninety (90) day action plan has expired may contact the Board for additional time.

CVS Health appreciates the opportunity to submit comments for the proposed amendments. It is our strong recommendation that the Board of Pharmacy carefully study the value of requiring the Pharmacist-in-Charge (PIC) of a nonresident pharmacy to be designated within 10 days of the departure of the prior pharmacist-in-charge compared to the potential safety and health issues that may occur when the inevitable lapse of therapy occurs. If you have any questions or require additional information, please contact me directly at 313-516-6915.

Sincerely,



Grace Sesi, PharmD

Executive Director, CVS Health

Grae Seri

313-516-6915

Grace.sesi@cvshealth.com

#### Rule

### Department of Health Board of Pharmacy

Transfer of Prescription Information (LAC 46:LIII.2523)

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 has amended §2523 of its rules relative to the transfer of prescription information to accommodate the transfer of prescriptions in electronic form. The deletion of language in §2523(A)(1)(a)(i)((b)) removes the reference to the written prescription form thereby making it inclusive of electronic prescriptions. The change of language in §2523(A)(1)(b) replaces the requirement to reduce the transferred prescription information to written form with the word "record" to accommodate electronic prescriptions. This Rule is hereby adopted on the day of promulgation.

#### Title 46

#### PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII: Pharmacists

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

### §2523. Transfer of Prescription Information

- A. Prescription Transfer Requirements
  - 1. Prescriptions for Controlled Dangerous Substances
- a. The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements:
- i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
  - (a) Invalidation of the prescription.
- (b) Record on the reverse of the invalidated prescription the name, address, and DEA registration of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.
  - (c) Record the date of the transfer and the name of the pharmacist transferring the information.
  - b. The pharmacist receiving the transferred prescription shall reduce to writing record the following:

A.1.b.i. – B.2. ...

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 29:2104 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007), LR 36:756 (April 2010), LR

M. Joseph Fontenot, Jr. Executive Director