



Louisiana Board of Pharmacy

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



July 28, 2023

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 2023-08 (Summary Report) ~ DATA Waiver
Registration Elimination

Dear Senator Cortez:

As we indicated in our first report to your office on April 4, 2023, the Board seeks to amend §2745 of its rules relative to prescriptions. The proposed rule change eliminates certain requirements concerning prescriptions of Schedule III, IV, or V controlled substances for detoxification or maintenance treatment. Previously, practitioners were required under federal law to obtain a special identification number from the DEA prior to prescribing or dispensing these drugs, or were required to submit a written notice of intent to obtain such a number. Board rules currently require that such prescriptions be accompanied by this identification number or written notice. The proposed rule change eliminates this requirement because federal law no longer requires practitioners to obtain this identification number. The proposed rule change also corrects the Code of Federal Regulations (CFR) reference for exemption of registration for certain military personnel engaged in certain controlled substance activities.

Subsequent to the publication of our Notice of Intent in the April 2023 edition of the *Louisiana Register*, we conducted a public hearing on May 26 to receive comments and testimony on the proposed rule. The Board received no comments or testimony. The Board subsequently determined no revisions were warranted. The Board of Pharmacy participates in the Department of Justice's Occupational Licensing Review Program for active state supervision and in regards to this project it was determined that a review would not be necessary. In connection with this regulatory project, you should find the following documents in this package:

- *Notice of Intent*, as published in the April 2023 edition of the *Louisiana Register*
- Record from the May 26, 2023 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, the Board proposes to publish the original proposed rules without amendment as a Rule in the September 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 jfontenot@pharmacy.la.gov 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: 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

DATA-Waiver Registration Elimination (LAC 46:LIII.2745)

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 §2745 of its rules relative to prescriptions. The proposed Rule change eliminates certain requirements concerning prescriptions of Schedule III, IV, or V controlled substances for detoxification or maintenance treatment. Previously, practitioners were required under federal law to obtain a special identification number from the DEA prior to prescribing or dispensing these drugs, or were required to submit a written notice of intent to obtain such a number. LBP rules currently require that such prescriptions be accompanied by this identification number or written notice. The proposed Rule change eliminates this requirement because federal law no longer requires practitioners to obtain this identification number. The proposed Rule change also corrects the Code of Federal Regulations (CFR) reference for exemption of registration for certain military personnel engaged in certain controlled substance activities.

Title 46
PROFESSIONAL AND OCCUPATIONAL
STANDARDS

Part LIII. Pharmacists

Chapter 27. Controlled Dangerous Substances

Subchapter F. Production, Distribution, and Utilization

§2745. Prescriptions

A. - B.3. ...

C. Manner of Issuance

1. - 2.e. ...

3. Repealed.

4. - 5. ...

6. An official exempted from registration under 21 CFR §1301.23 shall include on all prescriptions issued by him his branch of service or agency and his service identification number, in lieu of the registration number of the practitioner required by this Section. Each such prescription shall have the name of the officer stamped, typed, or hand printed on it, as well as the signature of the officer.

C.7. - E.3. ...

4. A practitioner may prescribe, administer or provide directly any narcotic drug listed in schedule III, IV, or V approved by the FDA specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of 21 CFR.

F. - G.3.c. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2149 (October 2008), amended LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 42:1090 (July 2016), amended LR 47:1645 (November 2021), amended LR 49:

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 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 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 amendments. The deadline for the receipt of all written comments is 12 p.m. on Friday, May 26, 2023.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for 9:00 a.m. on Friday, May 26, 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: DATA-Waiver Registration Elimination

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 printing expenses of \$750 in FY 2023 and \$750 in FY 2024. There will be no additional expenditures or cost savings for LBP or other state governmental units.

The proposed rule change eliminates certain requirements concerning prescriptions of Schedule III, IV, or V controlled substances for detoxification or maintenance treatment. Previously, practitioners were required under federal law to obtain a special identification number from the DEA prior to prescribing or dispensing these drugs, or were required to submit a written notice of intent to obtain such a number.

LBP rules currently require that such prescriptions be accompanied by this identification number or written notice. The proposed rule change eliminates this requirement because federal law no longer requires practitioners to obtain this identification number.

The proposed rule change also corrects the Code of Federal Regulations (CFR) reference for exemption of registration for certain military personnel engaged in certain controlled substance activities.

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 increasing access to medication approved for detoxification treatment or maintenance treatment for those in need. The proposed rule change will benefit prescribers and pharmacies by reducing the documentation required on prescriptions for those drugs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

M. Joseph Fontenot Jr.
Executive Director
2304#023

Evan Brasseaux
Interim Deputy Fiscal Officer
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 Friday, May 26, 2023 at the Board office, for the purpose to wit:

A G E N D A

Revised 04-19-2023

1. Call to Order **9:00 A.M.**
2. Appearances
3. Solicitation of Comments & Testimony on Proposed Rule Changes
 - A. Regulatory Project 2023-05 ~ Pharmacy Change of Ownership
 - B. Regulatory Project 2023-06 ~ Staffing Ratios
 - C. Regulatory Project 2023-07 ~ Marijuana Pharmacy
 - D. Regulatory Project 2023-08 ~ DATA-Waiver Registration Elimination
4. Opportunity for Public Comment
5. Adjourn **12:01 P.M.**

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 Friday, May 26, 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 reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

Louisiana Board of Pharmacy

Public Hearing Attendance Record ~ May 26, 2023

Regulatory Project 2023-05 ~ Pharmacy Change of Ownership
Regulatory Project 2023-06 ~ Staffing Ratios
Regulatory Project 2023-07 ~ Marijuana Pharmacy
Regulatory Project 2023-08 ~ DATA-Waiver Registration Elimination

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



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



Summary of Testimony & Public Comments

**Regulatory Project 2023-08 ~ DATA-Waiver Registration Elimination
at
May 26, 2023 Public Hearing**

No comments or testimony received.

RULE

Department of Health Board of Pharmacy

DATA-Waiver Registration Elimination (LAC 46:LIII.2745)

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 §2745 of its rules relative to prescriptions. The change eliminates certain requirements concerning prescriptions of Schedule III, IV, or V controlled substances for detoxification or maintenance treatment. Previously, practitioners were required under federal law to obtain a special identification number from the DEA prior to prescribing or dispensing these drugs, or were required to submit a written notice of intent to obtain such a number. LBP rules required that such prescriptions be accompanied by this identification number or written notice. The change eliminates this requirement because federal law no longer requires practitioners to obtain this identification number. The change also corrects the Code of Federal Regulations (CFR) reference for exemption of registration for certain military personnel engaged in certain controlled substance activities. This Rule is hereby adopted on the day of promulgation.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII: Pharmacists

Chapter 27. Controlled Dangerous Substances

§2745. Prescriptions

A. – B.3. ...

C. Manner of Issuance

1. – 2.e. ...

3. Repealed.

4. – 5. ...

6. An official exempted from registration under 21 CFR §1301.23 shall include on all prescriptions issued by him his branch of service or agency and his service identification number, in lieu of the registration number of the practitioner required by this Section. Each such prescription shall have the name of the officer stamped, typed, or hand printed on it, as well as the signature of the officer.

7. – E.3. ...

4. A practitioner may prescribe, administer or provide directly any narcotic drug listed in schedule III, IV, or V approved by the FDA specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of 21 CFR.

F. – G.3c. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2149 (October 2008), amended LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 42:1090 (July 2016), amended LR 47:1645 (November 2021), amended LR

M. Joseph Fontenot, Jr.
Executive Director