



Louisiana Board of Pharmacy

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



April 4, 2023

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

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2023-08 ~ DATA-Waiver Registration Elimination

Dear Senator Cortez:

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. 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.

In connection with this regulatory project, the following items are appended:

- Notice of Intent Page 2
- Fiscal & Economic Impact Statement Page 6

As indicated in the solicitation, we will convene a public hearing at 9:00 a.m. on Friday, May 26, 2023 to receive public comments and testimony on these proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, 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. — A prescription issued for a schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the DEA or a written notice stating that the practitioner is acting under the good faith exception of 21 CFR §1301.28(d).~~

~~4.3.~~ Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter, and they shall be manually signed by the prescriber.

a. The prescriptions may be prepared by the secretary or agent for the signature of the prescriber, but the prescriber is responsible in case the prescription does not conform in all essential respects to the law and regulations.

b. A corresponding liability rests upon the pharmacist who dispenses a prescription not prepared in the form prescribed by DEA regulations or these rules.

~~5.4.~~ A prescriber exempted from registration under 21 CFR §1301.22(c) shall include on all such prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution, in lieu of the registration number of the practitioner required by this Section. Each such written prescription shall have the name of the physician stamped, typed, or hand printed on it, as well as the signature of the physician.

~~6.5.~~ An official exempted from registration under ~~21 CFR §1301.22(e)~~ 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.

~~7.6.~~ Format Requirements. With the exception of medical orders written for patients in facilities licensed by the department, prescription forms shall adhere to the following requirements.

a. Written Prescriptions

i. The prescription form shall not be smaller than 4 inches by 5 inches, provided however, that forms used by pharmacists to record telephoned or transferred prescriptions shall be exempt from this requirement.

ii. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and DEA registration number. In the event multiple prescribers are identified on the prescription form, the prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling, the prescriber's printed name.

iii. The prescription form shall contain no more than four prescription drug or device orders. While nothing in these rules shall prohibit the pre-printing of any number of prescription drugs or devices on the prescription form, no prescription form issued by a prescriber shall identify more than four prescription drugs or devices to be dispensed.

iv. For each prescription drug or device ordered on a prescription form, there shall be a pre-printed check box labeled "Dispense as Written", or "DAW", or both.

v. For each prescription drug or device ordered on a prescription form, there shall be a refill instruction, if any.

vi. The prescription form shall bear a single printed signature line, and the prescriber shall manually sign the prescription.

b. Oral Prescriptions

i. With the exception of prescriptions for controlled substances listed in schedule II, a prescription issued by a prescriber may be communicated to a pharmacist by an employee or agent of the prescriber.

ii. Upon the receipt of an oral prescription from a prescriber or his agent, the pharmacist shall reduce the order to a written form prior to dispensing the controlled substance.

iii. The pharmacist shall record all of the information identified in this Subsection on the prescription form.

D. – D.3. ...

E. Administering Narcotic Drugs

1. – 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 ~~§1301.28~~.

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

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 GOVERNMENTAL 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 NON-GOVERNMENTAL 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.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

Person Preparing Statement: M. Joseph Fontenot Jr.
Executive Director

Dept.: Dept. of Health

Office: Board of Pharmacy

Telephone: 225.925.6481

Title: DATA-Waiver Registration Elimination

Return Address: 3388 Brentwood Drive
Baton Rouge, LA 70809

Effective Date of Rule: Upon promulgation
September 20, 2023 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL 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)

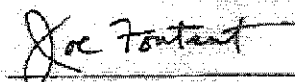
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III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

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.


Signature of Agency Head or Designee

M. Joseph Fontenot Jr. Executive Director
Typed Name and Title of Agency Head

March 31, 2023
Date of Signature


Legislative Fiscal Officer or Designee

3/31/23
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed rule change, in response to the federal Consolidated Appropriations Act of 2023 which eliminated the DATA-Waiver Program, removes the requirement for an identification number issued by the DEA or a written notice stating that the practitioner is acting under the good faith exception of 21 CFR §1301.28(d) to be included on prescriptions written for a schedule III, IV, or V narcotic drug approved by FDA specifically for detoxification treatment or maintenance treatment and removes the requirement for a practitioner who prescribes, administers, or provides those drugs to a narcotic dependent person to comply with the requirements of 21 CFR §1301.28. 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.

- B. Summarize the circumstances which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

21 USC §823(g) requires practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment to annually obtain a separate registration for that purpose. Until the passage of the Consolidated Appropriations Act 2023, 21 USC §823(g)(2) allowed certain practitioners to obtain a waiver to the separate registration requirement if they met certain conditions, including submitting a notice of intent to begin dispensing the drugs (the DATA-Waiver Program). When this waiver was issued, the practitioner received an identification number.

LAC Title 46:XLIII §2745(C)(3) currently requires that prescriptions of schedule III, IV, or V narcotic drugs approved by the FDA for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the DEA or a written notice stating that the practitioner is acting under the good faith exception of 21 CFR §1301.28(d).

Section 1262 of the Consolidated Appropriations Act 2023 removed all provisions of 21 USC §823(g) pertaining to this waiver and eliminated the separate registration requirement for practitioners who dispense narcotic drugs in Schedule III, IV, or V. In response to the federal Consolidated Appropriations Act of 2023, the Board of Pharmacy determined it appropriate to amend §2745 of its rules relative to Prescriptions for Controlled Substances to remove §2745(C)(3).

- C. Compliance with Act 11 of the 1986 First Extraordinary Session

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

LBP has allocated \$1500 for printing the Notice of Intent and the Rule. LBP operates on self-generated funds.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) _____ Yes. If yes, attach documentation.

(b) X No. If no, provide justification as to why this rule change should be published at this time

LBP operates on self-generated funds, and they have determined the proposed rule change is in the public's best interest and is an appropriate response to the elimination of the DATA-Waiver Program by the federal Consolidated Appropriations Act of 2023.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 23	FY 24	FY 25
Personal Services			
Operating Expenses	\$750	\$750	
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	\$750	\$750	None
POSITIONS (#)	None	None	None

2. Provide a narrative explanation of the costs or savings shown in "A. 1.," including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

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 agencies.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 23	FY 24	FY 25
State General Fund			
Agency Self-Generated	\$750	\$750	
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	\$750	\$750	None

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

LBP has sufficient self-generated funds available to implement the proposed rule change.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

The proposed rule change will not impact local governmental units.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

The proposed rule change will not impact sources of funding of local governmental units.

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

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

<u>REVENUE INCREASE/DECREASE</u>	<u>FY 23</u>	<u>FY 24</u>	<u>FY 25</u>
State General Fund			
Agency Self-Generated			
Dedicated Funds*			
Federal Funds			
Local Funds			
TOTAL	None	None	None

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

N/A

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

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

- A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

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.

- B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

The proposed rule change will not impact a licensee's receipts or revenue.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

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