

**NOTICE OF INTENT**

**Department of Health  
Board of Pharmacy**

Controlled Dangerous Substances (CDS) Licensing  
(LAC 46:LIII.2707 and 2711)

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 §2707 and §2711 of its rules relative to CDS licensing procedures and actions on CDS licenses. The proposed Rule change in §2707 streamlines the CDS license reinstatement process, updates the facility CDS license change of ownership procedures, and adds a new subsection to address changes to CDS license status. The proposed Rule change in §2711 repeals Subsection M and moves that language in a modified version to §2707.

**Title 46**

**PROFESSIONAL AND OCCUPATIONAL  
STANDARDS**

**Part LIII. Pharmacists**

**Chapter 27. Controlled Dangerous Substances**

**Subchapter B. Licenses**

**§2707. Licensing Procedures**

A. - B.3. ...

4. A CDS license not renewed within 30 days following the expiration date shall be considered terminated by the board. The reissuance of a terminated CDS license shall require compliance with the board's reinstatement procedures.

C. Application for Reinstatement of CDS License

1. ...

2. An application for the reinstatement of an expired credential which has been terminated may be approved when the applicant's primary credential is in an acceptable practice status with the issuing agency.

3. An application for the reinstatement of a CDS license inactivated as a consequence of the suspension or revocation of the primary credential by the issuing agency shall require verification of the reinstatement of the primary credential. Where the issuing agency reinstating the primary credential has restricted any privileges for controlled substances, the restrictions shall be attached to the reinstated CDS license.

4. An application for the reinstatement of a CDS license inactivated as a consequence of a Surrender for Cause of DEA Certificate of Registration to the DEA may be approved when the applicant's primary credential is in an acceptable practice status with the issuing agency.

5. An application for the reinstatement of a CDS license for a pharmacy which was suspended or revoked by the board may only be approved by the full board following a hearing to determine whether the reinstatement of the license is in the public's best interest.

6. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee identified in Section 115 of this Part.

D. - D.3....

E. Facility Change of Ownership Procedures

1. A CDS license is not transferable.

2. A new application shall be filed and a new CDS license obtained when a change in the identity of the natural person, partnership, or business entity which directly holds the credential has occurred or there is a change in the person or entity's Federal Employer Identification Number (FEIN).

3. The new owner shall submit an application to the board office at least 15 days before closing the transfer of ownership interests of said business.

4. An application for a new CDS license shall include the direct and first indirect level of ownership information. Any change in the first indirect level of ownership of 20 percent or more must be reported to the board within 30 days of the change.

5. Nothing in this section shall prohibit an entity from applying for a new CDS license in order to separate itself from actions which may have been committed by the previous ownership under the existing CDS license.

F. Change of CDS License Status

1. Any person or facility holding a valid CDS license which ceases to engage in activity requiring a CDS license may relinquish said license to the board.

a. Prior to relinquishment of said license, the person or facility shall dispose of all controlled substances and any unused order forms in his possession or under his control in compliance with federal laws and regulations.

2. In the event a person or facility agrees to a Surrender for Cause of DEA Certificate of Registration to the DEA, then the CDS license of the person or facility shall be inactivated.

3. In the event the primary credential of a person or facility is suspended or revoked by the issuing agency, then the CDS license of the person or facility shall be inactivated.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2131 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 43:957 (May 2017), LR 46:570 (April 2020), LR 47:1641 (November 2021), amended LR 50:

#### §2711. Actions on Licenses

A. - L.2. ...

M. - M.4. Repealed

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2132 (October 2008), 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 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 amendment. The deadline for the receipt of all written comments is 12 p.m. on Tuesday, May 28, 2024.

#### **Public Hearing**

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for 9 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

### **FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES**

#### **RULE TITLE: Controlled Dangerous Substances (CDS) Licensing**

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

In addition to the cost of rulemaking, which is approximately \$750 in FY 24 and \$500 in FY 25 related to publishing the proposed rule and final rule in the Louisiana Register, the proposed rule changes are expected to result in savings to the Louisiana Board of Pharmacy (LBP) due to fewer required inspections of Controlled Dangerous Substance (CDS) licensed facilities.

The proposed rule changes in §2707 streamline the CDS license reinstatement process. In circumstances where the CDS license has not been disciplined by the LBP directly (such as expiration of the license), the changes allow the CDS license to be reinstated as long as the license holder's primary credential is in an acceptable practice status with the issuing agency. The proposed changes also update the facility CDS license change of ownership procedures by reducing the number of circumstances under which a new license is needed, which LBP expects will result in a reduction in required inspections.

The proposed rule changes in §2711 repeal Subsection M-*Surrender of License* and moves that language to §2707 using modified language more reflective of current LBP practices concerning changes to CDS license status.

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

LBP anticipates the proposed rule changes will result in a reduction in revenue collections for LBP by eliminating the need for new CDS license applications (and commensurate fees) under certain circumstances relating to change of facility ownership. While the amount of the reduction is indeterminable, it is anticipated to be approximately \$400 per year.

The proposed rule changes will eliminate the need for some CDS license applications due to a change of ownership. The application fee for a CDS license ranges from \$20 to \$100, according to classification. Based on historical data, LBP estimates that the proposed rule changes will eliminate the need for approximately 8 such applications per year at \$50 per application, leading to an expected \$400 annual decrease in revenue, though the actual amount will vary depending on the number of applications which are no longer necessary under the proposed rule.

The proposed rule changes will not affect revenue collections of local governmental units.

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

The proposed rule changes will benefit certain CDS license holders undergoing a change in ownership by eliminating the need for a new CDS license in some circumstances. Eliminating the need to apply for a license due to a change of ownership will save the business between \$20 and \$100 in application fees.

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  
2404#042

Patrice Thomas  
Deputy Fiscal Officer  
Legislative Fiscal Office