

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement:	Kimberly B. Barbier	Dept.	Health & Hospitals
Phone:	(225) 295-8567	Office:	Board of Drug and Device Distributors
Return Address:	12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816	Rule Title:	LAC 46:XCI.103, 105, 301, 303, 305, 307, 311, 313, 315, 801, and Chapters 13 and 15 – General Provisions, Requirements, qualifications, recordkeeping, fees, wholesale distributors, and Third-party Logistics Providers
		Date Rule Takes Effect:	December 20, 2016

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 1 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 estimated implementation cost to the state for the proposed rule changes is approximately \$1,400 in FY17 associated with publishing the proposed rule changes. Licensees will be informed of the rule changes via the Board's regular newsletter or other direct mailings, which will result in minimal costs to the Board. Local governmental units will not incur any costs as a result of this rule.

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

The proposed rule changes are anticipated to increase annual revenues for the Board by approximately \$18,100 beginning in FY17. Proposed rule changes include the addition of license sub-types to the distributor license issued by the Board and re-structuring of the Board's current initial and renewal fees in association with the new distributor license sub-types. The proposed distributor license sub-types include standard distributor, wholesale distributor, and third-party logistics provider distributor. The delineation of license sub-types increases the initial license fee and annual license renewal fee by \$25 per additional sub-type delineated on the distributor license.

There are approximately 2,170 licenses in the current fiscal year. It is anticipated if twenty percent (20%) of these current licenses (434 licenses) will add one additional license sub-type (\$10,850) and 5% of these current licensees (108 licenses) will add two additional license sub-types (\$5,400) for a total projected increase in annual revenues of \$16,250. In addition, it is estimated there will be 250 new applicants and licensees in FY17. Using the same percentage projection for new applicants (250: 20%=50; 5%=12), there would be an annual estimated increase of \$1,850 in initial license fees.

The total estimated annual revenue increase is approximately \$18,100 beginning in FY17.

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

Current drug and device distributor licensees and applicants for licensure will pay \$25 per additional license sub-type based on the proposed rule changes.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary).

No impact on competition and employment is anticipated as a result of the proposed rule change.

George Lovecchio
Signature of Agency Head or Designee

George Lovecchio, Executive Director
Typed Name and Title of Agency Head or Designee

6/10/2016
Date of Signature

Evan Brassel, Staff Director
Legislative Fiscal Officer or Designee

6/23/16
Date of Signature

RECEIVED
JUN 23 2016
Legislative Fiscal Office

RECEIVED
JUL - 8 2016
BY: LBADD *KB*

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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 deliberations 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 amend portions indicated).

Proposed rule amendments and new rules for adoption parallel recent amendments to the Board's statutes passed by Act 443 of the 2015 regular session of the Louisiana legislature. Particularly, the rule changes include the transition to licensure for distribution of drugs and devices from licensure for wholesale distribution, the addition of license sub-types to the drug and device distributor license, and restructure of fees to correspond with licensure sub-type.

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

The proposed rule amendments and new rules for adoption support the Board's ability to license and regulate distribution of legend drugs and legend devices into and within the state of Louisiana in its efforts to safeguard the life and health of its citizens and promote public welfare.

- 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.

No, the proposed rule changes and rules for adoption will not result in any increase of the expenditures of funds of the Board.

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

- (a) _____ Yes. Attach documentation.
(b) _____ No. Provide justification as to why this rule change should be published at this time.