October 14, 2016

Hon. Fred H. Mills, Jr.
Chairman
Committee on Health and Welfare
Senate of the State of Louisiana
P.O. Box 94183
Baton Rouge, LA 70804
apa.s-h&w@legis.la.gov

Hon. John A. Alario, Jr.
President
Senate of the State of Louisiana
P.O. Box 94183
Baton Rouge, LA 70804
apa.senatepresident@legis.la.gov

Hon. Frank A. Hoffmann
Chairman
Committee on Health and Welfare
House of Representatives of the
State of Louisiana
Post Office Box 4486
Capitol Station
Baton Rouge, Louisiana 70804
apa.h-hw@legis.la.gov

Hon. Taylor F. Barras
Speaker
House of Representatives of the
State of Louisiana
Post Office Box 4486
Capitol Station
Baton Rouge, Louisiana 70804
apa.housespeaker@legis.la.gov

RE: Final Report: Proposed Rule Amendment
Regarding Medications Used in the Treatment
of Obesity (LAC 46:XLV.6905C.)

Dear Sirs:


Very truly yours,

LOUISIANA STATE BOARD OF
MEDICAL EXAMINERS

By: [Signature]

Eric D. Torres
Executive Director

Enclosure
FINAL REPORT: PROPOSED AMENDMENT OF
ADMINISTRATIVE RULES GOVERNING
MEDICATION USED IN THE TREATMENT OF OBESITY
(LAC 46:XLV.6905C)

By The

LOUISIANA STATE
BOARD OF MEDICAL EXAMINERS

Submitted To The-

COMMITTEE ON HEALTH AND WELFARE,
LOUISIANA SENATE,

COMMITTEE ON HEALTH AND WELFARE,
LOUISIANA HOUSE OF REPRESENTATIVES,

PRESIDENT OF THE SENATE

And

SPEAKER OF THE HOUSE OF REPRESENTATIVES

October 14, 2016
This Report is respectfully submitted by the Louisiana State Board of Medical Examiners (the "Board"), within the Department of Health and Hospitals, pursuant to La. Rev. Stat. §49:968(D).

By Notice of Intent published in the July 20, 2016, edition of the Louisiana Register, Vol. 42, No. 7, pp. 1156-1157, the Board proposed to amend its rules governing medication used in treatment of obesity, LAC Title 46:XLV, Subpart 3 (Practice), Chapter 69 (Prescription, Dispensation, and Administration of Medications), Subchapter A. (Medications Used in the Treatment of Obesity), Section 6905 (Prohibitions).

The proposed amendment adds a new subsection (6905C.) to the Board’s existing rules. The amendment would expand the non-controlled medications that may be prescribed, dispensed or administered by physicians in connection with the treatment of obesity. Currently, any drug, medication, compound, or substance which is not indicated for use in the treatment of exogenous obesity by express approval of the U.S. Food and Drug Administration (FDA) may not be utilized for such purposes. The amendment provides that the components of such non-controlled, FDA-approved medications may also be utilized by physicians in the treatment of obesity even though the components have not been separately approved by the FDA for such purposes.

Concurrently with submission of the Notice of Intent to the Register, in accordance with La. Rev. Stat. §40:968, the Board submitted a Report on the proposed changes to the Senate and House Committees on Health and Welfare, the President of the Senate and the Speaker of the House of Representatives. Following publication of Notice of Intent the Board did not receive a request for public hearing nor did it receive any written comments on the proposed amendments from a single organization or individual during the comment period provided by La. Rev. Stat. §49:953.

This Report, submitted by the Board pursuant to and as prescribed by La. Rev. Stat. §49:968(D), includes as Appendix A, a photocopy of the Notice of Intent containing the full text

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of the proposed amendments that were previously published and appeared in the July 2016 edition of the *Louisiana Register*, which the Board has adopted as final rules and intends to formally promulgate in the identical form as was previously published by and upon publication in the November 20, 2016, edition of the *Louisiana Register*.

*     *     *
The proposed rule changes to LAC 46:XXXIII.1709 revises language from when Louisiana accepted test results conducted by only one testing agency, the Council for Interstate Testing Agencies (CITA). The proposed rule change will allow Louisiana to accept test results conducted by any testing agency that administers the American Board of Dental Examiners (ADEX) Dental Hygiene Examination for purposes of licensure regardless of which testing agency gives the ADEX test.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)
There will be no estimated effect on revenue collections by the board, state, or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)
The acceptance of the American Board of Dental Examiners (ADEX) Dental Hygiene Examination for initial licensure will allow licensees who take the examination to obtain a license in 45 jurisdictions including Louisiana. Therefore, licensees will benefit from the mobility allowed by completing this examination.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)
The proposed rule change to LAC 46:XXXIII.1711 "Examination of Dental Hygienists" may increase competition and employment opportunities as individuals successfully completing the ADEX Dental Hygiene Examination accepted in 45 jurisdictions may also seek licensure in Louisiana.

Arthur F. Hickman, Jr.
Executive Director
16079668

John D. Carpenter
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT
Department of Health
Board of Medical Examiners

Medications Used in the Treatment of Obesity (LAC 46:LXV.6905)

Notice is hereby given in accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 et seq., and pursuant to the authority vested in the Louisiana State Board of Medical Examiners (board) by the Louisiana Medical Practice Act, R.S. 37:1270 and R.S. 37:1285(B), the board intends to amend its rules governing physician prescription, dispensation and administration of medications used in the treatment of obesity, LAC 46:LXV.6905. The proposed amendment would add a new Subsection (§6905.C) to the board's existing rules to expand the medication that may be utilized in the treatment of obesity to include the components of non-controlled drugs, which have been approved for the treatment of exogenous obesity by the U.S. Food and Drug Administration (FDA), even though such components have not been separately approved for such purpose by the FDA. The proposed amendment is set forth below.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XLV. Medical Professions
Subpart 3. Practice
Chapter 69. Prescription, Dispensation, and Administration of Medications
Subchapter A. Medications Used in the Treatment of Obesity
§6905. Prohibitions
A. - B. ...
C. When a non-controlled drug has been approved in the treatment of exogenous obesity by the FDA, the prohibitions in Subsection A of this Section shall not prevent the individual components of such drug from being separately prescribed, dispensed or administered for the treatment of obesity.

AUTHORITIES: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).
HISTORICAL: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, L.R. 18:744 (July 1992), amended by the Department of Health, Board of Medical Examiners, L.R. 42:

Family Impact Statement
In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed amendment on the family has been considered. It is not anticipated that the proposed amendment will have any impact on family, formation, stability or autonomy, as described in R.S. 49:972.

Poverty Impact Statement
In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the impact of the proposed amendment on those that may be living at or below one hundred percent of the federal poverty line has been considered. It is not anticipated that the proposed amendment will have any impact on child, individual or family poverty in relation to individual or community asset development, as described in R.S. 49:973.

Provider Impact Statement
In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed amendment on organizations that provide services for individuals with development disabilities has been considered. It is not anticipated that the proposed amendment will have any impact on the staffing, costs or overall ability of such organizations to provide the same level of services, as described in HCR 170.

Public Comments
Interested persons may submit written data, views, arguments, information or comments on the proposed amendment to Rita Arceaux, Confidential Executive Assistant, Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until 4 p.m., August 19 2016.
Public Hearing
A request pursuant to R.S. 49:953(A)(2) for a public hearing must be made in writing and received by the board within 20 days of the date of this notice. If a public hearing is requested to provide data, views, arguments, information or comments in accordance with the Louisiana Administrative Procedure Act, the hearing will be held on August 24, 2016 at 9 a.m. at the office of the Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130. Any person wishing to attend should call to confirm that a hearing is being held.

Eric D. Torres
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Medications Used in the Treatment of Obesity

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)
The estimated one-time implementation cost to the Board of Medical Examiners for the publication of the proposed notice and rules in the State Register is approximately $319 in FY 17. There are no estimated implementation cost or savings to state or local governmental units through promulgation of the proposed rules changes.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENT UNITS (Summary)
There is no anticipated effect on the Board's revenue collections or those of any other state or governmental unit.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)
The proposed rule change provides that the components of non-controlled medications that have been approved by the U.S. Food and Drug Administration (FDA) for use in the treatment of exogenous obesity may also be utilized by physicians in the treatment of obesity, even if these components have not been separately approved by the FDA for such purposes. Physicians and their patients, who may desire to receive such therapy on their physician's recommendation, will be directly affected by the proposed rule amendment. Otherwise, the proposed rule change will not have a material effect on costs, paperwork, or workload of physicians and/or income of licensees or non-governmental groups.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)
It is not anticipated that the proposed rule change will have any impact on competition or employment in either the public or private sector.

Eric D. Torres
Executive Director
16078667

John D. Carpenter
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT
Department of Health
Board of Speech-Language Pathology and Audiology

Speech-Language and Audiology
(LAC 46:11XXV.103, 107, 109, 119, 121, 123, 130, 131, 501, and 505)

Notice is hereby given in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., and through the authority granted in R.S. 37:3083, that the Board of Speech-Language Pathology and Audiology proposes to amend its current regulations to make technical changes and clarifications, add definitions for telehealth/telepractice, remove hearing aid dispensing fees from renewal and initial applications, and add telehealth registration fees.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LXV. Speech Pathology and Audiology
Chapter 1. General Rules
§103. Definitions
A. ...

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Asynchronous Store and Forward Transfer—the transmission of client information in the delivery of telehealth services from an originating site to the provider at the distant site without the client being present.

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Distant Site—the site at which the healthcare provider delivering the service is located at the time the service is provided via a telecommunication system.

***
Originating Site—the location of the client at the time the service is furnished via a telecommunication system or when the asynchronous store and forward transfer occurs.

***
Synchronous Interaction—communication through interactive technology in the delivery of telehealth services that enable an audiologist or speech-language pathologist and a client at two locations separated by distance to interact via two-way video and audio transmissions simultaneously.

***
Telehealth—a mode of delivering audiology and speech-language pathology services that utilizes information and communication technologies to enable the diagnosis, consultation, treatment, education care management, and self-management of clients at a distance from the audiologist or speech-language pathologist provider. Telehealth allows services to be accessed when providers are in a distant site and patients are in the originating site. Telehealth facilitates self-management and caregiver support for patients and includes synchronous interactions and asynchronous store and forward transfers.