

NOTICE OF INTENT

Department of Health Board of Medical Examiners

Physicians; Obesity Medication (LAC 46:XLV.6901)

Notice is hereby given that in accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 et seq., and pursuant to the authority vested in the Board of Medical Examiners (the board) by the Louisiana Medical Practice Act., R.S. 37:1270 et seq., the board proposes to amend its rules governing the medications used in the treatment of obesity. The proposed rule changes will clarify that the rules apply to physicians who supervise PAs and APRNs, update outdated language, require safety standards for compounded medications, and make typographical changes. The proposed amendments are set forth below.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Professions

Chapter 69. Prescription, Dispensation, and Administration of Medications

Subchapter A. Medications Used in the Treatment of Obesity

§6901. Scope of Subchapter

A. The rules of this Subchapter govern physician prescription, dispensation, administration, or other use of medications for weight control or weight reduction in the medical treatment of obesity.

B. These rules apply to physicians that supervise PAs and must be in accordance with R.S. 37:1360.31(C- D).

C. These rules apply to physicians that collaborate with APRNs and must comply with Chapter 79 of the rules for physicians.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992), amended by the Department of Health, Board of Medical Examiners, LR 52:

§6903. Definitions

A. As used in this Subchapter, the following terms shall have the meanings specified.

Anorectic—a drug, medication, or substance used or intended for use as an anti-obesity medication.

Schedule II Controlled Substance—any substance so classified under and pursuant to regulations of the Drug Enforcement Administration (DEA), U.S. Department of Justice, 21 CFR §1308.12, or any substance which may hereafter be so classified by amendment or supplementation of such regulation.

Schedule III Anti-Obesity Medication—benzphetamine, phendimetrazine, and any other substance now or hereafter classified as a Schedule III controlled substance under and pursuant to Federal DEA regulations, 21 CFR §1308.13, and which is indicated for use in the treatment of exogenous obesity by express approval of the U.S. Food and Drug Administration (FDA).

Schedule IV Anti-Obesity Medication—fenfluramine, dexfenfluramine, phentermine, diethylpropion, mazindol, and any other substance now or hereafter classified as a Schedule IV controlled substance under and pursuant to federal DEA regulations, 21 CFR §1308.14 and which is indicated for use in the treatment of exogenous obesity by express approval of the FDA.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992), amended LR 23:1146 (September 1997), amended by the Department of Health, Board of Medical Examiners, LR 52:

§6905. Prohibitions

A. Absolute Prohibitions. A physician shall not prescribe, dispense, administer, supply, sell, give, or otherwise use to or for any person for the purpose of weight control or weight reduction in the treatment of obesity any amphetamine, dextroamphetamine, methamphetamine, or phenmetrazine drug or compound; any Schedule II controlled substance; human chorionic gonadotropin (HCG); thyroid hormones; diuretic medications; or 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).

B. Schedule III-IV Anti-Obesity Medication. A physician shall not prescribe, dispense, or administer Schedule III or Schedule IV anti-obesity medication for the purpose of weight reduction or control in the treatment of obesity other than in strict conformity with each of the conditions and limitations prescribed by §6907 of this Subchapter.

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.

D. When drug has been shown to be effective in the treatment of obesity, but not specifically FDA approved for the treatment of obesity, it may be used as an off-label drug. Off-label drugs must be used with proper consent and full knowledge of the risks and benefits of the off-label use explained to the patient. This must be meticulously documented in the patient's record.

E. In situation where off-label drugs are used in periods of shortages, the drug may be FDA allowed (not approved) the drug must be provided by a vender recognized and licensed by the Louisiana Board of Drug and Device Distributors.

F. When components are used they should be provided by compounding pharmacies licensed by the Louisiana Board of Drug and Device Distributors.

G. When the anti-obesity medicine has been compounded, mixed, or otherwise provided by the physician, such medication must be prepared by a physician licensed to dispense and prepare under the dispensing rules of the Board Title 46 Part XLV Chapter 65 & 69.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992), amended by the Department of Health, Board of Medical Examiners, LR 42:2197 (December 2016), amended LR 52:

§6907. Use of Schedule III-IV Anorectics; Conditions; Limitations

A. Requisite Prior Conditions. Before initiating treatment utilizing a Schedule III or IV anti-obesity medication with respect to any patient, a physician shall:

1. obtain a thorough prior history, including the patient's weight loss/gain history and prior efforts at weight reduction;
2. perform a physical examination sufficient to address all of the patient's health problems;
3. rule out the presence of conditions recognized as contraindicating the use of anti-obesity medication medications, including, without limitation, pregnancy, hypertension, and hypersensitivity or idiosyncrasy to anorectics; and
4. provide the patient with a carefully prescribed diet, together with counseling on exercise and, as appropriate, other supportive or behavioral therapy.

B. Initiation of Anti-Obesity Medication Use. Upon completion and satisfaction of the conditions prescribed by §6907.A and B and upon the physician's judgment that the prescription, dispensation, or administration of an anorectic medication is medically warranted, the physician shall initiate anorectic treatment with the lowest dosage expected to be effective, as indicated by the manufacturer's FDA-approved dosage recommendation, employing a Schedule IV anorectic in preference to a Schedule III anorectic and refraining from use of Schedule III anorectics until and unless the anorectic initially used proves ineffective.

C. Continued Use of Anti-Obesity Medications. During the continued use of anti-obesity medications as permitted in this Section, and subject to the limitations prescribed in §6907.E, the physician shall monitor the patient's progress closely and frequently, shall re-examine the patient not less frequently than every twelve weeks during such continued use and shall continue use of anti-obesity medication only if, upon each such re-examination, the patient demonstrates continued clinically significant weight loss since the prior examination.

D. Limitations on Use. A physician shall not prescribe or dispense Schedule III or IV anti-obesity medications to any patient:

1. in dosage greater than the maximum dosage indicated by the anorectic manufacturer's FDA-approved dosage recommendation;
2. in number or dosage units greater than an amount sufficient for use of the anorectic for a period of 30 days; or
3. for an aggregate period in excess of 12 weeks during any 12-month period; provided, however, that this limitation shall not be applicable with respect to Schedule IV anorectics.

E. Termination of Anti-Obesity Medication Use. Without regard to the permissible limitations otherwise prescribed by §6907.E, a physician shall refuse to initiate or re-initiate or shall terminate the use of anorectics with respect to a patient on any date that the physician determines, becomes aware, knows, or should know that:

1. the patient is not a proper candidate for the use of anti-obesity medications under the conditions and limitations prescribed by this Section;
2. the patient has failed to demonstrate clinically significant weight loss since anti-obesity medications were last prescribed, dispensed, or administered to the patient by the physician;

3. the patient has developed tolerance to the appetite suppressant effect of the anti-obesity medication or has experienced euphoria followed by irritability or depression;

4. the patient has engaged in excessive use, misuse, or abuse of the anti-obesity medication or has otherwise consumed or disposed of the anti-obesity medications or any other controlled substance other than in strict compliance with the directions and indications for use given by the physician; or

5. the patient did not demonstrate clinically significant weight loss during a prior term of use of anti-obesity medications within the limitations of §6907.E.3 hereof.

F. Treatment Records. Satisfaction of each of the conditions and requirements prescribed by this Section, all material elements of the patient's history, all significant findings from physical examination and diagnostic testing, and all medication and other treatment, including diet, prescribed by the physician, shall be accurately and completely recorded, documented, and dated, in writing, by the physician in the patient's record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992), amended LR 23:1146 (September 1997), amended by the Department of Health, Board of Medical Examiners, LR 52:

§6909. Exemption of Controlled Scientific Studies

A. The prohibitions, conditions, and limitations on the use of Schedule III and Schedule IV anti-obesity medications prescribed by §6905.B and §6907 of this Subchapter shall not be applicable to a physician engaged in the conduct of a controlled scientific study of the efficacy of such medications in the medical treatment of obesity, provided that the physician is employed by or otherwise officially affiliated with an accredited medical school or college or other institution of higher learning located in the state of Louisiana, such study is conducted under the auspices of such school, college, or institution, and the interim and final results of such study are furnished to the board in writing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992), amended by the Department of Health, Board of Medical Examiners, LR 52:

§6911. Exceptions in Individual Cases

A. Availability of Exceptions. Upon written application to the board made in accordance with this Subsection, the board may authorize a physician, with respect to an identified individual patient, to exceed or otherwise depart from the prohibitions, conditions, and limitations on the use of Schedule III or Schedule IV anti-obesity medications otherwise prescribed by §6905.B and §6907 of this Subchapter.

B. Form, Content of Application for Exception. An application for board approval of an individual exception from the provisions of this Subchapter shall be submitted to the board's medical consultant in writing and shall contain:

1. individual identification of the patient to whom the physician proposes to prescribe, dispense, or administer anti-obesity medications other than in accordance with the provisions of this Subchapter;

2. a summary of the patient's medical and weight loss/gain history;

3. a complete copy of the patient's medical record, including a record of all anti-obesity medications prescribed, dispensed, or administered to or for the patient within 24 months prior to the application;

4. a statement by the physician of the specific manner in which the physician proposes to deviate from the provisions of this Subchapter respecting the prescription, dispensation, and administration of anti-obesity medications, together with a statement by the physician of the medical facts and circumstances deemed by the physician to justify such departure; and

5. such other information and documentation as the board or its medical consultant may request.

C. Board Action. The board may deny, grant, or grant in part any application for exception in an individual case made under this Section. The board's action on any such application shall be stated in writing and shall specify the manner and extent to which the physician shall be authorized to depart from the provisions of this Subchapter and the period of time during which such authorized exception shall be effective. A physician who makes application to the board under this Section shall not deviate from the prohibitions, conditions, and limitations provided in this Subchapter except following receipt of written authorization from the board or other than pursuant to the specifications and limitations of such authorization.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:745 (July 1992), amended by the Department of Health, Board of Medical Examiners, LR 52:

§6913. Effect of Violation

A. Any violation of or failure of compliance with the provisions of this Subchapter, §§6901-6913, shall be deemed a violation of R.S. 37:1285.A(6) and (29), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license or permit held or applied for by a physician culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 37:1270(B)(6), and 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:746 (July 1992), amended by the Department of Health, Board of Medical Examiners, LR 52:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed amendments on the family has been considered. It is not anticipated that the proposed amendments 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 amendments 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 amendments 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.

Small Business Analysis

It is not anticipated that the proposed amendments will have any adverse impact on small businesses as defined in the Regulatory Flexibility Act, R.S. 49:978.1 et seq.

Provider Impact Statement

In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed amendments on organizations that provide services for individuals with developmental disabilities has been considered. It is not anticipated that the proposed amendments 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 amendments to Jacintha Duthu, LSBME, 630 Camp Street, New Orleans, LA 70130. She is responsible for responding to inquiries. Written comments will be accepted until 4 p.m., Tuesday, April 28, 2026.

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 orally in accordance with the Louisiana Administrative Procedure Act, the hearing will be held on Tuesday, April 28, 2026 at 9 a.m., at the office of the LSBME, 630 Camp Street, New Orleans, LA 70130. Any person wishing to attend should call in advance to confirm.

Vincent A. Culotta, Jr., M.D.,
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Physicians; Obesity Medication

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

Other than the cost of rulemaking, there are no estimated implementation costs or savings for state or local government units resulting from the promulgation of the proposed rule change. The cost for the Louisiana State Board of Medical Examiners (LSBME) is approximately \$640 in FY 26 for the notice and rule publication in the *Louisiana Register*.

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

The proposed rule change is not anticipated to impact the 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 is not anticipated to result in a material economic impact on directly affected persons, small businesses, or non-governmental groups. The amendments clarify existing standards for physicians prescribing or supervising the use of anti-obesity medications and establish safety requirements for compounded preparations, without creating new costs or fees for healthcare providers or facilities. The rule further specifies that patients receiving Schedule III or IV anti-obesity medications must be re-examined at least every 12 weeks rather

than monthly, which may slightly reduce the administrative workload for physicians; however, since prescriptions remain limited to 30-day dosages, patients will continue to require monthly refills, and any resulting change in workload or cost is expected to be minimal.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

Vincent A. Culotta, Jr. M.D.
Executive Director
2603#006

Alan M. Boxberger
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Health Standards Section

Home and Community-Based Services Providers
Monitored In-Home Caregiving Module
Licensing Standards (LAC 48:I.Chapter 51)

The Department of Health, Health Standards Section (the department), proposes to amend LAC 48:I.Chapter 51 as authorized by 36:254 and R.S. 40:2120.2. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The department proposes to amend the provisions governing the licensing of home and community based providers, monitored in-home caregiving (MIHC) module licensing standards in order to update the MIHC registered nurse and care manager's requirements for conducting client visits.

The Rule text below has been drafted utilizing plain language principles to ensure clarity and accessibility for all users. It has also been reviewed and tested for compliance with web accessibility standards.

Title 48

PUBLIC HEALTH—GENERAL

Part I. General Administration

Subpart 3. Licensing and Certification

Chapter 51. Home and Community-Based Services (HCBS) Providers

Subchapter A. Monitored In-Home Caregiving (MIHC) Module

§5101. General Provisions

A. - A.2. ...

B. Providers applying for the MIHC module under the HCBS license shall meet:

1. the core licensing requirements (except those set forth in §5005.B.4, §5005.C.2., and §5007.F.1.c); and
2. the module-specific requirements of this Section.

C. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2639 (December 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 43:2522 (December 2017), amended by the Department of Health, Health Standards Section, LR 52:

§5103. Staffing Requirements, Qualifications, and Duties

A. - C.2. ...

D. The responsibilities of the registered nurse (RN) include:

1. - 6. ...

7. conducting on-site visits with each client at the qualified setting at least every other month. The RN shall conduct additional visits when the client experiences a change in health status that requires additional support.

a. Virtual visits may be conducted in accordance with R.S. 40:1223.4, or current law. Virtual visits may be conducted during the months that RN on-site visits are not conducted;

8. completing a nursing progress note corresponding with each on-site and virtual visit; and

D.9. - E.3 ...

F. Care Manager Responsibilities. The following responsibilities of the care manager for the MIHC module shall substitute for the requirements in §5055.L and §5055.M. The responsibilities of the MIHC care manager shall include:

1. - 4. ...

5. conducting on-site visits with each client at the qualified setting at least every other month or more often as deemed necessary by the client's health status;

a. Virtual visits may be conducted in accordance with R.S. 40:1223.4, or current law. Virtual visits may be conducted during the months that care manager on-site visit are not conducted;

6. completing a care management client progress note corresponding with each visit, whether on-site or virtual;

7. - 11. ...

12. being readily accessible and available to the principal caregivers either by telephone or other means of prompt communication.

a. The care manager shall maintain a file on each principal caregiver. The file shall include documentation of each principal caregiver's performance during the care manager's visit, whether on-site or virtual.

G. - H.6.h.v. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 41:2639 (December 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 43:2523 (December 2017), amended by the Department of Health, Health Standards Section, LR 52:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will not have an impact on family functioning, stability, and 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 poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule may have an impact on child, individual, or family poverty in relation to individual or community asset