

NOTICE OF INTENT

Department of Health Board of Medical Examiners

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

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 The proposed rule changes will clarify that the rules apply to physicians who supervise PAs and APRNs, update outdated language, require safety standards for compounded medications, and make typographical changes.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).

§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](#)~~appetite suppressant~~.

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 Anorectic—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 Anorectic—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).

§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](#)~~Anorectics~~. A physician shall not prescribe, dispense, or administer Schedule III or Schedule IV [anti-obesity medication](#)~~anorectics~~ 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).

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

~~A. General Conditions. A physician shall not prescribe, dispense, or administer a Schedule III or Schedule IV anorectic for the purpose of weight reduction or control in the treatment of obesity, except as an adjunct to a therapeutic regimen of weight reduction based on prescribed sound nutrition, caloric restriction, exercise, and behavior modification and otherwise in accordance with the FDA approved indications for the medication and contraindications for unapproved combinations of anorectic agents. Schedule III-IV anorectics may be prescribed, dispensed, or administered only to an adult patient who is obese under recognized generally accepted criteria for determining obesity, whose obesity is exogenous and not primarily metabolic, who is not pregnant, who does not suffer from or have any disease or condition constituting a recognized contraindication for use of the substance, and who otherwise satisfies the conditions requisite to treatment with anorectics as prescribed by this Section.~~

[A](#)B. Requisite Prior Conditions. Before initiating treatment utilizing a Schedule III or IV ~~anorectic~~[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 ~~thorough and complete~~ physical examination [sufficient to address all of the patient's health problems](#);

~~3.—determine that the patient is a proper candidate for weight reduction treatment and that the patient's obesity is not primarily metabolic;~~

~~34.~~ rule out the presence of conditions recognized as contraindicating the use of [anti-obesity medication](#)~~anorectic~~ medications, including, without limitation, pregnancy, hypertension, and hypersensitivity or idiosyncrasy to anorectics; ~~and~~

~~5.—determine whether the patient has a history of or any tendency or propensity toward abuse of drugs, including alcohol;~~

~~6.—determine that the patient has made a substantial good faith effort at weight reduction under a bona fide program not utilizing anorectics;~~

~~7.—take reasonable measures to ensure that the patient has not previously, in the course of treatment by one or more other practitioners, or otherwise, obtained and used anorectics in excess of the quantitative and durational limitations on the use of anorectics prescribed by §6907.E; and~~

~~48.~~ provide the patient with a carefully prescribed diet, together with counseling on exercise and, as appropriate, other supportive or behavioral therapy.

~~BC.~~ Initiation of [Anti-Obesity Medication](#)~~Anorectic~~ 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.

~~CD.~~ Continued Use of [Anti-Obesity Medications](#)~~Anorectics~~. During the continued use of ~~anorectics~~[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 ~~monthly~~[every twelve weeks](#) during such continued use and shall continue use of [anti-obesity medication](#)~~anorectics~~ only if, upon each such re-examination, the patient demonstrates continued clinically significant weight loss since the prior examination.

~~DE.~~ Limitations on Use. A physician shall not prescribe or dispense Schedule III or IV [anti-obesity medications](#)~~anorectics~~ 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.

~~EF.~~ Termination of ~~Anorectic~~[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 ~~anorectics~~[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](#)~~anorectics~~ 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](#)~~anorectic~~ 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](#)~~anorectic~~ or has otherwise consumed or disposed of the [anti-obesity medications](#)~~anorectics~~ 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](#)~~anorectics~~ within the limitations of §6907.E.3 hereof.

FG. 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).

§6909. Exemption of Controlled Scientific Studies

A. The prohibitions, conditions, and limitations on the use of Schedule III and Schedule IV [anti-obesity medications](#) ~~anorectic 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).

§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](#)~~anorectics~~ 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](#)~~anorectics~~ 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](#) ~~anorectic 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](#)~~anorectic 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).

§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).