SOS APA Form 001

#### **Mississippi Secretary of State**

#### 125 South Congress St., P. O. Box 136, Jackson, MS 39205-0136

#### ADMINISTRATIVE PROCEDURES NOTICE FILING

AGENCY NAME Mississippi State Board of Medical Licensure ADDRESS 1867 Crane Ridge Drive, Suite 200-B		CONTACT PERSON Rhonda Freeman CITY Jackson	TELEPHONE NUMBER (601) 987-3079	
			STATE MS	
EMAIL mboard@msbml.ms.gov	SUBMIT DATE 2/14/18	Name or number of rule(s): Part 2640 Prescribing, Administering and Dispensing		

Short explanation of rule/amendment/repeal and reason(s) for proposing rule/amendment/repeal: The rules in this Part have been

updated to reflect changes as proposed by the Governor's Opioid and Heroin Study Task Force and other guidelines previously

published by the CDC. Pursuant to public comments, additional changes have been included.

Specific legal authority authorizing the promulgation of rule: 73-43-11

List all rules repealed, amended, or suspended by the proposed rule: Part 2640: Prescribing, Administering and Dispensing ORAL PROCEEDING:

An oral proceeding is scheduled for this rule on Date: 03/07/2018 Time: 1:00 p.m. Place: Office of the Board

Presently, an oral proceeding is not scheduled on this rule.

If an oral proceeding is not scheduled, an oral proceeding must be held if a written request for an oral proceeding is submitted by a political subdivision, an agency or ten (10) or more persons. The written request should be submitted to the agency contact person at the above address within twenty (20) days after the filing of this notice of proposed rule adoption and should include the name, address, email address, and telephone number of the person(s) making the request; and, if you are an agent or attorney, the name, address, email address, and telephone number of the party or parties you represent. At any time within the twenty-five (25) day public comment period, written submissions including arguments, data, and views on the proposed rule/amendment/repeal may be submitted to the filing agency.

#### ECONOMIC IMPACT STATEMENT:

Economic impact statement not required for this rule. Concise summary of economic impact statement attached.

<b>TEMPORARY RULES</b>	PROPOSED ACTION ON RULES	FINAL ACTION ON RULES				
		Date Proposed Rule Filed:				
Original filing	Action proposed:	Action taken:				
Renewal of effectiveness	New rule(s)	Adopted with no changes in text				
To be in effect in days	X Amendment to existing rule(s)	Adopted with changes				
Effective date:	Repeal of existing rule(s)	Adopted by reference				
Immediately upon filing	Adoption by reference	Withdrawn				
Other (specify):	Proposed final effective date:	Repeal adopted as proposed				
	X 30 days after filing	Effective date:				
	Other (specify):	30 days after filing				
		Other (specify):				
Printed name and Title of person authorized to file rules: Rhonda Freeman						

Signature of person authorized t	o file rules:	
OFFICIAL FILING STAMP	DO NOT WRITE BELOW THIS LINE OFFICIAL FILING STAMP FEB 1 4 2018 MISSISSIPPI SECRETARY OF STATE	OFFICIAL FILING STAMP
Accepted for filing by	Accepted for filing by	Accepted for filing by

The entire text of the Proposed Rule including the text of any rule being amended or changed is attached.



# MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

The Board has scheduled an oral proceeding on Wednesday, March 7, 2018, to provide individuals an opportunity to address the Board regarding Proposed regulation Title 30: Part 2640: Prescribing, Administering and Dispensing. The oral proceeding is scheduled to begin at 1:00 p.m., in the Board Room located at 1867 Crane Ridge Drive, Suite 200 B, Jackson, MS 39216.

The Board's rules and regulations state that persons wishing to make oral presentations at such a proceeding shall notify the Board at least one (1) business day **prior** to the proceeding and indicate the subject or nature of their presentation. If you are planning on addressing the Board, **please be familiar with the proposed rule** as posted on the MSBML website: <u>Proposed Regulation Title 30: Part 2640: Prescribing, Administering and Dispensing Updated 2-13-2018</u>

Submit your request via email to <u>mboard@msbml.ms.gov</u>. Please provide the following information with your request:

- Identify yourself and any persons or organizations you may represent
- Please indicate the specific subject of your oral statement / comment: and
- Provide the section or rule (Rule number, paragraph letter or number) of the proposed regulation that your comment / statement is pertaining to. A copy of the regulation is available on the Mississippi State Board of Medical Licensure website to download and print. The link is provided above.

Should you have additional questions concerning the oral proceeding that will be held, please email Frances Carrillo at <u>frances@msbml.ms.gov</u>.

Hyperlink to google maps: <u>Map to MSBML, 1867 Crane Ridge Drive, Jackson, MS</u> Part 2640: Prescribing, Administering and Dispensing

# Part 2640 Chapter 1: Rules Pertaining to Prescribing, Administering and Dispensing of Medication

*Rule 1.1 Scope.* These rules apply to all individuals who have prescriptive authority and are licensed by the Mississippi State Board of Medical Licensure.

#### Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.2 Definitions.* For the purpose of Part 2640, Chapter 1 only, the following terms have the meanings indicated:

- A. "<u>Administer</u>", "<u>Controlled Substances</u>", and "<u>Ultimate User</u>" shall have the same meaning as set forth in Mississippi Code, Section 41-29-105, unless the context otherwise requires.
- B. "Board" means the Mississippi State Board of Medical Licensure.
- C. "<u>Physician</u>" means any person licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi.
- D. <u>"Physician Assistant</u>" means any person meeting the requirements of licensure in the state of Mississippi as required by Part 2617, Chapter 1.
- E. "Licensee" means any person licensed by this Board who has prescriptive authority.
- F. <u>"Prescriptive Authority</u>" means the legal authority of a professional licensed to practice in the state of Mississippi who prescribes controlled substances and is registered with the U. S. Drug Enforcement Administration in compliance with Title 21 CFR, Part 1301 Food and Drugs.
- G. "<u>Prescribe</u>" means to designate or order by means of either a written or oral prescription the delivery of a controlled substance or legend drug to an ultimate user.
- H. "<u>Dispense</u>" means to deliver a controlled substance or legend drug other than by administering or prescribing to an ultimate user or research subject including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.
- I. For the purpose of enforcement of the labeling requirements set forth in this chapter, Part 2640, Rule 1.7.B, "<u>Dispensing Physician</u>" means any physician who dispenses to a patient for the patient's use any controlled substance, legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made. As stated in Part 2617, it is understood that Physician Assistants may not dispense medications.
- J. "<u>Prescription Drug</u>" or "<u>Legend Drug</u>" means a drug required under federal law to be labeled with the following statement prior to being dispensed or delivered; "Caution: Federal law prohibits dispensing without prescription," or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by licensees only.
- K. "<u>Pain Management Practice</u>" means a public or privately owned practice for which 30% or more of the patients are issued, on a regular or recurring basis, a prescription for opioids, barbiturates, benzodiazepines, carisoprodol, butalbital compounds, or tramadol for the treatment of chronic non-cancerous/non-terminal pain. Included in this definition is any practice that advertises and/or holds itself out to provide pain management

services. Patients who are treated for pain resulting from a terminal illness do not count against the percentage stated herein.

- L. "<u>Inpatient</u>" means a patient in a hospital, nursing home, long term care facility, inpatient (not home-bound) hospice, or any other facility wherein medications are dispensed to a patient by a third party who is duly licensed and/or certified to dispense medications in a healthcare or related facility.
- M. "Bariatric Medicine, Medical Weight Loss, or Weight Management Practice" means a public or privately owned practice
  - 1. for which 30% or more of the patients are provided a comprehensive weight management treatment program or;
  - 2. 30% or more of the patients receive any controlled substance approved by the FDA for the pharmacologic management of weight loss or;
  - 3. which advertises weight loss by any means.

Excluded from this definition is any practice in which a licensee advertises the use of nonpharmacological products as part of the licensee's overall practice of medicine. In order to be excluded from this definition, the licensee's practice must have nonpharmacological weight loss and/or weight loss management as a component of the overall management of the patient's total health care. If the use of nonpharmacological products for weight loss and/or weight management exceeds 30% of the total outpatient clinic visits for any single 90-day consecutive period, the practice will be considered a bariatric medicine/medical weight loss practice and will be subject to all the rules and regulations pertaining to bariatric medicine/medical weight loss practice.

Bariatric surgeons whose primary practice is surgical weight loss and not long-term management of weight loss through medical, pharmaceutical, and/or behavioral management are also excluded from this definition.

#### Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.3 Registration for Controlled Substances Certificate.* Every licensee who prescribes, administers or dispenses any controlled substance within Mississippi or who proposes to engage in the prescribing, administering or dispensing of any controlled substance within Mississippi must be registered with the U.S. Drug Enforcement Administration in compliance with Title 21 CFR Part 1301 Food and Drugs.

Each individual who is licensed by the Mississippi State Board of Medical Licensure and has prescriptive authority must be registered with the Mississippi Prescription Monitoring Program (MPMP). Every licensee who provides medical care in a pain management practice as defined in Rule 1.2 (K) must review the MPMP at each patient encounter in which a prescription for a controlled substance is issued. Every licensee, regardless of practice specialty, must review the MPMP at each patient encounter in which an opioid is prescribed for acute and/or chronic non-cancerous/non-terminal pain. Those licensees whose practice is not a pain management practice as defined previously must actively utilize the MPMP upon initial contact with new patients and at least every three (3) months thereafter on any and all patients who are prescribed, administered, or dispensed controlled substances other than opioids. Licensees who issue a prescription for Lomotil, Lyrica, Testosterone, or Amphetamines prescribed to pediatric patients

under the age of sixteen (16) for the treatment of ADHD, are not required in that instance to utilize the MPMP as stated herein.

Reports generated on such patients should span the length of time from the previous review of the MPMP so that adequate information is obtained to determine patient compliance with treatment. Documentation, such as a copy of the report itself and/or reflection in the chart dictation and/or notes, must be kept within the patient's record and made available for inspection upon request. As allowed by the Mississippi Board of Pharmacy and the MPMP, properly registered designees of the licensee may run/obtain the report for the licensee's review as required herein.

Utilization of the MPMP as stated herein is not required when treating inpatient; however, upon discharge from said inpatient setting with a prescription for a controlled substance, the MPMP must be reviewed as required herein.

Pursuant to authority granted in Mississippi Code, Section 41-29-125, the Mississippi State Board of Medical Licensure hereby adopts, in lieu of a separate registration with the Board, the registration with the U.S. Drug Enforcement Administration as required in the above paragraph. In the event, however, a licensee has had limitations or other restrictions placed upon his or her license wherein he or she is prohibited from ordering, dispensing, or prescribing controlled substances in any schedule, said licensee shall be prohibited from registering with the U.S. Drug Enforcement Administration for a Uniform Controlled Substances Registration Certificate without first being expressly authorized to do so by order of the Mississippi State Board of Medical Licensure.

Persons registered to prescribe, administer, dispense or conduct research with controlled substances may order, possess, prescribe, administer, dispense or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of these rules and in conformity with provisions of the Mississippi Uniform Controlled Substances Law, Mississippi Code Section 41-29-101 et seq.

The registration requirement set forth in these rules does not apply to the distribution and manufacture of controlled substances. Any licensee who engages in the manufacture or distribution of controlled substances or legend drugs must register with the Mississippi State Board of Pharmacy pursuant to Mississippi Code, Section 73-21-105 and will be subject to all applicable federal statutes and regulations controlling such practices. For the purposes herein, "distribute" means the delivery of a drug other than by administering, prescribing or dispensing. The word "manufacture" has the same meaning as set forth in Mississippi Code, Section 41-29-105(q).

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.4 Maintenance of Records and Inventories.* Every licensee shall maintain inventories, logs, and records prescribed in this rule.

- A. Controlled substances inventory record. All controlled substances classified under Schedules II, IIN, III, IIIN, IV and V which are purchased by the licensee must be inventoried at least every two (2) years. All inventory records for controlled substances in Schedules II and IIN must be maintained separately from the inventory records for Schedules III, IIIN, IV and V controlled substances. To insure the reliability of an inventory, the physician must maintain a readily retrievable record of controlled substances purchased, including a copy of all purchase invoices identifying the name, quantity and strength/dose of the controlled substance purchased, the supplier and the date purchased. Controlled substances inventory must also meet all applicable federal statutes and regulations.
- B. Controlled substances dispensation/administration record. Every licensee who dispenses or administers, Schedules II, IIN, III, IIIN, IV and V controlled substances must maintain a separate readily retrievable record of all such substances dispensed or administered. This requirement does not apply to Schedules III, IIIN, IV and V prepackaged samples and starter packs. All dispensation/administration records for controlled substances in Schedules III and IIN must be maintained separately from the dispensation/administration records for Schedules III, IIIN, IV and V controlled substances. The record must contain the following information:
  - 1. The date the controlled substance was dispensed or administered.
  - 2. The name, quantity and strength/dose of the controlled substance dispensed or administered.
  - 3. The method of administration of the controlled substance, i.e. oral, IV or subcutaneous.
  - 4. The name and address of the patient to whom the controlled substance was dispensed or administered.
  - 5. For all Schedules II and III amphetamines, amphetamine-like anorectic drugs, or sympathomimetic amine drugs dispensed in the treatment of narcolepsy, hyperkinesis, brain dysfunction, epilepsy, or depression, the dispensing or administration records must include the diagnosis and the reason for use of the Schedules II and III controlled substances.

Controlled substances dispensation/administration records must also meet all applicable federal statutes and regulations.

Patient Record - A licensee who prescribes, dispenses or administers a legend drug or controlled substance must maintain a complete record of his or her examination, evaluation and treatment of the patient which must include documentation of the diagnosis and reason for prescribing, dispensing or administering any legend drug or controlled substance; the name, dose, strength, quantity of the legend drug or controlled substance and the date that the legend drug or controlled substance was prescribed, dispensed or administered. The record required by this rule must be maintained in the patient's medical records. If medical records are maintained at the office of the licensee, the records must be available for inspection by the representatives of the Mississippi State Board of Medical Licensure.

Licensees must not prescribe, administer or dispense any legend drug; any controlled substance; or any drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication. A determination as to whether a "good faith prior

examination and medical indication" exists depends upon the facts and circumstances in each case. One of the primary roles of a physician is to elicit detailed information about the signs and symptoms which a patient presents in order that he or she may recommend a course of treatment to relieve the symptoms and cure the patient of his or her ailment or maintain him or her in an apparent state of good health. In order for a licensee to achieve a reasonable diagnosis and treatment plan, a history and physical examination consistent with the nature of the complaint are necessary. The importance of these aspects of proper medical practice cannot be over emphasized. The paramount importance of a complete medical history in establishing a correct diagnosis is well established. Standards of proper medical practice require that, upon any encounter with a patient, in order to establish proper diagnosis and regimen of treatment, a licensee must take three steps: (a) take and record an appropriate medical history, (b) carry out an appropriate physical examination, and (c) record the results. The observance of these principles is an integral component of the "course of legitimate professional practice."

Some of the factors used in determining the presence or absence of "good faith" may include, but are not limited to:

- 1. the quality and extent of the documented history and physical exam;
- 2. the extent to which the prescribed therapy is supported by documented history and physical exam;
- 3. the licensee's permitting the patient to name the drug desired;
- 4. a licensee dispensing or prescribing drugs to patients having no medical need, when the licensee knew or should have known that the patients were addicts or abusing/misusing substances;
- repeated refills over relatively short periods of time or the issuance of prescriptions at a time when the patient should not have been finished taking the same medication from a prior prescription had the prescription directions been properly followed or the correct dosage taken;
- 6. general remarks of the licensee indicating his or her experience with non-therapeutic uses of the drug;
- 7. a licensee prescribing contraindicated medication such as amphetamines and depressants in a manner which results in therapeutic conflicts.

The aforementioned is of particular importance in cases in which controlled substances are to play a part in the course of treatment. It is the responsibility of the licensee to dispense, prescribe or administer all therapies with proper regard for the actual and potential dangers. This fact has been established in a number of closely related administrative and criminal cases, **United States v. Bartee**, 479 F.2d 484 (10th Cir. 1973) (No physical examination prior to issuance of prescriptions for controlled substances); **United States v. Greene**, 511 F.2d 1062 (7th Cir. 1975); **Arthurs v. Board of Registration of Medicine**, 418 N.E. 2d 1236 (MA 1981) (failure to record in patient file prescriptions for controlled substances, 157 P2d 7 (Ca. 1945); **Dannerberg v. Board of Regents**, 430 N.Y.2d 700 (1980) (issuance of three prescriptions for sleeping pills to an undercover agent without a physical examination; **Widlitz v. Board of Regents of New York**, 429 N.Y. 2d 794 (1980) (issuance of Desoxyn to patients whom physician knew were drug addicts without conducting physical examination); **United States v. Rosenberg**, 515 F.2d 190 (9th Cir. 1975) (no physical examination, evidences that prescriptions were not in course of

professional practice); and **United States v. Hooker**, 541 F.2d 300 (1st Cir. 1976), (little more than cursory physical examination, frequent neglect to inquire as to past medical history, little or no exploration of the type of problem the patient allegedly had "indicates that the minimal professional procedures followed were designed only to give an appearance of propriety to appellant's unlawful distributions").

A determination of proper "medical indication" requires examination of the nature of the therapy and all circumstances surrounding its implementation. Use of any therapy should be supported by standards of medical practice, reasonable scientific evidence or consensus and documented in the medical record. Case law developed by the courts in connection with controlled substances criminal violations and administrative decisions further illustrates several indications of lack of good faith. See United States v. Greene, 511 F.2d 1062 (7th Cir. 1975) and United States v. Rosenburg, 515 F.2d 190 (9th Cir. 1975). One of primary importance is the failure to follow at least the minimal professional procedures. Some of the factors used in determining the existence of "good faith" may include, but are not limited to: (a) the physician's permitting the patient to name the drug desired; (b) a physician dispensing drugs to patients having no medical need, when the physician knew or should have known that the patients were addicts; (c) repeated refills over relatively short periods of time or the issuance of prescriptions at a time when the patient should not have been finished taking the same medication from a prior prescription had the prescription directions been properly followed or the correct dosage taken; (d) general remarks of the physician indicating his or her experience with non-therapeutic uses of the drug; (e) a physician prescribing contraindicated medication such as amphetamines and depressants in a manner which results in therapeutic conflicts

A licensee must not sell or trade any medication which he or she receives as prepackaged samples or starter packs, whether or not said samples are controlled substances, legend drugs or other medication.

The Controlled Substances Inventory, Controlled Substance Dispensation/Administration Record, and Patient Record required by these rules must be maintained in the office of the licensee for a period of seven (7) years from the date that the record is completed or the controlled substances, legend drugs or other medications are prescribed, administered or dispensed and must be made available for inspection by representatives of the Mississippi State Board of Medical Licensure pursuant to authority granted in Mississippi Code, Section 41-29-125. Record retention for Controlled Substances Inventory, Controlled Substance Dispensation/Administration Record, and Patient Record must also meet all applicable federal statutes and regulations.

A licensee may use a data processing system or a manual record keeping system for the storage and retrieval of Controlled Substances Dispensation/Administration Records. If a licensee utilizes a data processing system, it must provide immediate retrieval of all dispensation/administration records of controlled substances.

Whether maintained manually or in a data processing system, all records of dispensation/administration of controlled substances must be readily retrievable. If a data processing system is utilized, a hard-copy printout of the records of dispensation/administration

must be made at regular intervals, not to exceed seven (7) days. Such hard-copy printouts must be maintained for a period of five (5) years and must be made available for inspection and copying by investigators of the Mississippi State Board of Medical Licensure.

# Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.5 Use of Diet Medication.* Pursuant to Mississippi Code, Section 41-29-139(e), it is unlawful for any licensee to prescribe, dispense or administer any medication classified as Schedule II, pursuant to Section 41-29-115, for the exclusive treatment of obesity, weight control, or weight loss.

Prescribing or dispensing a controlled substance for weight reduction or the treatment of obesity should be based on accepted scientific knowledge and sound clinical grounds. All such prescribing and dispensing must be in compliance with applicable state and federal laws.

The licensee providing comprehensive treatment of obesity must be present at the facility when he or she prescribes or dispenses<sup>1</sup> controlled substances for the purpose of weight reduction or the treatment of obesity. A licensee may administer, order, dispense or prescribe controlled substances for the purpose of weight loss or the treatment of obesity only as an adjunct to a clearly documented comprehensive program of behavior modification, comprehensive nutritional education, and exercise or physical therapy intervention. The licensee must comply with all of the following conditions:

- A. An initial comprehensive evaluation is to be conducted by and thoroughly recorded by the prescribing licensee prior to the prescribing, ordering, dispensing or administering of any drug. Such evaluation should include a thorough history and thorough physical exam of the patient to include at a minimum:
  - 1. Past medical history, past surgical history, social history, family history, weight history, dietary history, gynecological history, review of systems, allergies and medications.
  - 2. A physical exam to include height; weight; blood pressure; pulse; % body fat or waist circumference/weight hip ratio; lungs; heart; abdomen; and extremities.
  - 3. Appropriate testing related to medical weight loss (CBC, comprehensive metabolic profile, lipid panel, thyroid panel, EKG, if prior or present history of cardiac disease, hypertension, diabetes, dyslipidemia, or strong family history of cardiac disease age >60
  - 4. The licensee must determine and record the patient's Body Mass Index ("BMI"). No patient should receive anorexic medications unless the patient has (i) a BMI of  $\geq$  30.0 in a normal otherwise healthy patient, or (ii) a BMI  $\geq$  27.0 in an individual with at least one associated co-morbidity, or (iii) current body weight  $\geq$  120 percent of a well-documented, long standing healthy weight that the patient maintained after the age of 18, or (iv) body fat  $\geq$  30% in females, or body fat  $\geq$  25% in males, or (v) waist-hip circumference such that the individual is known to be at increased cardiovascular and/or co-morbidity risk because of abdominal visceral fat, or

<sup>&</sup>lt;sup>1</sup> Part 2640, Rule 1.9, controls in all cases. Physician assistants are not permitted to dispense medication.

presence of a co-morbidity condition or conditions aggravated by the patients excessive adiposity. The indication for anorexic therapy must be documented in the record and re-evaluated at each visit or with each prescription refill.

- 5. Absolute contraindications of Schedule III or IV anorectic drugs for purposes of weight loss management are pregnancy, breast feeding, or severe allergic reactions to these medications. Relative contraindications of Schedule III and IV anorectics for the purpose of weight loss management are uncontrolled bipolar, uncontrolled epilepsy, uncontrolled hypertension, episodic tachyarrhythmia, excessive stimulation, history of substance abuse, severe anticholinergic effects, such as, extreme dryness of mouth or unmanageable constipation should be addressed with licensee prior to starting weight loss medications. Schedule III and IV anorectics can be used in conjunction with any other medications deemed safe by the licensee.
- B. The licensee must not utilize any Schedules III, IV or V controlled substance when he or she knows or has reason to believe an absolute contraindication exists or relative contraindication exists that would be harmful to the patient.
- C. A licensee is not permitted to prescribe, order, or dispense controlled substances for the purpose of weight reduction or treatment of obesity greater than a 30 day supply. Exempted from this requirement are those licensees defined in Rule 1.2(M) and those licensees treating patients resulting from a referral to those licensees defined in Rule 1.2(M).
- D. A patient continued on a controlled substance for the purpose of weight reduction or the treatment of obesity must undergo an in-person re-evaluation once every 30 days; however, those licensees defined in Rule 1.2(M) may re-evaluate patients once every 90 days. A recording of weight, BMI, blood pressure, pulse, and/or any other test which may be necessary for monitoring potential adverse effects of drug therapy should be completed at each visit. Once medically established goals have been met for an individual patient, the need for ongoing medication should be re-evaluated and documented in the record.
- E. Continuation of the prescribing, ordering, dispensing, or administering of controlled substances should occur only if the patient has continued progress toward achieving or maintaining medically established goals and has no significant adverse effects from the medication.
- F. A licensee must not utilize a schedule III, IV or V controlled substance or legend drug for purposes of weight loss unless it has an FDA approved indication for this purpose and then only in accordance with all of the above enumerated conditions. The purpose of this rule is to prohibit the use of such drugs as diuretics and thyroid medications for the sole purpose of weight loss.

Off-label use of any medication that does not have Food and Drug Administration approval for use in the treatment of weight loss is prohibited if administered solely for the purpose of weight loss. Thyroid hormone, diuretics, vitamin B12, B1, B2, B6, methionine, choline, inositol, chromium picolate and human chorionic gonadotropin are examples of medications that may not be used in this manner. This prohibition does not apply to FDA categories of nutritional supplements sold without prescription.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

### Rule 1.6 Bariatric Medicine, /Medical Weight Loss, or Weight Management Practice

- A. No bariatric medicine, medical weight loss, or weight management practice shall operate in Mississippi unless the owner or operator of the facility is a Mississippi licensed physician. This licensee must meet all requirements below at all times while the facility is in operation. For the purposes of this rule, physicians who collaborate with mid-level providers will be considered an operator of the practice in the context of that collaborative arrangement.
- B. The physician owner/operator of the bariatric medicine, medical weight loss, weight management practice must register with the MSBML using a form prescribed by the board. Certificates of registration once issued are not transferable or assignable. Only the primary physician is required to register with the Board. All licensees associated with the practice, whether in the capacity as the owner or as a practitioner, must be listed on the application and must also meet all regulations governing the treatment of obesity/medical weight loss. Physicians who are added to the registration once a certificate is issued must be reported to the MSBML for approval prior to beginning practice. Physicians who are removed from the registration must be reported to the board within 30 days of removal. Each practice location requires a separate registration certificate.
- C. A bariatric medicine, medical weight loss, or weight management practice may not operate in the state of Mississippi without obtaining a registration certificate from the Mississippi State Board of Medical Licensure.
- D. Certificates are valid for one year and must be renewed annually along with practitioner's license to practice medicine in the state of Mississippi. There is a 30-day grace period for renewal after which the owner/operator must reapply for an original certificate. The clinic may not continue to operate while the certificate is expired.

If a physician's practice is a bariatric medicine, medical weight loss, or weight management practice as defined above or the physician collaborates, manages, oversees, or employs any licensed professional providing comprehensive treatment of obesity, the licensee must have 100 AMA or AOA Category 1 CME in the core-content of bariatric medicine or be currently certified by a board in bariatric medicine. A licensee currently practicing bariatric medicine, medical weight loss or weight management has 24 months from effective date of this regulation to comply with the initial CME requirement. All CME must be obtained within the 24 month period. Reference is made to exclusions noted in Rule 1.2, H.

Licensee must biennially obtain 60 AMA or AOA Category 1 CME in core-content of bariatric medicine before certification can be renewed with the MSBML.

E. A Medical Spa practice, Wellness practice, or other practice that meets the definition of Bariatric Medicine, Medical Weight Loss, or Weight Management Practice will be subject to all rules pertaining to Bariatric Medicine, Medical Weight Loss, or Weight Management Practice if the facility has a Mississippi licensee affiliated in any manner.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

#### Rule 1.7 Use of Controlled Substances for Chronic (Non-Terminal) Pain.

The following rules are not intended to supersede or exempt licensees from the requirements heretofore stated in Rule 1.4 *Maintenance of Records and Inventories*.

# A. Definitions

For the purpose of Part 2640, Rule 1.7 only, the following terms have the meanings indicated:

- 1. "<u>Chronic Pain</u>" is a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending licensee and one or more licensee specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain. Further, if a patient is receiving controlled substances for the treatment of pain for a prolonged period of time (more than three months), then they will be considered for the purposes of this regulation to have "de facto" chronic pain and subject to the same requirements of this regulation. "Terminal Disease Pain" should not be confused with "Chronic Pain."
- 2. "<u>Terminal Disease Pain</u>" is pain arising from a medical condition for which there is no possible cure and the patient is expected to live no more than six (6) months.
- 3. "<u>Acute Pain</u>" is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. Acute pain is generally self-limited and is responsive to therapies, including controlled substances.
- 4. "<u>Addiction</u>" is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm.
- 5. "<u>Physical Dependence</u>" is a physiological state of neuroadaptation to substance which is characterized by the emergence of a withdrawal syndrome if the use of the substance is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by re-administration of the substance.
- 6. "<u>Substance Abuse</u>" is the use of any substance for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.
- 7. "<u>Tolerance</u>" is a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Tolerance occurs to different degrees for various drug effects, including sedation, analgesia and constipation. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia.
- B. A licensee may order, prescribe, administer, or dispense controlled substances, or other drugs having addiction-forming and addiction-sustaining liability to a person for the treatment of chronic pain.
- C. The ordering, prescribing, administration, or dispensation of controlled substances, or other drugs having addiction-forming or addiction-sustaining liability for the treatment of chronic pain should be done with caution. A licensee may order, administer, dispense or prescribe said medications for the purpose of relieving chronic pain, provided that the following conditions are met:

- 1. Before initiating treatment with a controlled substance, or any other drug having addiction-forming or addiction-sustaining liability, the licensee must conduct a risk/benefit analysis by reviewing records of prior treatment. The risk/benefit analysis should weigh in favor of treatment and indicate the need for controlled substance therapy. Such a determination must take into account the specifics of each patient's diagnosis, past treatments, suitability for long-term controlled substance, with the need for other treatment modalities. The results of this analysis must be clearly entered into the patient medical record and must include supporting documentation such as consultation or referral reports and efforts to determine the underlying etiology of the chronic pain.
- 2. Documentation in the patient record must include a complete medical history and physical examination and supporting studies and reports of consultation.
- 3. The diagnosis must demonstrate the presence of one or more recognized medical indications for the use of controlled substances.
- 4. Documentation of a written treatment plan which must contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments. The plan must contain an informed consent agreement for treatment that details relative risks and benefits of the treatment course. The consent must also include specific requirements of the patient, such as using one licensee and pharmacy, urine/serum medication level monitoring when requested, pill counts, and the grounds for which the treatment may be terminated (e.g., 'doctor shopping' behavior, adverse urine/serum screens, etc.).
- 5. Periodic review and documentation of the treatment course is conducted no less frequently than every 3 months. The licensee's evaluation of progress toward the stated treatment objectives must support all changes in therapy. This should include referrals and consultations as necessary to achieve those objectives.
- D. No licensee shall order, administer, dispense or prescribe a controlled substance or other drug having addiction-forming and addiction-sustaining liability that is nontherapeutic in nature or non-therapeutic in the manner the controlled substance or other drug is administered, dispensed or prescribed.
- E. No licensee shall order, administer, dispense or prescribe a controlled substance for treatment of chronic pain to any patient who has consumed or disposed of any controlled substance or other drug having addiction-forming and addiction-sustaining liability other than in strict compliance with the treating licensee's directions. These circumstances include those patients obtaining controlled substances or other drugs having addiction-forming and addiction-sustaining liability from more than one licensee or healthcare provider and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other drug having addiction-sustaining liability before a prior prescription should have been consumed according to the treating licensee's directions. This requirement will not be enforced in cases where a patient has legitimately temporarily escalated a dose due to an acute exacerbation if the treating licensee documents that the escalation was due to a recognized indication and was within appropriate therapeutic dose ranges. Repetitive or continuing escalations should be a reason for concern and a re-evaluation of the present treatment plan must be undertaken by the licensee.

- F. No licensee shall order, prescribe, administer, or dispense any controlled substance or other drug having addiction-forming or addiction-sustaining liability for the purpose of "detoxification treatment" or "maintenance treatment" and no licensee shall order, prescribe, administer, or dispense any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" unless the licensee is registered in accordance with Section 21 U.S.C. 823(g). Nothing in this paragraph shall prohibit a licensee from administering narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Nothing in this paragraph shall prohibit a licensee from ordering, prescribing, administering, or dispensing controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.
- G. When initiating opioid therapy for chronic pain, the licensee must first run a MPMP on the patient. The licensee must prescribe the lowest effective dosage. While there is no single dosage threshold identified below which the risk of overdose is eliminated, licensees must strive to keep daily opioid doses less than or equal to 50 mg of morphine equivalence (mEq), as dosages larger than 50 mEq per day increases risk without adding benefits for pain control or function. Licensees must avoid dosages greater than or equal to 90 mg of morphine equivalence per day and must provide significant justification for exceeding the 90 mg ceiling stated herein. If the licensee determines that a patient requires greater than 100 mg of morphine equivalence per day, the licensee must refer the patient to a pain specialist for further treatment.
- H. When opioids are prescribed for acute pain, the licensee must prescribe the lowest effective dose of immediate release opioids, as the use of long acting opioids for acute non-cancer/non-terminal pain is prohibited. Licensees must prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Licensees are discouraged from prescribing or dispensing more than a three (3) day supply of opioids for acute non-cancer/non-terminal pain. And must not provide greater than a ten (10) day supply for acute non-cancer/non-terminal pain. Licensees may issue an additional ten (10) day supply if clinically necessary, but said supply must be issued in accordance with Title 21 CFR § 1306.12 *Refilling prescriptions; issuance of multiple prescriptions* (i.e., the prescription must be dated on the date of issuance with 'do not fill until' noting the date the prescription may be filled), and such need for an additional ten (10) day supply must be documented in the chart to evidence that no other alternative was appropriate or sufficient to abate the acute pain associated with that medical condition. Additional ten (10) day supplies, with one (1) refill, may be issued if deemed medically necessary and only if supported by additional clinical evaluation.
- I. As stated in Rule 1.3, every licensee must review an MPMP report at each patient encounter in which a Schedule II medication is prescribed for acute pain or chronic non-cancer/non-terminal pain. MPMP reports may be obtained by designees of the licensee as allowed by the MPMP program.
- J. When prescribing opioids for either chronic or acute pain, it is a relative contraindication (black box warning) to prescribe opioids concurrently with Benzodiazepines and/or Soma. However, opioids and benzodiazepines may be prescribed concurrently on a very short term basis, and in accordance with section H of this rule, when an acute injury

requiring opioids occurs. The need for such concurrent prescribing must be documented appropriately in the chart. Patients who are currently on an established regimen of concomitant opioids and benzodiazepines may be allotted a reasonable period of time to withdraw from one or both substances. Prescribing of opioids concurrently with benzodiazepines and/or Soma may be allowed only under very limited circumstances in which the combination is used to treat very specific chronic medical conditions for which there is no other treatment modality available.

- K. When a licensee treats chronic non-cancerous/non-terminal pain and/or psychiatric conditions outside the definition of a pain management practice (Rule 1.2) (K) the licensee must actively utilize the MPMP upon initial contact with a new patient and every 3 months thereafter on any and all patients who are prescribed, administered, or dispensed controlled substances. Reports generated on patients must span the length of time from the previous review of the MPMP so that adequate information is obtained to determine the patient's compliance for and with treatment. Documentation, such as a copy of the report itself and/or reflections in the charts dictation and/or notes must be kept within the patient's record and made available for inspection upon request.
- L. Point of service drug testing must be done at least three (3) times per calendar year when Schedule II medication is written for the treatment of chronic non-cancer/non-terminal pain. Point of service drug testing and MPMP review, as described in Rule 1.7 (K), must be done at least three (3) times per calendar year for patients prescribed benzodiazepines for chronic medical and/or psychiatric conditions which are non-cancer/non-terminal. Point of service drug testing must test, at a minimum, for opioids, benzodiazepines, amphetamines, cocaine, and cannabis. Inpatient treatment, as defined in Rule 1.2(L), is exempt from this requirement. Further, all hospice treatment is exempt from point of service drug testing requirements stated herein.
- M. The use of Methadone to treat acute non-cancer/non-terminal pain is prohibited. The use of Methadone for the treatment of chronic non-cancer/non-terminal pain is permissible within a registered Pain Management Practice, as defined in Rule 1.2(K), or when resulting from a referral to a certified pain specialist. If Methadone is prescribed to treat chronic non-cancer/non-terminal pain, it must be prescribed only by a physician.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.8 Drug Maintenance Requirements.* All medications maintained or stored in licensee's office must be maintained or stored in the manufacturer's or re-packager's original container. The label of any container in which drugs are maintained must bear the drug name, strength, the manufacturer's control lot number and the expiration date. Drugs that are pre-counted and prepackaged for purposes of dispensing must be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained must not be labeled in any false or misleading manner. The labeling requirements of this rule are in addition to all other applicable state and federal statutes and regulations.

A physician must not dispense out-of-date medications. Out-of-date medications must be promptly removed from current stock and stored separately until proper disposal. A physician, when dispensing a product in a manufacturer's original package or container must dispense the product with this information intact.

The medication storage and dispensing areas must be maintained in a sanitary fashion. All medications must be maintained, stored and dispensed in such a manner as to maintain the integrity of the product.

A licensee must not accept the return for subsequent resale or exchange any drugs after such items have been taken from the premises where sold, distributed or dispensed and from the control of the licensee.

#### Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.9 Labeling Requirements for Dispensing Physicians.* For the purposes of this rule, a "dispensing physician" means any physician who dispenses to a patient for the patient's use any controlled substance, legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made.

Every dispensing physician, as defined above, who dispenses a controlled substance, legend drug or any other medication must insure that all such substances dispensed be labeled containing the following information:

- A. The name of the patient to whom the medication was dispensed.
- B. The date that the medication was dispensed.
- C. The name, strength and quantity of the medication.
- D. Direction for taking or administering the medication.
- E. The name and address of the physician dispensing the medication.

The label required by this rule must be written in legible handwriting or typed and must be permanently affixed to the package or container in which the medication is dispensed. Prepackaged samples or starter packs in their original packages or containers need only have the patient name, date distributed, and physician's name if the manufacturer's packaging meets other requirements.

No physician may delegate dispensing authority to another person. A physician must personally dispense the medication. For the purpose of this regulation, "personally dispense" means the physician must actually obtain the medication, prepare, count, place the same into the appropriate container and affix the appropriate label to the container.

#### Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.10 Prescription Guidelines–Controlled Substances.* It is the responsibility of the licensee to determine the type, dosage, form, frequency of application and number of refills of any controlled substances prescribed to a patient. The following requirements apply to all prescriptions for controlled substances written by a licensee with controlled substance prescriptive authority:

- A. All prescriptions for controlled substances must be written in strict compliance with Mississippi Code, Sections 41-29-101 through 41-29-311 and Title 21 of U.S. Code of Federal Regulations, Part 1306.
- B. On all prescriptions of controlled substances wherein refills are permitted, licensees must indicate the appropriate refills, not to exceed five (5), or mark "none."
- C. Each licensee must insure that the complete name and address of the patient to whom the licensee is prescribing the controlled substance appears on the prescription.
- D. A licensee must not permit any prescription for controlled substances to be signed by anyone in the place of or on behalf of the licensee.
- E. A licensee must not pre-sign prescription pads or order forms.
- F. A licensee must not utilize prescription pads or order forms upon which the signature of the licensee has been affixed by any means other than manual signature. This prohibition includes the e-mailing of any controlled substance prescription. A hard copy prescription generated from an electronic prescription system must contain a manual signature unless: (i) the prescription is printed on security paper that ensures it is not subject to copying or alteration, and (ii) an electronic or digital signature is affixed. Electronic transmission of Schedule III-V controlled substance prescription information is limited to computer to facsimile (fax) transmissions or traditional fax to fax transmissions. Electronic transmission of Schedule II controlled substance prescription information is permitted under limited circumstances. Requirements for fax prescription orders and systems utilized for faxing prescriptions are as follows:
  - 1. The prescription order must contain the date, time, telephone number and location of the transmitting device. Prescription blanks utilized in this manner must bear a preprinted heading that indicates the blank is a "Fax Prescription Form." Fax prescription orders must contain a manual or authenticated electronic/digital signature of the prescriber. Only Schedule II narcotic substances that are to be prepared or compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intra spinal infusion may be transmitted by the licensee or the licensee's agent to a pharmacy of the patient's choice by facsimile. All original hardcopy faxed prescriptions must immediately be voided after successfully completing the fax transmission by writing across the face of the prescription from corner to corner the notation "faxed." The original prescription (or copy) must be retained in the licensee's patient file with additional information included on the back of the prescription as to the date it was faxed, the name or initials of the person faxing the prescription and the name/location of the pharmacy receiving the fax transmission.

In addition to filing the original prescription (or copy) in the patient file, a perpetual, chronological logbook of fax transactions must be established and maintained. Such a logbook would serve to protect the prescribing licensee in the event the original prescription is somehow lost or misfiled. The information contained in such a logbook must include the patient's name and address, date of issuance, name, strength and quantity of the drug prescribed and the name and fax number of the receiving pharmacy and a personal identifier of the person faxing the prescription. Such logs must be maintained in the licensee's clinic in a readily retrievable manner, and kept

for at least seven (7) years after the original record is established. The requirements set forth in this rule are in addition to documentation required in Part 2640, Rule 1.4.

- 2. When prescribing any controlled substance for a resident of a Long-term Care Facility (LTCF)(as defined in Section 1301.01(25), Code of Federal Regulations), such prescription may be transmitted by the licensee or the licensee's agent to the dispensing pharmacy by facsimile. The licensee or the licensee's agent must note on the prescription that the patient is a resident of a LTCF. The original prescription (or copy) and fax transaction log will be prepared and maintained in the same manner as described in Part 2640, Rule 1.10.F.1.
- 3. When prescribing any controlled substance for a patient residing in a hospice certified by Medicare under Title XVIII or licensed by the state, such prescription may be transmitted by the licensee or the licensee's agent to the dispensing pharmacy by facsimile. The licensee or the licensee's agent must note on the prescription that the patient is a hospice patient. The original prescription (or copy) and fax transmission log will be maintained in the same manner as described in Part 2640, Rule 1.10.F.1.
- G. No more than one (1) controlled substance shall be issued on a single prescription blank.
- H. Prescriptions for Benzodiazepines must be limited to a one (1) month supply, with no more than two (2) refills, or a ninety (90) day supply with no refills. The MPMP must be checked each time a prescription for benzodiazepines is authorized and evidence of such check must be noted within the patient file.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.11 Prescription Guidelines - All Medications.* In addition to any other requirements set forth in these rules pertaining to the issuance of prescriptions of controlled substances, the following additional requirements apply to all prescriptions, whether or not said prescriptions are for controlled substances, legend drugs or any other medication:

- A. Prescriptions may not be written outside of a valid licensee-patient relationship. While not all of the elements in subsection A are necessary each time a prescription is authorized (e.g., via appropriate telemedicine as defined in Rule 5.5 of Part 2635, calling in refills, taking call for a practice partner for short term care, etc.), all initial encounters, and at reasonable intervals thereafter, should conform to this rule and be done pursuant to a valid licensee-patient relationship. The elements of this valid relationship are:
  - 1. verify that the person requesting the medical treatment is in fact who they claim to be;
  - 2. conducting an appropriate history and physical examination of the patient that meets the applicable standard of care;
  - 3. establishing a diagnosis through the use of accepted medical practices, i.e., a patient history, mental status exam, physical exam and appropriate diagnostic and laboratory testing;
  - 4. discussing with the patient the diagnosis, risks and benefits of various treatment options to obtain informed consent;
  - 5. insuring the availability of appropriate follow-up care; and
  - 6. maintaining a complete medical record available to patient and other treating health care providers.

- B. Electronic prescription transmission is permitted provided the transmission meets applicable state and federal standards for transmission. E-prescribing is the electronic entry of a prescription by a licensee, the secure electronic transmission of the prescription to a pharmacy, the receipt of an electronic message by the pharmacy and E-prescription renewal requests sent electronically by the pharmacy to the practitioner.
- C. Every written prescription delivered to a patient, or delivered to any other person on behalf of a patient, must be manually signed on the date of issuance by the licensee. This does not prohibit the transmission of electronic prescriptions and telefaxed prescriptions (but not e-mail) for non-controlled drugs to the pharmacy of the patient's choice. Such telefaxed or electronic prescriptions must be authorized by a written or electronic signature and must be issued in accordance with all other provisions of this rule. No prescriptions for any form or compound containing nalbuphine HCl, carisoprodol, butalbital compounds, or tramadol HCl shall be telefaxed.
- D. Electronic prescriptions for controlled substances are permitted if a practitioner has complied with the DEA requirements and is using a certified electronic prescribing system for the transmission of control substances prescriptions.
- All written prescriptions must be on forms containing two lines for the licensee's E. There must be a signature line in the lower right-hand corner of the signature. prescription form beneath which must be clearly imprinted the words "substitution permissible." There must be a signature line in the lower left corner of the prescription form beneath which must be clearly imprinted with the words "dispense as written." The licensee's signature on either signature line must validate the prescription and designate approval or disapproval of product selection. Each prescription form must bear the preprinted name of the licensee or the licensee must clearly print his or her name on the prescription form, in addition to the licensee's original signature. In the event that the prescription form bears the pre-printed name of more than one licensee, the licensee must clearly indicate the name of the licensee writing the prescription. In the case of a prescription that is electronically generated and transmitted, the licensee must make an overt act when transmitting the prescription to indicate either "dispense as written" or "substitution permissible". When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.
- F. If a prescription form which does not contain two signature lines required in Part 2640, Chapter 1, Rule 1.11.D is utilized by the licensee, he or she must write in his or her own handwriting the words "dispense as written" thereupon to prevent product selection.

Every written prescription issued by a licensee for a legend drug should clearly state whether or not the prescription should be refilled, and if so, the number of authorized refills and/or the duration of therapy. Licensee s should avoid issuing prescriptions refillable on "prn" basis. If a licensee chooses to issue a prescription refillable "prn", the life of the prescription or time limitation must clearly be set forth on the prescription. In no case shall a prescription which is refillable on a "prn" basis be refilled after the expiration of one (1) year. Regardless of whether a prescription is refillable on a "prn" basis or the prescription expressly states the number of authorized refills, the use of said medication should be re-evaluated on at least an annual basis. Upon the expiration of one (1) year, a prescription becomes invalid, regardless of the number of refills indicated or "prn" designation.

- G. Every written prescription issued by a licensee, bearing more than one non-controlled medication, must clearly indicate the intended refill instructions for each medication. Lack of clearly indicated refill instructions prohibit the refilling of the medications. All unused lines on a multi-line prescription blank must be clearly voided by the issuing licensee.
- H. A prescription will no longer be valid after the occurrence of any one of the following events:
  - 1. Thirty (30) days after the death of the issuing licensee.
  - 2. Thirty (30) days after the issuing licensee has moved or otherwise changed practice location resulting in termination of the licensee patient relationship. Termination of the licensee patient relationship results when a patient is no longer able to seek personal consultation or treatment from the issuing licensee.
  - 3. Immediately after loss of DEA Controlled Substances Privilege by the issuing licensee if the prescription is for controlled substances.
  - 4. Immediately upon revocation, suspension or surrender of the licensee's license.

#### Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.12 Freedom of Choice.* A licensee must not be influenced in the prescribing of drugs, devices or appliances by a direct or indirect financial interest in a pharmaceutical firm, pharmacy or other supplier.

A licensee may own or operate a pharmacy if there is no resulting exploitation of patients. A licensee must not give patients prescriptions in code or enter into agreements with pharmacies or other suppliers regarding the filling of prescriptions by code. Patients are entitled to the same freedom of choice in selecting who will fill their prescription needs as they are in the choice of a provider. The prescription is a written direction for a therapeutic or corrective agent. A patient is entitled to a copy of the licensee's prescription for drugs or other devices as required by the principles of medical ethics. The patient has a right to have the prescription filled by any legal means. Where medication is to be dispensed or a prescription, excluding refills, called in to a pharmacist for medication, a licensee must inform each patient of that patient's right to a written prescription and the right to have the prescription filled wherever the patient wishes.

Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. The prescription is an essential part of the patient's medical record. If a patient requests a written prescription in lieu of an oral prescription, this request must be honored. Licensees must not discourage patients from requesting a written prescription or urge, suggest or direct in any manner that a patient fill a prescription at an establishment which has a direct telephone line or which has entered into a business or other preferential arrangement with the licensee with respect to the filling of the licensee's prescriptions.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.13 Security of Controlled Substances.* In all clinics or offices within the control of a licensee, all controlled substances and other drugs having addiction-forming or addiction-sustaining liability must be maintained in such a manner as to deter loss by theft or burglary. All controlled substances must be stored in a securely locked, substantially constructed container or area. Only the physician or persons authorized by the physician shall have access to this storage area. When a licensee detects a loss of controlled substances, the Board may issue an order requiring that person to appear before the Board and present a plan designed to prevent further loss of controlled substances. The Board has the authority to order implementation measures to improve security over controlled substances.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

#### Rule 1.14 Pain Management Medical Practice.

- A. The pain management medical practice must have, at all times, a majority ownership (more than 50%) by a physician or group of physicians licensed by the Board, and/or a hospital or health care entity registered with the Secretary of State to do business in the state of Mississippi. The physician or physician owners must practice an annual average of at least 20 hours per week within the state of Mississippi.
- B. The pain management medical practice must register with the Board unless it meets the exceptions defined above.
- C. Each physician owner of a pain management medical practice must meet the requirements set forth below.
- D. Each licensee who serves as medical director, manager, or employee or who provides care in a pain management medical practice must meet the requirements set forth below.

Application for Initial Registration and Renewal - A physician owner of a pain management medical practice must:

- 1. submit the documents demonstrating proof of ownership or provide alternative documents with a written request for special consideration;
- report ownership or investment interest in any other pain management facility operating within the state of Mississippi and provide the name and address of the other pain management facility(ies) in which the physician has ownership or vested interest;
- 3. identify all individuals with prescriptive authority who are employed or contracted in any capacity at each facility; and
- 4. report any changes of information provided in the application for registration or renewal within 30 days of the effective date of the change.
- E. Physician owners or operators may not operate a pain management practice in the state of Mississippi without obtaining a certificate from the Mississippi State Board of Medical Licensure. Certificates, once issued, are not transferable or assignable. Only the primary physician owner is required to register with the Board if there is more than one physician owner of the practice. Additional physician owners must register if they also provide patient care. Each practice requires a separate certificate.

- F. Physician owners or operators may not operate a pain management practice in Mississippi unless the practice is owned or operated by a hospital or healthcare entity registered with the Secretary of State to do business in the state of Mississippi, or by a physician who:
  - 1. practices at least 20 hours per week providing direct patient care;
  - 2. holds an active unrestricted medical license ; and
  - 3. holds a certificate of registration for that pain management practice.
- G. No physician owners or operators of a pain management practice, nor any physician, nor any physician assistant, nor any medical director, manager, or employee or any physician or physician assistant who provides care may:
  - 1. have been denied, by any jurisdiction, a certificate permitting the licensee to order, prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions;
  - 2. have been issued, by any jurisdiction, a limited certificate to order, prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions;
  - 3. have been denied a certificate issued by the Drug Enforcement Administration (DEA) permitting the licensee to order, prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions;
  - 4. have been issued a limited certificate by the Drug Enforcement Administration (DEA) permitting the licensee to order, prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions;
  - 5. have been subject to a disciplinary action by any licensing entity for conduct that was a result of inappropriately prescribing, dispensing, administering, supplying or selling a controlled substance or the other listed medications under definitions; or
  - 6. have been terminated from Mississippi's Medicaid Program, the Medicaid program of any other state, or the federal Medicare program, unless eligibility has been restored.
- H. No physician or physician assistant may own, operate, or practice in a pain management medical practice who has been convicted of, pled nolo contendere to or received deferred adjudication for:
  - 1. an offense that constitutes a felony; or
  - 2. an offense that constitutes a misdemeanor, the facts of which relates to the illegal distribution or sale of drugs or controlled substances.
- Training requirements for all physicians practicing in pain management medical practices. Effective July 1, 2014, all physician owners or operators or any physician who serves as medical director, manager, or employee or who provides care in pain management medical practice must meet the qualifications set forth in subsections (1) through (5) below. All physicians prescribing or dispensing controlled substance medications in pain management practices registered by the Board must meet one (1) of the following qualifications:
  - 1. board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) or the American Board of Addiction Medicine (ABAM) and hold a subspecialty certification in pain medicine;
  - 2. board certification by a specialty board recognized by the American Osteopathic Association Bureau of Osteopathic Specialists (BOS) in pain management;

- 3. board certification in pain medicine by the American Board of Pain Medicine (ABPM);
- 4. successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, neurology, or neurosurgery and approved by the ACGME or the AOA; or
- 5. successful completion of 100 hours of inter-active live participatory AMA or AOA Category 1 CME courses in pain management.

Upon qualifying under any of the 5 subsections above, physicians must also document completion of 30 hours of Category 1 CME for renewal of a pain management medical practice certificate.

- a. CME must have emphasis in the specific areas of pain management, addiction, or prescribing of opiates.
- b. CME may be included with the forty hour requirement for licensure renewal.
- c. Excess hours may not be carried over to another two year cycle. For the purpose of this regulation, the two year period begins with the fiscal year July 1, 2014, and every two years thereafter to be concurrent with the licensure requirement.
- J. Physicians and physician assistants practicing in a registered pain management medical practice must be registered with the Mississippi Prescription Monitoring Program (MPMP). A report from the MPMP must be obtained on the initial visit for each patient. Subsequent reports must be obtained for each patient at every visit.
- K. Requirements for physician assistants practicing in pain management medical practices. Physician assistants must meet the following qualifications prior to practicing in a registered pain management practice:
  - 1. A Board approved protocol in the practice of pain management as required by Part 2615, Chapter 1, Rules 5 and 6, with a physician who holds a license that is not designated as limited, restricted, retired, temporary, or in-training;
  - 2. Physician assistants with approved prescriptive authority must obtain 10 hours as required by the licensure requirement plus 5 hours of Category 1 CME related to prescribing and pain management for every year the physician assistant is practicing in a pain management medical practice;
  - 3. Physician assistants with prescriptive authority must be familiar with and adhere to the Administrative Rule Pertaining to Prescribing, Administering and Dispensing of Medication, Part 2640, Chapter 1; and
  - 4. Physician assistants with prescriptive authority must be registered with the Mississippi Prescription Monitoring Program (MPMP).
- L. A physician who is a current participant in the Mississippi Professionals Health Program (MPHP) may not be the primary physician owner of a pain practice. This does not prohibit a MPHP participant from working in a pain practice.
- M. Prior to the initial issuance of an opioid and/or benzodiazepine for the treatment of chronic non-cancer/non-terminal pain, each patient in a pain management practice must have an in-person evaluation by a registered pain management physician.

- N. Certificates are valid for one year and must be renewed annually. There is a thirty-day grace period for renewal after which the owner or operator must reapply for an original certificate. The physician owner or operator of the practice must post the certificate in a conspicuous location so as to be clearly visible to patients. The practice may not continue to operate while the certificate has expired.
- O. The Board has the authority to inspect a pain management medical practice. During such inspections, authorized representatives of the Board, who may be accompanied by investigators from state or federal law enforcement agencies, may inspect documents and medical records to ensure compliance with any applicable laws and rules.
- P. If the Board finds that a registered pain management practice no longer meets any of the requirements to operate as a pain practice, the Board may immediately revoke or suspend the physician's certificate to operate a pain management medical practice. The physician owner or operator shall have the right to an administrative hearing before the Board at the next available and scheduled meeting of the Board. Further, the Board has the discretion to lift the suspension of a certificate when the pain management medical practice demonstrates compliance with applicable rules and regulations.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

# Rule 1.15 Violation of Rules.

The prescribing, administering or dispensing of any controlled substance in violation of the above rules shall constitute the administering, dispensing or prescribing of any narcotic drug or other drug having addiction-forming or addiction-sustaining liability otherwise than in the course of legitimate professional practice, in violation of Mississippi Code, Section 73-25-29(3).

The prescribing, administering or dispensing of any legend drug or other medication in violation of the above rules constitutes unprofessional conduct, dishonorable or unethical conduct likely to deceive, defraud or harm the public, in violation of <u>Miss. Code Ann.</u>, § 73-25-29(8)(d).

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.16 Effective Date of Rules.* The above rules pertaining to prescribing, administering and dispensing of medication shall become effective October 31, 1987; as amended November 1, 1990; as amended January 3, 1994; as amended September 10, 1995; as amended June 30, 1996; as amended March 18, 1999; as amended May 20, 1999; as amended February 17, 2001; as amended March 22, 2001; as amended July 15, 2004; as amended October 14, 2004; as amended November 8, 2007; as amended May 15, 2008; as amended March 13, 2009; as amended March 24, 2011; as amended September 17, 2012; as amended September 19, 2013; as amended May 22, 2014; as amended November 13, 2015; and as amended March 22, 2018.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

Part 2640: Prescribing, Administering and Dispensing

# Part 2640 Chapter 1: Rules Pertaining to Prescribing, Administering and Dispensing of Medication

*Rule 1.1 Scope.* These rules apply to all individuals <u>who have prescriptive authority and are</u> licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of <u>Mississippi by the Mississippi State Board of Medical Licensure</u>.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.2 Definitions*. For the purpose of Part 2640, Chapter 1 only, the following terms have the meanings indicated:

- A. "<u>Administer</u>", "<u>Controlled Substances</u>", and "<u>Ultimate User</u>" shall have the same meaning as set forth in Mississippi Code, Section 41-29-105, unless the context otherwise requires.
- B. "Board" means the Mississippi State Board of Medical Licensure.
- C. "<u>Physician</u>" means any person licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi.
- D. <u>"Physician Assistant" means any person meeting the requirements of licensure in the state of Mississippi as required by Part 2617, Chapter 1.</u>
- E. "Licensee" means any person licensed by this Board who has prescriptive authority.
- F. <u>"Prescriptive Authority" means the legal authority of a professional licensed to practice in the state of Mississippi who prescribes controlled substances and is registered with the U. S. Drug Enforcement Administration in compliance with Title 21 CFR, Part 1301 Food and Drugs.</u>
- G. "<u>Prescribe</u>" means to designate or order by means of either a written or oral prescription the delivery of a controlled substance or legend drug to an ultimate user.
- H. "<u>Dispense</u>" means to deliver a controlled substance or legend drug other than by administering or prescribing to an ultimate user or research subject including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.
- I. For the purpose of enforcement of the labeling requirements set forth in this chapter, Part 2640, Rule 1.7.B, "<u>Dispensing Physician</u>" means any physician who shall dispenses to a patient for the patient's use any controlled substance, legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made. <u>As stated in Part 2617, it is understood that Physician Assistants may not dispense medications.</u>
- J. "<u>Prescription Drug</u>" or "<u>Legend Drug</u>" means a drug required under federal law to be labeled with the following statement prior to being dispensed or delivered; "Caution:

Federal law prohibits dispensing without prescription," or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by physicians licensees only.

- K. "<u>Pain Management Clinie-Practice</u>" means a public or privately owned facility practice for which the majority (530% or more) of the patients are issued, on a monthly regular or recurring basis, a prescription for opioids, barbiturates, benzodiazepines, carisoprodol, butalbital compounds, or tramadol for the treatment of chronic non-cancerous/nonterminal pain. Included in this definition shall be is any practice that advertises and/or holds itself out to provide pain management services. Physicians or practices that treat patients for pain resulting from a terminal illness are excluded from this definition. Patients who are treated for pain resulting from a terminal illness do not count against the percentage stated herein.
- L. "<u>Inpatient</u>" means a patient in a hospital, nursing home, long term care facility, inpatient (not home-bound) hospice, or any other facility wherein medications are dispensed to a patient by a third party who is duly licensed and/or certified to dispense medications in a healthcare or related facility.
- M. "Bariatric Medicine, Medical Weight Loss, or Weight Management Clinic Practice" means a public or privately owned facility practice.
  - 1. for which 30% or more of the patients are provided a comprehensive weight management treatment program <u>or;</u>
  - 2. 30% or more of the patients receive any controlled substance approved by the FDA for the pharmacologic management of weight loss or;
  - 3. any clinic operated by, staffed by, or affiliated with through affiliation, employment, or collaboration agreement with a Mississippi licensee or; which advertises weight loss by any means.

Excluded from this definition is any practice in which a licensee advertises the use of nonpharmacological products as part of the licensee's overall practice of medicine. In order to be excluded from this definition, the licensee's practice shall must have nonpharmacological weight loss and/or weight loss management as a component of the overall management of the patient's total health care. If the use of nonpharmacological products for weight loss and/or weight management exceeds 30% of the total outpatient clinic visits for any single 90-day consecutive period, the practice shall will be considered a bariatric medicine/medical weight loss practice and shall will be subject to all the rules and regulations pertaining to bariatric medicine/medical weight loss practice.

Bariatric surgeons whose primary practice is surgical weight loss and not long-term management of weight loss through medical, pharmaceutical, and/or behavioral management are also excluded from this definition.

N. Advertised medical weight loss must include behavior modification, comprehensive nutritional education, exercise or physical therapy intervention, long term maintenance programs, dispensing and/or prescribing FDA-approved medications as indicated for weight loss on a monthly basis as part of the patient's treatment plan.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.3 Registration for Controlled Substances Certificate.* Every physician licensee licensed to practice in Mississippi who prescribes, administers or dispenses any controlled substance within Mississippi or who proposes to engage in the prescribing, administering or dispensing of any controlled substance within Mississippi must be registered with the U.S. Drug Enforcement Administration in compliance with Title 21 CFR Part 1301 Food and Drugs.

In addition, that physician must be registered with the Mississippi Prescription Monitoring Program (MPMP) by December 31, 2013. Each individual who is licensed by the Mississippi State Board of Medical Licensure and has prescriptive authority must be registered with the Mississippi Prescription Monitoring Program (MPMP). Every licensee who provides medical care in a pain management practice as defined in Rule 1.2 (GK) shall-must review the MPMP at each patient encounter in which a prescription for a controlled substance is issued. Every licensee, regardless of practice specialty, shall-must review the MPMP at each patient encounter in which an opioid is prescribed for acute and/or chronic non-cancerous/non-terminal pain. Those licensees whose practice is not a pain management practice as defined previously shallmust actively utilize the MPMP upon initial contact with new patients and at least every three (3) months thereafter on any and all patients who are prescribed, administered, or dispensed controlled substances other than opioids. Licensees who issue a prescription for Lomotil, Lyrica, Testosterone, or Amphetamines prescribed to pediatric patients under the age of sixteen (16) for the treatment of ADHD, are not required in that instance to utilize the MPMP as stated herein.

Reports generated on such patients should span the length of time from the previous review of the MPMP so that adequate information is obtained to determine patient compliance with treatment. Documentation, such as a copy of the report itself and/or reflection in the chart dictation and/or notes, shallmust be kept within the patient's record and made available for inspection upon request. As allowed by the Mississippi Board of Pharmacy and the MPMP, properly registered designees of the licensee may run/obtain the report for the licensee's review as required herein.

In addition, licensees required to register under this section shall also utilize the MPMP to generate a global report to review their entire practice as a whole at least yearly. Documentation of the global report shall be kept in a separate file to be available for inspection upon request.

Utilization of the MPMP as stated herein is not required when treating inpatient; however, upon discharge from said inpatient setting with a prescription for a controlled substance, the MPMP must be reviewed as required herein.

Pursuant to authority granted in Mississippi Code, Section 41-29-125, the Mississippi State Board of Medical Licensure hereby adopts, in lieu of a separate registration with the Board, the registration with the U.S. Drug Enforcement Administration as required in the above paragraph. In the event, however, a physician licensee has had limitations or other restrictions placed upon his or her license wherein he or she is prohibited from handling ordering, dispensing, or prescribing controlled substances in any or all schedule, said physician licensee shall be prohibited from registering with the U.S. Drug Enforcement Administration for a Uniform

Controlled Substances Registration Certificate without first being expressly authorized to do so by order of the Mississippi State Board of Medical Licensure.

Persons registered to prescribe, administer, dispense or conduct research with controlled substances may order, possess, prescribe, administer, dispense or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of these rules and in conformity with provisions of the Mississippi Uniform Controlled Substances Law, Mississippi Code, Sections 41-29-101 et seq.

The registration requirement set forth in these rules does not apply to the distribution and manufacture of controlled substances. Any <u>physician licensee</u> who engages in the manufacture or distribution of controlled substances or legend drugs <u>shallmust</u> register with the Mississippi State Board of Pharmacy pursuant to Mississippi Code, Section 73-21-105 <u>and shallwill be</u> <u>subject to all applicable federal statutes and regulations controlling such practices</u>. For the purposes herein, "distribute" <u>shall means</u> the delivery of a drug other than by administering, prescribing or dispensing. The word "manufacture" <u>shall hasve</u> the same meaning as set forth in Mississippi Code, Section 41-29-105(q).

#### Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.4 Maintenance of Records and Inventories.* Every physician licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippilicensee shall maintain inventories, logs, and records prescribed in this rule.

- A. Controlled substances inventory record. All controlled substances classified under Schedules II, IIN, III, IIIN, IV and V which are purchased by the physician licensee must be inventoried at least every two (2) years. All inventory records for controlled substances in Schedules II and IIN must be maintained separately from the inventory records for Schedules III, IIIN, IV and V controlled substances. To insure the reliability of an inventory, the physician shall<u>must</u> maintain a readily retrievable record of controlled substances purchased, including a copy of all purchase invoices identifying the name, quantity and strength/dose of the controlled substance purchased, the supplier and the date purchased. <u>Controlled substances inventory must also meet all applicable federal statutes and regulations.</u>
- B. Controlled substances dispensation/administration record. Every physicianlicensee who shall dispenses or administers, Schedules II, IIN, III, IIIN, IV and V controlled substances shallmust maintain a separate readily retrievable record of all such substances dispensed or administered. This requirement shalldoes not apply to Schedules III, IIIN, IV and V prepackaged samples and starter packs. All dispensation/administration records for controlled substances in Schedules II and IIN must be maintained separately from the dispensation/administration records for Schedules III, IIIN, IV and V controlled substances. The record shallmust contain the following information:
  - 1. The date the controlled substance was dispensed or administered.
  - 2. The name, quantity and strength/dose of the controlled substance dispensed or administered.
  - 3. The method of administration of the controlled substance, i.e. oral, IV or subcutaneous.

- 4. The name and address of the patient to whom the controlled substance was dispensed or administered.
- 5. For all Schedules II and III amphetamines, amphetamine-like anorectic drugs, or sympathomimetic amine drugs dispensed in the treatment of narcolepsy, hyperkinesis, brain dysfunction, epilepsy, or depression, the dispensing or administration records shallmust include the diagnosis and the reason for use of the Schedules II and III controlled substances.

Controlled substances dispensation/administration records must also meet all applicable federal statutes and regulations.

Within thirty (30) days after the effective date of this rule the Mississippi State Board of Medical Licensure shall cause a notice to be mailed to every physician whose practice location is in the state of Mississippi notifying them of the Controlled Substance Inventory and separate Dispensation/Administration Record. Every physician shall within ninety (90) days of the effective date of this rule, prepare an initial inventory of controlled substances. An example combination Controlled Substances Inventory Record and Controlled Substances Dispensation/Administration Record are hereby incorporated as Appendixes "C" and "D" to these rules.

Patient Record - A <u>physicianlicensee</u> who prescribes, dispenses or administers a <u>legend drug or</u> controlled substance <u>shallmust</u> maintain a complete record of his or her examination, evaluation and treatment of the patient which must include documentation of the diagnosis and reason for prescribing, dispensing or administering any <u>legend drug or</u> controlled substance; the name, dose, strength, quantity of the <u>legend drug or</u> controlled substance and the date that the <u>legend drug or</u> controlled substance was prescribed, dispensed or administered. The record required by this rule <u>shallmust</u> be maintained in the patient's medical records.<del>, provided that such If</del> medical records are maintained at the office of the <u>physician licensee</u>, the records must be <u>and are</u> available for inspection by the representatives of the Mississippi State Board of Medical Licensure <del>pursuant to authority granted in Mississippi Code, Section 41-29-125</del>.

No physician Licensees shallmust not prescribe, administer or dispense any legend drug; any controlled substance; or other any drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication therefore. A determination as to whether a "good faith prior examination and medical indication therefore" exists depends upon the facts and circumstances in each case. One of the primary roles of a physician is to elicit detailed information about the signs and symptoms which a patient presents in order that he or she may recommend a course of treatment to relieve the symptoms and cure the patient of his or her ailment or maintain him or her in an apparent state of good health. In order for a physician licensee to achieve a proper reasonable diagnosis and treatment plan, a history and physical examination consistent with the nature and of the complaint are necessary. The importance of these aspects of proper medical practice cannot be over emphasized. The paramount importance of a complete medical history in establishing a correct diagnosis is well established. Standards of proper medical practice require that, upon any encounter with a patient, in order to establish proper diagnosis and regimen of treatment, a physician licensee must take three steps: (a) take and record an appropriate medical history, (b) carry out an appropriate

physical examination, and (c) record the results. The observance of these principles as is an integral component function of the "course of legitimate professional practice."

Some of the factors used in determining the existence presence or absence of "good faith" may include, but are not limited to:

- 1. the quality and extent of the documented history and physical exam;
- 2. <u>the extent to which the prescribed therapy is supported by documented history and physical exam;</u>
- 3. <u>the physician licensee's permitting the patient to name the drug desired;</u>
- 4. <u>a physicianlicensee dispensing or prescribing drugs to patients having no medical need,</u> <u>when the physicianlicensee knew or should have known that the patients were addicts or</u> <u>abusing/misusing substances;</u>
- repeated refills over relatively short periods of time or the issuance of prescriptions at a time when the patient should not have been finished taking the same medication from a prior prescription had the prescription directions been properly followed or the correct dosage taken;
- 6. <u>general remarks of the physicianlicensee indicating his or her experience with non-</u> <u>therapeutic uses of the drug;</u>
- 7. <u>a licensee prescribing contraindicated medication such as amphetamines and depressants</u> <u>in a manner which results in therapeutic conflicts.</u>

The aforementioned is of particularly of importance in cases in which controlled substances are to play a part in the course of treatment. It is the responsibility of the physician licensee to dispense, prescribe or administer such drugsall therapies with proper regard for the actual and potential dangers. This fact has been established in a number of closely related administrative and criminal cases, United States v. Bartee, 479 F.2d 484 (10th Cir. 1973) (No physical examination prior to issuance of prescriptions for controlled substances); United States v. Greene, 511 F.2d 1062 (7th Cir. 1975); Arthurs v. Board of Registration of Medicine, 418 N.E. 2d 1236 (MA 1981) (failure to record in patient file prescriptions for controlled substances issued or failure to record patient visit); Brainard v. State Board of Medical Examiners, 157 P2d 7 (Ca. 1945); Dannerberg v. Board of Regents, 430 N.Y.2d 700 (1980) (issuance of three prescriptions for sleeping pills to an undercover agent without a physical examination; Widlitz v. Board of Regents of New York, 429 N.Y. 2d 794 (1980) (issuance of Desoxyn to patients whom physician knew were drug addicts without conducting physical examination); United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975) (no physical examination, evidences that prescriptions were not in course of professional practice); and United States v. Hooker, 541 F.2d 300 (1st Cir. 1976), (little more than cursory physical examination, frequent neglect to inquire as to past medical history, little or no exploration of the type of problem the patient allegedly had "indicates that the minimal professional procedures followed were designed only to give an appearance of propriety to appellant's unlawful distributions").

A determination of proper "medical indication": also requires a careful examination of the nature of the drug therapy and all circumstances surrounding dispensation its implementation. Use of any therapy should be supported by standards of medical practice, reasonable scientific evidence or consensus and documented in the medical record. Case law developed by the courts in connection with controlled substances criminal violations and administrative decisions further

illustrates several indications of lack of good faith. See **United States v. Greene**, 511 F.2d 1062 (7th Cir. 1975) and **United States v. Rosenburg**, 515 F.2d 190 (9th Cir. 1975). One of primary importance is the failure to follow at least the minimal professional procedures. Some of the factors used in determining the existence of "good faith" may include, but are not limited to: (a) the physician's permitting the patient to name the drug desired; (b) a physician dispensing drugs to patients having no medical need, when the physician knew or should have known that the patients were addicts; (c) repeated refills over relatively short periods of time or the issuance of prescriptions at a time when the patient should not have been finished taking the same medication from a prior prescription had the prescription directions been properly followed or the correct dosage taken; (d) general remarks of the physician indicating his or her experience with non-therapeutic uses of the drug; (e) a physician prescribing contraindicated medication such as amphetamines and depressants in a manner which results in therapeutic conflicts

A <u>physicianlicensee</u> <u>shallmust</u> not sell or trade any medication which he or she receives as prepackaged samples or starter packs, whether or not said samples are controlled substances, legend drugs or other medication.

The Controlled Substances Inventory, Controlled Substance Dispensation/Administration Record, and Patient Record required by these rules <u>shallmust</u> be maintained in the office of the <u>physicianlicensee</u> for a period of seven (7) years from the date that the record is completed or the controlled substances, legend drugs or other medications are prescribed, administered or dispensed and <u>shallmust</u> be made available for inspection by representatives of the Mississippi State Board of Medical Licensure pursuant to authority granted in Mississippi Code, Section 41-29-125. Record retention for Controlled Substances Inventory, Controlled Substance Dispensation/Administration Record, and Patient Record must also meet all applicable federal statutes and regulations. In cases where Mississippi and federal requirements conflict, the latter shall control.

A <u>physicianlicensee</u> may use a data processing system or a manual record keeping system for the storage and retrieval of Controlled Substances Dispensation/Administration Records. If a <u>physicianlicensee</u> utilizes a data processing system, it must provide immediate retrieval of all dispensation/administration records of controlled substances.

Whether maintained manually or in a data processing system, all records of dispensation/administration of controlled substances must be readily retrievable. If a data processing system is utilized, a hard-copy printout of the records of dispensation/administration shall<u>must</u> be made at regular intervals, not to exceed seven (7) days. Such hard-copy printouts shall<u>must</u> be maintained for a period of five (5) years and shall<u>must</u> be made available for inspection and copying by investigators of the Mississippi State Board of Medical Licensure.

# Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.5 Use of Diet Medication.* Pursuant to Mississippi Code, Section 41-29-139(e), it is unlawful for any physician licenseein this state to prescribe, dispense or administer any amphetamine or amphetamine-like anorectic and/or central nervous system stimulantmedication classified as Schedule II, pursuant to Section 41-29-115, for the exclusive treatment of obesity, weight control, or weight loss.

The Board of Medical Licensure is obligated under the laws of the state of Mississippi to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including those used for the purpose of weight reduction, may lead to drug diversion and abuse by individuals who seek drugs for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

Prescribing or dispensing a controlled substance for weight reduction or the treatment of obesity should be based on accepted scientific knowledge and sound clinical grounds. All such prescribing and dispensing should <u>must</u> be in compliance with applicable state and federal laws.

The physicianlicensee and/or nurse practitioner/physician assistant being overseen/collaborating to-provideing comprehensive treatment of obesity shallmust be present at the facility when he or she prescribes or dispenses<sup>2</sup> controlled substances for the purpose of weight reduction or the treatment of obesity. As to the administration, dispensation or prescription of controlled substance anorectics in Schedules III, IV and V, use of said medications in the treatment of obesity or weight loss should be done with caution. A physicianlicensee may administer, order, dispense or prescribe said medicationscontrolled substances for the purpose of weight loss in or the treatment of obesity only as an adjunct to a regimento a clearly documented comprehensive program of behavior modification, comprehensive nutritional education, and exercise or physical therapy intervention. weight reduction based on caloric restriction, provided The physicianlicensee must complies comply with the following and that all of the following conditions are met:

- A. An initial comprehensive evaluation is to be conducted by and thoroughly recorded by the prescribing <u>physicianlicensee</u> and/or mid-level provider prior to the prescribing, ordering, dispensing or administering of any drug. Such evaluation should include a thorough history and thorough physical exam of the patient to include at a minimum:
- 1. Past medical history, past surgical history, social history, family history, weight history, dietary history, gynecological (GYN) history if female, review of systems, allergies and medications.
- 2. <u>A physical exam to include Hheight</u>; weight; Body Mass Index (BMI), blood pressure; pulse; % body fat or waist circumference/weight hip ratio; HEENT, chestlungs; heart; abdomen; and extremities.
- 3. Appropriate testing related to medical weight loss (CBC, comprehensive metabolic profile, lipid panel, thyroid panel, EKG, if prior or present history of cardiac disease, hypertension, diabetes, dyslipidemia, or strong family history of cardiac disease age >60
- 4. <u>The physicianlicensee must determine and record the patient's Body Mass Index ("BMI")</u>. No patient should receive anorexic medications unless <u>T</u>the patient should havehas (i) a BMI of ≥ 30.0 in a normal otherwise healthy patient, or (ii) a BMI ≥ 27.0 in an individual with at least one associated co-morbidity, or (iii) current body weight ≥ 120 percent of a well-documented, long standing healthy weight that the

<sup>&</sup>lt;sup>2</sup> <u>Part 2640, Rule 1.9, controls in all cases. Physician assistants are not permitted to dispense</u> medication.

patient maintained after the age of 18, or (iv) body fat  $\geq 30\%$  in females, or body fat  $\geq 25\%$  in males, or (v) waist-hip circumference such that the individual is known to be at increased cardiovascular and/or co-morbidity risk because of abdominal visceral fat, or presence of a co-morbidity condition or conditions aggravated by the patients excessive adiposity. The indication for anorexic therapy must be documented in the record and re-evaluated at each visit or with each prescription refill.

- 5. Absolute contraindications of Schedule III or IV anorectic drugs for purposes of weight loss management are pregnancy, breast feeding, or severe allergic reactions to these medications. Relative contraindications of Schedule III and IV anorectics for the purpose of weight loss management are uncontrolled bipolar, uncontrolled epilepsy, uncontrolled hypertension, episodic tachyarrhythmia, excessive stimulation, history of substance abuse, severe anticholinergic effects, such as, extreme dryness of mouth or unmanageable constipation should be addressed with physicianlicensee prior to starting weight loss medications. Schedule III and IV anorectics can be used in conjunction with any other medications deemed safe by the physicianlicensee.
- B. The <u>physician\_licensee</u> <u>shallmust</u> not utilize any Schedules III, IV or V controlled substance when he or she knows or has reason to believe an absolute contraindication exists or relative contraindication exists that would be harmful to the patient.
- C. The physician shall not initiate or discontinueor continue prescribing utilizing controlled scheduled medications for weight loss medication if the patient is in active detoxification and/or withdrawal from an addictive substance/ alcoholany program for alcohol or substance abuse recovery or detoxification.
- D. A <u>physicianlicensee</u> cannot <u>is not permitted to</u> prescribe, order, or dispense controlled substances for the purpose of weight reduction or treatment of obesity greater than a 30 day supply. <u>Exempted from this requirement are those licensees defined in Rule 1.2(M)</u> and those licensees treating patients resulting from a referral to those licensees defined in <u>Rule 1.2(M)</u>.
- E. A patient continued on a controlled substance in schedule III, IV, V for the purpose of weight reduction or the treatment of obesity should must undergo an in-person re-evaluation once every 30 days; however, those licensees defined in Rule 1.2(M) may re-evaluate patients once every 90 days. A recording of weight, BMI, blood pressure, pulse, and/or any other test which may be necessary for monitoring potential adverse effects of drug therapy should be completed at each visit. Once medically established goals have been met for an individual patient, the need for ongoing medication should be re-evaluated and documented in the record.it is strongly recommended that reduced dosing and drug holidays be implemented for those patients who need maintenance medication.
- F. Continuation of the prescribing, ordering, dispensing, or administering of controlled substances in schedule III, IV or V should occur only if the patient has continued progress toward achieving or maintaining medically established goals and has no significant adverse effects from the medication.
- G. A <u>physicianlicensee</u> <u>shallmust</u> not utilize a schedule III, IV or V controlled substance or legend drug for purposes of weight loss unless it has an FDA approved indication for this purpose and then only in accordance with all of the above enumerated conditions. The purpose of this rule is to prohibit the use of such drugs as diuretics and thyroid medications for the sole purpose of weight loss.

Any oOff-label use of any medication that does not have Food and Drug Administration approval for use in the treatment of weight loss is prohibited <u>if administered solely for the purpose of weight loss.</u> Thyroid hormone, diuretics, vitamin B12, B1, B2, B6, methionine, choline, inositol, chromium picolate and human chorionic gonadotropin are examples of medications that may not be used in th<u>ise sole treatment of weight loss and are not inclusive examples manner</u>. Off label use of medication that does not have Food and Drug Administration approval for the sole use and treatment of weight loss is prohibited in individual practice or allowing off-label use by midlevel providers will result in discipline by the Board. (Non FDA approved supplements may be used in the overall treatment of weight loss.)This prohibition does not apply to FDA categories of nutritional supplements sold without prescription.

Record keeping guidelines for medical weight loss: Every physician who prescribes, orders, dispenses, or administers a controlled substance to a patient for the purpose of weight reduction or treatment of obesity is required to maintain medical records in compliance to the above required guidelines. The treatment should be based on evidence based medicine. Adequate medical documentation should be kept so that progress as well as the success or failure of any modality is easily ascertained. The medical record should also contain the information demonstrating the patient's continued efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects and indicators of the need to discontinue treatment utilizing controlled substances.

#### Source: Miss. Code Ann. §73-43-11 (1972, as amended).

#### Rule 1.6 Bariatric Medicine, Amedical Weight Loss, or Weight Management Clinics Practice

- A. A Bariatric Medicine,/ Medical Weight Loss, or Weight Management Clinic Practice is defined as a public or privately owned facility for which 30% or more of the patients are provided a comprehensive weight management treatment programabove. Advertised medical weight loss must include behavior modification, comprehensive nutritional education, exercise or physical therapy intervention, and long-term maintenance programs. , Advertised medical weight loss may include ordering, administering, dispensing and/or prescribing medication with FDA-approved medications as indicated indications for weight loss on a monthly basis as part of the patient's treatment plan.
- A. <u>No bariatric medicine, medical weight loss, or weight management elinicpractice shall</u> operate in Mississippi unless the owner or operator of the facility is a Mississippi licensed physician. This licensee must meet all requirements below at all times while the facility is in operation. For the purposes of this rule, physicians who collaborate with mid-level providers will be considered an operator of the practice in the context of that collaborative arrangement.
- B. The physician owner/operator of the bariatric medicine, medical weight loss, weight management eliniepractice shallmust register with the MSBML using a form prescribed by the board. The form to register is attached hereto (Appendix F). Certificates of registration once issued are not transferable nor assignable. Only the primary physician and/or elinie areis required to register with the Board. All physicians licensees associated

with the <u>elinicpractice</u>, whether in the capacity as the owner or as a practitioner, <del>should</del> <u>must</u> be listed on the application and must also be required to meet all regulations governing the treatment of obesity/medical weight loss. All <u>Physicians who are added or</u> removed from the elinie to the registration once a certificate is issued must be reported to the MSBML for approval <u>prior to beginning practice</u>. <u>Physicians who are removed from</u> the registration must be reported to the board within 30 days of removal. Each elinie practice location requires a separate registration certificate.

- C. A bariatric medicine, medical weight loss, or weight management eliniepractice may not operate in the state of Mississippi without obtaining a registration certificate from the Mississippi State Board of Medical Licensure.
- D. Certificates are valid for one year and must be renewed annually along with practitioner's license to practice medicine in the state of Mississippi. There is a 30-day grace period for renewal after which the owner/operator must reapply for an original certificate. The clinic may not continue to operate while the certificate is expired.
- E. If a physician's practice is 30% or greater in bariatric medicine, advertising medical weight lossa Bariatric Medicine/Medical Weight Loss Clinic as defined above, or the physician collaborates, manages, oversee, or employs any licensed professional providing overseeing/collaborating with a nurse practitioner or physician assistant to provide comprehensive treatment of obesity, the physician must have expertise in the field of bariatric medicine with no less thanas demonstrated by:
  - 100 AMA or AOA Category 1 CME hours in the core content of bariatric medicine prior to practicing in the specialized field of bariatric medicine/medical weight loss. For any physician who is currently practicing 30% or greater in bariatric medicine or advertising medical weight loss, the physician has 24 months from effective date of this regulation to comply with the initial CME requirement or be board certified in bariatric medicine in order to continue practicing bariatric medicine/medical weight loss in the state of Mississippi. All Category 1 CME in core content of bariatric medicine should be obtained within a 24 month period.

Following the initial 0100 Category 1 CME, a physician is required to obtain 30 AMA or AOA Category 1 CME in core content of bariatric medicine annually in order to continue practicing bariatric medicine and to renew certification with the MSBML. If a physician's practice is a bariatric medicine, medical weight loss, or weight management practice as defined above or the physician collaborates, manages, oversees, or employs any licensed professional providing comprehensive treatment of obesity, the licensee must have 100 AMA or AOA Category 1 CME in the core-content of bariatric medicine or be currently certified by a board in bariatric medicine. A licensee currently practicing bariatric medical weight loss or weight management has 24 months from effective date of this regulation to comply with the initial CME requirement. All CME must be obtained within the 24 month period. Reference is made to exclusions noted in Rule 1.2, H.

Licensee must biennially obtain 60 AMA or AOA Category 1 CME in core-content of bariatric medicine before certification can be renewed with the MSBML.

F. A Medical Spa facilitypractice, Wellness Centerpractice, or other facilitypractice that meets the definition of Bariatric Medicine, Medical Weight Loss, or Weight Management

<u>ClinicPractice</u> shall will be subject to all rules pertaining to Bariatric Medicine, Medical Weight Loss, or Weight Management <u>ClinicsPractice</u> if the facility has a Mississippi licensed physicianlicensee affiliated in any manner.

for which 30% or more of the patients are provided a comprehensive weight management treatment program or advertises medical weight loss to the public must include behavior modification, comprehensive nutritional education, exercise or physical therapy intervention, long-term maintenance programs, the dispensation and/or prescribing of FDA-approved medications as indicated for weight loss on a monthly basis by a physician and/or nurse practitioner/physician assistant being overseen/collaborating to provide comprehensive treatment of obesity is prohibited unless all criteria above are met.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

#### Rule 1.7 Use of Controlled Substances for Chronic (Non-Terminal) Pain.

The following rules are not intended to supersede or exempt licensees from the requirements heretofore stated in Rule 1.4 *Maintenance of Records and Inventories*.

A. Definitions

For the purpose of Part 2640, Rule 1.7 only, the following terms have the meanings indicated:

- 1. "<u>Chronic Pain</u>" is a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physicianlicensee and one or more physicianslicensee specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain. Further, if a patient is receiving controlled substances for the treatment of pain for a prolonged period of time (more than sixthree months), then they will be considered for the same requirements of this regulation. "Terminal Disease Pain" should not be confused with "Chronic Pain." For the purpose of this rule, "Terminal Disease Pain" is pain arising from a medical condition for which there is no possible cure and the patient is expected to live no more than six (6) months.
- 2. <u>"Terminal Disease Pain" is pain arising from a medical condition for which there is</u> no possible cure and the patient is expected to live no more than six (6) months.
- "<u>Acute Pain</u>" is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. <u>ItAcute pain</u> is generally <u>time limitedself-limited</u> and is responsive to therapies, including controlled substances as defined by the U.S. Drug Enforcement <u>Administration</u>. <u>Title 21 CFR Part 1301 Food and Drugs</u>.
- 4. "<u>Addiction</u>" is a <u>neurobehavorialneurobehavioral</u> syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. <u>Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.</u>

- 5. "<u>Physical Dependence</u>" is a physiological state of neuroadaptation to a opioid therapy substancesubstance which is characterized by the emergence of a withdrawal syndrome if the use of the substance is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by re-administration of the substance. Physical dependence is a normal physiological consequence of extended opioid therapy for pain and should not be considered addiction.
- 6. "<u>Substance Abuse</u>" is the use of any substance for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.
- 7. "<u>Tolerance</u>" is a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Tolerance occurs to different degrees for various drug effects, including sedation, analgesia and constipation. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Such tolerance may or may not be evident during treatment and does not equate with addiction.
- B. Notwithstanding any other provisions of these rules, a<u>A</u> physician<u>licensee</u> may order, prescribe, administer, or dispense controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability to a person in the usual course of treatment of that person for a diagnosed condition causing for the treatment of chronic pain.
- C. Notwithstanding any other provisions of these rules, as to t<u>T</u>he <u>ordering</u>, prescribing, administration, or dispensation of controlled substances in <u>Schedules II, IIN, III, IIIN, IV</u> and <u>V</u>, or other drugs having addiction-forming and <u>or</u> addiction-sustaining liability, use of said medications in <u>for</u> the treatment of chronic pain should be done with caution. A <u>physicianlicensee</u> may <u>order</u>, administer, dispense or prescribe said medications for the purpose of relieving chronic pain, provided that the following conditions are met:
  - Before initiating treatment utilizing a Schedules II, IIN, III, IIIN, IV or Vwith a controlled substance, or any other drug having addiction-forming and or addiction-sustaining liability, the physicianlicensee shallmust conduct an appropriate risk/benefit analysis by reviewing his or her own records of prior treatment. or review the records of prior treatment which another treating physician has provided to the physician, The risk/benefit analysis should weigh in favor of treatment and indicate that there is an indicated the need for long-term controlled substance therapy. Such a determination shallmust take into account the specifics of each patient's diagnosis, past treatments, and suitability for long-term controlled substance, use either alone or in combination withwith the need for other indicated treatment modalities for the treatment of chronic pain. This shallThe results of this analysis must be clearly entered into the patient medical record and shallmust include supporting documentation such as consultation or referral reports and efforts to determine the underlying pathology or cause etiology of the chronic pain.
  - 2. Documentation in the patient record <u>shallmust</u> include a complete medical history and physical examination <u>and supporting studies and reports of consultation</u>.
  - 3. <u>The diagnosis must that indicates demonstrate</u> the presence of one or more recognized medical indications for the use of controlled substances.
  - 4. Documentation of a written treatment plan which shallmust contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g.,

psychiatric evaluation or other treatments. The plan should also<u>must</u> contain an informed consent agreement for treatment that details relative risks and benefits of the treatment course. The is should also consent must also include specific requirements of the patient, such as using one physicianlicensee and pharmacy, if possible, and urine/serum medication level monitoring when requested, pill counts, and the grounds for which the treatment shallmay be terminated (e.g., 'doctor shopping' behavior, adverse urine/serum screens, etc.).

- 5. Periodic review and documentation of the treatment course is conducted at reasonable intervals (no more than every six months)no less frequently than every 3 months. with modification of therapy dependent on tThe physicianlicensee's evaluation of progress toward the stated treatment objectives <u>must support all changes in therapy</u>. This should include referrals and consultations as necessary to achieve those objectives.
- D. No physicianlicensee shall order, administer, dispense or prescribe a controlled substance or other drug having addiction-forming and addiction-sustaining liability that is nontherapeutic in nature or non-therapeutic in the manner the controlled substance or other drug is administered, dispensed or prescribed.
- E. No physicianlicensee shall order, administer, dispense or prescribe a controlled substance for treatment of chronic pain to any patient who has consumed or disposed of any controlled substance or other drug having addiction-forming and addiction-sustaining liability other than in strict compliance with the treating physician licensee's directions. These circumstances include those patients obtaining controlled substances or other drugs having addiction-forming and addiction-sustaining liabilityother abusable drugs from more than one physicianlicensee or healthcare provider and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other drug having addiction-forming and addiction-sustaining liabilityother abusable drugs before a should have been consumed according to the treating prescription prior physicianlicensee's directions. This requirement will not be enforced in cases where a patient has legitimately temporarily escalated a dose of their pain medication due to an acute exacerbation of their condition but have maintained a therapeutic dose level; however, it will be required of if the treating physician licensee to document in the patient record that such increase in dose level documents that the escalation was due to a recognized indication and was within appropriate therapeutic dose ranges. Repetitive or continuing escalations should be a reason for concern and a re-evaluation of the present treatment plan shallmust be undertaken by the physician licensee.
- F. No physicianlicensee shall order, prescribe, administer, or dispense any controlled substance or other drug having addiction-forming or addiction-sustaining liability to a patient who is a drug addiet for the purpose of "detoxification treatment" or "maintenance treatment" and no physicianlicensee shall order, prescribe, administer, or dispenseadminister or dispense any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" or "maintenance treatment" or "maintenance treatment" unless they the physicianlicensee isare properly registered in accordance with Section 303(g) 21 U.S.C. 823(g). Nothing in this paragraph shall prohibit a physicianlicensee from administering narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one (1) day's

medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three (3) days. Nothing in this paragraph shall prohibit a physicianlicensee from ordering, prescribing, administering, or dispensing administering or dispensing narcotic controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.

- G. When initiating opioid therapy for chronic pain, the licensee shallmust first run a MPMP on the patient. The licensee shallmust prescribe the lowest effective dosage. While there is no single dosage threshold identified below which the risk of overdose is eliminated, licensees should must strive to keep daily opioid doses less than or equal to 50 mg of morphine equivalence (mEq), as dosages larger than 50 mEq per day increases risk without adding benefits for pain control or function. Licensees shouldmust avoid dosages greater than or equal to 90 mg of morphine equivalence per day and must provide significant justification for exceeding the 90 mg ceiling stated herein. If the licensee determines that a patient requires greater than 100 mg of morphine equivalence per day, the licensee must refer the patient to a pain specialist for further treatment.
- H. When opioids are prescribed for acute pain, the licensee should must prescribe the lowest effective dose of immediate release opioids, as the use of long acting opioids for acute non-cancer/non-terminal pain is prohibited. and shouldLicensees must prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less should be sufficient and more than 7 days should be avoided in absence of significant justification (Example: Postsurgical pain stemming from a significant procedure). Licensees are discouraged from prescribing or dispensing more than a three (3) day supply of opioids for acute non-cancer/non-terminal pain, and must not provide greater than a ten (10) day supply for acute non-cancer/non-terminal pain. Licensees may issue an additional ten (10) day supply if clinically necessary, but said supply must be issued in accordance with Title 21 CFR § 1306.12 *Refilling prescriptions*; issuance of multiple prescriptions (i.e., the prescription must be dated on the date of issuance with 'do not fill until' noting the date the prescription may be filled), and such need for an additional ten (10) day supply must be documented in the chart to evidence that no other alternative was appropriate or sufficient to abate the acute pain associated with that medical condition. Additional ten (10) day supplies may be issued, beyond the aforementioned but pursuant to those same requirements, if deemed medically necessary and only if supported by additional clinical evaluation which evidences no other alternative was appropriate or sufficient to abate the acute pain associated with that medical condition.
- As stated in Rule 1.3, every licensee must review an MPMP report at each patient encounter in which a Schedule II medication is prescribed for acute pain or chronic noncancer/non-terminal pain. MPMP reports may be obtained by designees of the licensee as allowed by the MPMP program.
- J. <u>When prescribing opioids for either chronic or acute pain, it shall beis considered a</u> relative contraindication (black box warning) to prescribe opioids concurrently with Benzodiazepines and/or Soma. However, opioids and benzodiazepines may be prescribed concurrently on a very short term basis, and in accordance with section H of this rule, when an acute injury requiring opioids occurs. The need for such concurrent prescribing

must be documented appropriately in the chart. Patients who are currently on an established regimen of concomitant opioids and benzodiazepines may be allotted a reasonable period of time to withdraw from one or both substances. Prescribing of opioids concurrently with benzodiazepines and/or Soma may be allowed only under very limited circumstances in which the combination is used to treat very specific chronic medical conditions for which there is no other treatment modality available.

- K. When a licensee treats chronic non-cancerous/non-terminal pain and/or psychiatric conditions outside the definition of a pain management practice (Rule 1.2) (GK) the licensee shallmust actively utilize the MPMP upon initial contact with a new patient and every 3 months thereafter on any and all patients who are prescribed, administered, or dispensed controlled substances. Reports generated on patients shallmust span the length of time from the previous review of the MPMP so that adequate information is obtained to determine the patient's compliance for and with treatment. Documentation, such as a copy of the report itself and/or reflections in the charts dictation and/or notes shallmust be kept within the patient's record and made available for inspection upon request. In addition, licensees required to register under this section shall also utilize the MPMP to generate a global report to review the entire practice as a whole at least yearly. Documentation of the global report shall be kept in a separate file to be available for inspection upon request.
- L. Point of service drug testing must be done at least three (3) times per calendar year when a Schedule II medication is written for the treatment of chronic non-cancer/non-terminal pain. Point of service drug testing and MPMP review, as described in Rule 1.7 (K), must be done at least three (3) times per calendar year for patients prescribed benzodiazepines for chronic medical and/or psychiatric conditions which are non-cancer/non-terminal. Point of service drug testing must test, at a minimum, for opioids, benzodiazepines, amphetamines, cocaine, and cannabis. Inpatient treatment, as defined in Rule 1.2(L), is exempt from this requirement. Further, all hospice treatment is exempt from point of service drug testing requirements stated herein.
- M. The use of Methadone to treat acute non-cancer/non-terminal pain is prohibited. The use of Methadone for the treatment of chronic non-cancer/non-terminal pain is permissible within a registered Pain Management Practice, as defined in Rule 1.2(K), or when resulting from a referral to a certified pain specialist. If Methadone is prescribed to treat chronic non-cancer/non-terminal pain, it must be prescribed only by a physician.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.8 Drug Maintenance Requirements.* All drug productsmedications which are maintained <u>or</u> stored in the office of a physicianphysician licensee's office shallmust be maintained <u>or</u> stored in the manufacturer's or re-packager's original container. The label of any container in which drugs are maintained must bear the drug name, strength, the manufacturer's control lot number and the expiration date. Drugs which that are pre-counted and prepackaged for purposes of dispensing shallmust be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained shallmust not be labeled in any false or misleading manner. The labeling requirements of the state of Mississippi, Rules of

the Mississippi State Board of Medical Licensure, and Laws of the United States or Federal Regulations all other applicable state and federal statutes and regulations. In the event of conflict, federal statutes and regulations shall control.

A physician shall<u>must</u> not dispense out-of-date drugs <u>medications</u>. or store out-of-date drugs intermixed with the stock of current drugs. Out-of-date drugs <u>medications</u> shall<u>must</u> be promptly removed from current stock and stored separately until proper disposal shall be made. A physician, when dispensing a product in a manufacturer's original package or container, the labeling of which bears an expiration date, a manufacturer's control lot number or other information which may be of value to the patient, shall<u>must</u> dispense the product with this information intact.

The drug <u>medication</u> storage and dispensing areas <u>shallmust</u> be maintained in a sanitary fashion. <u>All drug productsmedications shallmust</u> be maintained, stored and dispensed in such a manner as to maintain the integrity of the product.

A <u>physicianlicensee</u> <u>shallmust</u> not accept the return for subsequent resale or exchange any drugs after such items have been taken from the premises where sold, distributed or dispensed and from the control of the <u>physicianlicensee</u>.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.9 Labeling Requirements for Dispensing Physicians.* For the purposes of this rule, a "dispensing physician" shall means any physician who shall dispenses to a patient for the patient's use any controlled substance, legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made.

Every dispensing physician, as defined above, who shall dispenses a controlled substance, legend drug or any other medication shall<u>must</u> insure that all such substances dispensed be labeled containing the following information:

- A. The name of the patient to whom the medication was dispensed.
- B. The date that the medication was dispensed.
- C. The name, strength and quantity of the medication.
- D. Direction for taking or administering the medication.
- E. The name and address of the physician dispensing the medication.

The label required by this rule shall<u>must</u> be written in legible handwriting or typed and shall<u>must</u> be permanently affixed to the package or container in which the medication is dispensed. This labeling requirement shall not apply to pPrepackaged samples or starter packs in their original packages or containers <u>need only have the patient name</u>, date dispenseddistributed, and physician's name if the manufacturer's packaging meets other requirements.

No physician may delegate dispensing authority to another person. A physician must personally dispense the medication. For the purpose of this regulation, "personally dispense" shall means the physician must actually obtain the medication, prepare, count, place the same into the appropriate container and affix the appropriate label to the container.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.10 Prescription Guidelines–Controlled Substances.* It is the responsibility of the physician or physician assistant<u>licensee</u> to determine the type, dosage, form, frequency of application and number of refills of any controlled substances prescribed to a patient. It is recognized that other healthcare providers may prescribe controlled substances. The following requirements apply to all prescriptions for controlled substances written by <u>a healthcare professionalslicensee</u> with controlled substance prescriptive authority–regulated by the Mississippi State Board of Medical Licensure:

- A. All prescriptions for controlled substances must be written in strict compliance with Mississippi Code, Sections 41-29-101 through 41-29-311 and Title 21 of U.S. Code of Federal Regulations, Part 1306.
- B. On all prescriptions of controlled substances wherein refills are permitted, <u>physicianlicensees shallmust</u> indicate the appropriate refills, not to exceed five (5), or mark "none."
- C. Each <u>physician licensee shallmust</u> insure that the complete name and address of the patient to whom the <u>physician licensee</u> is prescribing the controlled substance appears on the prescription.
- D. A physician licensee shallmust not permit any prescription for controlled substances to be signed by anyone non-physician in the place of or on behalf of the physician licensee.
- E. A physician licensee shallmust not pre-sign blank prescription pads or order forms.-under any circumstances.
- F. A physician licensee shallmust not utilize blank prescription pads or order forms upon which the signature of the physician licensee has been electronically, mechanically or photo-statically reproduced affixed by any means other than manual signature. This prohibition includes the e-mailing of any controlled substance prescription. A hard copy prescription generated from an electronic prescription system must contain a manual signature <u>unless</u>; however, if it is (i) the prescription is printed on security paper that ensures it is not subject to copying or alteration, and (ii) an electronic or digital signature may be substituted affixed. Electronic transmission of Schedule III-V controlled substance prescription information is generally allowed (except Schedule II which is addressed below); however, for the purposes of this regulation, electronic transmission of controlled substance prescription data is limited to computer to facsimile (fax) transmissions or traditional fax to fax transmissions. Electronic transmission of Schedule II controlled substance prescription information is permitted under limited circumstances. Requirements for fax prescription orders and systems utilized for faxing prescriptions are as follows:
  - The prescription order shall<u>must</u> contain the date, time, telephone number and location of the transmitting device. Prescription blanks utilized in this manner shall<u>must</u> bear a pre-printed heading that indicates the blank is a "Fax Prescription Form." Fax prescription orders must contain a manual or authenticated electronic/digital signature of the prescriber. As to Schedule II drugs, oOnly Schedule II narcotic substances that are to be prepared or compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or

intra spinal infusion may be transmitted by the <u>physicianlicensee</u> or the <u>physicianlicensee's</u> agent to a pharmacy of the patient's choice by facsimile. All original hardcopy faxed prescriptions <u>shallmust</u> immediately be voided after successfully completing the fax transmission by writing across the face of the prescription from corner to corner the notation "faxed." The original prescription (or copy) <u>shallmust</u> be retained in the <u>physicianlicensee's</u> patient file with additional information included on the back of the prescription as to the date it was faxed, the name or initials of the person faxing the prescription and the name/location of the pharmacy receiving the fax transmission.

It is also required, that iIn addition to filing the original prescription (or copy) in the patient file, a perpetual, chronological logbook of fax transactions be shall<u>must be</u> established and maintained. Such a logbook would serve to protect the prescribing physician licensee in the event the original prescription is somehow lost or misfiled. The information contained in such a logbook shall<u>must</u> include the patient's name and address, date of issuance, name, strength and quantity of the drug prescribed and the name and fax number of the receiving pharmacy and the initials or namea personal identifier of the person faxing the prescription. Such logs shall<u>must</u> be maintained in the physicianlicensee's clinic in a readily retrievable manner, and kept for at least seven (7) years after the original record is established. The requirements set forth in this rule are in addition to, and not in lieu of documentation required in Part 2640, Rule 1.4.

- 2. When a prescription is prepared and written for prescribing any controlled substance for a resident of a Long-term Care Facility (LTCF)(as defined in Section 1301.01(25), Code of Federal Regulations), such prescription may be transmitted by the practitioner licensee or the practitioner's licensee's agent to the dispensing pharmacy by facsimile. The licensee or the licensee's physician or the physician's agent will must note on the prescription that the patient is a resident of a LTCF. The original prescription (or copy) and fax transaction log will be prepared and maintained in the same manner as described in Part 2640, Rule 1.10.F.1.
- 3. When a prescription is written for prescribing any controlled substance for a patient residing in a hospice certified by Medicare under Title XVIII or licensed by the state, such prescription may be transmitted by the licensee or the licensee's practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The licensee or the licensee or the licensee or the patient is a hospice patient. The original prescription (or copy) and fax transmission log will be maintained in the same manner as described in Part 2640, Rule 1.10.F.1.
- 4. Each system shall have policies and procedures that address the following:
  - i. The patient shall not be restricted from access to the pharmacy of their choice.
  - ii. The system shall have security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information, as well as physical safeguards to protect computer systems and other pertinent equipment from intrusion.
  - iii. Processes to protect, control and audit access to confidential patient information, including the prevention of unauthorized access to data when transmitted over

communication networks or when data physically moves from one location to another using media such as magnetic tape, removable drives or other media used to store downloaded information.

- G. No more than one (1) controlled substance shall be issued on a single prescription blank.
- H. <u>Prescriptions for Benzodiazepines must be limited to a one (1) month supply, with no more than two (2) refills, or a ninety (90) day supply with no refills. The MPMP must be checked each time a prescription for benzodiazepines is authorized and evidence of such check must be noted within the patient file.</u>

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.11 Prescription Guidelines - All Medications.* In addition to any other requirements set forth in these rules pertaining to the issuance of prescriptions of controlled substances, the following additional requirements apply to all prescriptions, whether or not said prescriptions are for controlled substances, legend drugs or any other medication:

A. <u>Prescriptions may not be written outside of a valid physicianlicensee-patient relationship.</u> While not all of the elements in subsection A are necessary each time a prescription is authorized (e.g., via appropriate telemedicine as defined in Rule 5.5 of Part 2635, calling in refills, taking call for a practice partner for short term care, etc.), all initial encounters, and at reasonable intervals thereafter, should conform to this rule and be done pursuant to a valid licensee-patient relationship. The elements of this valid relationship are:

1. verify that the person requesting the medical treatment is in fact who they claim to be;

- 2. <u>conducting an appropriate history and physical examination of the patient that meets</u> <u>the applicable standard of care;</u>
- 3. <u>establishing a diagnosis through the use of accepted medical practices, i.e., a patient history, mental status exam, physical exam and appropriate diagnostic and laboratory testing;</u>
- 4. <u>discussing with the patient the diagnosis, risks and benefits of various treatment</u> <u>options to obtain informed consent;</u>
- 5. <u>insuring the availability of appropriate follow-up care; and</u>
- 6. <u>maintaining a complete medical record available to patient and other treating health</u> <u>care providers.</u>
- B. Electronic prescription transmissions are allowed is permitted using standards established and approved by the United States Department of Health and Human Services--Agency for Healthcare Research and Quality (HHS-AHRQ) provided the transmission meets applicable state and federal standards for transmission. E-prescribing is the electronic entry of a prescription by a practitionerlicensee, the secure electronic transmission of the prescription to a pharmacy, the receipt of an electronic message by the pharmacy and Eprescription renewal requests sent electronically by the pharmacy to the practitioner. Electronic transmissions may be computer to computer or computer to facsimile.
- C. Every written prescription delivered to a patient, or delivered to any other person on behalf of a patient, must be manually signed on the date of issuance by the <u>physicianlicensee</u>. This does not prohibit, however, the transmission of electronic prescriptions and telefaxed prescriptions (but not e-mail) for non-controlled drugs to the pharmacy of the patient's choice. Such telefaxed or electronic prescriptions shallmust be

authorized by a written or electronic signature and <u>shallmust</u> be issued in accordance with all other provisions of this rule. No prescriptions for <del>brand name or generic equivalents of any form or compound containing <u>n</u>Nalbuphine H<u>C</u>el, <u>c</u>Carisoprodol, <u>b</u>Butalbital compounds, or <u>t</u>Tramadol HCl shall be telefaxed.</del>

- D. Electronic prescriptions for controlled substances (schedules II, III, IV, and V) are permitted if (or when) a practitioner has complied with the DEA requirements and is using a certified electronic prescribing system for the transmission of control substances prescriptions. The Board of Medical Licensure considers Nalbuphine Hcl, Carisoprodol, Butalbital compounds and Tramadol to be controlled substances.
- All written prescriptions shallmust be on forms containing two lines for the physician's E. licensee's signature. There shallmust be a signature line in the lower right-hand corner of the prescription form beneath which shallmust be clearly imprinted the words "substitution permissible." There shallmust be a signature line in the lower left corner of the prescription form beneath which shallmust be clearly imprinted with the words "dispense as written." The physician's licensee's signature on either signature line shallmust validate the prescription and designate approval or disapproval of product selection. Each prescription form shallmust bear the pre-printed name of the physician licensee or the physician licensee shallmust clearly print his or her name on the prescription form, in addition to the licensee'sphysician's original signature. In the event that the prescription form bears the pre-printed name of more than one licenseephysician, the licensee physician shallmust clearly indicate the name of the phy licensee sician writing the prescription. In the case of a prescription that is electronically generated and transmitted, the licensee physician must make an overt act when transmitting the prescription to indicate either "dispense as written" or "substitution permissible". When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.
- F. If a prescription form which does not contain two signature lines required in Part 2640, Chapter 1, Rule 1.11.D is utilized by the <u>licenseephysician</u>, he or she <u>shallmust</u> write in his or her own handwriting the words "dispense as written" thereupon to prevent product selection.

Every written prescription issued by a <u>licensee physician</u> for a legend drug should clearly state whether or not the prescription should be refilled, and if so, the number of authorized refills and/or the duration of therapy. <u>ILicensee Physicians</u> should avoid issuing prescriptions refillable on "prn" basis. If a <u>licensee physician</u> chooses to issue a prescription refillable "prn", the life of the prescription or time limitation must clearly be set forth on the prescription. In no case shall a prescription which is refillable on a "prn" basis be refilled after the expiration of one (1) year. Regardless of whether a prescription is refillable on a "prn" basis or the prescription expressly states the number of authorized refills, the use of said medication should be re-evaluated on at least an annual basis. Upon the expiration of one (1) year, a prescription becomes invalid, regardless of the number of refills indicated or "prn" designation. Thereafter, a new prescription, if indicated, must be issued.

- G. Every written prescription issued by a <u>licenseephysician</u>, bearing more than one noncontrolled medication, <u>shallmust</u> clearly indicate the intended refill instructions for each medication. Lack of clearly indicated refill instructions prohibit the refilling of the medications. All unused lines on a multi-line prescription blank <u>shallmust</u> be clearly voided by the issuing <u>licenseephysician</u>.
- H. A prescription shall<u>will</u> no longer be valid after the occurrence of any one of the following events:
  - 1. Thirty (30) days after the death of the issuing licenseephysician.
  - Thirty (30) days after the issuing <u>licensee</u> physician has moved or otherwise changed the practice location of his or her practice so as to resulting in terminateion of the doctor/<u>licensee</u> patient relationship. Termination of the <u>doctor/licensee</u> patient relationship results when a patient is no longer able to seek personal consultation or treatment from the issuing <u>licenseephysician</u>.
  - 3. Insofar as controlled substances are concerned, iImmediately after loss of DEA Controlled Substances Privilege by the issuing <u>licenseephysician</u> if the prescription is for controlled substances.
  - 4. Immediately after upon revocation, suspension or surrender of the <u>licenseephysician's</u> license.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.12 Freedom of Choice.* A <u>licensee</u> physician shall<u>must</u> not be influenced in the prescribing of drugs, devices or appliances by a direct or indirect financial interest in a pharmaceutical firm, pharmacy or other supplier. Whether the firm is a manufacturer, distributor, wholesaler, or repackager of the product involved is immaterial. Reputable firms rely on the quality and the efficacy to sell their products under competitive circumstances and do not appeal to physicians to have financial involvements with the firm in order to influence their prescribing, administering or dispensing.

A <u>licensee physician may own or operate a pharmacy if there is no resulting exploitation of patients.</u> A <u>licensee physician shallmust</u> not give a patients prescriptions in code or enter into agreements with pharmacies or other suppliers regarding the filling of prescriptions by code. Patients are entitled to the same freedom of choice in selecting who will fill their prescription needs as they are in the choice of a <u>physicianprovider</u>. The prescription is a written direction for a therapeutic or corrective agent. A patient is entitled to a copy of the <u>licensee physician's prescription</u> for drugs or other devices as required by the principles of medical ethics. The patient has a right to have the prescription filled wherever the patient wishes<u>by any legal means</u>. Where medication is to be dispensed or a prescription, excluding refills, called in to a pharmacist for medication, a <u>licensee physician shallmust</u> inform each patient of that patient's right to a written prescription and the right to have the prescription filled wherever the patient wishes.

Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. The prescription is an essential part of the patient's medical record. If a patient requests a written prescription in lieu of an oral prescription, this request shallmust be honored. Licensees Physicians shallmust not discourage patients from

requesting a written prescription or urge, suggest or direct in any manner that a patient fill a prescription at an establishment which has a direct telephone line or which has entered into a business or other preferential arrangement with the <u>physicianlicensee</u> with respect to the filling of the <u>licensee physician's prescriptions</u>.

## Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.13 Other Drugs Having Addiction forming Liability.* All physicians shall maintain inventory, dispensation/administration and patient records in the same format as that required by Part 2640, Rule 1.4 when administering or dispensing the drug Nalbuphine Hydrochloride (Nubain) or its generic equivalent. The inventory and dispensation/administration records for said drug may be maintained separately or included as a part of the physician's controlled substance records.

*Rule 1.14<u>3</u> Security of Controlled Substances.* In all clinics or offices wherein within the control of a licensee, all controlled substances or and other drugs having addiction-forming or addiction-sustaining liability are maintained, said medication shallmust be maintained in such a manner as to deter loss by theft or burglary. <u>Aall controlled substances shallmust be stored in a securely locked, substantially constructed container or area.</u> Only the physician or persons authorized by the physician shall have access to this storage area. When a licensee physician who is registered with the U.S. Drug Enforcement Administration has experienced detects a loss of controlled substances, the Board may issue an order requiring that person to appear before the Board and present a plan designed to prevent further loss of controlled substances. or he or she may be ordered by tThe Board has the authority to order implementation any other reasonable measures to improve security over controlled substances.

In all clinics or offices of a physician registered to handle controlled substances with the U.S. Drug Enforcement Administration,

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

## *Rule 1.154 Pain Management Medical Practice.*

- A. Definitions. For the purpose of Part 2640, Rule 1.15 only, the following terms have the meanings indicated:
  - 1. "Board" means the Mississippi State Board of Medical Licensure.

<u>"Physician</u>" means any person licensed to practice medicine or osteopathic medicine in the state of Mississippi as required by Part 2601, Chapter 02."Physician Assistant" means any person meeting the requirements of licensure in the state of Mississippi as required by Part 2617, Chapter 1.

"Licensee" means any person licensed and/or regulated by the Mississippi State Board of Medical Licensure to practice in the state of Mississippi.

- 2. <u>"Prescriptive Authority</u>" means the legal authority of a professional licensed to practice in the state of Mississippi who prescribes controlled substances and is registered with the U. S. Drug Enforcement Administration in compliance with Title 21 CFR, Part 1301 Food and Drugs.
- 3. "<u>Pain Management Medical Practice</u>" is defined as means a public or privately owned medical practice for which that provides pain management services to patients, a

majority (more than 530%) of the patients are issued on a regular or recurring basis which are issued a prescription for, or are dispensed, opioids, barbiturates, benzodiazepines, carisoprodol, butalbital compounds, or tramadol for the treatment of chronic noncancerous pain. Included in this definition shall be any practice that advertises and/or otherwise holds itself out to provide pain management services. more than one hundred eighty days (180) days in a twelve month period. Excluded from this definition are all licensed hospitals, state health department facilities, federally qualified community health clinics, volunteer clinics, hospice services, and out-patient surgical clinics. Physicians or practices or physician/clinic practice(s) at which the majority of the patients are treated for pain as a result of a terminal illness are also excluded from the definition of pain management practice.

- A. The <u>physician owner(s)/operator(s) of the</u> pain management medical practice must <u>possess and maintainhave, at all times,</u> a majority ownership (more than 50%) <u>by a</u> <u>physician or group of physicians licensed by the Board, and/or a hospital or health care</u> <u>entity registered with the Secretary of State to do business in the state of Mississippi. The</u> <u>physician or physician owners must practice an annual average of at least 20 hours per</u> week within the state of Mississippi.
- B. The pain management medical practice and shall<u>must</u> register with the Board unless it meets the exceptions defined above. the practice with the Board. No physician may practice in a pain management medical practice unless that practice is majority owned (over 50 %) by a physician or physicians, unless exempted under A.5 above. A hospital or hospital-system owned pain management practice is exempt from the majority ownership requirement.
- C. <u>Each</u> Aphysician <u>owner of a pain management medical practice</u> or <u>medical director who</u> owns, operates or is employed in any pain management medical practice must meet the requirements set forth below.
- <u>D.</u> Each <u>physicianlicensee</u> who serves as medical director, manager, or employee or who provides care in <u>a pain management medical practice must meet the requirements set forth below</u>.

Application for Initial Registration and Renewal - A physician owner(s)/operator(s) of the <u>a</u> pain <u>management medical</u> practice must:

- 1. submit the documents required by the application process <u>fordemonstrating</u> proof of ownership or provide alternative documents with a written request for special consideration;
- report ownership or investment interest of <u>in</u> any other pain management facility operating within the state of Mississippi and provide the name and address of the other pain management facility(ies) in which there <u>the physician hasis an</u> ownership or vested interest;
- identify all individuals with prescriptive authority who are employed or contracted in any capacity and will be prescribing or dispensing controlled substances to patients of at each the facility; and
- 4. report any changes of information provided in the application for registration or renewal within 30 days <u>of the effective date of the change</u>.

- E. Physician owner(s or )/operator(s) may not operate a pain management practice in the state of Mississippi without obtaining a certificate from the Mississippi State Board of Medical Licensure. Certificates, once issued, are not transferable or assignable. Only the primary physician owner is required to register with the Board if there is more than one physician owner of the practice. Additional physician owners must register if they also provide patient care. Each practice requires a separate certificate.
- <u>F.</u> Physician <u>owners or operators</u><del>owner(s)/operator(s) or employees</del> may not operate <u>a pain</u> <u>management practice</u> in Mississippi unless the practice is owned or operated by a hospital or <u>healthcare entity registered with the Secretary of State to do business in the state of</u> <u>Mississippi, or by a medical directorphysician</u> who:
  - 1. is a physician who practices full time in Mississippi; (Full time is defined as at least 20 hours per week of providing direct patient care.);
  - 2. holds an active unrestricted medical license that is not designated as limited, retired, temporary, or in-training; and
  - 3. holds a certificate of registration for that pain management practice.
- <u>G.</u> <u>NoIn addition, the physician owners or operatorsowner(s)/operator(s)</u> of a pain management practice, <u>nor any physician, nor any physician assistant</u>, <u>employee, of the practice nor any medical director, manager, or employee or any physician or physician assistant who provides carea physician or physician assistant with whom the physician owner(s)/operator(s) of a practice contracts for services may not:</u>
  - 1. have been denied, by any jurisdiction, a certificate <u>permitting the licensee to order</u>, <u>prescribe</u>, <u>dispense</u>, <u>administer</u>, <u>supply or sell a controlled substance or the other</u> <u>listed medications under definitions</u>;
  - 2. <u>have been issued</u>, by any jurisdiction, a limited certificate to order, prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions;
  - <u>have been denied a certificate</u> issued by the Drug Enforcement Administration (DEA) permitting the licensee to order, prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitionsunder which the person may prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions;
  - 4. <u>have been issued a limited certificate by the Drug Enforcement Administration</u> (DEA) permitting the licensee to order, prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions;
  - 5. have held a certificate issued by the Drug Enforcement Administration under which the person may prescribe, dispense, administer, or supply, or sell a controlled substance that has been restricted;
  - 5. have been subject to a disciplinary action by any licensing entity for conduct that was a result of inappropriately prescribing, dispensing, administering, supplying or selling a controlled substance or the other listed medications under definitions; or
  - 6. have been terminated from Mississippi's Medicaid Program, the Medicaid program of any other state, or the federal Medicare program, unless eligibility has been restored.
- <u>H.</u> No physician or physician assistant may <u>own, operate, or</u> practice in a pain management medical practice who has been convicted of, pled nolo contendere to or received deferred adjudication for:

- 1. an offense that constitutes a felony; or
- 2. an offense that constitutes a misdemeanor, the facts of which relates to the illegal distribution or sale of drugs or controlled substances.
- <u>I.</u> Training <u>r</u>Requirements for all physicians practicing in pain management medical practices. Effective July 1, 2014, <u>all physician owners or operators or any physician who serves as medical director, manager, or employee or who provides care in a pain management medical practice must meets who have not met the qualifications set forth in subsections (1) through (5) below., shall have successfully completed a pain residency fellowship or a pain medicine residency that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA). All physicians prescribing or dispensing controlled substance medications in pain management practices registered by the Board must meet one (1) of the following qualifications:</u>
  - 1. board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) or the American Board of Addiction Medicine (ABAM) and hold a subspecialty certification in pain medicine;
  - 2. board certification by a specialty board recognized by the American Osteopathic Association Bureau of Osteopathic Specialists (BOS) in pain management;
  - 3. board certification in pain medicine by the American Board of Pain Medicine (ABPM);
  - 4. successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, neurology, or neurosurgery and approved by the ACGME or the AOA; or
  - 5. successful completion of 100 hours of in-person, face to fact, inter-active live participatory AMA or AOA Category 1 CME courses in pain management.

Upon qualifying under any of the 5 subsections above, physicians must also document completion of 30 hours of live lecture format, Category 1 CME for renewal of a pain management medical practicepain practice certificate.

- d. Live lecture format participation may be in person; or remotely as is the case of teleconference;s or live iInternet webinars.
- a. CME must have emphasis in the specific areas of pain management, addiction, and/or prescribing of opiates.
- b. CME is tomay be included with the forty hour requirement for licensure renewal.
- c. Excess hours may not be carried over to another two year cycle. For the purpose of this regulation, the two year period begins with the fiscal year July 1, 2014, and every two years thereafter to be concurrent with the licensure requirement.
- <u>J.</u> Physicians and physician assistants practicing in a registered <u>pain management medical</u> <u>practicepain practice</u> must be registered with the Mississippi Prescription Monitoring Program (MPMP). A report <u>from the MPMP shallmust</u> be obtained on the initial visit <u>for</u> <u>each patient</u>. Subsequent reports must be obtained for each patient at every visit. and at intervals deemed appropriate forconsistent with good patient care from the MPMPbut no less frequently than every three months. for every patient receiving controlled substances in a registered pain management practice.

- <u>K.</u> Requirements for physician assistants practicing in pain management medical practices. Physician assistants must meet the following qualifications prior to practicing in a registered pain management practice:
  - 1. A Board approved protocol in the practice of pain management as required by Part 2615, Chapter 1, Rules 5 and 6, <u>with a physician who holds a license</u> that is not designated as limited, restricted, retired, temporary, or in-training;
  - 2. Physician assistants with approved prescriptive authority must obtain 10 hours as required by the licensure requirement plus 5 hours of Category 1 CME related to prescribing and pain management for every year the physician assistant is practicing in a pain management medical practice Board registered pain practice;
  - 3. Physician assistants with prescriptive authority must be familiar with and adhere to the Administrative Rule Pertaining to Prescribing, Administering and Dispensing of Medication, Part 2640, Chapter 1; and
  - 4. Physician assistants with prescriptive authority must be registered with the Mississippi Prescription Monitoring Program (MPMP).
- L. A physician who is a current participant in the Mississippi Professionals Health Program (MPHP) may not be the primary physician owner of a pain practice. Notwithstanding, <u>\$\pm T\$</u>his does not prohibit an MPHP participant from working in a pain practice.
- <u>M.</u> The initial visit for each patient in a pain management practice must include an in person evaluation and plan of care by a registered pain management physician prior to the issuance of an opioid and/or benzodiazepine for the treatment of chronic non-cancer/non-terminal pain. Prior to the initial issuance of an opioid and/or benzodiazepine for the treatment of chronic non-cancer/non-terminal pain, each patient in a pain management practice must have an in-person evaluation by a registered pain management physician.
- <u>N.</u> Certificates are valid for one year and must be renewed annually<u>along</u> with the practitioner's license to practice medicine in the state of Mississippi. There is a thirty-day grace period for renewal after which the owner(s)/ or operator(s) must reapply for an original certificate. The physician owner(s)/ or operator(s) of the practice shallmust post the certificate in a conspicuous location so as to be clearly visible to patients. The practice may not continue to operate while the certificate has expired.
- O. The Board shall have has the authority to inspect a pain management medical practice pain management practice. During such inspections, authorized representatives of the Board, who may be accompanied by agents of the Mississippi Bureau of Narcotics investigators from state or federal law enforcement agencies, may inspect all necessary documents and medical records to ensure compliance with all any applicable laws and rules.
- P. If the Board finds that a registered pain management practice no longer meets any of the requirements to operate as a pain practice, the Board may immediately revoke or suspend the physician's certificate to operate a pain management medical practicepain management practice. The physician owner(s)/ or operator(s) shall have the right to an administrative hearing before the Board at the next available and scheduled meeting of the Board. Further, the Board has the discretion to lift the suspension of a certificate when the pain management medical practice demonstrates compliance with the Board'sapplicable rules and regulations.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).

## Rule 1.165 Violation of Rules.

The prescribing, administering or dispensing of any controlled substance in violation of the above rules shall constitute the administering, dispensing or prescribing of any narcotic drug or other drug having addiction-forming or addiction-sustaining liability otherwise than in the course of legitimate professional practice, in violation of Mississippi Code Miss. Code Ann., Section § 73-25-29(3).

The prescribing, administering or dispensing of any legend drug or other medication in violation of the above rules <u>shall</u> constitutes unprofessional conduct, dishonorable or unethical conduct likely to deceive, defraud or harm the public, in violation of <u>Mississippi CodeMiss</u>. Code Ann., <u>Section§</u> 73-25-29(8)(d).

## Source: Miss. Code Ann. §73-43-11 (1972, as amended).

*Rule 1.176 Effective Date of Rules.* The above rules pertaining to prescribing, administering and dispensing of medication shall become effective October 31, 1987; as amended November 1, 1990; as amended January 3, 1994; as amended September 10, 1995; as amended June 30, 1996; as amended March 18, 1999; as amended May 20, 1999; as amended February 17, 2001; as amended March 22, 2001; as amended July 15, 2004; as amended October 14, 2004; as amended November 8, 2007; as amended May 15, 2008; as amended March 13, 2009; as amended March 24, 2011; as amended September 17, 2012; as amended September 19, 2013; as amended May 22, 2014; and as amended November 13, 2015; and as amended March 22, 2018.

Source: Miss. Code Ann. §73-43-11 (1972, as amended).