

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 to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi by the Mississippi State Board of Medical Licensure.

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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. “Administer”, “Controlled Substances”, and “Ultimate User” shall have the same meaning as set forth in Mississippi Code, Section 41-29-105, unless the context otherwise requires.

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A-B. “Board” means the Mississippi State Board of Medical Licensure.

C. “Physician” means any person licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi.

D. “Physician Assistant” 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.

B-F. “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.

E-G. “Prescribe” 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.

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D-H. “Dispense” 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.

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E-I. For the purpose of enforcement of the labeling requirements set forth in this chapter, Part 2640, Rule 1.7.B, “Dispensing Physician” 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. As stated in Part 2617, it is understood that Physician Assistants may not dispense medications.

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F-J. “Prescription Drug” or “Legend Drug” 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.

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G-K. “Pain Management Clinic Practice” 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-

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cancerous/non-terminal pain. Included in this definition shall be 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. "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 or;

2. -30% or more of the patients receive any controlled substance approved by the FDA for the pharmacologic management of weight loss or; any clinic operated by, staffed by, or affiliated with through affiliation, employment, or collaboration agreement with a Mississippi licensee 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 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.

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 (G) shall must review the MPMP at

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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 shall 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.

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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, shall 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.

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In addition, licensees required to register under this section shall must 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 must be kept in a separate, secure file, to be available for inspection upon request.

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Rule 1.3 does not apply to inpatient settings wherein orders for patients are administered by a third party within said facility.

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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~~ schedules, 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 physician-licensee who engages in the manufacture or distribution of controlled substances or legend drugs shall must register with the Mississippi State Board of Pharmacy pursuant to Mississippi Code, Section 73-21-105 and shall will be subject to all applicable federal statutes and regulations controlling such practices. For the purposes herein, "distribute" shall means the delivery of a drug other than by administering,

prescribing or dispensing. The word “manufacture” shall have 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 Mississippi~~ 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, IIN, 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, IIN, IV and V controlled substances. To insure the reliability of an inventory, the physician shall 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 ~~physician licensee~~ who shall dispense or administer Schedules II, IIN, III, IIN, IV and V controlled substances shall must maintain a separate readily retrievable record of all such substances dispensed or administered. This requirement shall does not apply to Schedules III, IIN, 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, IIN, IV and V controlled substances. The record shall 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 shall 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.

~~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~~

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~~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 physicianlicensee who prescribes, dispenses or administers a legend drug or controlled substance ~~shall~~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 ~~shall~~must be maintained in the patient's medical records, ~~provided that such~~ If medical records are maintained at the office of the physicianlicensee, ~~the records must be~~ are available for inspection by the representatives of the Mississippi State Board of Medical Licensure ~~pursuant to authority granted in Mississippi Code, Section 41-29-125.~~

~~No physician licensees shall~~must 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 physicianlicensee 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 physicianlicensee 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 -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 physicianlicensee's permitting the patient to name the drug desired;
4. a physicianlicensee dispensing or prescribing drugs to patients having no medical need when the physicianlicensee knew or should have known that the patients were addicts;
5. 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;

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6. general remarks of the ~~physician~~ licensee indicating his or her experience with non-therapeutic uses of the drug;

7. a- ~~physician~~ licensee prescribing contraindicated medication such as amphetamines and depressants in a manner which results in therapeutic conflicts.

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The ~~above~~ mentioned 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 drugs~~ 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 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. Rosenberg**, 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 ~~physieian~~ licensee shall 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 ~~shall~~must be maintained in the office of the ~~physician~~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 ~~shall~~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. In cases where Mississippi and federal requirements conflict, the latter shall control.

A ~~physician~~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 ~~physician~~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 ~~shall~~must be made at regular intervals, not to exceed seven (7) days. Such hard-copy printouts ~~shall~~must be maintained for a period of five (5) years and ~~shall~~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 ~~physician licensee in this state~~ to prescribe, dispense or administer any ~~amphetamine or amphetamine-like anorectic and/or central nervous system stimulant medication~~ 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~~must be in compliance with applicable state and federal laws.

~~The ~~physician~~licensee and/or nurse practitioner/physician assistant being overseen/collaborating to provide~~ing comprehensive treatment of obesity ~~shall~~must be present at the facility when he or

she prescribes or dispenses¹ 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 physician licensee may administer, order, dispense or prescribe said medications controlled substances for the purpose of weight loss in or the treatment of obesity only as an adjunct to a regimen to a clearly documented comprehensive program of behavior modification, comprehensive nutritional education, and exercise or physical therapy intervention, weight reduction based on caloric restriction, provided that the physician licensee must 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 physician licensee and/or mid-level provider, or licensed and approved delegate, 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. ~~A physical exam to include Hheight, weight, Body Mass Index (BMI), blood pressure, pulse, % body fat or waist circumference/weight hip ratio, HEENT, chest/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 physician licensee must determine and record the patient's Body Mass Index ("BMI"). No patient should receive anorexic medications unless the patient should have has (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 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,

¹ Part 2640, Rule 1.9, controls in all cases. Physician assistants are not permitted to dispense medication.

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history of substance abuse, severe anticholinergic effects, such as, extreme dryness of mouth or unmanageable constipation should be addressed with physicianlicense prior to starting weight loss medications. Schedule III and IV anorectics can be used in conjunction with any other medications deemed safe by the physicianlicense.

B. The physician license shallmust 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.

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~~C. The physician shall not initiate or discontinue or 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.~~

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~~D.C.~~ A physicianlicense ~~cannot 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.

~~E.D.~~ 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. 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.~~

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~~F.E.~~ 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.

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F. A physicianlicense ~~shallmust~~ not utilize a ~~s~~Schedules 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.

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~~Any o~~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 ~~thise sole treatment of weight loss and are not inclusive examples manner.~~ 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.

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~~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.~~

Comment [JH4]: Covered elsewhere

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

Rule 1.6 ~~Bariatric Medicine, Medical Weight Loss, or Weight Management Clinics Practice~~

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- ~~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 program above. Advertis~~
~~ed medical weight loss must include behavior modification, comprehensive nutritional education, exercise or physical therapy intervention, and long term maintenance programs. Advertis~~
~~ed 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. ~~No bariatric medicine, medical weight loss, or weight management clinic 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 clinic practice shall 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 clinic are required to register with the Board. All physicians licensees associated
with the clinic practice, whether in the capacity as the owner or as a practitioner, should
must be listed on the application and must also be required to meet all regulations
governing the treatment of obesity/medical weight loss. All physicians who are added
or removed from the clinic 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
clinic practice location requires a separate registration certificate.
- C. A bariatric medicine, medical weight loss, or weight management clinic 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.

~~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:~~

~~1. 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 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 facilitypractice, Wellness Centerpractice, or other facilitypractice that meets the definition of Bariatric Medicine, Medical Weight Loss, or Weight Management ClinicPractice shall will be subject to all rules pertaining to Bariatric Medicine, Medical Weight Loss, or Weight Management CliniesPractice if the facility has a Mississippi licensed physicianlicensee, affiliated in any manner.~~

~~F. 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).~~

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

A. Definitions

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

1. “Chronic Pain” 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 ~~six~~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.” 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. “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.
- ~~3.~~ “Acute Pain” 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 ~~time limited~~self-limited and is responsive to therapies, including controlled substances ~~as defined by the U.S. Drug Enforcement Administration. Title 21 CFR Part 1301 Food and Drugs.~~
- ~~2.~~ “Addiction” is a ~~neurobehavioral~~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. ~~Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.~~
- ~~3.~~ “Physical Dependence” is a physiological state of neuroadaptation to ~~a opioid therapy substance~~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. ~~Physical dependence is a normal physiological consequence of extended opioid therapy for pain and should not be considered addiction.~~
- ~~4.~~ “Substance Abuse” is the use of any substance~~(s)~~ for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.
- ~~5.~~ “Tolerance” 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~~ physicianlicensee may order, prescribe, administer, or dispense controlled substances ~~in Schedules II, IIN, III, IIN, 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~~ ~~the ordering, prescribing, administration, or dispensation of controlled substances in Schedules II, IIN, III, IIN, IV and V~~, or other drugs having addiction-forming ~~and or~~ addiction-sustaining liability, ~~use of said medications in for~~ the treatment of chronic pain should be done with caution. A physicianlicensee 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 ~~utilizing a Schedules II, IIN, III, IIN, IV or V~~ with a controlled substance, or any other drug having addiction-forming ~~and or~~ addiction-sustaining liability, the physicianlicensee shall ~~must~~ 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 shall ~~must~~ 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 with~~ with the need for other indicated treatment modalities for the treatment of chronic pain. ~~This shall~~ The results of this analysis must be clearly entered into the patient medical record and shall ~~must~~ 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 shall ~~must~~ include a complete medical history and physical examination and supporting studies and reports of consultation.
 - ~~2-3.~~ The diagnosis must that indicates ~~demonstrate~~ the presence of one or more recognized medical indications for the use of controlled substances.
 - ~~3-4.~~ Documentation of a written treatment plan which shall ~~must~~ contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments. The plan ~~should also~~ must 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 shall ~~must~~ be terminated (e.g., 'doctor shopping' behavior, adverse urine/serum screens, etc.).
 - ~~4-5.~~ 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 ~~the~~ physicianlicensee'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.

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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 physicianlicensee's directions. These circumstances include those patients obtaining controlled substances or other drugs having addiction-forming and addiction-sustaining liability~~other abusable drugs~~ from more than one physicianlicensee and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other drug having addiction-forming and addiction-sustaining liability~~other abusable drugs~~ before a prior prescription should have been consumed according to the treating 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 physicianlicensee ~~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 ~~shall~~must be undertaken by the physicianlicensee.

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 addict~~ for the purpose of "detoxification treatment" or "maintenance treatment" and no physicianlicensee shall order, prescribe, administer, or dispense~~administer or dispense~~ any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" unless ~~they~~ the physicianlicensee ~~is~~are 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 shall must first run a MPMP on the patient. The licensee shall must 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 should must avoid dosages greater than or equal to 90 mg of morphine equivalence per day and must

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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 ~~should~~ licensees 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 seven (7) day supply for acute non-cancer/non-terminal pain. Licensees may issue an additional seven (7) 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 seven (7) 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.

I. When prescribing opioids for either chronic or acute pain, it ~~shall be~~ considered a contraindication 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.

J. 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) (G) the licensee ~~shall~~ 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 ~~shall~~ 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 treatment. Documentation, such as a copy of the report itself and/or reflections in the charts dictation and/or notes ~~shall~~ must be kept within the patient’s record and made available for inspection upon request. In addition, licensees required to register under this section ~~shall~~ must 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~~ must be kept in a separate file to be available for inspection upon request.

K. Point of service drug testing must be done each time a Schedule II medication is written for the treatment of chronic non-cancer/non-terminal pain. Point of service drug testing and MPMP review must be done at least every ninety (90) days for patients prescribed benzodiazepines for chronic medical and/or psychiatric conditions which are non-cancer/non-terminal.

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L. The use of Methadone to treat chronic and/or acute non-cancer/non-terminal pain is prohibited.

F.M. Rule 1.7 does not apply to inpatient settings wherein orders for patients are administered by a third party within said inpatient facility.

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

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~~Rule 1.8 Drug Maintenance Requirements. All drug products/medications which are maintained or stored in the office of a physician/physician licensee's office shall 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 which that are pre-counted and prepackaged for purposes of dispensing shall must be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained shall must not be labeled in any false or misleading manner. The labeling requirements of this rule are in addition to, and not in lieu of, other labeling requirements of the Laws 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 must not dispense out-of-date drugs/medications, or store out of date drugs intermixed with the stock of current drugs. Out-of-date drugs/medications shall must 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 must dispense the product with this information intact.~~

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

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~~A physician/licensee shall 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 physician/licensee.~~

~~All drug products shall be maintained, stored and dispensed in such a manner as to maintain the integrity of the product.~~

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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 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 ~~shall must~~ be written in legible handwriting or typed and ~~shall must~~ be permanently affixed to the package or container in which the medication is dispensed. ~~This labeling requirement shall not apply to prepackaged samples or starter packs in their original packages or containers need only have the patient name, date dispensed 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" ~~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 licensee~~ 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 ~~a healthcare professional licensee~~ 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, ~~physician licensee~~ ~~shall must~~ indicate the appropriate refills, not to exceed five (5), or mark "none."
- C. Each ~~physician licensee~~ ~~shall must~~ insure that the complete name and address of the patient to whom the ~~physician licensee~~ is prescribing the controlled substance appears on the prescription.
- D. A ~~physician licensee~~ ~~shall must~~ not permit any prescription for controlled substances to be signed by any ~~one non-physician unauthorized individual~~ in the place of or on behalf of the ~~physician licensee~~.
- E. A ~~physician licensee~~ ~~shall must~~ not pre-sign ~~blank~~ prescription pads or order forms ~~under any circumstances.~~

Comment [DBM6]: I am not sure that I agree with this for legend drugs that are prepackaged samples.

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F. A ~~physician licensee shall~~must 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 ~~unless; 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~~is 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:

1. The prescription order ~~shall~~must contain the date, time, telephone number and location of the transmitting device. Prescription blanks utilized in this manner ~~shall~~must 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, o~~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 ~~physician licensee~~ or the ~~physician licensee's~~ agent to a pharmacy of the patient's choice by facsimile. All original hardcopy faxed prescriptions ~~shall~~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) ~~shall~~must be retained in the ~~physician 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.

~~It is also required, that i~~In addition to filing the original prescription (or copy) in the patient file, a perpetual, chronological logbook of fax transactions ~~be~~shall must be 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~~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 ~~the initials or name a~~ personal identifier of the person faxing the prescription. Such logs ~~shall~~must be maintained in the ~~physician 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, ~~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's physician or the physician's~~ agent ~~will~~ **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.
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.~~

Comment [JH7]: What is this? JOHN- I BELIEVE IT IS ELECTRONIC RECORD SYSTEM

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- G. No more than one (1) controlled substance shall be issued on a single prescription blank.
- G-H. Prescriptions for Benzodiazepines must be limited to a one (1) month supply, with no more than two (2) 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 ~~physician~~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;

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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.

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~~A-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 practitioner~~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. Electronic transmissions may be computer to computer or computer to facsimile.

~~B-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 physician~~licensee~~. 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 shall~~must~~ be authorized by a written or electronic signature and shall~~must~~ be issued in accordance with all other provisions of this rule. No prescriptions for brand name or generic equivalents of any form or compound containing n~~Nalbuphine HCl, c~~Carisoprodol, b~~Butalbital compounds, or t~~Tramadol HCl shall be telefaxed.

~~C-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.~~

~~D-E.~~ All written prescriptions shall~~must~~ be on forms containing two lines for the physician's licensee's signature. There shall~~must~~ be a signature line in the lower right-hand corner of the prescription form beneath which shall~~must~~ be clearly imprinted the words "substitution permissible." There shall~~must~~ be a signature line in the lower left corner of the prescription form beneath which shall~~must~~ be clearly imprinted with the words "dispense as written." The physician's licensee's signature on either signature line shall~~must~~ validate the prescription and designate approval or disapproval of product selection. Each prescription form shall~~must~~ bear the pre-printed name of the physician~~licensee~~; or the physician~~licensee~~ shall~~must~~ clearly print his or her name on the prescription form, in addition to the licensee~~physician~~'s original signature. In the event that the prescription form bears the pre-printed name of more than one licensee~~physician~~, the licensee~~physician~~ shall~~must~~ clearly indicate the name of the phy~~licensee~~ licieian 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.

~~E-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 physician, he or she shall 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 physician 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 Physicians~~ should avoid issuing prescriptions refillable on "prn" basis. If a licensee physician 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.~~

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G. Every written prescription issued by a licensee physician, bearing more than one non-controlled medication, shall 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 shall must be clearly voided by the issuing licensee physician.

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~~F-H.~~ A prescription shall 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 physician.
2. Thirty (30) days after the issuing licensee physician has moved or otherwise changed ~~the practice location of his or her practice so as to resulting in~~ termination of the ~~doctor/~~ licensee patient relationship. Termination of the ~~doctor/~~ licensee patient relationship results when a patient is no longer able to seek personal consultation or treatment from the issuing licensee physician.
3. ~~Insofar as controlled substances are concerned, i~~ Immediately after loss of DEA Controlled Substances Privilege by the issuing licensee physician if the prescription is for controlled substances.
4. Immediately ~~after upon~~ revocation, suspension or surrender of the licensee physician's license.

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

Rule 1.12 Freedom of Choice. A licensee physician shall 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. ~~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 ~~licensee physician~~ may own or operate a pharmacy if there is no resulting exploitation of patients. A ~~licensee physician shall~~ must not give ~~a patient's~~ 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 ~~physician~~ provider. The prescription is a written direction for a therapeutic or corrective agent. A patient is entitled to a copy of the ~~licensee physician'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 ~~wherever the patient wishes~~ by any legal means. Where medication is to be dispensed or a prescription, excluding refills, called in to a pharmacist for medication, a ~~licensee physician shall~~ 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 ~~shall~~ must be honored. ~~Licensees Physicians shall~~ 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 ~~physician~~ licensee with respect to the filling of the ~~licensee physician's~~ prescriptions.

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.~~

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

~~Rule 1.143 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 shall~~ must be maintained in such a manner as to deter loss by theft or burglary. ~~All controlled substances shall~~ 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 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~~

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present a plan designed to prevent further loss of controlled substances, ~~or he or she may be ordered by~~ The Board has the authority to order implementation any other reasonable measures to improve security over controlled substances ~~deemed necessary by the Board to prevent further loss of the controlled substances.~~

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

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.
2. “Physician” 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.
3. “Licensee” means any person licensed and/or regulated by the Mississippi State Board of Medical Licensure to practice in the state of Mississippi. “Licensee” means any person licensed to practice in the State of Mississippi by the Board who has prescriptive authority.

4. “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.

5. “Pain Management Medical Practice” 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 physician owner(s)/operator(s) of the pain management medical practice must possess and maintain 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

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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 of the pain management medical practice and shall must 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.
- ~~B-C.~~ Each A-physician owner of a pain management medical practice or medical director who owns, operates or is employed in any pain management medical practice must meet the requirements set forth below.
- ~~C-E.~~ Each -physician 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(s)/operator(s) of the a pain management medical practice must:

1. submit the documents required by the application process for demonstrating proof of ownership or provide alternative documents with a written request for special consideration;
2. report ownership or investment interest of 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 there the physician has an ownership or vested interest;
3. 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 of the effective date of the change.

~~D-F.~~ 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.

~~E-G.~~ Physician owners or operators owner(s)/operator(s) or employees 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 medical director/physician 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

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3. holds a certificate of registration for that pain management practice.

~~F.H.~~ ~~No~~In addition, the physician owners or operators~~owner(s)/operator(s)~~ of a pain management practice, nor any physician, nor any physician assistant~~employee of the practice nor any medical director, manager, or employee or any physician or physician assistant who provides care~~ physician or physician assistant with whom the physician owner(s)/operator(s) of a practice contracts for services may not:

- ~~1.~~ 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.~~ 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.~~ 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 definitionsunder which the person may prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions;
- ~~4.~~ 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.~~ 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;
- ~~6.~~ 6. 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
- ~~7.~~ 7. 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.

~~G.I.~~ 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.

~~H.J.~~ Training rRequirements 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 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:

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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-face, 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 practice~~ certificate.

~~a. Live lecture format participation may be in person, or remotely as is the case of teleconferences or live Internet webinars.~~

~~b. a. CME must have emphasis in the specific areas of pain management, addiction, and/or prescribing of opiates.~~

~~e. b. CME is to may be included with the forty hour requirement for licensure renewal.~~

~~d. 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. K. 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 shall~~ must be obtained on the initial visit for each patient. Subsequent reports must be obtained for each patient at every visit, and at intervals deemed appropriate for consistent with good patient care from the MPMP but no less frequently than every three months, for every patient receiving controlled substances in a registered pain management practice.~~

~~J. L. 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~~ 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).

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M. 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,~~ ~~¶~~This does not prohibit a MPHP participant from working in a pain practice.

~~K-N.~~ 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.

~~L-O.~~ Certificates are valid for one year and must be renewed annually ~~along 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 ~~shall~~ 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.

~~M-P.~~ 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.

~~N-Q.~~ 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 ~~pain 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's~~ applicable 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, Section 73-25-29(3).~~

The prescribing, administering or dispensing of any legend drug or other medication in violation of the above rules ~~shall~~ constitutes unprofessional conduct, dishonorable or unethical conduct likely to deceive, defraud or harm the public, in violation of ~~Mississippi Code~~ Miss. Code Ann., Section § 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

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Comment [JH11]: This addresses concerns related to physician involvement in management

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Comment [JD12]: Just my opinion but we should probably keep this as is.

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.

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