Mississippi Secretary of State
125 South Congress St., P. O. Box 136, Jackson, MS 39205-0136

ADMINISTRATIVE PROCEDURES NOTICE FILING

AGENCY NAME		CONTACT PERSON	TELEPHONE NUMBER	
Mississippi State Board Of Medical Licensure		Mike Lucius	(601)987-0248	
ADDRESS		CITY	STATE	ZIP
1867 Crane Ridge Drive, Suite 200-B		Jackson	MS	39216
EMAIL	SUBMIT DATE	Name or number of rule(s):		
mboard@msbml.ms.gov	12/7/18	Part 2640 Chapter 1: Prescribing, Administering and Dispensing, Rule 1.7		

Short explanation of rule/amendment/repeal and reason(s) for proposing rule/amendment/repeal: Rule 1.7 is being modified to clarify the rules regarding the use of controlled substances for chronic pain.

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

List all rules repealed, amended, or suspended by the proposed rule: Part 2640: Prescribing, Administering and Dispensing, Rule 1.7

ORAL PROCEEDING:

☐ An oral proceeding is scheduled for this rule on Date: _____ Time: _____ Place: _____

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

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

ECONOMIC IMPACT STATEMENT:

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

TEMPORARY RULES	PROPOSED ACTION ON RULES	FINAL ACTION ON RULES
_____ Original filing	**Action proposed:**	**Date Proposed Rule Filed:**
_____ Renewal of effectiveness	_____ New rule(s)	**Action taken:**
To be in effect in _____ days	X Amendment to existing rule(s)	_____ Adopted with no changes in text
Effective date:	_____ Repeal of existing rule(s)	_____ Adopted with changes
_____ Immediately upon filing	_____ Adoption by reference	_____ Adopted by reference
_____ Other (specify): _____	**Proposed final effective date:**	_____ Withdrawn
	X 30 days after filing	_____ Repeal adopted as proposed
	_____ Other (specify): _____	**Effective date:**
		_____ 30 days after filing
		_____ Other (specify): _____

Printed name and Title of person authorized to file rules: Mike Lucius, Deputy Director

Signature of person authorized to file rules: Mike Lucius

OFFICIAL FILING STAMP	DO NOT WRITE BELOW THIS LINE OFFICIAL FILING STAMP	OFFICIAL FILING STAMP
	FILED DEC 07 2018 MISSISSIPPI SECRETARY OF STATE	
Accepted for filing by	**Accepted for filing by** #23815	**Accepted for filing by**

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

Part 2640: Prescribing, Administering and Dispensing

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

Rule 1.7 Use of Controlled Substances for Chronic (Non-Cancer/Non-Terminal) Pain.
The following rules are not intended to supersede or exempt licensees from the requirements heretofore stated in Rule 1.4 *Maintenance of Records and Inventories.*

A. Definitions

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

1. "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 licensee and one or more licensee specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain. Further, if a patient is receiving controlled substances for the treatment of pain for a prolonged period of time (more than three months), then they will be considered for the purposes of this regulation to have "de facto" chronic pain and subject to the same requirements of this regulation. "Terminal Disease Pain" should not be confused with "Chronic Pain."
2. "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 self-limited and is responsive to therapies, including controlled substances.
4. "Addiction" is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm.
5. "Physical Dependence" is a physiological state of neuroadaptation to substance which is characterized by the emergence of a withdrawal syndrome if the use of the substance is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by re-administration of the substance. .
6. "Substance Abuse" is the use of any substance for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.
7. "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.

B. A licensee may order, prescribe, administer, or dispense controlled substances, or other drugs having addiction-forming and addiction-sustaining liability to a person for the treatment of chronic pain.

C. The ordering, prescribing, administration, or dispensation of controlled substances, or other drugs having addiction-forming or addiction-sustaining liability for the treatment of chronic pain should be done with caution. A licensee may order, administer, dispense or

prescribe said medications for the purpose of relieving chronic pain, provided that the following conditions are met:

1. Before initiating treatment with a controlled substance, or any other drug having addiction-forming or addiction-sustaining liability, the licensee must conduct a risk/benefit analysis by reviewing records of prior treatment. The risk/benefit analysis should weigh in favor of treatment and indicate the need for controlled substance therapy. Such a determination must take into account the specifics of each patient's diagnosis, past treatments, suitability for long-term controlled substance, with the need for other treatment modalities. The results of this analysis must be clearly entered into the patient medical record and must include supporting documentation such as consultation or referral reports and efforts to determine the underlying etiology of the chronic pain.
2. Documentation in the patient record must include a complete medical history and physical examination and supporting studies and reports of consultation.
3. The diagnosis must demonstrate the presence of one or more recognized medical indications for the use of controlled substances.
4. Documentation of a written treatment plan which must contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments. The plan must contain an informed consent agreement for treatment that details relative risks and benefits of the treatment course. The consent must also include specific requirements of the patient, such as using one licensee and pharmacy, urine/serum medication level monitoring when requested, pill counts, and the grounds for which the treatment may be terminated (e.g., 'doctor shopping' behavior, adverse urine/serum screens, etc.).
5. Periodic review and documentation of the treatment course is conducted no less frequently than every 3 months. The licensee's evaluation of progress toward the stated treatment objectives must support all changes in therapy. This should include referrals and consultations as necessary to achieve those objectives.

D. No licensee shall order, administer, dispense or prescribe a controlled substance or other drug having addiction-forming and addiction-sustaining liability that is non-therapeutic in nature or non-therapeutic in the manner the controlled substance or other drug is administered, dispensed or prescribed.

E. No licensee shall order, administer, dispense or prescribe a controlled substance for treatment of chronic pain to any patient who has consumed or disposed of any controlled substance or other drug having addiction-forming and addiction-sustaining liability other than in strict compliance with the treating licensee's directions. These circumstances include those patients obtaining controlled substances or other drugs having addiction-forming and addiction-sustaining liability from more than one licensee or healthcare provider and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other drug having addiction-forming and addiction-sustaining liability before a prior prescription should have been consumed according to the treating licensee's directions. This requirement will not be enforced in cases where a patient has legitimately temporarily escalated a dose due to an acute exacerbation if the treating licensee documents that the escalation was due to a recognized indication and was within appropriate therapeutic dose ranges. Repetitive or continuing escalations

should be a reason for concern and a re-evaluation of the present treatment plan must be undertaken by the licensee.

F. No licensee shall order, prescribe, administer, or dispense any controlled substance or other drug having addiction-forming or addiction-sustaining liability for the purpose of "detoxification treatment" or "maintenance treatment" and no licensee shall order, prescribe, administer, or dispense any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" unless the licensee is registered in accordance with Section 21 U.S.C. 823(g). Nothing in this paragraph shall prohibit a licensee from administering narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Nothing in this paragraph shall prohibit a licensee from ordering, prescribing, administering, or dispensing controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.

G. When initiating opioid therapy for chronic pain, the licensee must first run a MPMP on the patient. The licensee must prescribe the lowest effective dosage. While there is no single dosage threshold identified below which the risk of overdose is eliminated, licensees must strive to keep daily opioid doses less than or equal to 50 mg of morphine equivalence (mEq), as dosages larger than 50 mEq per day increases risk without adding benefits for pain control or function. Licensees must avoid dosages greater than or equal to 90 mg of morphine equivalence per day and must provide significant justification for exceeding the 90 mg ceiling stated herein. If the licensee determines that a patient requires greater than 100 mg of morphine equivalence per day, the licensee must refer the patient to a pain specialist for further treatment.

H. When opioids are prescribed for acute pain, the licensee must prescribe the lowest effective dose of immediate release opioids, as the use of long acting opioids for acute non-cancer/non-terminal pain is prohibited. Licensees must prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Licensees are discouraged from prescribing or dispensing more than a three (3) day supply of opioids for acute non-cancer/non-terminal pain, and must not provide greater than a ten (10) day supply for acute non-cancer/non-terminal pain. Licensees may issue an additional ten (10) day supply if clinically necessary, but said supply must be issued in accordance with Title 21 CFR § 1306.12 *Refilling prescriptions; issuance of multiple prescriptions* (i.e., the prescription must be dated on the date of issuance with 'do not fill until' noting the date the prescription may be filled), and such need for an additional ten (10) day supply must be documented in the chart to evidence that no other alternative was appropriate or sufficient to abate the acute pain associated with that medical condition. Additional ten (10) day supplies, with one (1) refill, may be issued if deemed medically necessary and only if supported by additional clinical evaluation.

I. As stated in Rule 1.3, every licensee must review an MPMP report at each patient encounter in which a Schedule II medication is prescribed for acute pain or chronic non-cancer/non-terminal pain. MPMP reports may be obtained by designees of the licensee as allowed by the MPMP program.

J. When prescribing opioids for either chronic or acute pain, it is a relative contraindication (black box warning) to prescribe opioids concurrently with Benzodiazepines and/or Soma. However, opioids and benzodiazepines may be prescribed concurrently on a very

short term basis, and in accordance with section H of this rule, when an acute injury requiring opioids occurs. The need for such concurrent prescribing must be documented appropriately in the chart. Patients who are currently on an established regimen of concomitant opioids and benzodiazepines may be allotted a reasonable period of time to withdraw from one or both substances. Caution and care should be taken to prescribe the lowest effective dose of each medication if unable to discontinue one or the other completely. Clinicians involved in managing a patient's care should document communication regarding the patient's needs, goals, risks and coordination of care. Prescribing of opioids concurrently with benzodiazepines and/or Soma may be allowed only under very limited circumstances in which the combination is used to treat very specific chronic medical conditions for which there is no other treatment modality available.

K. When a licensee treats chronic non-cancerous/non-terminal pain and/or psychiatric conditions outside the definition of a pain management practice (Rule 1.2) (K) the licensee must actively utilize the MPMP upon initial contact with a new patient and every 3 months thereafter on any and all patients who are prescribed, administered, or dispensed controlled substances. Reports generated on patients must span the length of time from the previous review of the MPMP so that adequate information is obtained to determine the patient's compliance for and with treatment. Documentation, such as a copy of the report itself and/or reflections in the charts dictation and/or notes must be kept within the patient's record and made available for inspection upon request.

L. In-office drug testing must be done at least three (3) times per calendar year when Schedule II medication is written for the treatment of chronic non-cancer/non-terminal pain. In-office drug testing and MPMP review, as described in Rule 1.7 (K), must be done at least three (3) times per calendar year for patients prescribed benzodiazepines for chronic medical and/or psychiatric conditions which are non-cancer/non-terminal. In-office drug testing must test, at a minimum, for opioids, benzodiazepines, amphetamines, cocaine, and cannabis. Inpatient treatment, as defined in Rule 1.2(L), is exempt from this requirement. Further, all hospice treatment is exempt from in-office drug testing requirements stated herein.

M. The use of Methadone to treat acute non-cancer/non-terminal pain is prohibited. The use of Methadone for the treatment of chronic non-cancer/non-terminal pain is permissible within a registered Pain Management Practice, as defined in Rule 1.2(K), or when resulting from a referral to a certified pain specialist. If Methadone is prescribed to treat chronic non-cancer/non-terminal pain, it must only be initiated by a physician.

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

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