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		Jonathan Dalton	601-987-3079	
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	4/1/25	30 Miss. Admin. Code, Pt. 2640, Ch. 1 *Rules Pertaining to Prescribing, Administering and Dispensing of Medication*, R. 1.4 *Maintenance of Records and Inventories*		

Short explanation of rule/amendment/repeal and reason(s) for proposing rule/amendment/repeal: Proposed revision of the section of the prescribing rules related to maintenance of patient medical records. The Board is updating the requirements listed in this rule to reflect updates in statutory requirements for maintenance of patient records and imaging, and for condensing regulations in related rule filings to point to a single chapter (Part 2635, Ch. 10) regarding maintenance of records.

Specific legal authority authorizing the promulgation of rule: Miss. Code Ann., §73-43-11

List all rules repealed, amended, or suspended by the proposed rule: Pt. 2640, Ch. 1, R. 1.4

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

_____ Original filing
_____ Renewal of effectiveness
To be in effect in _____ days
Effective date:
_____ Immediately upon filing
_____ Other (specify): _____

PROPOSED ACTION ON RULES

Action proposed:
_____ New rule(s)
__X__ Amendment to existing rule(s)
_____ Repeal of existing rule(s)
_____ Adoption by reference
Proposed final effective date:
__X__ 30 days after filing
_____ Other (specify): _____

FINAL ACTION ON RULES

Date Proposed Rule Filed: _____
Action taken:
_____ Adopted with no changes in text
_____ Adopted with changes
_____ Adopted by reference
_____ Withdrawn
_____ Repeal adopted as proposed
Effective date:
_____ 30 days after filing
_____ Other (specify): _____

Printed name and Title of person authorized to file rules: Jonathan Dalton, Director of Investigations
Signature of person authorized to file rules: Jonathan Dalton

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

Rule 1.4 | Maintenance of Records and Inventories.

Every licensee shall maintain inventories, logs, and records prescribed in this rule.

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

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

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

Licensees must not prescribe, administer or dispense any legend drug; any controlled substance; or any drug having addiction-forming or addiction-sustaining liability without a good faith prior

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

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

1. the quality and extent of the documented history and physical exam, which may also be accomplished through appropriate telemedicine as defined in Part 2635 Rule 5.5;
2. the extent to which the prescribed therapy is supported by documented history and physical exam;
3. the licensee's permitting the patient to name the drug desired;
4. a licensee dispensing or prescribing drugs to patients having no medical need, when the licensee knew or should have known that the patients were addicts or abusing/misusing substances;
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;
6. general remarks of the licensee indicating his or her experience with non-therapeutic uses of the drug;
7. a licensee prescribing contraindicated medication such as amphetamines and depressants in a manner which results in therapeutic conflicts.

The aforementioned is of particular importance in cases in which controlled substances are to play a part in the course of treatment. It is the responsibility of the licensee to dispense, prescribe or administer all therapies with proper regard for the actual and potential dangers. This fact has been established in a number of closely related administrative and criminal cases, **United States v. Bartee**, 479 F.2d 484 (10th Cir. 1973) (No physical examination prior to issuance of prescriptions for controlled substances); **United States v. Greene**, 511 F.2d 1062 (7th Cir. 1975); **Arthurs v. Board of Registration of Medicine**, 418 N.E. 2d 1236 (MA 1981) (failure to record in patient file prescriptions for controlled substances 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" requires examination of the nature of the therapy and all circumstances surrounding its implementation. Use of any therapy should be supported by standards of medical practice, reasonable scientific evidence or consensus and documented in the medical record. Case law developed by the courts in connection with controlled substances criminal violations and administrative decisions further illustrates several indications of lack of good faith. See **United States v. Greene**, 511 F.2d 1062 (7th Cir. 1975) and **United States v. Rosenburg**, 515 F.2d 190 (9th Cir. 1975). One of primary importance is the failure to follow at least the minimal professional procedures. Some of the factors used in determining the existence of "good faith" may include, but are not limited to: (a) the physician's permitting the patient to name the drug desired; (b) a physician dispensing drugs to patients having no medical need, when the physician knew or should have known that the patients were addicts; (c) repeated refills over relatively short periods of time or the issuance of prescriptions at a time when the patient should not have been finished taking the same medication from a prior prescription had the prescription directions been properly followed or the correct dosage taken; (d) general remarks of the physician indicating his or her experience with non-therapeutic uses of the drug; (e) a physician prescribing contraindicated medication such as amphetamines and depressants in a manner which results in therapeutic conflicts

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

The Controlled Substances Inventory, Controlled Substance Dispensation/Administration Record, and Patient Record required by these rules must be maintained in accordance with Part 2635, Chapter 10 *Maintenance, Production, and Release of Medical Records*. Record retention for Controlled Substances Inventory, Controlled Substance Dispensation/Administration Records, and Patient Records must also meet all applicable federal statutes and regulations.

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

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

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

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    C. The method of administration of the controlled substance, i.e. oral, IV or subcutaneous.
    D. The name and address of the patient to whom the controlled substance was dispensed or administered.
    E. For all Schedules II and III amphetamines, amphetamine-like anorectic drugs, or sympathomimetic amine drugs dispensed in the treatment of narcolepsy, hyperkinesis, brain dysfunction, epilepsy, or depression, the dispensing or administration records must include the diagnosis and the reason for use of the Schedules II and III controlled substances.

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The Controlled Substances Inventory, Controlled Substance Dispensation/Administration Record, and Patient Record required by these rules must be maintained in accordance with Part 2635, Chapter 10 *Maintenance, Production, and Release of Medical Records*.~~in the office of the licensee for a period of seven (7) years from the date that the record is completed or the controlled substances, legend drugs or other medications are prescribed, administered or dispensed and must be made available for inspection by representatives of the Mississippi State Board of Medical Licensure pursuant to authority granted in Mississippi Code, Section 41-29-125~~. Record retention for Controlled Substances Inventory, Controlled Substance Dispensation/Administration Records, and Patient Records must also meet all applicable federal statutes and regulations.

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