Chapter 25 Regulations Pertaining to Prescribing, Administering and Dispensing of Medication

Scope

100 These regulations apply to all individuals licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi.

Definitions

200 For the purpose of Chapter 25 only, the following terms have the meanings indicated:

1. "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.
2. "Physician" means any person licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi.
3. "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.
4. "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.
5. For the purpose of enforcement of the labeling requirements set forth in Section 601 of these regulations, "Dispensing Physician" means any physician who shall dispense 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.
6. "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 only.

Registration for Controlled Substances Certificate

300 Every physician 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.

301 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 Section 300 above. In the event, however, a physician has had limitations or other restrictions placed upon his or her license wherein he or she is prohibited from handling controlled substances in any or all schedules, said physician 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.

302 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 regulations and in conformity with provisions of the Mississippi Uniform Controlled Substances Law, Mississippi Code, Section 41-29-101 et seq.

303 The registration requirement set forth in these regulations does not apply to the distribution and manufacture of controlled substances. Any physician who engages in the manufacture or distribution of controlled substances or legend drugs shall register with the Mississippi State Board of Pharmacy pursuant to Mississippi Code, Section 73-21-105. For the purposes herein, "distribute" shall mean 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).

Maintenance of Records and Inventories

400 Every physician licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi shall maintain inventories, logs, and records prescribed in this chapter.

401 Controlled substances inventory record. All controlled substances classified under Schedules II, IIN, III, IIIN, IV and V which are purchased by the physician must be inventoried at least every two (2) years. All inventory records for controlled substances in Schedules II and IIN must be maintained separately from the inventory records for Schedules III, IIIN, IV and V controlled substances. To insure the reliability of an inventory, the physician shall 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.

402 Controlled substances dispensation/administration record. Every physician who shall dispense or administer Schedules II, IIN, III, IIIN, IV and V controlled substances shall maintain a separate readily retrievable record of all such substances dispensed or administered. This requirement shall 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 shall 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

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 include the diagnosis and the reason for use of the Schedules II and III controlled substances.

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

404 Patient Record. A physician who prescribes, dispenses or administers a controlled substance shall 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 controlled substance; the name, dose, strength, quantity of the controlled substance and the date that the controlled substance was prescribed, dispensed or administered. The record required by this section shall be maintained in the patient's medical records, provided that such medical records are maintained at the office of the physician and 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.

405 No physician shall prescribe, administer or dispense any controlled substance or other drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication therefore.[1]

---

[1] COMMENT: A determination as to whether a "good faith prior examination and medical indication therefore" exists depends upon the facts and circumstances in each case. One of the primary roles of a physician is to elicit detailed information about the signs and symptoms which a patient presents in order that he or she may recommend a course of treatment to relieve the symptoms and cure the patient of his or her ailment or maintain him or her in an apparent state of good health. In order for a physician to achieve a proper diagnosis and treatment plan, a history and physical examination consistent with the nature and complaint are necessary. The importance of these aspects of proper medical practice cannot be over emphasized. The paramount importance of a complete medical history in establishing a correct diagnosis is well established. Standards of proper medical practice require that, upon any encounter with a patient, in order to establish proper diagnosis and regimen of treatment, a physician 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 a function of the "course of legitimate professional practice" is 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 to dispense, prescribe or administer such drugs 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

406 A physician shall 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.

407 The Controlled Substances Inventory, Controlled Substance Dispensation/Administration Record, and Patient Record required by these regulations shall be maintained in the office of the physician 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 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.

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

Use of Diet Medication

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

---

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 and all circumstances surrounding dispensation. 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.

501 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 may administer, dispense or prescribe said medications for the purpose of weight loss in the treatment of obesity only as an adjunct to a regimen of weight reduction based on caloric restriction, provided, that all of the following conditions are met:

1. Before initiating treatment utilizing a Schedules III, IV or V controlled substance, the physician determines through review of his or her own records of prior treatment, or thorough review of the records of prior treatment which another treating physician or weight-loss program has provided to the physician, that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without the utilization of controlled substances, and that said treatment has been ineffective.
2. Before initiating treatment utilizing a Schedules III, IV or V controlled substance, the physician obtains a thorough history, performs a thorough physical examination of the patient, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized. "Recognized contraindication" means any contraindication to the use of a drug which is listed in the United States Food and Drug Administration (hereinafter, "F.D.A.") approved labeling for the drug.
3. The physician shall not utilize any Schedules III, IV or V controlled substance when he or she knows or has reason to believe that a recognized contraindication to its use exists.
4. The physician shall not utilize any Schedules III, IV or V controlled substance in the treatment of a patient whom he or she knows or should know is pregnant.
5. As to those controlled substances in Schedules III, IV or V which are classified as amphetamine or amphetamine-like anorectics and/or central nervous system stimulants, hereinafter referred to as "stimulant", the physician shall not initiate or shall discontinue utilizing said controlled substance stimulant immediately upon ascertaining or having reason to believe:
   a. That the patient has failed to lose weight while under treatment with said stimulant over a period of thirty (30) days, which determination shall be made by weighing the patient at least every thirtieth (30th) day, except that a patient who has never before received treatment for obesity utilizing a stimulant, and who fails to lose weight during his or her first such treatment attempt may be treated with a different controlled substance for an additional thirty (30) days.
   b. That the patient has developed tolerance (a decreasing contribution of the drug toward further weight loss) to the anorectic effects of said stimulant being utilized.
   c. That the patient has a history of or shows a propensity for alcohol or drug abuse.
   d. That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions.

   In addition to the above the physician shall not issue a prescription or dispense a stimulant for any greater than a thirty (30) day supply; and a patient's

use of stimulants, whether by dispensation or prescription shall be limited to no more than six (6) thirty (30) day supplies during any twelve (12) month period of time. In any case, the total amount of medication shall not exceed a six (6) month supply in the twelve month time period. For the purposes of this paragraph, a twelve (12) month time period is considered to begin on the day of the initial dispensation or prescription issuance.

6. As to all other legend drugs or controlled substances in Schedules III, IV and V which are not considered stimulants but which have received FDA approved indication for long-term use for weight loss, the physician shall administer, dispense or prescribe said medications in strict compliance with the FDA-approved labeling. In addition to the requirements enumerated at 501.5.a-d above, each prescription shall be issued for no more than a total of three months supply (including refills) and further, before subsequent new prescriptions can be issued the patient shall receive a thorough reevaluation of the effectiveness of the medication, including a physical examination to document any potential harmful side effects.

502 A physician shall not utilize a 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.

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

600 Definitions

For the purpose of Section 600 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 physician and one or more physicians 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 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 section, "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. "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. It is generally time 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.
3. "Addiction" is a neurobehavorial 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.

4. "Physical Dependence" is a physiological state of neuroadaptation to a 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.
5. "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.
6. "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.

601 Notwithstanding any other provisions of these rules and regulations, a physician may prescribe, administer, or dispense controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability to a person in the usual course of treatment of that person for a diagnosed condition causing chronic pain.

602 Notwithstanding any other provisions of these rules and regulations, as to the prescribing, administration, or dispensation of controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability, use of said medications in the treatment of chronic pain should be done with caution. A physician may 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, IIIN, IV or V controlled substance, or any other drug having addiction-forming and addiction-sustaining liability, the physician shall 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, that there is an indicated need for long-term controlled substance therapy. Such a determination shall take into account the specifics of each patients diagnosis, past treatments and suitability for long-term controlled substance use either alone or in combination with other indicated modalities for the treatment of chronic pain. This shall be clearly entered into the patient medical record and shall include consultation/referral reports to determine the underlying pathology or cause of the chronic pain.
2. Documentation in the patient record shall include a complete medical history and physical examination that indicates the presence of one or more recognized medical indications for the use of controlled substances.
3. Documentation of a written treatment plan which shall contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments. The plan should also contain an

4. Periodic review and documentation of the treatment course is conducted at reasonable intervals (no more than every six months) with modification of therapy dependent on the physician's evaluation of progress toward the stated treatment objectives. This should include referrals and consultations as necessary to achieve those objectives.

603 No physician shall 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.

604 No physician shall administer, dispense or prescribe a controlled substance for treatment of chronic pain to any patient who has consumed or disposed of any controlled substance or other drug having addiction-forming and addiction-sustaining liability other than in strict compliance with the treating physician's directions. These circumstances include those patients obtaining controlled substances or other abusable drugs from more than one physician and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other abusable drugs before a prior prescription should have been consumed according to the treating physician'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 the treating physician to document in the patient record that such increase in dose level 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 be undertaken by the physician.

605 No physician shall prescribe 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 physician shall administer or dispense any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" unless they are properly registered in accordance with Section 303(g) 21 U.S.C. 823(g). Nothing in this paragraph shall prohibit a physician 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 physician from 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.

<u>Drug Maintenance Requirements</u>

700 All drug products which are maintained/stored in the office of a physician shall be maintained/stored in the manufacturer's or repackager'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 are precounted and prepackaged for purposes of dispensing shall be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained shall not be labeled in any false or misleading manner. The labeling requirements of this section are in addition to, and not in lieu of, other labeling requirements of the Laws of the state of Mississippi, Rules and Regulations of the Mississippi State Board of Medical Licensure, and Laws of the United States or Federal Regulations.

701 A physician shall not dispense out-of-date drugs or store out-of-date drugs intermixed with the stock of current drugs. Out-of-date drugs shall 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 dispense the product with this information intact.

702 The drug storage and dispensing area shall be maintained in a sanitary fashion.

703 A physician shall 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.

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

Labeling Requirements for Dispensing Physicians

800 For the purposes of this rule, a “dispensing physician” shall mean any physician who shall dispense 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.

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

1. The name of the patient to whom the medication was dispensed.
2. The date that the medication was dispensed.
3. The name, strength and quantity of the medication.
4. Direction for taking or administering the medication.
5. The name and address of the physician dispensing the medication.

The label required by this section shall be written in legible handwriting or typed and shall 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.

802 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 mean the physician must actually obtain the medication, prepare, count, place the same into the appropriate container and affix the appropriate label to the container.

Prescription Guidelines–Controlled Substances

900 It is the responsibility of the physician or physician assistant 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 healthcare professionals with controlled substance prescriptive authority regulated by the Mississippi State Board of Medical Licensure:

1. 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.
2. On all prescriptions of controlled substances wherein refills are permitted, physicians shall indicate the appropriate refills, not to exceed five (5), or mark "none."
3. Each physician shall insure that the complete name and address of the patient to whom the physician is prescribing the controlled substance appears on the prescription.
4. A physician shall not permit any prescription for controlled substances to be signed by any non-physician in the place of or on behalf of the physician.
5. A physician shall not pre-sign blank prescription pads or order forms under any circumstances.
6. A physician shall not utilize blank prescription pads or order forms upon which the signature of the physician has been electronically, mechanically or photostatically reproduced. 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; however, if it is printed on security paper that ensures it is not subject to copying or alteration, an electronic or digital signature may be substituted. Electronic transmission of 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. Requirements for fax prescription orders and systems utilized for faxing prescriptions are as follows:
    a. The prescription order shall contain the date, time, telephone number and location of the transmitting device. Prescription blanks utilized in this manner shall 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, only Schedule II narcotic substances that are to be prepared or

It is also required, that in addition to filing the original prescription (or copy) in the patient file, a perpetual, chronological logbook of fax transactions be established and maintained. Such a logbook would serve to protect the prescribing physician in the event the original prescription is somehow lost or misfiled. The information contained in such a logbook shall 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 of the person faxing the prescription. Such logs shall be maintained in the physician'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 section are in addition to, and not in lieu of documentation required in Section 404.

b. When a prescription is prepared and written for 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 or the practitioner's agent to the dispensing pharmacy by facsimile. The physician or the physician's agent will 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 Section 900.6.a above.

c. When a prescription is written for 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 practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The physician or the physician's agent will 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 Section 900.6.a above.

d. 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

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.

7. No more than one (1) controlled substance shall be issued on a single prescription blank.

Prescription Guidelines - All Medications

1000 In addition to any other requirements set forth in these regulations 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:

6. Electronic prescription transmissions are allowed using standards established and approved by the United States Department of Health and Human Services--Agency for Healthcare Research and Quality (HHS-AHRQ). E-prescribing is the electronic entry of a prescription by a practitioner, 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.
7. 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. 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 be authorized by a written or electronic signature and shall be issued in accordance with all other provisions of this section. No prescriptions for brand name or generic equivalents of Nalbuphine Hcl, Carisoprodol, Butalbital compounds, or Tramadol Hcl shall be telefaxed or electronically transmitted.
8. All written prescriptions shall be on forms containing two lines for the physician's signature. There shall be a signature line in the lower right-hand corner of the prescription form beneath which shall be clearly imprinted the words "substitution permissible." There shall be a signature line in the lower left corner of the prescription form beneath which shall be clearly imprinted the words "dispense as written." The physician's signature on either signature line shall validate the prescription and designate approval or disapproval of product selection. Each prescription form shall bear the pre-printed name of the physician, or the physician shall clearly print his or her name on the prescription form, in addition to the physician's original signature. In the event that the prescription form bears the pre-printed name of more than one physician, the physician shall clearly indicate the name of the physician writing the prescription. In the case of a prescription that is electronically generated and transmitted, the physician must

9. If a prescription form which does not contain two signature lines required in Section 1000.3 of this Chapter is utilized by the physician, he or she shall write in his or her own handwriting the words “dispense as written” thereupon to prevent product selection.

10. Every written prescription issued by a 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. Physicians should avoid issuing prescriptions refillable on “prn” basis. If a 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.

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

11. A prescription shall no longer be valid after the occurrence of any one of the following events:
    a. Thirty (30) days after the death of the issuing physician.
    b. Thirty (30) days after the issuing physician has moved or otherwise changed the location of his or her practice so as to terminate the doctor/patient relationship. Termination of the doctor/patient relationship results when a patient is no longer able to seek personal consultation or treatment from the issuing physician.
    c. Insofar as controlled substances are concerned, immediately after loss of DEA Controlled Substances Privilege by the issuing physician.
    d. Immediately after revocation, suspension or surrender of the physician's license.

<u>Freedom of Choice</u>

1100 A physician shall 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.

1101 A physician may own or operate a pharmacy if there is no resulting exploitation of patients. A physician shall not give a patient 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. The prescription is a written direction for a therapeutic or corrective agent. A patient is entitled to a copy of the 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. Where medication is to be dispensed or a prescription, excluding refills, called in to a pharmacist for medication, a physician shall inform each patient of that patient's right to a written prescription and the right to have the prescription filled wherever the patient wishes.

1102 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 be honored. Physicians shall 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 with respect to the filling of the physician's prescriptions.

Other Drugs Having Addiction-forming Liability

1200 All physicians shall maintain inventory, dispensation/administration and patient records in the same format as that required by Section 400 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.

Security of Controlled Substances

1300 In all clinics or offices wherein controlled substances or other drugs having addiction-forming or addiction-sustaining liability are maintained, said medication shall be maintained in such a manner as to deter loss by theft or burglary. When a physician who is registered with the U.S. Drug Enforcement Administration has experienced a loss of controlled substances, the Board may issue an order requiring that person to appear before the Board and present a plan designed to prevent further loss of controlled substances or he or she may be ordered by the Board to implement any other reasonable measures to improve security over controlled substances deemed necessary by the Board to prevent further loss of the controlled substances.

1301 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.

Violation of Regulations

1400 The prescribing, administering or dispensing of any controlled substance in violation of the above rules and regulations 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).

1401 The prescribing, administering or dispensing of any legend drug or other medication in violation of the above rules and regulations shall constitute unprofessional conduct, dishonorable or unethical conduct likely to deceive, defraud or harm the public in violation of Mississippi Code, Section 73-25-29(8)(d).

Effective Date of Regulations

1500 The above rules and regulations 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 April 20, 1999; as amended May 20, 1999; as amended February 17, 2001; as amended March 22, 2001; as amended July 15, 2004; as amended October 14, 2004; as amended November 8, 2007; as amended May 15, 2008; and as amended March 13, 2009.

Chapter 25 Regulations Pertaining to Prescribing, Administering and Dispensing of Medication

Scope

100 These regulations apply to all individuals licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi.

Definitions

200 For the purpose of Chapter 25 only, the following terms have the meanings indicated:

7. "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.
8. "Physician" means any person licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi.
9. "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.
10. "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.
11. For the purpose of enforcement of the labeling requirements set forth in Section 601 of these regulations, "Dispensing Physician" means any physician who shall dispense 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.
12. "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 only.
13. "Pain Management Clinic"means a public or privately owned facility for which the majority (50% or more) of the patients are issued, on a monthly basis, a prescription for opiods, barbaturates, benzodiazepines, carisoprodol, butabital compounds, or tramadol.

Registration for Controlled Substances Certificate

300 Every physician 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.

301 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

Section 300 above. In the event, however, a physician has had limitations or other restrictions placed upon his or her license wherein he or she is prohibited from handling controlled substances in any or all schedules, said physician 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.

302 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 regulations and in conformity with provisions of the Mississippi Uniform Controlled Substances Law, Mississippi Code, Sections 41-29-101 et seq.

303 The registration requirement set forth in these regulations does not apply to the distribution and manufacture of controlled substances. Any physician who engages in the manufacture or distribution of controlled substances or legend drugs shall register with the Mississippi State Board of Pharmacy pursuant to Mississippi Code, Section 73-21-105. For the purposes herein, "distribute" shall mean 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).

Maintenance of Records and Inventories

400 Every physician licensed to practice medicine, osteopathic medicine or podiatric medicine in the state of Mississippi shall maintain inventories, logs, and records prescribed in this chapter.

401 Controlled substances inventory record. All controlled substances classified under Schedules II, IIN, III, IIIN, IV and V which are purchased by the physician must be inventoried at least every two (2) years. All inventory records for controlled substances in Schedules II and IIN must be maintained separately from the inventory records for Schedules III, IIIN, IV and V controlled substances. To insure the reliability of an inventory, the physician shall 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.

402 Controlled substances dispensation/administration record. Every physician who shall dispense or administer Schedules II, IIN, III, IIIN, IV and V controlled substances shall maintain a separate readily retrievable record of all such substances dispensed or administered. This requirement shall 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 shall contain the following information:

6. The date the controlled substance was dispensed or administered.
7. The name, quantity and strength/dose of the controlled substance dispensed or administered.

8. The method of administration of the controlled substance, i.e. oral, IV or subcutaneous.
9. The name and address of the patient to whom the controlled substance was dispensed or administered.
10. 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 include the diagnosis and the reason for use of the Schedules II and III controlled substances.

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

404 Patient Record. A physician who prescribes, dispenses or administers a controlled substance shall 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 controlled substance; the name, dose, strength, quantity of the controlled substance and the date that the controlled substance was prescribed, dispensed or administered. The record required by this section shall be maintained in the patient's medical records, provided that such medical records are maintained at the office of the physician and 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.

405 No physician shall prescribe, administer or dispense any controlled substance or other drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication therefore.[2]

---

[2] COMMENT: A determination as to whether a "good faith prior examination and medical indication therefore" exists depends upon the facts and circumstances in each case. One of the primary roles of a physician is to elicit detailed information about the signs and symptoms which a patient presents in order that he or she may recommend a course of treatment to relieve the symptoms and cure the patient of his or her ailment or maintain him or her in an apparent state of good health. In order for a physician to achieve a proper diagnosis and treatment plan, a history and physical examination consistent with the nature and complaint are necessary. The importance of these aspects of proper medical practice cannot be over emphasized. The paramount importance of a complete medical history in establishing a correct diagnosis is well established. Standards of proper medical practice require that, upon any encounter with a patient, in order to establish proper diagnosis and regimen of treatment, a physician 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 a function of the "course of legitimate professional practice" is 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 to dispense, prescribe or administer such drugs 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

406 A physician shall 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.

407 The Controlled Substances Inventory, Controlled Substance Dispensation/Administration Record, and Patient Record required by these regulations shall be maintained in the office of the physician 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 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.

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

Use of Diet Medication

---

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 and all circumstances surrounding dispensation. 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.

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

501 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 may administer, dispense or prescribe said medications for the purpose of weight loss in the treatment of obesity only as an adjunct to a regimen of weight reduction based on caloric restriction, provided, that <u>all</u> of the following conditions are met:

7. Before initiating treatment utilizing a Schedules III, IV or V controlled substance, the physician determines through review of his or her own records of prior treatment, or thorough review of the records of prior treatment which another treating physician or weight-loss program has provided to the physician, that the patient has made a substantial good-faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise, without the utilization of controlled substances, and that said treatment has been ineffective.
8. Before initiating treatment utilizing a Schedules III, IV or V controlled substance, the physician obtains a thorough history, performs a thorough physical examination of the patient, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized. "Recognized contraindication" means any contraindication to the use of a drug which is listed in the United States Food and Drug Administration (hereinafter, "F.D.A.") approved labeling for the drug.
9. The physician shall not utilize any Schedules III, IV or V controlled substance when he or she knows or has reason to believe that a recognized contraindication to its use exists.
10. The physician shall not utilize any Schedules III, IV or V controlled substance in the treatment of a patient whom he or she knows or should know is pregnant.
11. As to those controlled substances in Schedules III, IV or V which are classified as amphetamine or amphetamine-like anorectics and/or central nervous system stimulants, hereinafter referred to as "stimulant", the physician shall not initiate or shall discontinue utilizing said controlled substance stimulant immediately upon ascertaining or having reason to believe:
    a. That the patient has failed to lose weight while under treatment with said stimulant over a period of thirty (30) days, which determination shall be made by weighing the patient at least every thirtieth (30th) day, except that a patient who has never before received treatment for obesity utilizing a stimulant, and who fails to lose weight during his or her first such treatment attempt may be treated with a different controlled substance for an additional thirty (30) days.
    b. That the patient has developed tolerance (a decreasing contribution of the drug toward further weight loss) to the anorectic effects of said stimulant being utilized.
    c. That the patient has a history of or shows a propensity for alcohol or drug abuse.

d. That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions.

In addition to the above the physician shall not issue a prescription or dispense a stimulant for any greater than a thirty (30) day supply; and a patient's use of stimulants, whether by dispensation or prescription shall be limited to no more than six (6) thirty (30) day supplies during any twelve (12) month period of time. In any case, the total amount of medication shall not exceed a six (6) month supply in the twelve month time period. For the purposes of this paragraph, a twelve (12) month time period is considered to begin on the day of the initial dispensation or prescription issuance.

12. As to all other legend drugs or controlled substances in Schedules III, IV and V which are not considered stimulants but which have received FDA approved indication for long-term use for weight loss, the physician shall administer, dispense or prescribe said medications in strict compliance with the FDA-approved labeling. In addition to the requirements enumerated at 501.5.a-d above, each prescription shall be issued for no more than a total of three months supply (including refills) and further, before subsequent new prescriptions can be issued the patient shall receive a thorough reevaluation of the effectiveness of the medication, including a physical examination to document any potential harmful side effects.

502 A physician shall not utilize a 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.

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

600 Definitions

For the purpose of Section 600 only, the following terms have the meanings indicated:

7. "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 physician and one or more physicians 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 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 section, "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.
8. "Acute Pain" is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma

9. "Addiction" is a neurobehavorial 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.
10. "Physical Dependence" is a physiological state of neuroadaptation to a 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.
11. "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.
12. "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.

601 Notwithstanding any other provisions of these rules and regulations, a physician may prescribe, administer, or dispense controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability to a person in the usual course of treatment of that person for a diagnosed condition causing chronic pain.

602 Notwithstanding any other provisions of these rules and regulations, as to the prescribing, administration, or dispensation of controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability, use of said medications in the treatment of chronic pain should be done with caution. A physician may administer, dispense or prescribe said medications for the purpose of relieving chronic pain, provided that the following conditions are met:

5. Before initiating treatment utilizing a Schedules II, IIN, III, IIIN, IV or V controlled substance, or any other drug having addiction-forming and addiction-sustaining liability, the physician shall 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, that there is an indicated need for long-term controlled substance therapy. Such a determination shall take into account the specifics of each patients diagnosis, past treatments and suitability for long-term controlled substance use either alone or in combination with other indicated modalities for the treatment of chronic pain. This shall be clearly entered into the patient medical record and shall include consultation/referral reports to determine the underlying pathology or cause of the chronic pain.

6. Documentation in the patient record shall include a complete medical history and physical examination that indicates the presence of one or more recognized medical indications for the use of controlled substances.
7. Documentation of a written treatment plan which shall contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments. The plan should also contain an informed consent agreement for treatment that details relative risks and benefits of the treatment course. This should also include specific requirements of the patient, such as using one physician and pharmacy if possible, and urine/serum medication level monitoring when requested.
8. Periodic review and documentation of the treatment course is conducted at reasonable intervals (no more than every six months) with modification of therapy dependent on the physician's evaluation of progress toward the stated treatment objectives. This should include referrals and consultations as necessary to achieve those objectives.

603 No physician shall 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.

604 No physician shall administer, dispense or prescribe a controlled substance for treatment of chronic pain to any patient who has consumed or disposed of any controlled substance or other drug having addiction-forming and addiction-sustaining liability other than in strict compliance with the treating physician's directions. These circumstances include those patients obtaining controlled substances or other abusable drugs from more than one physician and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other abusable drugs before a prior prescription should have been consumed according to the treating physician'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 the treating physician to document in the patient record that such increase in dose level 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 be undertaken by the physician.

605 No physician shall prescribe 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 physician shall administer or dispense any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" unless they are properly registered in accordance with Section 303(g) 21 U.S.C. 823(g). Nothing in this paragraph shall prohibit a physician 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 physician from 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.

Drug Maintenance Requirements

700 All drug products which are maintained/stored in the office of a physician shall be maintained/stored in the manufacturer's or repackager'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 are precounted and prepackaged for purposes of dispensing shall be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained shall not be labeled in any false or misleading manner. The labeling requirements of this section are in addition to, and not in lieu of, other labeling requirements of the Laws of the state of Mississippi, Rules and Regulations of the Mississippi State Board of Medical Licensure, and Laws of the United States or Federal Regulations.

701 A physician shall not dispense out-of-date drugs or store out-of-date drugs intermixed with the stock of current drugs. Out-of-date drugs shall 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 dispense the product with this information intact.

702 The drug storage and dispensing area shall be maintained in a sanitary fashion.

703 A physician shall 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.

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

Labeling Requirements for Dispensing Physicians

800 For the purposes of this rule, a “dispensing physician” shall mean any physician who shall dispense 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.

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

6. The name of the patient to whom the medication was dispensed.
7. The date that the medication was dispensed.
8. The name, strength and quantity of the medication.
9. Direction for taking or administering the medication.

10. The name and address of the physician dispensing the medication.

The label required by this section shall be written in legible handwriting or typed and shall 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.

802 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 mean the physician must actually obtain the medication, prepare, count, place the same into the appropriate container and affix the appropriate label to the container.

Prescription Guidelines–Controlled Substances

900 It is the responsibility of the physician or physician assistant 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 healthcare professionals with controlled substance prescriptive authority regulated by the Mississippi State Board of Medical Licensure:

8. 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.
9. On all prescriptions of controlled substances wherein refills are permitted, physicians shall indicate the appropriate refills, not to exceed five (5), or mark "none."
10. Each physician shall insure that the complete name and address of the patient to whom the physician is prescribing the controlled substance appears on the prescription.
11. A physician shall not permit any prescription for controlled substances to be signed by any non-physician in the place of or on behalf of the physician.
12. A physician shall not pre-sign blank prescription pads or order forms under any circumstances.
13. A physician shall not utilize blank prescription pads or order forms upon which the signature of the physician has been electronically, mechanically or photostatically reproduced. 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; however, if it is printed on security paper that ensures it is not subject to copying or alteration, an electronic or digital signature may be substituted. Electronic transmission of 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. Requirements for fax prescription orders and systems utilized for faxing prescriptions are as follows:
    a. The prescription order shall contain the date, time, telephone number and location of the transmitting device. Prescription blanks utilized in this

It is also required, that in addition to filing the original prescription (or copy) in the patient file, a perpetual, chronological logbook of fax transactions be established and maintained. Such a logbook would serve to protect the prescribing physician in the event the original prescription is somehow lost or misfiled. The information contained in such a logbook shall 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 of the person faxing the prescription. Such logs shall be maintained in the physician'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 section are in addition to, and not in lieu of documentation required in Section 404.

b. When a prescription is prepared and written for 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 or the practitioner's agent to the dispensing pharmacy by facsimile. The physician or the physician's agent will 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 Section 900.6.a above.

c. When a prescription is written for 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 practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The physician or the physician's agent will 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 Section 900.6.a above.

d. 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.

14. No more than one (1) controlled substance shall be issued on a single prescription blank.

Prescription Guidelines - All Medications

1000 In addition to any other requirements set forth in these regulations 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:

1. Electronic prescription transmissions are allowed using standards established and approved by the United States Department of Health and Human Services--Agency for Healthcare Research and Quality (HHS-AHRQ). E-prescribing is the electronic entry of a prescription by a practitioner, 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.
2. 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. 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 be authorized by a written or electronic signature and shall be issued in accordance with all other provisions of this section. No prescriptions for brand name or generic equivalents of Nalbuphine Hcl, Carisoprodol, Butalbital compounds, or Tramadol Hcl shall be telefaxed or electronically transmitted.
3. All written prescriptions shall be on forms containing two lines for the physician's signature. There shall be a signature line in the lower right-hand corner of the prescription form beneath which shall be clearly imprinted the words "substitution permissible." There shall be a signature line in the lower left corner of the prescription form beneath which shall be clearly imprinted the words "dispense as written." The physician's signature on either signature line shall validate the prescription and designate approval or disapproval of product selection. Each prescription form shall bear the pre-printed name of the physician, or the physician shall clearly print his or her name on the prescription form, in addition to the physician's original signature. In the event that the prescription form bears the pre-printed name of more than one physician, the physician shall clearly

4. If a prescription form which does not contain two signature lines required in Section 1000.3 of this Chapter is utilized by the physician, he or she shall write in his or her own handwriting the words “dispense as written” thereupon to prevent product selection.
5. Every written prescription issued by a 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. Physicians should avoid issuing prescriptions refillable on “prn” basis. If a 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.

   Every written prescription issued by a physician, bearing more than one non-controlled medication, shall 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 be clearly voided by the issuing physician.
6. A prescription shall no longer be valid after the occurrence of any one of the following events:
   a. Thirty (30) days after the death of the issuing physician.
   b. Thirty (30) days after the issuing physician has moved or otherwise changed the location of his or her practice so as to terminate the doctor/patient relationship. Termination of the doctor/patient relationship results when a patient is no longer able to seek personal consultation or treatment from the issuing physician.
   c. Insofar as controlled substances are concerned, immediately after loss of DEA Controlled Substances Privilege by the issuing physician.
   d. Immediately after revocation, suspension or surrender of the physician's license.

Freedom of Choice

1100 A physician shall 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.

1101 A physician may own or operate a pharmacy if there is no resulting exploitation of patients. A physician shall not give a patient 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. The prescription is a written direction for a therapeutic or corrective agent. A patient is entitled to a copy of the 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. Where medication is to be dispensed or a prescription, excluding refills, called in to a pharmacist for medication, a physician shall inform each patient of that patient's right to a written prescription and the right to have the prescription filled wherever the patient wishes.

1102 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 be honored. Physicians shall 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 with respect to the filling of the physician's prescriptions.

Other Drugs Having Addiction-forming Liability

1200 All physicians shall maintain inventory, dispensation/administration and patient records in the same format as that required by Section 400 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.

Security of Controlled Substances

1300 In all clinics or offices wherein controlled substances or other drugs having addiction-forming or addiction-sustaining liability are maintained, said medication shall be maintained in such a manner as to deter loss by theft or burglary. When a physician who is registered with the U.S. Drug Enforcement Administration has experienced a loss of controlled substances, the Board may issue an order requiring that person to appear before the Board and present a plan designed to prevent further loss of controlled substances or he or she may be ordered by the Board to implement any other reasonable measures to improve security over controlled substances deemed necessary by the Board to prevent further loss of the controlled substances.

1301 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.

Pain Management Clinics

1400 The physician owner/operator of the pain management clinic shall register with MSBML. The form to register is attached hereto (Appendix E). 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 clinic. Each clinic requires a separate certificate.

1401 A pain management clinic may not operate in the State of Mississippi without obtaining a certificate from the Mississippi State Board of Medical Licensure.

1402 A pain management clinic may not operate in Mississippi unless the clinic is owned and operated by a medical director who:

1. Is a physician who practices full time in Mississippi. Full time is defined as at least 20 hours per week of direct patient care.
2. Holds an active unrestricted medical license.
3. Holds a certificate of registration for that pain management clinic.

1403 In addition , the owner/operator of a pain management clinic, an employee of the clinic or a person with whom a clinic contracts for services may not:

1. Have been denied, by any jurisdiction, a license issued by the Drug Enforcement Administration (DEA) under which the person may prescribe, dispense, administer, supply or sell a controlled substance or the other listed medications under definitions.
2. Have held a license 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; or
3. 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.

1404 A pain management clinic may not be owned wholly or partly by any person who has been convicted of, pled nolo contendere to or received deferred adjudication for:

1. an offense that constitutes a felony; or
2. an offence that constitutes a misdemeanor, the facts of which relates to the illegal distribution or sale of drugs or controlled substances.

1405 Certificates are valid for one year and must be renewed annually with the practitioners 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 has expired.

Violation of Regulations

1500 The prescribing, administering or dispensing of any controlled substance in violation of

the above rules and regulations 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).

14~~4~~501 The prescribing, administering or dispensing of any legend drug or other medication in violation of the above rules and regulations shall constitute unprofessional conduct, dishonorable or unethical conduct likely to deceive, defraud or harm the public in violation of Mississippi Code, Section 73-25-29(8)(d).

Effective Date of Regulations

15~~5~~600 The above rules and regulations 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 April 20, 1999; as amended May 20, 1999; as amended February 17, 2001; as amended March 22, 2001; as amended July 15, 2004; as amended October 14, 2004; as amended November 8, 2007; as amended May 15, 2008; and as amended March 13, 2009.

Source: *Miss. Code Ann.* §73-43-11 (Rev. 1972)