SUMMARY OF PROPOSED REGULATION CHANGES TO 2640

Compiled by Ashley Thompson

- Registration for Controlled Substances Certificate/MPMP Review/Documentation
  - Every licensee who provides medical care in a pain management practice must review the MPMP at each patient encounter in which a prescription for a controlled substance is issued.
  - Every licensee regardless of practice specialty must review the MPMP at each patient encounter in which an opioid is prescribed for acute and/or chronic non-cancerous/non-terminal pain.
  - Those licensees whose practice is not a pain management practice must actively utilize the MPMP upon initial contact with new patients and at least every three (3) months thereafter on any and all patients who are prescribed, administered, or dispensed controlled substances other than opioids.
  - Licensees who issued a prescription for Lomotil, Lyrica, or Testosterone are not required in that instance to utilize the MPMP.
  - Reports generated on such patients should span the length of time from the previous review of the MPMP so that adequate information is obtained to determine patient compliance with treatment.
  - Documentation, such as a copy of the report itself and/or reflection in the chart dictation and/or notes must be kept within the patient’s record and made available for inspection upon request.
  - Properly registered designees of the licensee may run/obtain the report of the licensee’s review as requested.
  - Utilization of the MPMP is not required when treating inpatient; however, upon discharge from the inpatient setting with a prescription for a controlled substance, the MPMP must be reviewed.
  - In the event a licensee has had limitations or other restrictions placed upon his or her licensee wherein he or she is prohibited from ordering, dispensing, or prescribing controlled substances in any schedules said licensee shall be prohibited from registering with the USDEA 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.

- Maintenance of Records and Inventories
  - Use of any therapy should be supported by standards of medical practice, reasonable scientific evidence or consensus and documented in the medical record.

- Use of Controlled Substances for Chronic (Non-Terminal) Pain
  - A licensee may order, administer, dispense, or prescribe said medications for the purpose of relieving chronic pain, provided that the following conditions are met:
    - Before initiating treatment with a controlled substance or any other drug having addiction-forming or addiction sustaining lability, the licensee must conduct a risk/benefit analysis by reviewing records of prior treatment. The risk/benefit analysis should weigh in favor of treatment and indicate the need for controlled substances therapy. The results of this analysis must be clearly entered into the patient’s medical
record and must include supporting documentation such as consultation or referral reports and efforts to determine the underlying etiology of the chronic pain.

- Documentation in the patient record must include a complete medical history and physical examination and supporting studies and reports on consultation.
- The diagnosis must demonstrate the presence of one or more recognized medical indications for the use of controlled substances.
- Documentation of written treatment plan must contain stated objectives as a measure of successful treatment and planned diagnostic evaluations. The plan must contain an informed consent agreement for treatment that details relative risks and benefits of the treatment course. The consent must also include specific requirements of the patient, such as using one licensee and pharmacy, urine/serum medication level monitoring when requested, pill counts, and the grounds for which the treatment may be terminated.
- Periodic review and documentation of the treatment course is conducted no less frequently than every 3 months. The licensee’s evaluation of progress toward the stated treatment objectives must support all changes in therapy.
- When initiating opioid therapy for chronic pain:
  - The licensee must first run a MPMP on the patient.
  - The licensee must prescribe the lowest effective dosage.
  - While there is no single dosage threshold identified below which the risk of overdose is eliminated, licensees must strive to keep daily opioid doses less than or equal to 50mg of morphine equivalence as dosages larger than 50mEq per day increase risk without adding benefits for pain control or function.
  - Licensees must avoid dosages greater than or equal to 90mg of morphine equivalence per day and must provide significant justification for exceeding the 90-mg ceiling stated herein.
  - If the licensee determines that patient requires greater than 100 mg of morphine equivalence per day, the licensee must refer the patient to a pain specialist for further treatment.
- When opioids are prescribed for acute pain:
  - The licensee must prescribe the lowest effective dose of immediate release opioids, as the use of long acting opioids for acute non-cancer/non-terminal pain is prohibited.
  - Licensees must prescribe no greater quantity than needed for the expected duration of pain severe enough they require opioids.
  - Licensees are discouraged from prescribing or dispensing more than a three (3) day supply of opioids for acute non-cancer/non-terminal pain, and must not provide greater than a ten (10) day supply for acute non-cancer/non-terminal pain.
  - Licensees may issue an additional ten (10) day supply if clinically necessary, but said supply must be issued in accordance with Title 21 CDE 1306.12 – Refilling prescriptions; issuance of multiple prescriptions and such need for an additional ten (10) day supply must be documented in the chart to evidence that no other alternative was appropriate or sufficient to abate the acute pain associated with that medical condition.
- Every licensee must review an MPMP report at each patient encounter in which a Schedule II medication is prescribed for acute or chronic non-cancer/non-terminal pain. MPMP reports may be obtained by designees of the licensee as allowed by the MPMP program.
- When prescribing opioids for either chronic or acute pain:
• It is a relative contraindication (black box warning) to prescribe opioids concurrently with Benzodiazepines and/or Soma.
• However, opioids and benzodiazepines may be prescribed concurrently on a very short-term basis, and in accordance with regulations for prescribing acute pain, when an acute injury requiring opioids occurs.
• The need for such concurrent prescribing must be documented appropriately in the chart.
• Patients who are currently on an established regimen of concomitant opioids and benzodiazepines may be allotted a reasonable period of time to withdraw from one or both substances.
• Prescribing of opioids concurrently with benzodiazepines and/or Soma may be allowed under very limited circumstances in which the combination is used to treat very specific chronic medical conditions for which there is no other treatment modality available.

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

□ Point of Service Drug Testing
  • Must be done each time a Schedule II medication is written for the treatment of chronic non-cancer/non-terminal pain.
  • Point of Service drug testing and MPMP review must be done at least every ninety (90) days for patients prescribed benzodiazepines for chronic medical and/or psychiatric conditions which are non-cancer/non-terminal.
  • Point of Service drug testing must test, at a minimum, for opioids, benzodiazepines, amphetamines, cocaine, and cannabis.
  • Inpatient treatment is exempt from this requirement.
  • All hospice treatment is exempt from point of service drug testing.

□ The use of Methadone to treat acute non-cancer/non-terminal pain is prohibited.
□ The use of Methadone for the treatment of chronic non-cancer/non-terminal pain is permissible within a registered Pain Management Practice or when resulting from a referral to a certified pain specialist.
  • If Methadone is prescribed to treat chronic non-cancer/non-terminal pain, it must be prescribed only by a physician.

- Prescription Guidelines – Controlled Substances
  o Prescriptions for Benzodiazepines must be limited to a one (1) month supply, with no more than two (2) refills, or a ninety (90) day supply with no refills. The MPMP must be checked each time a prescription for benzodiazepines is authorized and evidence of such check must be noted within the patient file.
Prescription Guidelines – All Medications
- Prescriptions may not be written outside of a valid licensee-patient relationship, the elements are this valid relationship are:
  - Verify that the person requesting the medical treatment is in fact who they claim to be;
  - Conducting an appraise history and physical examination of the patient that meets the applicable standard of care;
  - Establishing a diagnosis through the use of accepted medical practices, i.e., a patient history, mental status exam, physical exam and appropriate diagnostic laboratory testing;
  - Discussing with the patient the diagnosis, risk, and benefits of various treatment options to obtain informed consent;
  - Insuring the availability of appropriate follow-up care; and
  - Maintaining a complete medical record available to patient and other treating health care professionals.

Pain Management Practice
- Means a public or privately-owned practice for which 30% or more of the patients are issued on a regular or recurring basis, a prescription for opioids, barbiturates, benzodiazepines, carisoprodol, butalbital compounds, or tramadol for the treatment of chronic non-cancerous/non-terminal pain. Included in this definition is any practice that advertises and/or holds itself out to provide pain management services. Patients who are treated for pain resulting for a terminal illness do not count against the percentage stated herein.

- All physician owners or operators or any physician who serves as medical director, manager, or employee or who provides care in pain management medical practice must meet the following qualifications. All physicians prescribing or dispensing controlled substances must meet one of the following.
  - Board certification by a specialty board recouped by the American Board of Medical Specialties or the American Board of Addiction medicine and hold a subspecialty certification in pain medicine;
  - Board certification by a specialty board recognized by the American Osteopathic Association Bureau of Osteopath Specialists in pain management;
  - Board certification in pain medicine by the American Board of Pain medicine;
  - Successful completion of residency programs in physical medicine and rehabilitation, anesthesiology, neurology, or neurosurgery and approved by the ACGME or the AOA; and/or
  - Successful completion of 100 hours of inter-active live participatory AMA or AOC Category 1 CME courses in pain management

- Upon qualifying under any of the 5 above, physicians must also document completion of 30 hours of Category 1 CME for renewal of a pain management medical practice certificate. CME must have emphasis in the specific areas of pain management, addiction, or prescribing opiates.

- CME may be included with the forty-hour requirement for licensure renewal.
- A report from the MPMP must be obtained on the initial visit for each patient. Subsequent reports must be obtained for each patient at every visit.
- The initial visit for each patient in a pain management practice must include an in-person evaluation and plan of care by a registered pain management physician.