CORE FSMB GUIDELINES AND CHECKLIST 2013

The purpose of this checklist is to take the core directives published in the Federation of State Medical Boards' 2013 Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain and place them into an easy to use self-audit form for the practitioner. Where necessary, we have corrected grammatical and spelling errors but have not in any way changed the substance of the material.

Practitioners should use these new materials as a supplement to their current professional licensing board rules and policy statements on the management of chronic pain with controlled medications. It is likely that within the next six to nine months, the 57 or so professional licensing boards presently using the FSMB's 2004 Policy Statement (or some version thereof) will adopt the 2013 version.

We have attached the full FSMB document to this checklist. We encourage providers to review the definitions and resource list for the same. We preserved the resource citations for your reference.

Patient Evaluation And Risk Stratification

The medical record should document:

___ 1. The presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38].

___ 2. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

___ 3. The nature and extent of the evaluation depends on the type of pain and the context in which it occurs.

> For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain.

___ 4. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

___ 5. For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53].

Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

___ 6. Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environ- ment stressful or nurturing? [14].

___ 7. Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation [11,14,21-23,45], *and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics* [56-58].

This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31].

___ 8. Use of a validated screening tool (such as the Screener and Opioid As- sessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

___ A. All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

___ B. Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed).

___ C. Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional.

___ D. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Patient Provided Information

Information provided by the patient is a necessary but insufficient part of the evaluation process.

___ 9. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible.

> Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

___ 10. If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50].

___ 11. Where available, the state prescription drug monitoring program (PDMP) should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

Patients On High Doses

___ 12. In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance [21-23].

___ 13. With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community [21-23].

Development Of A Treatment Plan And Goals

___ 14. The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8].

> Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

___ 15. The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38].

___ 16. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and non-pharmacologic options. It also

should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

___ 17. The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent And Treatment Agreement

___ 18. The decision to initiate opioid therapy should be a shared decision between the physician and the patient.

___ 19. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity [32,35].

___ 20. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

___ A. CRITICAL - Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is recommended [21-23,35,38].

___ 21. Informed consent documents typically address:

___ A. The potential risks and anticipated benefits of chronic opioid therapy.

___ B. Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.

___ C. The likelihood that tolerance to and physical dependence on the medication will develop.

___ D. The risk of drug interactions and over-sedation.

___ E. The risk of impaired motor skills (affecting driving and other tasks).

___ F. The risk of opioid misuse, dependence, addiction, and overdose.

___ G. The limited evidence as to the benefit of long-term opioid therapy.

___ H. The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.

___ I. Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

___ 22. Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

___ A. The goals of treatment, in terms of pain management, restoration of function, and safety.

___ B. The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).

___ C. The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.

___ D. The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).

___ E. The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience, [subject to State Licensing Board Rules and local standards of care].

Initiating an Opioid Trial

___ 23. Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain.

___ 24. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points.

___ 25. *The physician* should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51].

___ 26. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect.

___ A. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

___ 27. A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29] and/or potential risks.

Ongoing Monitoring And Adapting The Treatment Plan

___ 28. The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50].

___ 29. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP.

___ 30. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51].

___ 31. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently.

> (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

___ 32. At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, whether there is evidence of Aberrant substance-related behaviors, and mood of the individual (Affect) [38,52].

___ 33. Validated brief assessment tools that measure pain and function, such as the three- question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

___ 34. Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion [21-23,45].

> ___ A. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29].
>
> ___ B. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36].
>
> ___ C. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing

Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59].

___ 35. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

URINE MAY BE PREFERRED

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53].

FORENSIC STANDARDS GENERALLY NOT NECESSARY

When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed.

Testing Platform

___ 36. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug.

___ 37. If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

___ A. Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54].

For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

___ B. While immunoassay, point of care (POC) testing has its utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study.

___ 38. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained.

> A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of "false negatives and positives" [53,81].

___ 39. Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

Medication Counts

___ 40. Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications).

Use Of State Prescription Drug Monitoring Programs (PDMP)

___ 41. Where available, consulting the state's PDMP *before prescribing opioids for pain and during ongoing use is highly recommended*.

> A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

Unsatisfactory Treatment Progress

___ 42. If the patient's progress is unsatisfactory, *the physician must decide* whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence Of Misuse Of Prescribed Opioids

___ 43. Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35].

___ 44. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23].

___ A. *The presence of illicit or unsanctioned prescription drugs (by another physician or from a third-party, non-physician) in drug tests similarly requires action on the part of the prescriber.*

___ B. Some aberrant behaviors are more closely associated with medication misuse than others [62-63].

Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

___ C. *Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46].*

The failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67].

___ D. Physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation And Referral:

___ 45. The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38].

___ A. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

___ 46. Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39]. SEE FSMB Model Policy for the Office Based Treatment of Opioid Addiction.

Discontinuing Opioid Therapy:

___ 47. Throughout the course of opioid therapy, *the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].*

___ 48. If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

___ 49. Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

___ A. If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen.

___ B. Withdrawal can be managed either by the prescribing physician or by refer- ring the patient to an addiction specialist [63].

___ C. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

___ D. *Providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement*.

Medical Records

___ 50. Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

___ A. Copies of the signed informed consent and treatment agreement.

___ B. The patient's medical history.

___ C. Results of the physical examination and all laboratory tests.

___ D. Results of the risk assessment, including results of any screening instruments used.

___ E. A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).

___ F. Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.

___ G. Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.

___ H. Notes on evaluations by and consultations with specialists.

___ I. Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.

___ J. Authorization for release of information to other treatment providers.

___ 51. The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned.

___ 52. Written instructions for the use of all medications should be given to the patient and documented in the record [25].

___ A. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23].

___ B. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [23,38,45,68].

Compliance With Controlled Substance Laws And Regulations

___ 53. To prescribe, dispense or administer con- trolled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

___ 54. Physicians are referred to the Physicians' Manual of the U.S. Drug Enforcement Administration (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances.

Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (any relevant documents issued by the state medical board).