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# Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

Scott M. Fishman, M.D.  
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# FSMB Policy Preamble

- Pain management is important and integral to the practice of medicine
- Use of opioids may be necessary for pain relief of moderate to severe pain
- However, the use of opioids for other than a legitimate medical purpose such as prescription drug abuse and/or diversion poses a threat to the individual and society

# FSMB Policy Preamble

- Physicians have a responsibility to minimize the potential for abuse and diversion
- Physicians may deviate from the recommended treatment steps based on good cause and documentation in the medical records
- The validity of prescribing will be judged on the physician's management of the patient

# FSMB Model Policy Guidelines

- Complete patient evaluation
- Written treatment plan based on mutual responsibilities
- Informed patient consent and agreement for treatment
- Periodic review of the course of treatment
- Willingness to refer
- Maintenance of complete and current medical record
  - If you do not document the information in the records, medical-legally it is a figment of your imagination

# FSMB Model Policy Statement on Management of Chronic Pain

- The board will consider inappropriate management of chronic pain to be a departure from accepted best clinical practices including, but not limited to the following:
  - Inadequate initial assessment to determine if opioids are clinically indicated
  - Not discussing the risk/benefit ratio with the prescribing of a CS
  - Inadequate monitoring of the patient's clinical course
  - Inadequate documentation of the reason for dose escalation or discussion of alternative treatment methods
  - Not making use of available tools for risk evaluation mitigation strategies (REMS) such as:
    - Treatment agreements
    - Screening tools
    - Urine drug tests

# The Prescriber's Responsibilities

- Evaluate a patient with risk stratification
- Develop a treatment plan & discussion of realistic functional goals and initial pain ratings i.e. 1 to 10
- Discuss informed consent with a treatment agreement
- Initiating a *therapeutic* trial of opioids
- Monitoring and modifying the treatment plan as needed
- Understand and do random drug testing (usually UDT)
- Know ones' limitations with consultation and referral as needed
- Have an exit strategy of discontinuing opioid therapy
- Keep accurate medical records
- Compliance with controlled substance laws and regulations

# Patient's Evaluation and Risk Stratification

- **Document**

- Presence of one or more recognized medical indications for prescribing an opioid analgesic
- Initial work-up which should include a current and past history with a systems review
- Relevant physical examination
- Current medications
- Diagnostic tests reviewed or ordered as indicated



# Patient's Evaluation and Risk Stratification

- Such information aids the physician to 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/or drug use
- Social and vocational assessments are useful in identifying supports and obstacles to treatment and rehabilitation

# Patient's Evaluation and Risk Stratification

- Assessment of the patient's personal and family history of alcohol or drug abuse and addiction
- Respectful query into history of physical, emotional or sexual abuse
- All patients should be screened for depression and other mental health disorders
  - Patients with these diagnoses are at increased risk for substance misuse or abuse, including addiction and overdose
    - Left untreated markedly decreases the probability of successful pain management

# Patient's Evaluation and Risk Stratification

- Use validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R] or the Opioid Risk Tool [ORT], or other validated screening tools, may aid in determining the patient's level of risk
- Do a complete evaluation prior to making a decision as to whether to prescribe opioid analgesics or other controlled substances is indicated

# Patient's Evaluation and Risk Stratification

- Patients with a history of substance use disorder (including alcohol)
  - Elevated risk for failure of opioid analgesic therapy
  - Higher risk for experiencing harm from opioid analgesics
    - Exposure to certain control substances may be trigger to relapse
      - » If available, consultation with an addiction specialist before opioid therapy is initiated (with follow-up as needed) is helpful
- *History of addiction is not contraindicated to prescribe opioid analgesic but increases complexity of treatment and monitoring*

# Patient's Evaluation and Risk Stratification

- Patients who have active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional
- Physicians who treat patients with chronic pain should be encouraged to be knowledgeable about the treatment of addiction, including the role of replacement agonists with methadone by ORT and office-based buprenorphine treatment
- There are advantages to becoming eligible to treat addiction using office-based buprenorphine

# Patient's Evaluation and Risk Stratification

- Information provided by the patient is necessary but insufficient for the evaluation
- Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible
- Patients have occasionally provided fraudulent records
  - 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

# Patient's Evaluation and Risk Stratification

- If possible, the patient evaluation should include information from family members and/or significant others
- Where available, the state PDMP should be consulted to determine whether the patient is receiving prescriptions from other physicians
  - PDMP results should be documented in the patient record
- The evaluation and risk stratification assume greater importance if the patient is inherited and taking opioids prescribed by another physician – particularly if the patient is on high doses

# Patient's Evaluation and Risk Stratification

- The physician's decision as to whether to prescribe opioid analgesics should reflect the following:
  - The totality of the information collected
  - The physician's own knowledge and comfort level in prescribing such medications
  - The resources for patient support that are available in the community



# Development of a Treatment Plan & Goals

The goals of pain treatment should include:

- Reasonably attainable improvement in pain and function
- Improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety
- Avoidance of unnecessary or excessive use of medications
- Effective means of achieving these goals vary widely
  - Depending on the type and causes of the patient's pain
  - Other concurrent issues
  - Preferences of the physician and the patient

# Informed Consent and Treatment Agreement

- Shared decision between physician and patient
- Discuss the risks and benefits of the treatment plan, including any proposed use of opioid analgesics
- Counsel on safe storage and disposal of medications
- Use of a written informed consent and treatment agreement is recommended

# Informed Consent and Treatment Agreement

Elements of a treatment agreement:

- Anticipated benefits of chronic opioid therapy
- Potential long/short-term AEs (constipation, cognitive & sedation)
- Impaired motor skills (affecting driving and other tasks)
- Drug-drug interactions
- Defining and discussing
  - Addiction, tolerance and physical dependence
  - Consequences of opioid misuse & overdose

# Informed Consent and Treatment Agreement

Expected elements of a treatment agreement:

- Limited evidence of the benefit of long-term opioid therapy
- Physician's prescribing policies and expectations
  - The number and frequency of prescription refills
    - i.e. early refills and replacement of lost or stolen medications
- Specific reasons for which drug therapy may be changed or discontinued
  - Including violation of the policies and agreements set forth in the treatment agreement

# Informed Consent and Treatment Agreement

- **Joint responsibilities**

- Informed consent document and treatment agreement can be part of one document
- The goals of treatment, in terms of pain management, reasonable restoration of function

- **Patient's responsibility for safe medication use**

- Not using more medication than prescribed
- Not using the opioid in combination with alcohol, non-prescribed CS or illicit drugs
- Storing medications in a secure location; and safe disposal of any unused medication
- Obtain prescribed opioids from single physician or practice
- Agrees to periodic drug testing

- **Physician's responsibility**

- Be available to care for unforeseen problems
- Appropriate prescribing of scheduled CSs
- Always be responsible for the safety and well being of the patient



# Initiating an Opioid Trial

- Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-cancer pain
- Opioid therapy should be presented to the patient as a therapeutic trial for a defined period of time (usually no more than 90 days) and with specified evaluation points in order to determine if medication is effectively treating the chronic pain diagnosis
- 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

# Initiating an Opioid Trial

- When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect
- It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated
- Continuing opioid therapy beyond the trial period should reflect a careful evaluation of benefits vs AEs and/or potential risks

# Ongoing Monitoring and Adapting the Treatment Plan

- Regularly review the patient's progress and include any new information about the etiology of the pain or the patient's overall health and level of function
- 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
- The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted
- As the patient is stabilized, f/u may be scheduled less frequently
  - 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



# Ongoing Monitoring and Adapting the Treatment Plan

At each visit, the results of chronic opioid therapy should be monitored by assessing the “**5As**” of chronic pain management

- **Analgesia:** determination of whether the patient is experiencing a reduction in pain
- **Activity:** demonstrated improvement in level of function
- **Adverse Effects**
- **Aberrant Behaviors:** ie. substance-related behavior
- **Affect:** mood of the individual

# Ongoing Monitoring and Adapting the Treatment Plan

- Continuation, modification or termination of opioid therapy should be contingent on the physician's evaluation of the following:
  - Evidence of progress toward treatment objectives
  - Absence of substantial risks or AEs, such as overdose or diversion
- Satisfactory response to treatment indicated by --
  - Reduced level of pain
  - Increased level of function
  - Improved quality of life Information from family members or other caregivers if possible

# 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 or illicit drugs
- 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
- 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 the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing

# Periodic Drug Testing

- When 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
- Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based)
  - Typically does not identify particular drugs within a class unless specific for that drug
  - If necessary, testing may be followed up with a more specific technique, i.e. liquid chromatography/mass spectrometry (LC/MS-MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites
- **It is important to identify the specific drug not just the drug class especially in pain management**

# Periodic Drug Testing

- Immunoassay drug testing (limited sensitivity for many opioids)
  - Know the capability of the testing method ordered
    - Will the test you ordered identify the opioid being prescribed?
- Because of the complexities involved in interpreting test results, confirm significant or unexpected results with the lab toxicologist or a clinical pathologist
- Immunoassay, point of care (POC) testing has utility in making temporary and “on the spot” changes in clinical management, its limitations in accuracy have recently been the subject of study
  - High rate false positives and negatives
    - Use of POC obtained for the making of long term and permanent changes in management of people with addiction disorder and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are known

# Periodic Drug Testing

- Drug tests results that are inappropriately positive or negative should be discussed with the patient in a positive, supportive fashion
- Both the test results and subsequent discussions with the patient should be documented in the medical record

# Clinical Course

- Evidence of aberrant behavior demands prompt intervention
  - Patient behaviors that require physician intervention
    - 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)
    - Pressuring or threatening behaviors
    - The presence of illicit or un-prescribed drugs (drugs not prescribed by a physician) in drug tests
    - Recurring misuse, such as unsanctioned dose escalations
    - Deteriorating function
    - Failure to comply with the treatment plan

# Clinical Course

- Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response
- 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
- 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



# Clinical Course

- Periodic pill counting may be a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications)
- Consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended
  - Useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers

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
- If a different approach is indicated; referral to a pain specialist or other health professional may be in the physician and patient's best interest

# Consultation and Referral

- The treating physician should be willing to seek consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as indicated
- Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction
  - Including those available in licensed opioid treatment programs [OTPs])
  - Those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT])
  - Make appropriate referrals when needed

# Discontinuing Opioid Therapy

- Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment
- If 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
- 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
  - Significant aberrant medication use

# Discontinuing Opioid Therapy

- If opioid therapy is discontinued, the patient who has become physically dependent should be provided a safely structured tapering regimen
- Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist
- Termination of opioid therapy should not mark the end of treatment and should continue with other modalities, either through direct care or referral, as appropriate
- Physicians should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement

# Medical Records

Information in the medical record should include:

- Copies of the signed informed consent and treatment agreement
- The patient's medical history
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity)
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others

# Medical Records

- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement
- Notes on evaluations by and consultations with specialists
- Any other information used to support the initiation, continuation, revision, or termination of treatment
- Steps taken in response to any aberrant medication use behaviors
- These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers
- Authorization for release of information to other treatment providers

# Medical Records

- All prescription orders for opioid analgesics and other controlled substances, whether written or telephoned
- Written instructions for medication use should be given to the patient and documented in the record
- The name, telephone number, and address of the patient's pharmacy
- Records should be up-to-date and maintained in an accessible manner so as to be readily available for review
- 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*



# Compliance with Controlled Substance Laws and Regulations

- To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which s/he practices, and comply with applicable federal and state regulations
- 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.dea diversion.usdoj.gov](http://www.dea diversion.usdoj.gov)), as well as from (*any relevant documents issued by the state medical board*)