

GEORGIA COMPOSITE STATE BOARD OF MEDICAL EXAMINERS

Guidelines for the Use of Controlled Substances for the Treatment of Pain: Ten Steps

Disclaimer

These guidelines are primarily intended to provide orientation for physicians intending to prescribe schedule II and III analgesics for the purpose of treating chronic pain conditions and do not necessarily apply to clinical conditions where rapid adjustments in medical management are required such as acute pain management following surgery, emergency care pain management and end-of-life care.

The Georgia Composite State Board of Medical Examiners (the Medical Board) recognizes that principles of quality medical practice dictate that the people of the state of Georgia have access to appropriate and effective pain relief by licensed physicians. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of these guidelines, the inappropriate treatment of pain includes no treatment, under treatment, over treatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as an essential part of quality medical practice for all patients with pain, including both acute and chronic disease. All physicians should be or seek to become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as becoming familiar with statutory requirements for prescribing controlled substances. These guidelines have been developed to clarify the Board's position on pain management, particularly as it relates to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management practices. The guidelines are also intended to curtail drug diversion, a serious public safety concern for the Board and law enforcement agencies.

Adherence to the guidelines outlined here will not only improve quality medical practice but will also improve the board's efficiency in its investigations by distinguishing legitimate practice from foul play.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice.

To prevent any misunderstanding, it is necessary to state what the Board does not have.

The Board does not have a list of “bad” or “disallowed” drugs. All formulary drugs are generally effective if prescribed and administered when properly indicated. Conversely, drugs are potentially ineffective, dangerous, or even lethal when used inappropriately.

The Board does not have a “magic formula” for determining the dosage and duration of administration for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case and continued under proper monitoring. What is good for one patient may be insufficient or fatal for another.

The Board does have the expectation that physicians will create a record that shows evaluation of every patient receiving a controlled substance prescription as follows:

- Proper indication for the use of drug or other therapy
- Monitoring of the patient where necessary
- The patient’s response to therapy on follow-up visits
- All rationale for continuing or modifying the therapy
- Discussion of risks/benefits
- Periodic medical record review
- Prescription records

STEP ONE

A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance. Perform a workup sufficient to support a diagnosis including all necessary tests, history and physical examination. If medical testing is negative, carefully document the rationale of therapy and its effectiveness. When a diagnosis is undetermined, despite the complaint of severe pain, consider consultation for further analysis. The medical record will need to document sufficient and appropriate H&P and diagnostic testing to support the diagnosis necessitating the use of controlled substances.

STEP TWO

Create a treatment plan, which includes the use of appropriate non-controlled drugs, and consider referrals to appropriate specialists, such as neurologists, orthopedists, pain management specialists,

addictionologists, psychiatrists, etc. The result of the referral should be included in the patient's chart. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.

STEP THREE

Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history and physical that non-controlled drugs are not appropriate or effective for the patient's condition. The above does NOT apply to acutely painful conditions such as an acute injury or surgery, nor does it apply to the management of pain in cancer or hospice patients. It may also not apply for patients who have a contraindication to, or are at high risk of experiencing side effects from non-steroidal anti-inflammatory drugs such as the elderly.

Although non-controlled drugs (e.g., aspirin, acetaminophen, NSAIDS) often are adequate to treat painful conditions of mild severity, the Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. This does not mean that opioids and other controlled substances cannot be used as a first-line therapy, but it is important to document the rationale when used as such.

STEP FOUR

Review the patient's prescription records and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum obtain an oral drug history and medication allergies, and discuss chemical use and family chemical history with the patient and obtain old records which may include pharmacy records.

STEP FIVE

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient does not have decision making capacity. The physician must remain in compliance with HIPAA regulations. Take the time to explain the relative risks and benefits of the drug and record in the chart the fact that this was done. When embarking on what appears to be the long-term use of a dependence-causing or potentially addictive substance, it may be wise to hold a family conference and explain differences between physical dependence, tolerance and addiction.

STEP SIX

Maintain regular monitoring of the patient, including frequent physical monitoring. If the regimen is for prolonged need for the drug use it is very important to monitor the patient for the underlying condition which necessitates the drug and for the side effects of the drug itself. This is true no matter what type of controlled substance is used or to what schedule it belongs. It is very important to monitor the patient for the underlying condition which necessitates the use of controlled substances. It is also important to monitor the patient for side effects that may occur with the use of the selected controlled substance(s).

STEP SEVEN

The physician must keep detailed records of the type, dosage and amount of the drug prescribed. Prescribing physicians should also monitor and personally control all refills. One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time. Records of the cumulative dosage and average daily dosage are especially valuable. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities and checking on whether the patient is obtaining drugs from other physicians. Checking with pharmacies may indicate a patient is obtaining additional drugs or is doctor shopping. It is a felony in Georgia for a patient to fail to disclose to his physician that he has received controlled substances of a similar therapeutic use from another practitioner at the same time. If you are aware of these situations occurring, contact your local police or the Georgia Drug and Narcotics Agency.

STEP EIGHT

With the patient's permission, the patient's family may be a valuable source of information on the patient's response to the therapy regimen and the patient's functional status, and may provide more accurate and objective feedback than the patient alone.

Family may be a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is discontinued. These changes, at the time, may be symptoms of dependency or addiction. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

STEP NINE

Maintaining adequate records is extremely important. The physician who carefully manages pain treatment and maintains detailed records which reflect all the steps involved in the process will be able to assess and review the treatment course and progress.

STEP TEN

Document

Document

Document

Keep accurate and complete records to include:

The medical history and physical examination

Diagnostic, therapeutic and laboratory results

Evaluations and consultations

Treatment objectives

Medications (including date, type, dosage and quantity prescribed)

Instructions and agreements, pain contracts (where applicable)

Definitions:

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.