

Florida Board of Medicine, Board of Osteopathic Medicine, Agency for Health Care Administration

FLORIDA GENERIC CLINICAL PRACTICE GUIDELINE MANAGEMENT OF PAIN USING DANGEROUS DRUGS AND CONTROLLED SUBSTANCES

PREFACE

The State of Florida recognizes that pain, including intractable pain, is often undertreated. Unrelieved pain can have harsh and sometimes disastrous influence on the quality of life for patients and their families.

PAIN MANAGEMENT SHOULD BE A HIGH PRIORITY IN FLORIDA

Principles of quality medical practice dictate that citizens of Florida who suffer from pain should seek relief with treatment that is currently available. The appropriate application of current knowledge and treatments can greatly improve the quality of life for many Florida citizens and reduce the morbidity and costs associated with untreated pain.

In addition to promoting competent patient care, these guidelines are intended to help physicians avoid investigation if controlled substances are appropriately prescribed for short or long-term pain management.

PRESCRIBING DANGEROUS DRUGS AND CONTROLLED SUBSTANCES FOR PAIN

The proper treatment for any patient's pain depends upon a careful diagnosis of the etiology of the pain, selection of appropriate and cost effective treatments and the ongoing evaluations of the results of treatment. Patients with chronic pain may demand more time of the practitioner because of the complexity of their problem.

Opioid analgesics and other dangerous and controlled substances are useful for pain treatment. They are the cornerstone of treatment for acute pain due to trauma or surgery and of chronic pain due to progressive diseases, such as cancer. Other than that specified in the Physician's Desk Reference (PDR), large doses, if documented, may be necessary to control severe pain. Extended therapy may also be needed to alleviate chronic pain. Published formularies, relating to commercial financial incentives, should not be a deterrent to achieving optimal pain relief.

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Opioid analgesics may also be useful in treating patients with intractable nonmalignant pain especially when efforts to remove or treat the pain with other modalities have failed. Such intractable pain may have a number of different etiologies and might require several treatment methods. In addition, the extent to which pain is associated with physical and psychosocial impairment varies greatly. Therefore, when patients are selected for therapy trials using dangerous drugs and opioid therapy, care should be used to assess the pain as well as the patient's disability. The duration of drug therapy should depend on the physician's evaluation of the results of treatment, including the degree of pain relief, the changes in physical and psychological functioning and the appropriate utilization of health care resources.

Addiction in relation to these substances should be placed in proper perspective. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant, drug-related behaviors. Addicts use drugs in a compulsive manner and not for medical purposes. An addict may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts merely because they are being treated with opioids. Physicians need to be cognizant of the fact that patients with a history of drug abuse may be particularly problematic to the management of pain.

PAIN MANAGEMENT, CONTROLLED SUBSTANCES AND THE LAW

Federal government laws and regulations and those of the State of Florida impose special requirements for dangerous drugs and controlled substances prescription. These regulations are aimed at preventing harm to the consumer from dangerous prescription drugs which are diverted to nonmedical uses. It is legitimate medical practice for physicians to prescribe controlled substances for the treatment of pain, including intractable pain.

The Agency for Health Administration supports the examination of prescriptions for analgesics and opioids for the treatment of pain. This examination must be based on the documented diagnosis and treatment rather than on the drug dosage or on the number of prescriptions written.

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Concerns about regulatory scrutiny should not cause physicians to be reluctant to prescribe or administer dangerous and controlled substances, including Schedules II-V drugs as provided for in Florida Statutes s. 893.03, for patients with legitimate medical needs. Physicians need not fear administrative action when prescribing dangerous drugs and controlled substances to patients in their care for a pathology or condition when the prescription is issued after a good faith examination and there is medical indication for the prescription.

The regulatory boards may identify a pattern of dangerous and controlled substance use which merits further examination, but private, courteous and professional inquiry can usually determine whether the physician is appropriately prescribing for patients in good faith or whether an investigation is warranted. The Florida Board of Medicine and the Florida Board of Osteopathic Medicine must judge the prescription validity relative to the physician's documented diagnosis and treatment and if the prescribed drugs are appropriate for the patient's condition. Predetermined limits should not be placed on dosages or length of drug therapy.

It is the goal of the Agency for Health Care Administration to change practitioner perception of regulatory scrutiny and recognize the commitment of regulatory boards to improving pain management in order to enhance the quality of lives of pain-affected patients in Florida. Federal and State laws and regulatory policies should not hamper the appropriate use of dangerous drugs and controlled substances for the relief of pain.

DEFINITIONS

INTRACTABLE PAIN - 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.

NONTHERAPEUTIC USE - A medical use or purpose that is not legitimate in nature or in manner.

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ABUSER OF NARCOTIC DRUGS, CONTROLLED SUBSTANCES AND DANGEROUS DRUGS - An individual who takes a drug or drugs for other than legitimate medical purposes.

1. The treatment of pain, including intractable pain, with dangerous drugs and controlled substances has a legitimate medical purpose when performed in the usual course of medical practice.

2. Physicians duly authorized to practice under their respective practice act and to prescribe controlled substances and dangerous drugs in Florida, shall not be subject to disciplinary action by their respective licensure board for prescribing, ordering, administering or dispensing dangerous drugs or controlled substances for the treatment and relief of pain, including intractable pain, in the usual course of professional practice for a legitimate medical purpose in compliance with applicable state and federal law.

3. The prescribing, ordering, administering or dispensing of dangerous drugs or controlled substances for pain will be considered to be for a legitimate medical purpose if based upon scientific knowledge of the treatment of pain, including intractable pain, and are not in contravention of applicable state and federal law, and if prescribed, ordered, administered or dispensed in compliance with the following guidelines where appropriate and as is necessary to meet the individual needs of the patient.

A physician will be considered in compliance if:

- a. The medication is prescribed after a documented patient history and physical examination by the physician prescribing or providing the medication, which includes: an assessment and consideration of the physical and psychological impact of the pain, any patient history or potential for substance abuse, for coexisting diseases and conditions and the prescience of a recognized medical indication for the use of a dangerous drug or controlled substance.

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- b. If medications are prescribed pursuant to a written treatment plan tailored for the individual needs of the patient and if treatment progress and success can be evaluated with stated objectives such as pain relief and improved physical and psychosocial function. Such a written treatment plan will consider pertinent medical history and physical examination as well as the need for further testing, consultations, referrals or the use of other treatment modalities.
 - c. The physician should discuss with the patient, significant other(s) or legal guardian, if appropriate, the risks, i.e. narcotic bowel syndrome (information attached), addiction and other side effects in comparison to the benefits from the use of dangerous and controlled substances.
 - d. The patient will be subject to documented periodic review of the care by the physician at reasonable intervals and in view of the individual circumstances of the patient in regard to progress toward reaching the stated objectives. The review will take into consideration the course of medications prescribed, ordered, administered or dispensed, as well as any new information about the etiology of the pain.
 - e. Complete and accurate records of the care provided are kept as set forth in a-d, above. When controlled substances are prescribed, records are made which include names, quantities prescribed, dosages and number of authorized refills. This record takes into account that pain-affected patients with a history of substance abuse, or patients who live in an environment that may pose a risk for medication misuse or diversion, may require special consideration. Management of these patients may warrant closer monitoring by the physician managing the pain and require consultation with appropriate health care professionals.
4. A physician's decision not to adhere strictly to the provisions of number 3. above, will not if "good faith or cause" is shown, constitute grounds for board disciplinary action. Each case of prescribing for pain will be evaluated on an individual basis. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account: 1/ whether the drug used is medically or pharmacologically recognized to be appropriate for the diagnosis, 2/ the patient's individual needs, including any improvement in functioning, and 3/ recognizing that some types of pain cannot be completely relieved.

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5. If the provisions set out in numbers 1-4, above, are met, and if all drug treatment is properly documented, the board will consider such practices as prescribing in a therapeutic manner, and as prescribing and practicing in a manner consistent with public health and welfare.

6. Quantity of pharmaceutical and chronicity of the prescription will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication. Documented persistence of the recognized medical indication, and properly documented follow-up evaluations with appropriate continuing care as set out in these guidelines, will also be evaluated.

7. A physician may use any number of treatment modalities for the treatment of pain, including intractable pain, which are consistent with legitimate medical purposes.

Source: Florida Board of Medicine

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