Pursuant to section 453-1.5, Hawaii Revised Statutes, the Board of Medical Examiners ("Board") has established guidelines for physicians with respect to the care and treatment of patients with severe acute pain or severe chronic pain. These pain management guidelines are considerations that the Board will take into account in the proper treatment of pain.

HAWAII BOARD OF MEDICAL EXAMINERS
PAIN MANAGEMENT GUIDELINES

Section I: Introduction

The Board of Medical Examiners ("Board") recognizes that principles of quality medical practice dictate that the people of the State of Hawaii have access to appropriate and effective pain relief. The Board affirms that controlled substances may be necessary to relieve pain, and the medical use of opioid analgesics is recognized to be part of legitimate medical practice.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. The Board believes that all physicians who treat patients directly should have sufficient knowledge about pain and its management to provide comfort for those in pain, or utilize consultations when possible to obtain necessary information to make treatment decisions for their patients. Accordingly, this policy has been developed to clarify the Board's position on pain management, particularly as related to the use of controlled substances.

The Board is obligated under the laws of the State of Hawaii to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances. The Board considers acceptable the ordering, prescribing, dispensing or administration of controlled substances, including opioid analgesics, for a legitimate

medical purpose to be acceptable particularly in the case of terminal illness. The Board considers the use of controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain.

The Board will consider the inappropriate treatment of pain to be a departure from standards of practice and therefore investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate to the diagnosis.

Section II: Evaluation of Physician Practice

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on a case-by-case basis. Deviation from this policy may be appropriate when contemporaneous medical records document reasonable cause for deviation.

In determining whether the physician has acted appropriately, the Board will consider the clinical outcome, whether drugs used are appropriate for the type of pain, and whether there is improvement in patient functioning and/or quality of life as factors.

Section III: Practice Guidelines for Chronic Pain Management

Evaluation of the Patient – A medical history and physical examination should be performed 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 or other compulsive behaviors.

Treatment Plan – 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. The treatment plan should be adjusted and documented according to the individual needs of each patient.

Informed Consent and Agreement for Treatment – 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. The patient's pain medication should be managed by 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 have written treatment agreements outlining the patient's responsibilities during treatment and should obtain informed consent before prescriptions are provided.

The treatment agreements may specify many of the following items:

- Urine or blood samples will be provided by patients upon request for urine/serum drugs of abuse screening and/or determining medication levels by their physicians;
- The number and frequency of all prescription refills may be limited at their physicians' discretion;
- Therapy with controlled substances may be discontinued by physicians under certain situations (e.g. significant violation of treatment agreements by patients);
- Physician/patient relationships may be discontinued under certain situations (e.g. violation of treatment agreements by patients);
- Medication refills will be provided under specified rules, within mutually agreed upon time-frames (e.g. early refills may not be allowed, lost medications may not be replaced, refills may only occur during regular business hours, etc.);
- All therapies may be provided on a time-limited basis to determine potential effectiveness, and may be discontinued if judged ineffective or unacceptably toxic;
- Referral of patients to substance abuse treatment programs will occur when use of controlled substances is determined to be due to underlying addiction and not pain.

Periodic Review - The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives.

Use of consultation with pain management specialists, addiction medicine specialists, and other medical specialties is encouraged. Physicians should be willing to refer their patients as necessary for additional evaluations and therapies to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion.

Medical Records – The physician should keep accurate, current and complete medical records. Elements considered for completeness may include, but are not limited to the following:

1. An initial medical history and physical examination;
2. Diagnostic imaging, therapeutic and laboratory results;
3. Ongoing evaluations and consultations;
4. Establishment of treatment objectives;
5. Discussion and documentation of risks, benefits and alternatives;
6. Results of treatment(s) provided (changes in pain intensity and character, interference with activities of daily living), and management of side effects;
7. Intended use of medications (information about date, name of medication, dosage, quantity prescribed with instructions);
8. Treatment instructions and agreements provided; and
9. Evidence of ongoing periodic review process with treatment modification if necessary.

Compliance With Controlled Substances Laws and Rules – To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state laws and rules.

Section IV: Definitions (as taken from the Federation of State Medical Boards)

For the purpose of these guidelines, the following terms are defined as follows:

Pain - An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute Pain – Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with an invasive procedure, trauma or disease. It is generally time-limited.

Chronic Pain – Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

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 physiological 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.

Substance Abuse – Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.