

APPENDIX C

JOINT REVISED PAIN MANAGEMENT GUIDELINES APPROVED BY THE SOUTH CAROLINA BOARDS OF MEDICAL EXAMINERS, DENTISTRY AND NURSING

November 2014

The South Carolina Board of Medical Examiners (Medical Board) published Pain Management Guidelines (Guidelines) to assist physicians in safely prescribing controlled substances in July of 2009. Increasing opioid misuse and abuse, recent research and clinical studies now require the revision of those Guidelines to provide adequate information to ensure safe and appropriate treatment of pain. Additionally, the Medical Board recognizes that physicians, dentists, physician assistants, and advance practice registered nurses with prescriptive authority should all adhere to uniform prescriptive guidelines. Accordingly, the South Carolina Board of Dentistry (Dental Board) and South Carolina Board of Nursing (Nursing Board) have joined the Medical Board in approving these Joint Revised Pain Management Guidelines (Revised Guidelines).¹ These Revised Guidelines strongly consider the evidence that the health risks of high dose opioid use have increased, while the evidence for benefits remains controversial and insufficient. In the Revised Guidelines, the Dental Board, Medical Board and Nursing Board (the Boards), adopt language, in part, similar to that used by the North Carolina Medical Board in an effort to create a uniform policy along our common border.

These Revised Guidelines are designed to communicate to licensees that the Boards view pain management as an important area of patient care integral to the practice of medicine; that opioid analgesics may be necessary for the relief of certain pain conditions; and that prescribers will not be sanctioned solely for prescribing opioid analgesics of the dose prescribed for legitimate medical purposes. Further, the Revised Guidelines are intended to alleviate prescriber uncertainty and to encourage patient-centered care. These Revised Guidelines are intended to reinforce the exercise of sound clinical judgment while discouraging prescriptive behaviors that may lead to misuse or abuse of controlled substances, including opioids.

These Revised Guidelines serve to protect South Carolinians' access to pain care while combating prescription drug misuse, abuse, diversion and addiction. Prescribers must be held to a safe and best clinical practice. The Federal Controlled Substances Act defines a "lawful prescription" as one that is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The use of opioids for other than legitimate medical purposes poses a threat to the individual and to the public health, thus imposing on prescribers a

^{1 1} The Board of Medical Examiners endorsed the Revised Guidelines on November 3, 2014. The Board of Dentistry endorsed the Revised Guidelines on November 13, 2014. The Board of Nursing endorsed the Revised Guidelines on November 20, 2014.

responsibility to minimize potential for misuse, abuse and diversion of opioids and all other controlled substances.

Prescribers must recognize that inappropriate prescribing of controlled substances may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes. Inappropriate treatment can result from a mistaken belief on the part of patients and their prescribers that complete eradication of pain is an attainable goal that can be achieved without disabling adverse effects. Accordingly, the Boards urge prescribers to incorporate safeguards into their practices to minimize the risks of misuse, abuse and diversion of opioid analgesics and other controlled substances. The consensus is that utilization of SCRIPTS prior to prescribing opiates is the best safeguard against these risks and the best practice for prescribers.

Preamble

The Boards recognize that principles of quality medical practice dictate that South Carolinians have access to appropriate and effective pain relief.

The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain, as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. These Revised Guidelines apply to the treatment of both acute and chronic pain with opioid analgesics, as well as clinical strategies to improve appropriate, safe prescribing of controlled substances and treatments. The use of opiates in end of life and palliative care may present unique benefits and risks not fully addressed herein. However, concepts presented will be relevant and generally applicable to the use of opiates for end of life and palliative care.

Persistent, intractable pain, like all chronic illnesses, is managed optimally with a biopsychosocial model and not with opio-centric practices of the past. A continuum of care in choosing possible opioid and nonopioid alternatives is preferred, depending on the clinical situation and prescriber discretion as to safe and appropriate treatment.

Below, the Boards issue guidance on the Treatment of Pain, including chronic and acute pain and pain in the emergency department; the Inappropriate Treatment of Pain; Actions Outside the Scope of Appropriate Pain Management; and other Special Considerations.

I. GENERAL PRINCIPLES ON STANDARD OF CARE

It will be considered the standard of care to assess and evaluate the current status of pain treatment prior to initiating new treatment or adjusting current treatment. The registration and utilization of SC PMP/SCRIPTS program (SCRIPTS), which provides both a current and historical survey of narcotic, sedative and controlled substance use, is considered mandatory for prescribers to provide safe, adequate pain treatment. Drug screening is strongly recommended, when indicated. Prescribers are responsible for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Boards regulating prescribers will consider prescribing, ordering, dispensing or administering controlled substances for pain to be

for a legitimate medical purpose if based upon documented, sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a practitioner-patient relationship must exist and the prescription should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and federal law is required.

The Boards recognize 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 cancerous or noncancerous origins. The Boards will refer to current clinical practice guidelines and expert review in the investigation and review of cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and nonpharmacologic modalities according to the judgment of the prescriber.

Pain should be assessed and treated promptly. The selection of therapeutic modalities, including the quantity and frequency of medication doses, should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential. Prescribers should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

II. GUIDELINES FOR THE TREATMENT OF PAIN

These Revised Guidelines are meant to help prescribers evaluate and manage pain appropriately, prescribe opiates responsibly, and prevent opioid diversion and abuse. Incorporation of these best practices will help prescribers mitigate some of the burden that pain and its attendant opiate use place on patients, prescribers, medical institutions and society. The Boards strongly recommend the following as a reference for behavior when using opiates to treat pain.

A. TREATMENT OF CHRONIC PAIN

Prescribers who treat patients with chronic pain are strongly encouraged to be knowledgeable about addiction, including behaviors that indicate addiction and circumstances under which it is appropriate to refer a patient for addiction evaluation and treatment. Essential elements of appropriate pain management include: evaluation of the patient, consideration of alternative treatments, development of a treatment plan and goals individualized to the patient's needs, informed consent and a treatment agreement, initiation of treatment on a trial basis, periodic review and possible drug testing, consideration of drug diversion, possible consultation and referrals, thoughtful discontinuation of treatment, and appropriate documentation of medical records.

Evaluation of the Patient

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.

SCRIPTS utilization should be part of every patient's initial evaluation and subsequent monitoring program and is considered the standard of care. Failure to utilize SCRIPTS to assess risk of opiate/sedative prescribing may be considered misconduct by the responsible regulatory board, depending upon the clinical situation. Prescribers should register with SCRIPTS and become familiar with analyzing and using SCRIPTS data. Information from the SCRIPTS should be used to help confirm each patient's compliance with treatment plans and opiate medication agreements. Relevant information from the SCRIPTS should become part of the patient's medical record.

A toxicology screen, such as a urine drug screen, is a useful tool in the assessment of risks associated with prescribing higher dose opioids and should be utilized prior to prescribing opioids for treatment of chronic pain. It may reveal the use of controlled medications other than those prescribed, such as opioids or benzodiazepines, or the use of illicit drugs.

Evaluation and risk stratification assume even greater importance when dealing with a patient who is taking opioids prescribed by another prescriber. The prescriber's decision to prescribe opioid analgesics should reflect the totality of the information collected, the prescriber's own knowledge and comfort level in prescribing, and the resources available in the community for patient support.

Consideration of Alternative Treatments to Opioid Therapy

Consideration and utilization of a multimodal approach to patient care is essential. A prescriber treating a patient seeking care for pain should have knowledge of all available treatment options, including, but not limited to: physical therapy; non-opioid medications; injections; surgical options; cognitive and behavioral methods; rehabilitation approaches; and complementary treatments. These should be explored and documented as part of a routine evaluation. Early treatment with non-pharmacologic interventions including physical therapy, exercise, and cognitive behavioral techniques, should be employed whenever possible. First line pharmacotherapy should be the appropriate use of non-opioid analgesics, including over the counter medication, non-steroidal anti-inflammatory drugs, and acetaminophen. Other treatment modalities, including minor intervention such as anesthetic and steroid joint injections, cutaneous stimulation, topical anesthetics, and local therapies employing heat, massage, and manipulations, should be considered before using opiates.

If the prescriber determines that opioid therapy is the best course of treatment after review and/or utilization of alternative treatments, the prescriber should minimize the risks of respiratory depression, addiction, and diversion. When opioids are identified as the best treatment option for complex or high-risk patients, specialists in psychology, psychiatry, and addiction management should be consulted, if possible.

Development of a Treatment Plan and Goals

The decision to initiate opioid therapy for treatment of chronic pain should be the prescriber and patient's joint decision. This decision may extend to another person responsible for the patient's care (Caretaker). Once the joint decision to prescribe is made, a treatment plan and goals should be established as early as possible in the treatment process and revisited regularly. The prescriber should discuss the risks and benefits of the treatment plan, including any proposed use of opioid analgesics, with the patient and any Caretaker or other person(s) designated by the patient. If opioids are prescribed, the patient and any Caretaker should be counseled on safe ways to store and dispose of medications.

Appropriate goals of pain treatment include: reasonable attainable improvement in pain and activity; improvement in pain-associated problems such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Individualized goals for pain relief and improved physical, functional and psychosocial activity should be set to help guide the choice and response to treatment. The treatment plan should contain information supporting the selection of pharmacologic and non pharmacologic control of pain and achievement of specific physical, functional and psychosocial activity goals. The plan should document any further diagnostic evaluations, consultations or referrals, and/or additional therapies that have been considered, including any follow up plans. A prescriber may reduce risks of abuse, misuse, diversion, and/or unintentional overdose by incorporating a schedule for reassessment and re-evaluation in the treatment plan, as discussed in Periodic Review herein below.

Informed Consent and Treatment Agreement

Use of a written informed consent, memorializing the joint decision to prescribe, **and** a treatment agreement, memorializing the treatment plan and goals, is the standard of care. They may be combined into one document for convenience. Informed consent should always be considered for higher dose or ongoing acute or chronic pain opiate prescribing.

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy;
- Potential short and long term side effects of the medication, such as constipation and cognitive impairment;
- The likelihood that tolerance to and physical dependence on the medication will develop;
- The risk of drug interactions and over-sedation, including the increased risk of using opiates in disease and conditions such as obesity and sleep apnea;
- The risk of impaired motor skills affecting driving and other tasks;
- The risk of opioid misuse, dependence, addiction and overdose;
- The limited evidence of the benefit of long-term opioid therapy;

- The prescriber's policies and expectations, including the number and frequency of prescription refills, early refills, and replacement of lost or stolen medications; and
- Specific reasons for which drug therapy may be changed or discontinued, including violation of the policies and agreements spelled out in the treatment agreement.

Treatment agreements outline the joint responsibilities of the prescriber and the patient in the management of chronic pain and may be applicable in some cases of acute pain. Treatment agreements are indicated when opioid or other abusable medications are prescribed. Agreements typically discuss:

- The treatment goals for pain management, restoration of activities, and safety;
- The patient's responsibility for using medication safely, including not using more medication than prescribed, not using an opioid in combination with alcohol or other potentially dangerous substances, storing medications in a secure location, and safely disposing of unused medication;
- The patient's responsibility to obtain opioids from only one prescriber or practice and to fill prescriptions at an in-state pharmacy or one that participates in SCRIPTS reporting;
- The patient's agreement to submit to periodic drug testing of blood, urine, hair, saliva, or other body material;
- The prescriber's responsibility to be available or to have a covering prescriber be available to care for unforeseen problems and to prescribe scheduled refills; and
- The prescriber's responsibility to provide referrals to substance abuse counseling when abuse potential is present and for failed drug screens.

Initiating an Opioid Trial

Safer alternative treatments should be considered before initiating opioid therapy. When the decision to use an opiate has been made, it should be presented to the patient as a therapeutic trial to test for a defined period of time, usually no more than ninety (90) days, and with specified evaluation points. The prescriber should explain that progress will be carefully monitored for benefit and harm in terms of the effect of opioids on the patient's level of pain, physical function and psychosocial activities. Attention will be focused on adverse events and risks to safety. Prescribers should develop and implement appropriate safe practices for patients identified as at risk for misuse, abuse, diversion, and/or overdose. At risk patients should be candidates for abuse deterrent formulations of the prescribed opioid.

The lowest dose possible should be given to an opioid naive patient at the beginning of opioid therapy and titrated to effect while monitoring for complication. Opioid therapy should begin with a short acting drug and rotate to a long acting/extended release, if indicated. A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits, adverse events, and potential risks.

Periodic Review

As stated previously, review of SCRIPTS data at the time of clinical exam and prescription writing of opiates is the standard of care. The prescriber 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 activities. When possible, collateral information about the patient's response to opioid therapy, including the medication's affect on physical, functional, and psychosocial activities, as well as signs of adverse effects, such as sedation or other impairment, should be obtained from family members or other close contacts. The prescriber should regularly review SCRIPTS data. The patient should be seen more frequently while the treatment plan is being initiated and when the opioid dose is being adjusted. As the patient is stabilized in the treatment regimen, follow up visits may be scheduled less frequently.

Continuation, modification or termination of opioid therapy for pain should be contingent on the prescriber's evaluation of the patient's progress toward treatment goals and assessments of substantial risks or adverse events. A satisfactory response to treatment would be indicated by a reduced level of pain and improved physical, functional, and psychosocial activities. Use of measurement tools to assess the patient's level of pain, activity, and quality of life can be helpful in documenting therapeutic outcomes.

Risks associated with opioids increase with escalating doses. When a patient is prescribed 80 Morphine Equivalent Dose (MED) for longer than three continuous months, it is recommended that the prescriber: re-establish informed consent; review the patient's functional status, including daily activities, analgesia, aberrant behavior, and adverse effects, as it relates to progress toward treatment objectives established at the onset of opioid therapy; consult SCRIPTS to verify compliance; re-establish office visit intervals; review frequency of drug screens; and review and execute a new treatment agreement. Relevant information from SCRIPTS should become part of the patient's medical record.

The prescriber should avoid opiate dose escalation without adequate attention to risks or alternative treatments. The prescriber should be mindful that not all pain can be alleviated through the use of opioids. Clinicians should avoid over-reliance on opioids as the primary or only treatment modality, including using opioid dose escalation as the only response to a complaint of inadequate pain relief. The prescriber should be continuously attentive to the use of opiates in the presence of other comorbidities, such as mental illness, respiratory disorders and sleep apnea, and a pre-existing substance use disorder. The prescriber should dispel any mistaken expectation that complete eradication of pain is an attainable goal when a reasonable level of discomfort is the best clinical outcome a patient may achieve.

Prescribers should reconsider a referral to one or more other providers specializing in the treatment of the area, system or organ of the body perceived to be the source of the patient's pain. This may include consultation with a pain specialist if the prescriber is not a pain specialist.

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. Drug testing is an important monitoring tool because self-reports of medication use and behavioral observations are not always reliable. Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing. When testing is conducted as part of a pain treatment plan, forensic standards are generally not employed. Sample collection may not need to be observed and chain-of-custody protocols are not customarily followed. Initial testing may be done using class-specific immunoassay point-of-care or laboratory-based test. These tests do not typically identify a particular specific drug within a class. However, the tests are available as panels and immunoassays for specific drugs can be included. It is important that the clinician formulate these panels to include the specific medications being prescribed, and, if possible, the drugs commonly abused in the local community. If necessary, initial testing can be followed with more specific techniques, including gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests. It is important to identify the specific drug, not just the class of the drug, when drug testing a pain patient.

Prescribers should be knowledgeable about the specific drug tests they order. They should be aware of the limitation, sensitivity and specificity of the tests they order and take care to order tests appropriately. When a drug test is ordered, it is important to specify that it include the opioid being prescribed. Because of the complexities involved in interpreting drug test results appropriately, it is advisable to confirm significant or unexpected results with the testing laboratory's toxicologist or a clinical pathologist.

Test results that suggest illicit or prescribed medication misuse should be discussed with the patient. Results of drug testing and subsequent discussion with the patient should be documented in the medical record.

If the patient's progress is unsatisfactory, the prescriber 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 a referral to a pain specialist or other health professional, should be employed.

Drug Diversion

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require an immediate response. Failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempt, arrest and incarceration or death. For this reason, prescribers who prescribe chronic opioid therapy should be knowledgeable about substance use disorders and be able to distinguish substance use disorder from physical dependence on opiates. Detection of opioid diversion is one of the most difficult duties a prescriber has. The combination of periodic, unscheduled and random pill counting and a concomitant UDS with a confirmation is an effective way to ascertain whether a patient is diverting.

Warning signs that a patient may be seeking opioid medications for reasons other than legitimate pain relief include:

Suspicious history:

- Patient referred is already taking controlled substances, especially a combination of narcotics, muscle relaxants, and sedative/hypnotics;
- Soft diagnosis, perhaps based solely on chief complaint;
- Multiple doctors and pain physicians in the past;
- Patient travelled out of the way to come to your clinic;
- Solicitous behavior (“You’re the best. I always wanted to come to you.”);
- No past medical records are provided and patient states he is unable to obtain records from “referring doctor”;
- Patient brings records that look old, tattered or suspicious in some other way; or
- Patient asks for a specific controlled substance (example: prefers Lortab® over Norco).

Suspicious physical exam:

- No abnormal findings;
- Abnormal findings in exam room inconsistent with witnessed behavior (For example, the patient has normal gait from car to office door, but limps once inside door.);
- Exaggerative behaviors, pain is always a 10 on a scale of 1 to 10;
- Unimpressive imaging;
- Presence of injecting behavior (old or recent “track marks” or multiple healed or current abscesses) or marked nasal erythema from insufflation (snorting); or
- Patient smells like marijuana smoke.

Equivocal compliance:

- SCRIPTS shows multiple providers, multiple pharmacies, prescriptions for multiple types of medications, and prescriptions from out of area doctors, etc.
- UDS is refused or abnormal, for which patient offers multiple excuses, or detects any illegal substance;
- Inconsistent tests results over time;
- Patient seeks recurrent early refills for lost or stolen prescriptions or for increased opioid use without consultation with prescriber; or
- Patient has excuses for lost pills.

No or equivocal clinical improvement:

- Subjective improvement alone does not count;
- Lack of evidence of objective improvement in physical, functional and psychosocial activities; or
- Lack of evidence of decreasing use of opioid medications, decreasing visits to emergency rooms, etc.

What you should do when the clinician suspects misuse, abuse or addiction:

- Request picture I.D. or other I.D. and a Social Security Number. Photocopy these documents and include in the patient's record;
- Call a previous practitioner, pharmacist or hospital to confirm the patient's story;
- Confirm a telephone number, if provided by the patient;
- Confirm the current address at each visit;
- Investigate suspicions further by presenting and discussing specific concerns with the patient, re-checking SCRIPTS data, increasing the use of drug screens, and talking with family members;
- Write prescriptions for limited quantities until conflicts are resolved and it is safe to do so;
- Increase frequency of visits and drug screens; and
- Document all activities in support of mitigating potential misuse, abuse, or addiction.

Consultation and Referral

The treating prescriber should seek a consultation with or refer the patient to a pain, psychiatric, addiction, or other mental health specialist as needed. A patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment.

Prescribers 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.

Discontinuing Opioid Therapy

The prescriber and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate. Opioids should be tapered or discontinued when a patient's pain is poorly controlled on appropriate doses of medication or if when opioid treatment produces no improvement in physical, functional, or psychosocial activity. Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, deteriorating physical, functional or psychosocial activities or significant aberrant medication use.

If opioid therapy is discontinued in the setting of appropriate use, but inadequate response, and the patient has become physically dependent, they should be provided with a safely structured tapering regimen. In the setting of abuse or addiction, when it is necessary to discontinue opioids quickly because of safety, withdrawal can be managed either by the prescriber or by referring the patient to an addiction specialist. 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. The discontinuation of opioid therapy where continuation is not clinically indicated does not constitute patient abandonment.

Medical Records

Every prescriber who treats patients for pain must maintain accurate and complete medical records. The medical record should include the following:

- Copies of the signed consent and/or treatment agreement as appropriate for level of treatment;
- 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 treatment provided, including all medications prescribed or administered (including date, type, dose, and quantity.);
- SCRIPTS data;
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others;
- Results of ongoing monitoring of patient progress in terms of pain management and physical, functional and psychosocial improvement;
- Notes on evaluation by and consultations with specialists;
- 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. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers;
- Authorization for release of medical information to other treatment providers; and
- All prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record. The name, telephone number, and address of the patient's pharmacy should also be recorded in an accessible manner so as to be readily available for review.

Good records demonstrate that a medically necessary service was provided to the patient. Even if the outcome is less than optimal, thorough records protect both the prescriber and the patient.

B. TREATMENT OF ACUTE PAIN

Acute pain was defined historically simply in terms of duration. It is now viewed as a complex, unpleasant experience with emotional and cognitive, as well as sensory, features that occur in response to tissue trauma. In contrast to chronic pain, relatively high levels of pathology usually accompany acute pain. Acute pain resolves with healing of the underlying injury. Acute pain is usually nociceptive, but may be neuropathic. Common sources of acute pain include trauma, surgery, labor, medical and dental procedures and acute disease states.

Acute pain, by definition, does not last longer than six months and resolves when the underlying cause of pain has been treated or healed. An accurate assessment of acute pain should be performed when a patient presents with pain to the health care setting. A solid understanding of the patient and the etiology of the pain are essential for the development of an effective and appropriate short-term pain management plan.

Recommendations for Treatment of Acute Pain:

- Develop an office policy for opioid prescribing and have this clearly posted and available for patients;
- Perform a thorough history and physical at the onset;
- Utilize SCRIPTS data as part of every patient's initial evaluation prior to prescribing opiates. Failure to utilize SCRIPTS to assess risk of opiate/sedative prescribing may be considered misconduct by the responsible regulatory board, depending upon the clinical situation.
- Maintain accurate and complete medical records that include all of the components outlined above in the Chronic Pain section.
- Evaluate acute pain patients frequently for physical, functional and psychosocial improvement, with adjustment to treatment as needed. It is generally contraindicated to include refills on opioid prescriptions for acute pain;
- Educate your patients about pain and analgesia. Explain the underlying diagnosis causing the pain, the natural history of the condition, and how your patient can help the healing process;
- Exhaust non-opioid medications and collaborate with other professionals, including physical therapists and pain specialists, if possible. Consider nontraditional therapies such as acupuncture and massage therapy;
- Prescribe a complete pain management program when an opioid is used to treat acute pain: utilize NSAIDS, develop and recommend specific exercises, and utilize other modalities (e.g. heat, ice, massage, topical medications);
- Prescribe opioids intentionally. With the first opioid prescription, set patient responsibilities and the expectation that opioids will be discontinued when the pain problem has resolved or is not responding to what you are doing;
- Write the taper on the prescription (e.g., po every 6 hours for 3 days, po every 12 hours for 3 days, po every 24 hours for 3 days, stop);
- Do not prescribe long-acting or controlled-release opioids (e.g. long-acting oxycodone and oxymorphone, fentanyl patches, long-acting hydromorphone and morphine or methadone) for acute pain;
- Consider performing risk stratification, including urine drug monitoring, after accessing SCRIPTS at the onset of pain care;
- Clearly instruct patients to take opiates only as prescribed, not more frequently or in greater quantities. Educate your patients about the risks of taking opioid analgesics, including, but not limited to: overdose that can slow or stop their breathing and even lead to death; fracture from falls especially in patients over 60; drowsiness leading to injury, especially when driving or operating heavy or dangerous equipment; and tolerance and addiction. Educate your patients about acute pain – tell them it is likely that their acute pain will diminish and resolve,

and tell them that prolonged use of scheduled opioids may actually impair their ability to fully recover;

- Advise patients to avoid medications that are not part of their treatment plan because they may worsen the side effects and increase the risk of overdose from opiates;
- Prepare patients that it may be difficult to taper off opioids, particularly from higher dose regimens, even when they are eager to do so;
- Consider referrals and consultations with a pain specialist if the patient is not responding to your treatment plan. You may want to do this early in the course of treatment if the patient does not respond to standard first line medications and before you prescribe narcotics. Pain specialists may offer procedures or other interventions that will help your patient improve and avoid unnecessary opiate use; and
- Assure that patients are provided with easy to follow and graduated activity instructions that help them quickly improve their quality of life in physical, functional and social domains.

C. TREATMENT OF PAIN IN THE EMERGENCY DEPARTMENT

Emergency medical physicians practice in a unique clinical setting, whereby the urgency of the healthcare services available naturally render the practitioners prime targets for patients seeking prescriptions for opioids for non-medical reasons. In addition to the emergent nature of the patient encounters, these practitioners often must treat patients without the benefit of prior medical records, creating a higher probability of presentation with an incomplete or inaccurate medical history. These factors necessitate the identification of additional prescribing considerations:

- Emergency medical prescribers are reminded that patterns of prescription of opiate/sedative medications in quantities or frequencies excessive of what may be considered reasonable by prudent emergency physicians practicing in a similar circumstance may be considered misconduct by the responsible regulatory board;
- Emergency medical prescribers should maintain a high index of suspicion for potential diversion or abuse of their prescriptions, and should utilize SCRIPTS data and consult with a patient's primary opioid prescriber, as feasible, prior to prescribing opiate/sedative medications when there is a suspect clinical presentation or in the circumstance of chronic pain management. If a rare case should occur where such a prescription is indicated, only a quantity sufficient to prevent morbidity until the patient's primary provider can be seen should be provided;
- Emergency medical prescribers should not provide replacement prescriptions for controlled substances that were lost, destroyed or stolen;
- Emergency medical prescribers should not provide replacement doses of methadone for patient in a methadone treatment program;
- Long-acting or controlled-release opioids (such as OxyContin[®], fentanyl patches and methadone) should not be prescribed routinely by emergency department prescribers, and then only in a quantity sufficient to prevent morbidity until the patient's primary provider can be seen;

- Emergency department prescribers should utilize SCRIPTS data prior to prescribing opioids. Failure to utilize SCRIPTS to assess risk of opiate/sedative prescribing may be considered misconduct by the responsible regulatory board, depending upon the clinical situation as documented in the patient's medical record;
- All prescribers who manage patients with chronic pain should be encouraged to send patient agreements to local emergency departments for reference, and work to develop appropriate plans for the evaluation and management of their patients in the emergency department in conjunction with emergency department prescribers;
- Prescriptions for opioid pain medication from emergency department providers for acute injuries, such as fractured bones, should not exceed a five day supply in most cases; and
- When appropriate, emergency department patients should be screened for substance abuse prior to receiving a prescription for opioids for acute pain management.

III. INAPPROPRIATE TREATMENT OF PAIN

The inappropriate treatment of pain includes nontreatment, under treatment, overtreatment and the continued use of ineffective treatments. Inappropriate pain treatment may result from a prescriber's lack of knowledge about pain management. Fear of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating prescriber's responsibility. Accordingly, the appropriate regulatory board will consider a departure from standards of practice to be the inappropriate treatment of pain and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

While acknowledging that undertreatment of pain exists in certain instances, it must be understood that chronic pain often is intractable, that the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases, and that the existence of persistent and disabling pain does not in and of itself constitute evidence of undertreatment.

Circumstances that contribute to both the inadequate treatment of pain and the inappropriate prescribing of opioid may include: (1) prescriber's lack of knowledge as to prevailing best clinical practices; (2) inadequate research into the sources of and treatments for pain; (3) sometimes conflicting clinical guidelines for appropriate treatment of pain; (4) prescriber's concern that prescribing needed amounts of opioid analgesics will result in added scrutiny by regulatory authorities; (5) prescriber's misunderstanding of causes and manifestations of opioid dependence and addiction; (6) prescriber's fear of causing addiction or being deceived by a patient who seeks drugs for purpose of misuse; (7) prescriber's practice outside the bounds of professional conduct by prescribing opioid analgesics without a legitimate medical purpose; and (8) inadequate prescriber education about regulatory policies and processes. Inappropriate treatment also can result from a mistaken belief on the part of patients and their prescribers that complete eradication of pain is an attainable goal, and one that can be

achieved without disabling adverse effects. Additionally, treatment options may be limited based on availability and/or health plan policies on covered benefits or drug formularies.

IV. ACTIONS OUTSIDE THE SCOPE OF APPROPRIATE PAIN MANAGEMENT

The applicable regulatory boards will consider a departure from accepted best clinical practices for the management of pain, particularly chronic pain, to be improper, including, but not limited to the following:

- **Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine the risks associated with their use in a particular individual with pain:** There are significant risks associated with opioids; therefore, benefits must outweigh the risks.
- **Inadequate monitoring during the use of potentially abusable medications:** Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional behavioral problems. Some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.
- **Inadequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain should be a shared decision of the prescriber and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and that taking opioids with other substances or certain conditions (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.
- **Unjustified dose escalation without adequate attention to risks or alternative treatments:** Risks associated with opioids increase with escalating doses as well as in the presence of other comorbidities (i.e., mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants, such as benzodiazepines or alcohol.
- **Excessive reliance on opioids, particularly high dose opioids for chronic pain management:** Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic noncancerous pain only when safer and reasonable effective options have failed. The prescriber should maintain the lowest opioid dosage possible and continue only if clear and objective outcomes are being met.
- **Not making use of available tools for risk mitigations:** SCRIPTS should be utilized prior to prescribing opioids and for ongoing monitoring.

The appropriate regulatory board will judge the validity of the prescriber's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administered. 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.

The appropriate evaluation and management of a patient's pain, including the prescription of opiate medications, is the treating prescriber's responsibility. Prescribers should not fear disciplinary action from the respective regulatory board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met. In fact, the regulatory body will consider the failure to prescribe controlled substances responsibly to be a departure from the standards of practice and will investigate such allegations, utilizing current clinical practice guidelines and expert review in determining whether or not standard of care have been met.

Allegations of inappropriate pain management will be evaluated on a case by case basis. The regulatory board may not necessarily take disciplinary action against a prescriber for deviating from these guidelines when contemporaneous medical records document reasonable cause for deviation. The prescriber's conduct will be evaluated by the outcome of pain treatment, recognizing that some type of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient function and/or quality of life.

V. SPECIAL CONSIDERATIONS

Compliance with Controlled Substances Laws and Regulations

In order to dispense or administer controlled substances, the prescriber must be registered with the DEA, licensed by the state in which he or she practices, and in compliance with applicable federal and state regulations. Prescribers are referred to the *Physician's Manual of the U.S. Drug Enforcement Administration* for specific rules and regulations governing the use of controlled substances; relevant provisions of the South Carolina Dental Practice Act, the South Carolina Medical Practice Act, and the South Carolina Nurse Practice Act; relevant regulations promulgated by the regulatory authorities governing these professions; and advisory opinions issued by the regulatory authorities governing these professions.

Naloxone

Patients prescribed more than 80 mg MED are at an increased risk of death from respiratory depression. These patients require closer monitoring and other respiratory depressants, such as alcohol and benzodiazepines, should be avoided. The Board recognizes that a prescription of Naloxone may be appropriate in certain situations involving patients who are prescribed high dose opioids or are more vulnerable to the risk of opioid overdose due to co-morbidities or other factors. Whether Naloxone is medically necessary for a particular patient is within the discretion of the patient's primary opioid prescriber.

Pregnancy

When treating females of childbearing age, prescribers must consider pregnancy or the risk of pregnancy and provide appropriate counseling before prescribing opioids. Female patients of childbearing age should be counseled regarding the risks of opioid use during pregnancy, the effect of chronic opioid therapy on the neonate (neonatal abstinence

syndrome) and the consideration for a high risk obstetrical consult prior to attempting conception.

Telemedicine

Chronic pain shall not be treated by the use of controlled substances through telemedicine.