# North Carolina Medical Board Policy Committee Meeting Wednesday, January 16, 2013

Committee Members: Dr. Greene, Chairman; Judge Lewis; Dr. Hill and Dr. Udekwu

### 1. Old Business:

a. Position Statement Review - Request from Board

Issue: NCGS Chapter 90; Article 27, entitled "Referral Fees and Payment for Certain Solicitations Prohibited" states, in part, "A health care provider shall not financially compensate in any manner a person, firm, or corporation for recommending or securing the health care provider's employment by a patient". MD pays a fee to Groupon for pre-paid vouchers issued by Groupon to Groupon subscribers who purchase the vouchers. Groupon "facilitates" the purchase of MD's pre-paid vouchers which offer promotional discounts for MD's services. A patient purchasing a voucher from Groupon pays for the price of MD's discounted service plus additional promotional, advertising, administrative, and "offer facilitation" fees to Groupon.

b. Position Statement Review: End-of-Life Responsibilities and Palliative Care

Issue: At the November 2012 meeting the Committee discussed the distinction between palliative care and hospice. The Board also reviewed the Position Statement. There was also discussion about the need for relief of symptoms other than pain associated with palliative care.

## c. Social Media

Issue: At the November 2012 meeting the Committee discussed the potential need for guidance regarding licensee use of social media and other organizations that have commented on the benefits and pitfalls of this phenomenon.

### New Business:

a. Position Statement Review

Issue: In November 2009, the Board approved the Policy Committee's recommendation to review Position Statements at least once every four years. A review schedule has been formulated for the Committee's consideration.

Position Statements for review:

- i. Drug Overdose Prevention
- ii. Policy for the Use of Controlled Substances for the Treatment of Pain

North Carolina Medical Board Policy Committee Meeting Wednesday, January 16, 2013

#### 1. Old Business

a. Position Statement Review - Request from Board

Issue: NCGS Chapter 90; Article 27, entitled "Referral Fees and Payment for Certain Solicitations Prohibited" states, in part, "A health care provider shall not financially compensate in any manner a person, firm, or corporation for recommending or securing the health care provider's employment by a patient". MD pays a fee to Groupon for pre-paid vouchers issued by Groupon to Groupon subscribers who purchase the vouchers. Groupon "facilitates" the purchase of MD's pre-paid vouchers which offer promotional discounts for MD's services. A patient purchasing a voucher from Groupon pays for the price of MD's discounted service plus additional promotional, advertising, administrative, and "offer facilitation" fees to Groupon.

Board Action: Request Policy Committee to amend Referral fees and fee splitting position statement as it relates to social networking offers.

07/2012 Committee discussion: The Committee decided to delegate revisions to the position statement to Mr. Brosius in consultation with Mr. Jimison. Proposed changes will be presented to the Committee at the September meeting.

07/2012 Committee Recommendation: Tabled until September.

07/2012 Board Action: Accept committee recommendation.

09/2012 Committee Discussion: The Committee discussed the advertising voucher business model. Questions were raised about the requirement that the licensee be responsible for the purchase price in the event the advertising company will not provide a refund.

09/2012 Committee Recommendation: Table discussion until November. Mr. Brosius will research the advertising voucher reimbursement process and report back to the Committee.

09/2012 Board Action: Accept Committee Recommendation

11/2012 Committee Discussion: The Committee received a brief update from Mr. Brosius and discussed the implications of the section addressing advertising vouchers. Mr. Brosius indicated that he would report back with additional information at the January meeting.

11/2012 Committee Recommendation: Table until January meeting.

11/2012 Board Action: Accept Committee Recommendation.

#### **CURRENT POSITION STATEMENT:**

### Referral fees and fee splitting

Payment by or to a physician solely for the referral of a patient is unethical. A physician may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company, or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source. In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the physician on matters of referral. All referrals and prescriptions must be based on the skill and quality of the physician to whom the patient has been referred or the quality and efficacy of the drug or product prescribed.

It is unethical for physicians to offer financial incentives or other valuable considerations to patients in exchange for recruitment of other patients. Such incentives can distort the information that patients provide to potential patients, thus distorting the expectations of potential patients and compromising the trust that is the foundation of the patient-physician relationship.

Furthermore, referral fees are prohibited by state law pursuant to N.C. Gen. Stat. Section 90-401. Violation of this law may result in disciplinary action by the Board.

Except in instances permitted by law (NC Gen Stat §55B-14(c)), it is the position of the Board that a physician cannot share revenue on a percentage basis with a non-physician. To do so is fee splitting and is grounds for disciplinary action.

(Adopted November 1993) (Amended May 1996, July 2006)

### PROPOSED REVISIONS

Referral fees and fee splitting

Created: Nov 1, 1993

Modified: May 1996, July 2006

Payment by or to a physician licensee solely for the referral of a patient is unethical. A physician licensee may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company, or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source. In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the physician licensee on matters of referral. All referrals and prescriptions must be based on the skill and quality of the physician to whom the patient has been referred or the quality and efficacy of the drug or product prescribed.

It is unethical for <u>physicians</u> <u>licensees</u> to offer financial incentives or other valuable considerations to patients in exchange for recruitment of other patients. Such incentives can distort the information that patients provide to potential patients, thus distorting the expectations of potential patients and compromising the trust that is the foundation of the patient- <u>physician licensee</u> relationship.

Furthermore, referral fees are prohibited by state law pursuant to N.C. Gen. Stat. Section 90-401. Violation of this law may result in disciplinary action by the Board.

Except in instances permitted by law (N.C. Gen. Stat. § 55B-14(c)), it is the position of the Board that a physician licensee cannot share revenue on a percentage basis with a non-physician licensee. To do so is fee splitting and is grounds for disciplinary action.

## **Voucher Advertising**

It is the Board's position that, so long as certain conditions are followed, advertising involving the utilization of vouchers (e.g. Groupon) does not constitute unethical fee-splitting or a prohibited solicitation or referral fee under North Carolina law. Those conditions include: (1) ensuring that the negotiated fee between the voucher advertising company and the licensee represents reasonable compensation for the cost of advertising; and (2) incorporating the following terms and conditions in a clear and conspicuous manner in all advertisements:

- (a) A description of the discounted price in comparison to the actual cost of services;
- (b) A disclosure that all patients may not be eligible for the advertised medical service and that decisions about medical care should not be made in haste. Determinations regarding the medical indications for individual patients will be made on an individual basis by applying accepted and prevailing standards of medical practice; and
- (c) A disclosure to prospective patients that, if it is later decided that the patient is not a candidate for the previously purchased medical service, the patient's purchase price

will be refunded in its entirety. If the patient does not claim the service, then the patient's purchase price must still be refunded in its entirety. In the event that the voucher advertising company does not refund the purchase price in its entirety, it will be the sole obligation of the licensee to refund the entire purchase price.

## 1. Old Business:

b. Position Statement Review - End-of-Life Responsibilities and Palliative Care

11/2012 Committee Discussion: The Committee discussed the distinction between palliative care and hospice. The Board also reviewed the Position Statement. There was also discussion about the need for relief of symptoms other than pain associated with palliative care.

11/2012 Committee Recommendation: Accept changes to Position Statement.

11/2012 Board Action: Table until January 2013 meeting. Mr. Brosius to edit the first sentence of the Palliative Care section.

**CURRENT POSITION STATEMENT:** 

# **End-of-life responsibilities and palliative care**

## **Assuring Patients**

Death is part of life. When appropriate processes have determined that the use of life prolonging measurers or invasive interventions will only prolong the dying process, it is incumbent on physicians to accept death "not as a failure, but the natural culmination of our lives."\*

It is the position of the North Carolina Medical Board that patients and their families should be assured of competent, comprehensive palliative care at the end of their lives. Physicians should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

### **Palliative Care**

Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification an impeccable assessment and treatment of pain and other physical, psychosocial and spiritual problems. Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- intends neither to hasten nor postpone death;
- integrates the psychological and spiritual aspects of patient care;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patient's illness and in their own bereavement;
- uses a team approach to address the needs of patients and their families, including bereavement counseling, if indicated;

- will enhance quality of life, and may also positively influence the course of illness;
- [may be] applicable early in the course of illness, in conjunction with other therapies that are
  intended to prolong life, such as chemotherapy or radiation therapy, and includes those
  investigations needed to better understand and manage distressing clinical complications.\*\*

## **Opioid Use**

The Board will assume opioid use in such patients is appropriate if the responsible physician is familiar with and abides by acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan. (See the Board's position statement on the Policy for the Use of Controlled Substances for the Treatment of Pain for an outline of what the Board expects of physicians in the management of pain.) Because the Board is aware of the inherent risks associated with effective pain relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

\*Steven A. Schroeder, MD, President, Robert Wood Johnson Foundation.

\*\* Taken from the World Health Organization definition of Palliative Care (2002) www.who.int/cancer/palliative/definition/en

(Adopted October 1999) (Amended May 2007; March 2008)

### PROPOSED REVISIONS

# End-of-life responsibilities and palliative care

### **Assuring Patients**

Death is part of life. When appropriate processes have determined that the use of life prolonging measurers or invasive interventions will only prolong the dying process, it is incumbent on physicians licensees to accept death "not as a failure, but the natural culmination of our lives."\*

It is the position of the North Carolina Medical Board that patients and their families should be assured of competent, comprehensive palliative care at the end of their lives. Physicians <u>Licensees</u> should be knowledgeable regarding effective and compassionate pain relief, and patients and their families should be assured such relief will be provided.

#### **Palliative Care**

Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life threatening illness, through the prevention and relief of suffering by means of early identification an impeccable assessment and treatment of pain and other physical, psychosocial and spiritual problems. Palliative care is specialized medical care for people with serious illnesses. It is focused on providing patients with relief from the symptoms, pain, and stress of a serious illness—whatever the diagnosis. The goal is to improve quality of life for both the patient and the family.

Palliative care is provided by healthcare providers who work together with a patient's other caregivers to provide an extra layer of support. It is appropriate at any age and at any stage in a serious illness and can be provided along with curative treatment.\*\*

### Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- intends neither to hasten nor postpone death;
- integrates the psychological and spiritual aspects of patient care;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patient's illness and in their own bereavement;
- uses a team approach to address the needs of patients and their families, including bereavement counseling, if indicated;
- will enhance quality of life, and may also positively influence the course of illness;

• [may be] applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.\*\*\*

## **Opioid Use**

The Board will assume opioid use in such patients is appropriate if the responsible <a href="https://physician.licensee">physician.licensee</a> is familiar with and abides by acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan. (See the Board's position statement on the Policy for the Use of Controlled Substances for the Treatment of Pain for an outline of what the Board expects of <a href="https://physicians.licensees">physicians.licensees</a> in the management of pain.) Because the Board is aware of the inherent risks associated with effective <a href="pain.symptom">pain.symptom</a> relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.

\*Steven A. Schroeder, MD, President, Robert Wood Johnson Foundation.

\*\* Taken from the Center to Advance Palliative Care (2012) http://www.capc.org/building-a-hospital-based-palliative-care-program/case/definingpc

\*\*\* Taken from the World Health Organization definition of Palliative Care (2002) www.who.int/cancer/palliative/definition/en

(Adopted October 1999) (Amended May 2007; March 2008)

## 1. Old Business:

c. Social Media

11/2012 Committee Discussion: The Committee discussed the potential need for guidance regarding licensee use of social media and other organizations that have commented on the benefits and pitfalls of this phenomenon.

11/2012 Committee Recommendation: The Committee recommended drafting a Position Statement addressing this issue based on Dr. Kirby's Forum article.

11/2012 Board Action: Accept the Committee Recommendation.

## 2. New Business:

# a. Position Statement Review

1/2010 Committee Recommendation: (Loomis/Camnitz) Adopt a 4 year review schedule as presented. All reviews will be offered to the full Board for input. Additionally all reviews will be documented and will be reported to the full Board, even if no changes are made.

1/2010 Board Action: Adopt the recommendation of the Policy Committee.

POSITION STATEMENT	ADOPTED	SCHEDULED FOR REVIEW	LAST REVISED/ REVIEWED/ ADOPTED	REVISED/ REVIEWED	REVISED/ REVIEWED	REVISED/ REVIEWED	REVISED/ REVIEWED
End-of-Life Responsibilities and Palliative Care	Oct-99	Jan-13	Mar-08	May-07			
Drug Overdose Prevention	Sep-08	Jan-13	Sep-08	- 7			
Policy for the Use of Controlled Substances for the Treatment of Pain Medical Record	Sep-96	Jan-13	Sep-08	Jul-05			
Documentation Retention of Medical	May-94		May-09	May-96			
Records	May-98		May-09				
Capital Punishment	Jan-07		Jul-09				
Departures from or Closings of Medical Professional Obligations	Jan-00		Jul-09	Aug-03			
pertaining to incompetence, impairment, and unethical conduct of healthcare providers	Nov-98		Mar-10	Nov-98			
Unethical Agreements in Complaint Settlements	Nov-93		Mar-10	May-96			
What Are the Position Statements of the Board and To Whom Do They Apply?	Nov-99		May-10	Nov-99			
Telemedicine	May-10		May-10				
Contact With Patients Before Prescribing	Nov-99		Jul-10	Feb-01			
Guidelines for Avoiding Misunderstandings During Physical Examinations	May-91		Jul-10	Oct-02	Feb-01	Jan-01	May-96
Access to Physician Records	Nov-93		Sep-10	Aug-03	Mar-02	Sep-97	May-96
Medical Supervisor- Trainee Relationship	Apr-04		Nov-10	Apr-04			
The Treatment of Obesity	Oct-87		Nov-10	Jan-05	Mar-96		
Advertising and Publicity	Nov-99		Nov-10	Sep-05	Mar-01		
Medical, Nursing, Pharmacy Boards: Joint Statement on Pain Management in End-of-Life Care	Oct-99		Jan-11	Oct-99			
HIV/HBV Infected Health Care Workers	Nov-92		Jan-11	Jan-05	May-96		
Writing of Prescriptions	May-91		Mar-11	Mar-05	Jul-02	Mar-02	May-96

Laser Surgery	Jul-99	Mar-11	Jul-05	Aug-02	Mar-02	Jan-00
Office-Based Procedures	Sep-00	May-11	Jan-03			
Sale of Goods From						
Physician Offices	Mar-01	May-11	Mar-06			
Competence and Reentry						
to the Active Practice of						
Medicine	Jul-06	Jul-11	Jul-06			
Prescribing Legend or						
Controlled Substances for						
Other Than Valid Medical						
or Therapeutic Purposes, with Particular Reference						
to Substances or						
Preparations with Anabolic						
Properties	May-98	Sept-11	Nov-05	Jan-01	Jul-98	
Referral Fees and Fee	may 00	σορί 11	1107 00	our or	oui co	
Splitting	Nov-93	Jan-12	Jul-06	May-96		
Self- Treatment and						
Treatment of Family						
Members and Others With						
Whom Significant						
Emotional Relationships			_			
Exist	May-91	Mar-12	Sep-05	Mar-02	May-00	May 96
Availability of Physicians to						
Their Patients	Jul-93	May-12	Nov-11	Jul-06	Oct-03	Jan-01
Sexual Exploitation of						
Patients	May-91	May-12	Sep-06	Jan-01	Apr-96	
Care of the Patient						
Undergoing Surgery or						
Other Invasive Procedure	Sep-91	Jul-12	Sep-06	Mar-01		
The Physician-Patient	11.05	1.1.40	C-= 0C	A 02	M== 00	lan 00
Relationship	Jul-95	Jul-12	Sep-06	Aug-03	Mar-02	Jan-00
The Retired Physician	Jan-97	Jul-12	Sep-06			
Physician Supervision of						
Other Licensed Health	1.1.07	04 = 40	11.07			
Care Practitioners	Jul-07	Sep-12	Jul-07			
Medical Testimony	Mar-08	Sep-12	Mar-08			
Advance Directives and						
Patient Autonomy	Jul-93	Nov-12	Mar-08	May-96		

## 2. New Business:

- a. Position Statement Review
  - i. Drug Overdose Prevention

## **CURRENT POSITION STATEMENT:**

# **Drug overdose prevention**

The Board is concerned about the three-fold rise in overdose deaths over the past decade in the State of North Carolina as a result of both prescription and non-prescription drugs. The Board has reviewed, and is encouraged by, the efforts of Project Lazarus, a pilot program in Wilkes County that is attempting to reduce the number of drug overdoses by making the drug naloxone\* and an educational program on its use available to those persons at risk of suffering a drug overdose.

The prevention of drug overdoses is consistent with the Board's statutory mission to protect the people of North Carolina. The Board therefore encourages its licensees to cooperate with programs like Project Lazarus in their efforts to make naloxone available to persons at risk of suffering opioid drug overdose.

\* Naloxone is the antidote used in emergency medical settings to reverse respiratory depression due to opioid toxicity.

(Adopted September 2008)

### 2. New Business:

- a. Position Statement Review
  - ii. Policy for the Use of Controlled Substances for the Treatment of Pain

## **CURRENT POSITION STATEMENT:**

# Policy for the use of controlled substances for the treatment of pain

- Appropriate treatment of chronic pain may include both pharmacologic and non-pharmacologic modalities. The Board realizes that controlled substances, including opioid analgesics, may be an essential part of the treatment regimen.
- All prescribing of controlled substances must comply with applicable state and federal law.
- Guidelines for treatment include: (a) complete patient evaluation, (b) establishment of a treatment plan (contract), (c) informed consent, (d) periodic review, and (e) consultation with specialists in various treatment modalities as appropriate.
- Deviation from these guidelines will be considered on an individual basis for appropriateness.

#### **Section I: Preamble**

The North Carolina Medical Board recognizes that principles of quality medical practice dictate that the people of the State of North Carolina 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. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, 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 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. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice 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.

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. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The North Carolina Medical Board is obligated under the laws of the State of North Carolina to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose 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.

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. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on 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 physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

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 an individual basis. The Board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types 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 functioning and/or quality of life.

### **Section II: Guidelines**

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

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.

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. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

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 if the patient is without medical decision-making capacity. 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, including
- urine/serum medication levels screening when requested;

- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement); and
- the North Carolina Controlled Substance Reporting Service can be accessed and its results used to make treatment decisions.

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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. Reviewing the North Carolina Controlled Substance Reporting Service should be considered if inappropriate medication usage is suspected and intermittently on all patients.

Consultation —The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records —The physician should keep accurate and complete records to include

- the medical history and physical examination,
- diagnostic, therapeutic and laboratory results,
- evaluations and consultations.
- treatment objectives.
- discussion of risks and benefits,
- informed consent,
- treatments.
- medications (including date, type, dosage and quantity prescribed),
- instructions and agreements and
- periodic reviews including potential review of the North Carolina Controlled Substance Reporting Service.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations —To prescribe, dispense or administer controlled substances, the physician must be licensed in the state 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 of North Carolina for specific rules governing controlled substances as well as applicable state regulations.

## **Section III: Definitions**

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

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

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.

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.

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

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.

Pseudoaddiction —The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

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.

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.

(Adopted September 1996 as "Management of Chronic Non-Malignant Pain.") (Redone July 2005 based on the Federation of State Medical Board's "Model Policy for the Use of Controlled Substances for the Treatment of Pain," as amended by the FSMB in 2004.) (Amended September 2008)