

**POLICY FOR THE USE OF OPIATES**  
**FOR THE TREATMENT OF PAIN**

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# **POLICY FOR THE USE OF OPIATES**

## **FOR THE TREATMENT OF PAIN**

### **Introduction**

Since the 2004 publication of the North Carolina Medical Board's Policy for the Use of Controlled Substances for the Treatment of Pain, a considerable body of research and experience has made it evident that the Board's 2004 Policy required revision. The updated policy presented here takes into consideration recent evidence that risk associated with opiates has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade opioid sales have increased in parallel with an increase in the morbidity and mortality associated with these drugs. At the same time approximately one in four patients seen in primary care settings suffers from pain that interferes with the activities of daily living (1).

The challenges faced by North Carolina Medical Board licensees who care for patients taking opiates for pain are significant. The North Carolina Medical Board is committed to helping its licensees meet those challenges successfully. By doing so the Board and its licensees will help promote public health and the individual well-being of the citizens of our state. For the sake of simplicity, in the document that follows the word "physician" is used to represent all North Carolina Medical Board Licensees who use opiates for the treatment of pain.

The majority of this updated policy applies to the treatment of chronic pain and the use of opioid analgesics. Guidance for assessing and managing acute pain in primary care is also provided. The Board recognizes that the use of opiates in end of life and palliative care may present unique benefits and risks. Concepts and guidelines presented in this policy will be useful and generally apply to the use of opiates for end of life and palliative care. However, the Board's Position Statements on end of life and palliative care take precedence over information presented here.

The updated policy contains three sections. Section 1 begins with a preamble of information and a statement of the Board's goals. The preamble is followed by conceptual overviews discussing responsibility for appropriate pain management and opiate prescribing, and prevention of opiate diversion and abuse. Section 2 provides guidelines to physicians that are linked to concepts presented in Section 1. The guidelines provide information that physicians can use to help them evaluate

and manage pain appropriately and prescribe opiates responsibly. The guidelines provide the Board a framework to assess physicians' treatment of pain, and a means to determine whether opiate medications are used in a manner that is medically appropriate and in compliance with North Carolina State and federal laws and regulations. Section 3 contains a glossary of terms.

In developing this updated policy the Board has relied heavily on the Federation of State Medical Board's 2013 Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain. The Board also acknowledges the work of, and extends its thanks to the Indiana Medical Licensing Board, and the efforts of the State of Indiana's Attorney General, the Indiana State Department of Health's Chief Medical Officer, and the Indiana Prescription Drug Abuse Task Force. As the North Carolina Medical Board has developed this updated policy, it has borrowed freely and taken material verbatim, with permission, from "*First Do No Harm, The Indiana Healthcare Providers Guide to the Safe, Effective Management of Chronic Non-Terminal Pain*."

The Board encourages all physicians to review the Federation of State Medical Board's 2013 Model Policy at [http://www.fsmb.org/pdf/pain\\_policy\\_july2013.pdf](http://www.fsmb.org/pdf/pain_policy_july2013.pdf), and the State of Indiana's "*First Do No Harm*" document at [http://www.in.gov/bitterpill/docs/First\\_Do\\_No\\_Harm\\_V\\_1\\_0.pdf](http://www.in.gov/bitterpill/docs/First_Do_No_Harm_V_1_0.pdf) for additional helpful information.

## **SECTION I - Preamble**

The North Carolina Medical Board is obligated under the laws of the State of North Carolina to protect public health and safety. This obligation is reflected in the Board's mission statement to "...regulate the practice of medicine and surgery for the benefit and protection of the people of North Carolina." The Board believes that a fundamental component of good medical practice includes the appropriate evaluation and management of pain. Responsibly prescribed opiate medications may help North Carolina physicians treat their patients' pain safely and effectively, and improve their quality of life. The Board is aware that the undertreatment of pain is recognized as a serious public health problem that compromises patients' function and quality of life (2, 3).

However, it must be understood that chronic pain is often intractable, and that in most cases the current state of medical knowledge and medical therapies, including the use of opioid analgesics, does not provide for the complete elimination of chronic pain (4, 5, 6). Furthermore, chronic pain and its attendant opioid use have become an enormous burden to patients, medical institutions and our society. There are over 50 million estimated chronic pain patients in the United States. Medical expense data places the cost of chronic pain, including direct and indirect costs, at well over \$100 billion per year. As many as 15-20% of primary care visits result in a prescription being given for opioids. However, despite the increased use of pain interventions, including opioids, many patients are dissatisfied and report inadequate pain control. The aggressive use of pain intervention resources has not been associated with commensurate clinical benefit. Robust increases in pain expenditures from 1997 to 2005 did not translate into improvements in self-assessed health status and pain (7).

Persistent pain, like all chronic illnesses, is managed optimally with a biopsychosocial model and not with the opio-centric practices of the past. Data from a large population-based study suggests that those on chronic high-dose opioids may fare worse over time than those on lower doses or none at all. Quality of life measures for patients in the study using high-dose opioids were lower than those on a low dose regimen, and patients were four times less likely to “recover” significantly during the five years of the study (8).

Between 1997 and 2010, opioid use increased dramatically. However, increased use of opioids has not been accompanied by adequate evidence to support the effectiveness and safety of long-term opioid therapy, and has been complicated by opioid-related overdoses, substance abuse, and prescription costs to society that have escalated to unacceptable levels. Leonard J. Paulozzi, a medical epidemiologist at the Center for Disease Control and Prevention (CDC), during congressional testimony reported that “the number of deaths in the narcotics category that involved prescription opioid analgesics increased from 2,900 in 1999 to at least 7,500 in 2004, an increase of 160% in just five years.” Accidental drug overdose is currently the leading cause of injury-related death in the United States for people between the ages of 35-54 (9). In addition to nearly 16,000 prescription opioid-related deaths in 2010, the rise in opioid use has fueled a substantial increase in

substance use disorders. Approximately nine people are admitted for prescription opioid abuse treatment for every one opioid prescription-related death (10).

An analysis on 2006 data related to the cost of nonmedical use of prescription opioids placed the total at \$53.4 billion (11). The CDC's estimate on those same costs in 2009 was over \$70 billion. Lost productivity was the largest single contributing factor, contributing to 79% of this cost. Clearly, suboptimal risk stratification and monitoring of patients prior to opioid therapy, combined with current practices of prescription writing, are creating enormous emotional and financial burdens on a national level.

In North Carolina, six-hundred and seventy three North Carolinians were reported to have died in 2012 from unintentional poisoning by opioids other than opium and heroin (12). Extrapolating data from the 2011 and 2012 National Survey on Drug Use and Health suggests that as many as 70% of these opiate related deaths are associated with a prescription medication shared by or stolen from the individual for whom the drug was prescribed.

In presenting this Policy for the Use of Opiates for the Treatment of Pain, it is the North Carolina Medical Board's goal to provide guidelines that may help to improve the quality of life for those North Carolinians who suffer from pain, and reduce the morbidity and mortality associated with the inappropriate use of opiates and other controlled substances prescribed to treat pain.

***Responsibility for Appropriate Pain Management and Opiate Prescribing:***

The evaluation and management of pain is integral to the practice of medicine. All physicians should be knowledgeable about the process of evaluating their patients' pain and function, and be familiar with methods of managing pain safely and effectively. The process of evaluation and management of a patient's pain should be based on an established physician-patient relationship. Patients with chronic pain should be assessed for the potential for substance abuse and coexistent mental health conditions. Objective and verifiable goals that incorporate physical, functional and social domains should be prominent components of a patient's treatment plan. Non-pharmacologic treatment interventions and use of non-opiate pain medications should be explored before beginning opioid medications. When controlled substances are to be used to treat chronic pain, their use should be accompanied by informed consent and treatment agreements. If opiate

medications are part of a treatment plan, they should be prescribed or administered in response to an identified medical condition that qualifies for treatment with a controlled substance. Physicians should be aware that there is very little data to support the use of long term opioid therapy for common causes of chronic pain such as fibromyalgia, low back pain, pelvic pain, functional bowel disorders and chronic headache. Physicians prescribing controlled substances should understand and comply with applicable federal and North Carolina State requirements. Follow up monitoring of a patient's response to treatment should include the patient's progress in achieving objective and verifiable goals, and should insure that the patient is using prescribed medications safely. Treatment plans and prescribed medications should be adjusted as needed, and referral to consultants made when necessary. Opioids should be tapered or discontinued when a patient's pain is poorly controlled on appropriate doses of medication or if there is no physical, functional, and psychosocial improvement with opioid treatment. The medical record should provide documentation of all relevant aspects of the physician's evaluation and management, including diagnoses and treatment plans, periodic assessment of the patient's progress toward identified goals, medications prescribed and results of medication monitoring, evidence of compliance with treatment agreements, and pertinent results of laboratory, radiographic and ancillary services, including consultations and referrals.

***Preventing Opioid Diversion and Abuse:***

The Board recognizes that patients and other individuals who inappropriately use opiates place their own health in jeopardy and create a public health problem (13). Physicians who fail to prescribe opiates responsibly may contribute to patients' and other individuals' drug misuse and diversion (14, 15, 16). The Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opiates as well as other controlled substances (17, 18, 19, 20, 21, 22, 23, 24).

The appropriate evaluation and management of a patient's pain, including the prescribing of opiate medications is the treating physician's responsibility. Physicians who prescribe, order, dispense, or administer controlled substances using evidence based or current best clinical practices should not fear disciplinary action from the Board. Conversely, the Board 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 standards of care have been met.

Allegations of inappropriate pain management, including the failure to prescribe controlled substances responsibly, will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the North Carolina Controlled Substance Reporting System (NCCSRS). The Board will not take disciplinary action against a physician for deviating from this Policy when the physician can establish a reasonable cause for the deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation. Goals of treatment are the effective control of the patient's pain using appropriate doses of medication, achieving improved physical, functional, and psychosocial activities, and mitigating risk of misuse, abuse, diversion, and overdose (25, 26, 27).

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

## **SECTION II – *Guideline*<sup>28</sup>**

### **Overview:**

The guidelines in the North Carolina Medical Board's Policy on the Use of Opiates for the Treatment of Pain are meant to help physicians evaluate and manage pain appropriately, prescribe opiates responsibly, and prevent opioid diversion and abuse. Incorporating the guidelines into best practices behavior will help physicians mitigate some of the burdens that pain and its attendant opiate use place on patients, physicians, medical institutions, and society. The Board recommends the following as best practices behavior when using opiates to treat pain.

### ***Patient Evaluation and Risk Stratification***

The physician should personally participate in the process of every patient's evaluation. The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain demands a more detailed evaluation than an assessment of acute pain. Assessment of a patient's pain should include the nature and intensity of the pain, past and current treatments for

the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical, functional and psychosocial activities (29).

For every patient with pain, the initial work-up should include a systems review and relevant physical examination, and laboratory investigations as indicated (30, 31, 32, 33). Such investigations help the physician address the nature and intensity of the pain, and its impact on the patient's physical, functional and psychosocial activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation. For example, does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing (34)? When applicable, the patient's evaluation should include information from family members and/or significant others (35, 36, 37, 38).

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse should be part of the initial evaluation (39, 40, 41, 42, 43, 44). These assessments, should ideally be completed prior to a decision to prescribe opioid analgesics, and should inquire into any history of physical, emotional or sexual abuse, which are risk factors for substance misuse (45, 46, 47, 48). Use of a validated screening tool, such as the Screener and Opioid Assessment for Patients with Pain (SOAPP-R; 49) or the Opioid Risk Tool (ORT; 50) can save time in collecting and evaluating information and determining the patient's level of risk.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy and are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse (51, 52, 53). Whenever possible treatment of a patient who has a history of substance use disorder should involve consultation with an addiction specialist before opioid therapy is initiated and include follow-up as needed. Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program (54), or alternatives such as co-management with an addiction professional are established. Physicians who treat patients with chronic pain are strongly encouraged to be knowledgeable



about addiction, including recognizing behaviors that indicate addiction, and how and when to refer patients for addiction evaluation and treatment.

All patients should be screened for depression and other mental health disorders as part of risk evaluation. There is a clear association between mental illness and opioid related morbidity and mortality. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, addiction, and overdose (55).

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers. Patients occasionally provide fraudulent records. If there is reason to question the truthfulness of a patient's report, records should be requested directly from the patients other providers (56, 57).

Information from the North Carolina Controlled Substance Reporting System (NCCSRS) should be part of every patient's initial evaluation and subsequent monitoring program. Physicians should register with the NCCSRS and become familiar with analyzing and using NCCSRS data. Information from the NCCSRS should be used to help confirm each patient's compliance with treatment plans and opiate medication agreements. Relevant information from the NCCSRS should become part of the patient's medical record.

Obtaining a toxicology screen, such as a urine drug screen, is a useful tool in the setting of risk assessment prior to prescribing opioids. It may reveal the use of controlled medications such as opioids or benzodiazepines other than those prescribed or may reveal the use of other illicit drugs.

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses - evaluation and risk stratification assume even greater importance (58, 59, 60). As with all patients the physician's decision to prescribe opioid analgesics should reflect the totality of the information collected, the physician's own knowledge and comfort level in prescribing and the resources for patient support that are available in the community (61, 62, 63).

### ***Development of a Treatment Plan and Goals:***

In chronic pain the goals of treatment include reasonably 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 (64, 65). According to the International Association of the Study of Pain, activity goals should be set in three separate domains. The physical domain is the exercise program the patient follows. The functional domain involves tasks of everyday living. The social domain relates to pleasurable social activities (66). Effective means of achieving treatment goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

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 medications, non-steroidal anti-inflammatory drugs, and acetaminophen. Other treatment modalities including minor interventions such as anesthetic and steroid joint injections, cutaneous stimulators, topical anesthetics, and local therapies employing heat, massage, and manipulations should be considered before using opiates.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly. Clear-cut, individualized goals for pain relief and improved physical, functional and psychosocial activity should be set to help guide the choice and response to treatment (67). The treatment plan should contain information supporting the selection of pharmacologic and nonpharmacologic therapies. The plan should specify the objectives that will be used to evaluate the control of pain and achievement of specific physical, functional and psychosocial activity goals (68, 69, 70, 71). The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered (72, 73, 74, 75).

***Informed Consent and Treatment Agreement:***

The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity (76, 77). If opioids are

prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications (78, 79).

When treating chronic pain, use of a written informed consent, and a treatment agreement are recommended (80, 81, 82, 83, 84). They may be combined into one document for convenience.

*Informed consent* documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) 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 diseases 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 as to the benefit of long-term opioid therapy.
- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- 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 physician and patient in the management of chronic pain (85, 86, 87) 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 goals of treatment, in terms of pain management, restoration of activities, and safety.
- The patient's responsibility for using medication safely (e.g., 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 prescribed opioids from only one physician or practice.

- The patient's agreement to periodic drug testing of blood, urine, hair, saliva, or other body material.
- The physician's responsibility to be available or to have a covering physician be available to care for unforeseen problems and to prescribe scheduled refills.

***Initiating an Opioid Trial:***

Generally, safer alternative treatments including non-pharmacologic and minor interventions and first line pharmaco-therapy with over the counter medications, non-steroidal anti-inflammatory drugs, and acetaminophen 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 or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for benefit and harm in terms of the effects of opioids on the patient's level of pain, and on the patient's physical, functional and psychosocial activities. Attention will be focused on adverse events and risks to safety (88). Patients at risk of an opiate overdose should be identified. The Board expects physicians who prescribe opiates to help insure that naloxone is readily available to patients who are identified as being at risk of an opiate overdose. Readers are referred to the Board's Position Statement, "Drug overdose prevention."

When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrated to affect while monitoring for complications. 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 (89).

***Ongoing Monitoring and Adapting the Treatment Plan:***

The physician 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 (90, 91, 92). When possible, collateral information about the patient's response to opioid therapy including the medications' effects 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 physician should regularly review North Carolina Controlled Substance Reporting System data. The patient should be seen more frequently while the treatment plan is being initiated and when the opioid dose is being adjusted (93 - 100). As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently.

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the “5As” of chronic pain management. These include a determination of whether the patient has had a reduction in pain (Analgesia), improved physical, functional and psychosocial Activity, the presence of Adverse effects, evidence of Aberrant substance-related behaviors, and a change in Affect (101, 102). Validated brief assessment tools that measure pain and physical, functional and psychosocial activities, such as the three- question “Pain, Enjoyment and General Activity” (PEG) scale (103) may be helpful and more time efficient in general medical settings.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician’s evaluation of the patient’s progress toward treatment goals and assessment of substantial risks or adverse events (104, 105, 106, 107). A satisfactory response to treatment would be indicated by a reduced level of pain, and improved physical, functional and psychosocial activities (108, 109). Information from family members or other caregivers should be considered in evaluating the patient’s response to treatment (110, 111, 112). Use of measurement tools to assess the patient’s level of pain, activity, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes (113, 114).

Risks associated with opioids increase with escalating doses. The physician should avoid opiate dose escalation without adequate attention to risks or alternative treatments. 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 physician should be continuously attentive to the use of opiates with other respiratory depressants such as benzodiazepines or alcohol, and using opiates in the setting of other comorbidities such as mental illness, respiratory disorders and sleep apnea, and a pre-existing substance use disorder.

### ***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 (115, 116). Drug testing is an important monitoring tool because self-reports of medication use and behavioral observations are not always reliable (117, 118, 119, 120, 121). Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing (122). When testing is conducted as part of pain treatment, 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 tests. 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 (123). In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians should be knowledgeable about the specific drug tests they order. They should be aware of the limitations, sensitivity and specificity of the tests they order, and take care to order tests appropriately (124). When a drug test is ordered, it is important to specify that it include the opioid being prescribed (125). 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 (126, 127).

While immunoassay, point of care (POC) testing has utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. The use of point of care testing for making long term and permanent changes in patient management may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following

immunoassay POC testing in addiction treatment settings found very high rates of “false negatives and positives” (128, 129).

Test results that suggest illicit or prescribed medication misuse should be discussed with the patient. The discussion should occur in a positive, supportive fashion, to strengthen the physician-patient relationship, encourage healthy behaviors, and produce behavioral change when needed. Results of drug testing and subsequent discussion with the patient should be documented in the medical record (130). Periodic pill counting is a useful strategy to confirm medication adherence and minimize diversion. Data from the North Carolina Controlled Substance Reporting System (NCCSRS) should be reviewed before beginning opiates and as a routine part of monitoring and adapting a patient’s treatment plan. (131, 132, 133, 134, 135). If the patient’s progress is unsatisfactory, the physician 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 referral to a pain specialist or other health professional—should be employed (136, 137, 138, 139, 140).

Evidence of misuse of prescribed opioids demands prompt intervention by the physician (141, 142, 143, 144, 145, 146). Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician’s knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors (147). The presence of illicit or un-prescribed drugs, (drugs not prescribed by a physician) in drug tests requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others (148, 149). Most worrisome are patterns of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating physical, functional or psychosocial activities, and failure to comply with a treatment plan (150).

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response (151, 152, 153, 154). 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 (155, 156, 157, 158). For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable about substance use disorders and be able to distinguish substance use disorders from physical dependence on opiates.

***Tips on Diversion:***<sup>159</sup>

One of the most difficult duties that a physician has as it relates to the prescribing of opioids to patients with chronic pain is the issue of opioid diversion. Even in light of a failed urine drug screen (UDS) with confirmation, an inconsistent NCCSRS report, and or noncompliance (not attending physical therapy, failure to obtain prescribed imaging, failure to attend appropriate interventional procedures, etc.) it is difficult to know when a patient is diverting prescription opioids. However, the prescriber may feel the patient is diverting after ascertaining a history, or the medical office receives a phone call from an anonymous source that the patient is selling his/her opioid medication. Perhaps the most effective way to appropriately decide if the patient is diverting is the combination of a random pill count and a concomitant UDS with a confirmation.

If you believe a patient may be diverting a medication, he or she should be notified to come in to the office between scheduled appointments for a random pill count. This is one reason that it is of vital importance that a random pill count be part of the Physician-Patient Informed Consent and Treatment Agreement and be reviewed with the patient at the time the agreement is signed. If a random pill count reveals medication quantities that fall short of amounts expected from prescribing instructions, it is vital to perform at that exact point in time a urine drug screen with confirmation. If the patient's UDS confirmation is negative for the prescribed opioid, it is very strong evidence that the patient is diverting, and it is safe to stop prescribing. If the UDS conformation comes back with the appropriate medication in the patient's urine, but the random pill count is short, it is highly likely that the patient is either taking more medication than prescribed, or the patient is taking some of the medication but is diverting a portion of the prescription. At this point, a conversation with the patient should occur. If the patient is over-taking the medication, it may be a good idea to seek a pain management consultation to get a reassessment of the true pain generator(s). If you believe the patient is diverting or abusing medication, a referral to an addiction specialist is in order. If you have strong evidence that the patient is diverting opioid medication, the medication should be discontinued and alternative treatments initiated. If the physician believes the diversion represents a significant



risk to public health, consideration should be given to reporting the individual to law enforcement or asking the NCCSRS for assistance.

A list of items that should raise the physician's awareness about the possibility that a patient is seeking opioid medications for reasons other than legitimate pain relief includes:

#### Suspicious history:

- Patient referred is already taking controlled substances; especially combinations of narcotics, muscle relaxants, use of 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 frequently heard: "You're the best. I always wanted to come to you."
- No past medical records; unable to obtain records from "referring doctor"
- Patient brings records that look old, tattered or suspicious in some other way
- 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 (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")
- Patient smells like marijuana smoke

#### Equivocal compliance:

- NCCSRS shows multiple providers, multiple pharmacies, prescriptions for multiple types and of medications, out of the area doctors, etc.

- UDS is refused or abnormal; patient offers multiple excuses; presence of any illegal substances (marijuana)
- Inconsistent test results over time
- Patient seeks recurrent early refills for lost or stolen prescriptions or for increased opioid use without consultation with prescriber
- Patient has excuses for lost pills (lost my prescription, my dog ate my pills, etc.)

No or equivocal clinical improvement:

- Subjective improvement alone does not count
- Lack of evidence of objective improvement in physical, functional and psychosocial activities,
- 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 NCCSRS information, increase the use of drug screens, talk with family members
- Write prescriptions for limited quantities until concerns are resolved and it is safe to do so, and increase frequency of visits and drug screens.

### ***Consultation and Referral:***

The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction, or mental health specialist as needed (160, 161). For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment (162, 163).

Physicians 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 (164, 165, 166, 167).

***Discontinuing Opioid Therapy:***

Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate (168). Opioids should be tapered or discontinued when a patient's pain is poorly controlled on appropriate doses of medication OR if there is no improvement in physical, functional or psychosocial activity with opioid treatment. 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 (169, 170).

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 prescribing physician or by referring the patient to an addiction specialist (171). 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 (172, 173, 174).

***Medical Records:***

Every physician who treats patients for chronic pain must maintain accurate and complete medical records. The medical record should include the following (175, 176, 177, 178):

- Copies of the signed informed consent and treatment agreement.
- 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 treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.

- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and physician, functional and psychosocial improvement.
- Notes on evaluations 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 (179, 180, 181, 182, 183, 184, 185). These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.
- The medical record must include 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 (186). The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed (187). Records should be up-to-date and maintained in an accessible manner so as to be readily available for review (188).
- Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient (189, 190, 191, 192).

### ***Assessing and Managing Pain in Primary Care***<sup>193</sup>

Acute pain was once defined 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. The 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 procedure and acute disease states.

Acute pain serves an important biological function, as it warns of the potential for, or extent of, injury. A host of protective reflexes (e.g., withdrawal of a damaged limb, muscle spasm, autonomic responses) often accompany it. Acute pain might be mild and last just a moment, or it might be severe and more prolonged. Acute pain, by definition, does not last longer than six months and it

resolves when the underlying cause of pain has been treated or has healed. An accurate assessment of acute pain should be performed when a patient presents with pain to the healthcare setting. A solid understanding of the person and the etiology of the pain are essential for the development of an effective and appropriate short-term pain management plan.

### Recommendations For Primary Care

- 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.
- Acute pain patients should be frequently evaluated for physical, functional and psychosocial improvement, with adjustments to treatment as needed. It is almost always 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.
- If medically possible, exhaust non-opioid medications and collaborate with other professionals, including physical therapists and pain specialists. Consider nontraditional therapies such as acupuncture and massage therapy.
- Opioids are often not required for acute pain. If you feel a brief course of opioids are indicated and appropriate, be thoughtful and thorough in your discussions and practice.
- Always prescribe a complete pain management program when an opioid is used to treat acute pain:
  - utilize NSAIDS
  - develop and recommend specific exercises
  - 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. 1 po every 6 hours for 3 days, 1 po every 8-12 hr for 3 days, 1 po every 24 hr 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, urine drug monitoring and have a low threshold for accessing and monitoring the NCCSRS at the onset of pain care.
- Give clear instructions 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; fractures from falls, especially in patients aged 60 years and older; 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 (several weeks of) scheduled opioids may actually impair their ability to fully recover.
- Patients should be advised 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.

- It is critical to 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.

### Recommendations for Emergency Departments

- Emergency medical physicians should not provide replacement prescriptions for controlled substances that were lost, destroyed or stolen.
- Emergency medical physicians should not provide replacement doses of methadone for patients in a methadone treatment program.
- Long-acting or controlled-release opioids (such as OxyContin®, fentanyl patches and methadone) should not be prescribed by emergency department physicians.
- Emergency department physicians are encouraged to use information from the NCCSRS before prescribing opioids.
- Physicians who manage patients with chronic pain should be encouraged to send patient pain 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 physicians.
- Whenever possible when evaluating a patient with an exacerbation of chronic pain, the emergency medicine physician should contact the patient's primary opioid prescriber and access the NCCSRS. If analgesics are to be prescribed, only enough pills to last until the office of the primary opioid prescriber's opens should be provided.
- Prescriptions for controlled substances from emergency department physicians should state the patient is required to provide a government issued picture identification (ID) to the pharmacy filling the prescription.

- Prescriptions for opioid pain medication from emergency department physicians for acute injuries, such as fractured bones, in most cases should not exceed 30 pills.
- When appropriate, emergency department patients should be screened for substance abuse prior to prescribing opioid medication for acute pain.

***Compliance with Controlled Substance Laws and Regulations:***

To prescribe, dispense or administer controlled substances, the physician 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 (194).

Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov),

**SECTION III: Definitions** <sup>195</sup>

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

**Aberrant drug-related behaviors:** Actions that indicate addiction, including the following: rapidly escalating drug dosage, running out of prescriptions early, acquiring prescription drugs from outside sources, inconsistent UDS, multiple providers from NCCSRS data, stolen medications chewing/snorting/injecting medications, and altering/stealing/selling prescriptions.

**Abuse:** A term with a wide array of definitions, depending on context. The American Psychiatric Association defines drug abuse as “a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by one or more behaviors.” DSM-V replaces the term “abuse” with “misuse” (196) In addition; **Substance abuse (SA)** can mean the use of any substance(s) for non-therapeutic purposes, or use of medication for purposes other than those for which it is prescribed. The medical diagnosis of SA is defined by any one of the following four criteria during a 12-month period: (1) failure to fulfill major obligations at work, school, or home; (2) recurrent use in situations in which it is physically hazardous; (3) recurrent substance-related legal problems;



(4) continued use despite persistent social or interpersonal problems (197). Substance abuse can lead to substance dependence.

**Acupuncture:** An ancient oriental medical technique where needles are placed at anatomic points along the 12 meridians of the body. Oriental medical theory, passed down for thousands of years, states that vital energy (chi) flows through the body along these 12 meridians. Although current medicine does not fully understand how acupuncture works, we do know from functional MRI studies that acupuncture activates/deactivates particular areas of the brain during needling. In addition, it is known that endorphin (endogenous opioid) levels rise during needling. Clinically, acupuncture has been successfully employed to treat a variety of disorders including opioid addiction (198).

**Acute pain:** The normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. Acute pain is generally time-limited. Duration of acute pain generally coincides with the time frame of normal healing, and serves to protect an injured body segment.

**Addiction:** A primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Addiction is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, 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 (199).

**Adverse childhood events (ACE):** This refers to childhood abuse (physical, emotional, or sexual), neglect, domestic violence, and household dysfunction. ACE is a significant risk factor for alcohol and drug abuse. There is a linear relationship between amount of ACEs and negative health outcomes (200).

**Biofeedback:** This behavioral therapy method can teach a person to gain awareness and control over physiologic processes like blood pressure, skin temperature, heart rate, and etc. via real-time feedback of said parameters to the person. Biofeedback has been used to treat a wide variety of diseases, including psychiatric disorders such as anxiety, attention-deficit hyperactivity disorder (ADHD), and substance use disorders (SUD) (201).

**Change:** To make or become different. Major life changes, such as overcoming an addiction, often occur in five stages, as follow: (1) pre-contemplation stage is when a person has not yet considered making a change; (2) contemplation stage is when a person thinks of making a change, but doesn't know how, or even if the change is worth making; (3) preparation stage is when a person becomes ready to change and makes change plans; (4) action stage occurs when people carry out their change plans; (5) and finally, the maintenance stage occurs when a person tries to make the change stick over time. Relapses sometimes occur, and can be a normal part of change. A person may relapse several times before permanent change takes hold. Research shows that skipping any one of the change stages often results in failure of change to take hold (202).

**Childhood sexual abuse (CSA):** This is a strong predictor of psychopathologies in adulthood, including a three-fold elevated risk for alcohol and drug dependence (203).

**Chronic pain:** The 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.

**Comorbidity:** The presence and effect of two illnesses occurring in the same person simultaneously or sequentially. For example, there is significant psychiatric comorbidity in persons with substance dependence. That is, many individuals who abuse and depend on drugs or alcohol may have an underlying psychiatric condition such as depression, bipolar disorder, post-traumatic stress disorder (PTSD), anxiety disorder, obsessive-compulsive disorder (OCD), etc. Other non-psychiatric comorbidities such as respiratory, cardiac, renal, or hepatic disease, sleep apnea, or seizures are also important in the consideration of chronic opiate therapy (204).

**Conversion:** A person is helped to see their addiction as a disorder which needs treatment. Unfortunately, so many people lose nearly everything in their lives and hit rock bottom before conversion is achieved (205).

**Counter-motivation:** Is resistance against change. The term includes the complex biological, psychological, and social factors involved with resisting a change. When asked about a making a change, a person may display counter-motivation by interrupting, ignoring, arguing, denying, daydreaming, reminiscing, etc. (206).

**Dependence or Physical dependence:** 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 drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction. The medical diagnosis of **Substance dependence (SD)** is defined by any three of the following seven criteria during a 12-month period: (1) tolerance; (2) withdrawal; (3) substance often taken in larger amounts or over longer period than intended; (4) persistent desire or unsuccessful efforts to cut down or control use; (5) great deal of time spent in activities necessary to obtain, use, or recover from the substance; (6) important social, occupational, or recreational activities given up or reduced; (7) continued use despite knowledge of having persistent or recurrent physical or psychological problem likely to have been caused or exacerbated by the substance (207).

**Detoxification (Detox) or medically supervised withdrawal:** Gradual reduction, or tapering, of a medication dose over time, under the supervision of a physician, to achieve elimination of tolerance and physical dependence [109]. Detoxification may be aided by medical intervention, or occur naturally via the body's detoxification pathways. Detoxification is one of the first steps in the treatment of addiction (208).

**Discrepancy:** This can refer to the difference between current situation and future goals. A counselor may help a client develop this in order to incite a desire to change (209). For example, a person is currently unemployed, living on the streets, and using heroin which has caused poor health. This person has wanted children and their own home since childhood, but now sees the discrepancy between current situation and future dreams. Perhaps this person will gain new motivation to change.

**Diversion:** The use of prescription drugs for recreational consumption, i.e. diverting them from their original medical purpose (210). The Federal Controlled Substances Act (CSA) establishes a closed system of distribution for drugs classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Any pharmaceutical which escapes the closed system is said to have been "diverted" and is illegal. Those people who "diverted" the drug are in violation of the law (211). Conversely, drug diversion

may also refer to legal programs which educate, rehabilitate, and “divert” first-time drug offenders from jail and their original destructive life course (212).

**Guided Imagery:** This technique uses the imaginative capacity of one’s own mind to create a relaxed state or, alternatively, to overcome some troubling aspect of life. This method of therapy has been used with success as one treatment for chronic pain (213).

**High:** Abused drugs (e.g. alcohol, nicotine, some prescription medications, and opioids) raise dopamine levels in the limbic system faster, higher, and longer than any natural reward (e.g. food and sex), causing a euphoric sensation (214).

**Hypnosis:** A procedure which alters one’s state of consciousness to a mode that is more accepting of suggestion. This procedure is believed to create a way around the typical evaluative, critical, conscious mind and communicate directly with one’s subconscious. Hypnosis has been used for smoking cessation, but with conflicting results (215).

**Lapse:** A brief episode of drug use after a period of abstinence which is usually unexpected, of short duration, has relatively minor consequences, and is marked by a patient’s desire to return to abstinence. A lapse can progress into a full-blown relapse with sustained loss of control (216).

**Maintenance treatment:** Dispensing or administering an opioid medication (e.g. methadone or buprenorphine) at a stable dose over 21 days or more for the treatment of opioid addiction (217).

**Medication-assisted treatment (MAT):** Any treatment of opioid addiction that includes a medication (i.e. methadone, buprenorphine, or naltrexone) and is approved by the FDA for opioid detoxification or maintenance treatment (218)).

**Meditation:** The self-regulation of attention. During mindfulness meditation one must focus their full attention on a designated object of meditation, like one’s breath. This exercise trains the mind and provides a person with relaxation, metacognition, and the revelation of previously subconscious ideas. By focusing the mind, one can work to reduce pain and change the negative mental/emotional states involved with addiction (219).

**Misuse or non-medical use:** Incorporates all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and requirements of good medical practice (220).

**Motivation:** Complex mixture of biological, psychological, and social factors that together drive a person (221).

**Motivational interviewing:** A directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence (222). Ambivalence is the conflict of opposing ideas and attitudes which the client must articulate and resolve on his/her own, only guided by the counselor. For example, a client must first ask, “Am I ready to quit?” honestly and then decide within themselves which path to trod. It is the counselor’s duty to lead them to this question, guide the process, and instill within them the confidence to pursue a change.

**Neuroplasticity:** The ability of the nervous system to adjust or compensate to an injury or disease (223). Often neuroplasticity is a good thing, but with persistent pain or chronic drug/alcohol use, these changes can make matters worse, or cause new problems altogether (e.g. psychiatric disorders or opioid induced hyperalgesia).

**Opioid abuse/dependence:** Repeated use of a drug while producing problems in three or more areas over a 12-month period. Areas include tolerance, withdrawal, overdose, and use despite impending adverse consequences. The most commonly abused opioid is oxycodone from diverted prescriptions. Others include hydrocodone, morphine, meperidine, fentanyl, methadone, buprenorphine, butorphanol, tramadol and pentazocine (224).

**Opioid Treatment Program (OTP), Methadone Clinic, or Narcotic Treatment Program:** Any federally certified treatment program which provides supervised assessment and medication-assisted treatment of patients who are addicted to opioids (225).

**Pain:** An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Pain is a complex experience embracing physical, mental, social, and behavioral processes, compromising the life of many individuals (226).

**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 of pseudoaddiction resolve upon institution of effective analgesic therapy. Addiction and pseudoaddiction can both occur in the same person (227).

**Reciprocal risk factors:** One primary condition puts you at risk for a second condition, but the second condition also can exacerbate symptoms of the first. For example, bipolar disorder puts a person at risk for developing substance abuse or addiction via cyclical mood changes. In return, substance abuse exacerbates a person's bipolar disorder – creating a destructive cycle (228).

**Recovery:** A process of change through which individuals improve health and wellness, live a self-directed life, and strive to reach full potential. Recovery must arise from hope and is person-driven. Recovery occurs via many pathways; is holistic; and must be supported by peers, allies, relationships, and social networks. Recovery is culturally-based and influenced; is supported by addressing trauma; involves individual, family, and community strengths and responsibility. Finally, recovery must be based on respect (229).

**Rehabilitation (Rehab):** Rebuilding a person's life as a whole after addiction or some other traumatic event. This process is complex and may involve a combination of changes in the biological, psychological, and social aspects of a person's life. This is often the most time intensive element of recovery and may take months to years (230).

**Relapse:** A breakdown or setback in a person's attempt to change or modify any target behavior. Relapse may also be defined as an unfolding process in which resumption of substance misuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli. Relapse may be influenced by many aspects of life including physiologic and environmental factors (231).

**Self-efficacy:** A person's belief that change is possible and that they can accomplish it (232). In general, a person must first believe that they are fully capable before they undertake a change. For example, one must have confidence and know they are strong enough to leave drugs/alcohol. During this process it is important for both counselors and clients to remember that everyone has unused potential and that everyone is capable of change.

**Self-medication:** The use of un-prescribed drugs to treat a medical problem. Self-medication is sometimes used by individuals with mental disorders to ameliorate the discomfort of their disease. However, these patients often become addicted to their medications and thus comorbidity develops (233).

**Tolerance:** 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. Tolerance can occur to an opioid's analgesic effects and to its unwanted side effects, i.e. sedation, and nausea (234). Physiologically, when using a drug like alcohol, nicotine, some prescription medications, or opioids, changes take place in the brain. Over time, these changes down-regulate natural dopamine production and reduce the brain's ability to respond to dopamine. An addict will perceive this relative lack of dopamine in the brain as increased tolerance, and he/she will often counter it with increased drug use (235).

**Trial period:** The period of time when medication or other treatment efficacy is tested to determine whether treatment goals can be met. If goals cannot be met, the trial is discontinued and an alternate treatment may be considered (236).

**Waiver:** Documented authorization from Secretary of Health and Human Services that exempts a qualified physician from rules applied to Opioid Treatment Programs (OTPs) and allows him/her to use buprenorphine for treating addiction in an office-based practice (237).

**Withdrawal:** If drug use is stopped abruptly, a withdrawal syndrome can occur where adaptive body responses, originally present to counter and detoxify the drug, become unopposed and often produce a painful experience for the drug user. Withdrawal is the cardinal sign of physical dependence on a drug (238).

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