

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

## **PAIN PROGRAM MEDICATION POLICY**

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### **SECTION 01 - INTRODUCTION:**

The following policy was developed in an effort to comply with the following:

1. Federation of State Medical Boards Controlled Substance Guidelines.
2. North Carolina Medical Board's Policy for the Use of Controlled Substances for the Treatment of Pain.
3. North Carolina Controlled Substance Act, Article 5, Chapter 90. (State Laws).
4. U.S. Code, Title 21, Controlled Substance Act. (Federal Laws).
5. Drug Enforcement Administration Diversion Control recommendations. (DEA)

### **PURPOSE:**

This policy has been developed as part of the NC Pain Management Services PA (**NCPMS**) "Risk Evaluation and Mitigation Strategy" (**REMS**) portion of our "Medication Safety Plan" (**MSP**). This policy was developed specifically to deal with chronic opioid/opiate therapy. Before NCPMS considers prescribing any chronic opioid/opiate medications, patients will need to be aware and become familiar with the program's medication policy, and agree to follow it at all times. In addition patients will also need to be aware of the risks involved with the use of such medications. **Patients seeking this type of therapy are required to take the time to carefully read this document.**

### **AVAILABILITY:**

Electronic copies of this policy are readily available to the general public via the internet at:  
Free paper copies can also be obtained from our affiliated facilities at Alamance Regional Medical Hospital Pain Management Clinics.

A copy of the policy is also provided to all patients interested in being treated with opioids/opiates.

### **TARGET POPULATION:**

Any clients of NCPMS considering the chronic use of opioids/opiates, for the treatment of chronic pain.

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## **CONTACT INFORMATION:**

NCPMS and its affiliates can be contacted by phone at **(336) 538-7180**, during normal business hours, for emergencies and non-emergency matters.

**Emergency contact:** NCPMS and its affiliates are available 24 hours a day, 7 days a week, 365 days a year, and may be reached after-hours, and/or during non-business days, by calling the hospital operator at **(336) 538-7000**. This is an emergency service only and should never be misused or abused. Please read **NCPMS' General Practice Policy 001** for more information on emergency services.

## **DEVELOPMENT:**

This policy has been developed using public resources obtained via the internet, in addition to over 17 years of personal experience in the specialty field of Pain Management. When applicable, guidelines have been modified to reflect the standard of care for the Burlington, North Carolina area of practice. Available resources used included, but are not limited to:

1. Federation of State Medical Boards Controlled Substance Guidelines, via their website.
2. North Carolina Medical Board's Policy for the Use of Controlled Substances for the Treatment of Pain, via their website.
3. North Carolina Controlled Substance Act, Article 5, Chapter 90. (State Laws).
4. U.S. Code, Title 21, Controlled Substance Act. (Federal Laws).
5. Drug Enforcement Administration Diversion Control website. (DEA)

## **UPDATES:**

As NCPMS becomes aware of applicable changes and updates to Guidelines, Regulation, and Laws, appropriate evaluations and modifications to the policy may be implemented to comply with those changes. NCPMS reserves the right to amend, update, and/or change the policy, at any given time.

## **SECTION 02 - DEFINITIONS:**

- Article 02.01**     **Chronic Pain:** Pain that has been present either constantly or intermittently for three (3) months or more.
- Article 02.02**     **Chronic Opioid/Opiate Therapy:** Medical modality option where opioids/opiates are prescribed to a patient/client for more than three (3) consecutive months, for the management/treatment of the patient/client's chronic pain.
- Article 02.03**     **Opioid:** Opioid is a blanket term used for any drug which binds to the opioid receptors in the central nervous system (CNS). Opioids include all of the opiates as well as any synthesized drug that attaches itself to the CNS or gastrointestinal tract opioid receptors. Synthetic Opioids include: **Methadone**, Pethidine, **Meperidine (Demerol)**, **Fentanyl**, Alfentanil, Sufentanil, Remifentanil, Carfentanil, Pentazocine, Phenazocine, **Tramadol (Ultram or Ultracet)**, and Loperamide.
- Article 02.04**     **Opiate:** Opiate is an often-misused term. Any drug which affects the opioid receptors is often incorrectly labeled an opiate, however by definition, opiates refer to alkaloids extracted from poppy pods and their semi-synthetic counterparts which bind to the opioid receptors. Basically to be called an opiate one has to either be a natural opioid receptor agonist or start the refining process with one of the natural alkaloid molecules. Once chemically altered, such as the process of converting Morphine into Heroin, the drug is then labeled a semi-synthetic opiate or semi-synthetic opioid - the terms can be used interchangeably. This distinction can be a little confusing since Morphine, Codeine and Thebaine are all pure alkaloids that bind to the Opioid receptors, but Papaverine, which is also a naturally occurring alkaloid inside the poppy pod is not an opiate because it does not act on the opioid receptors. Natural Opiates

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are: **Morphine, Codeine** and Thebaine. Semi-synthetic opiates (or semi-synthetic opioids) are: **Heroin** (diamorphine), **Oxycodone, Hydrocodone**, Dihydrocodeine, **Hydromorphone, Oxymorphone**, Buprenorphine, Etorphine, Naloxone and Naltrexone.

- Article 02.05** **Withdrawals**: Opioid/opiate Abstinence Syndrome, or Withdrawal syndrome is a term most commonly used to describe the group of symptoms that occurs upon the abrupt discontinuation/separation or a decrease in dosage of the intake of medications, recreational drugs, and/or alcohol. In order to experience the symptoms of withdrawal, one must have first developed a physical dependence (often referred to as chemical dependency). This happens after consuming one or more of these substances for a certain period of time, which is both dose dependent and varies based upon the drug consumed. Contrary to withdrawals from alcohol or benzodiazepine (VALIUM, ATIVAN, XANAX, etc.), narcotic withdrawals are, for the most part, not lethal. **Timeline**: In the case of short acting narcotics, such as morphine, withdrawals can occur 12 to 14 hours after the last dose, reaching their peak at 48 to 72 hours, and disappearing in 7 to 10 days. With longer acting narcotics, such as methadone, withdrawals can begin 24 to 48 hours after the last dose, reaching a peak at the 3<sup>rd</sup> day, and may not begin to decrease until the 3<sup>rd</sup> week. **Symptoms**: They usually consist of lacrimation, runny nose, yawning, heavy sweating, dilated pupils, loss of appetite, goose bumps, restlessness, irritability, tremors, insomnia, sneezing, weakness, depression, nausea, vomiting, diarrhea, abdominal cramps, chills, bone and muscle pains, increased in respiratory rate, heart rate and blood pressure, muscle spasms, cold and hot flashes, craving for opioids/opiates, increase in body temperature, anxiety, and a feeling of being ready to “climb up the walls” or “jump out of your skin”. For the most part, withdrawals are more severe for the short-acting narcotics than for the long-acting.
- Article 02.06** **Tolerance**: This is what happens when the patient’s medicines are no longer as effective as they use to. Tolerance may develop to the effects of many drugs, especially the opioids, barbiturates, and other CNS (central nervous system) depressants. When this occurs, *cross-tolerance* may develop to the effects of pharmacologically related drugs. Tolerance to a pain medication will be manifested as an increase in pain after the frequent use of the analgesic (pain medication). Tolerance has been described to develop in as short as 10 days. Although this process may take as long as a year in some patients, it is safe to assume that it will occur to everybody who takes this type of medication on a regular basis. A common complaint of patients is that, *“the medications don’t seem to work as well as they use to.”*
- Article 02.07** **Physical Dependence**: (Also known as *Physiological Dependence*) Refers to a state resulting from chronic use of a drug that has produced *tolerance* and where physical symptoms of *withdrawal* result from abrupt discontinuation or dosage reduction. Physical dependence can develop from low-dose therapeutic use of certain medications as well as misuse of recreational drugs such as alcohol. The higher the dose used typically the worse the physical dependence and thus the worse the withdrawal symptoms.
- Article 02.08** **Addiction**: The concept of drug addiction has many different definitions:  
**(01)** According to the current Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), substance dependence is defined as: *“When an individual persists in use of alcohol or other drugs despite problems related to use of the substance, substance dependence may be diagnosed. Compulsive and repetitive use may result in tolerance to the effect of the drug and withdrawal symptoms when use is reduced or*

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*stopped. This, along with Substance Abuse are considered Substance Use Disorders...."*

- (02) The American Society of Addiction Medicine has defined addiction as a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in the individual pursuing reward and/or relief by substance use and other behaviors. The addiction is characterized by impairment in behavioral control, craving, inability to consistently abstain, and diminished recognition of significant problems with one's behaviors and interpersonal relationships. Like other chronic diseases, addiction involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.
- (03) Federal Law defines an "Addict" as "someone who has lost self-control over their own medications".

**Article 02.09** Drug Holidays: Also known as "Short-Term Detoxification". This is the name given to the period of time during which the opioid/opiate are stopped for the purpose of treating tolerance to the medications. During the Drug Holidays, because of *cross-tolerance*, patients will not be allowed to switch to another opioid/opiate. When returning to the opioid/opiate, at the end of the Drug Holiday, the patient is likely to be started at a lower dose than the dose prior to the Drug Holiday. They should be repeated as often as necessary to allow the patient to control his/her medication tolerance, rather than allowing the medication to control the patient. Drug Holidays are done as outpatients. They can be monitored by physicians, but they are primarily managed by the patients. Because they demonstrate the patient's ability for self-control, they serve as evidence of non-addiction. The opposite is also true. Patients that do not comply with this requirement. Federal Law defines an "Addict" as "someone who has lost self-control over their own medications". Following this definition, it then states that "it is illegal for any physician to prescribe narcotics to an 'addict'." Because of this, any patients refusing to undergo a "Drug Holiday", may be considered as having lost self-control over their medications, subsequently triggering the permanent cessation of all controlled substances by the prescribing physician. The other side of that coin is that by complying with the "Drug Holidays", the patient demonstrates that he/she continues to have self control over their own medicines, and therefore, it makes it legal for the treating physician to continue prescribing the pain medication.

## **SECTION 03 - PREREQUISITES TO TREATMENT WITH OPIOIDS/OPIATES:**

**Article 03.01** Primary Care Physician (PCP): In order to be treated at our program, all patients must have an established and currently active Primary Care Physician.

**Article 03.02** Initial Patient Evaluation: No controlled substances will be prescribed on the patient's first visit. By law and by the State's Medical Board, we are required to gather a comprehensive medication history before beginning treatment with the prescription of these substances. It is also our policy not to write prescriptions for controlled substances, before the "***Consent for Chronic Opioid Therapy***" is read and signed. The law requires that there be a patient-physician relationship established before treatment is undertaken. The purpose of this evaluation is to determine if the patient/client has chronic pain, as defined on **Article 02.01** of this policy. In addition, this evaluation seeks to determine the appropriateness of

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chronic opioid/opiate therapy, as defined on **Article 02.02** of this policy, for the subject in question. Prescriptions will not be written for any non-patients.

**Article 03.03**     **Client/Patient Responsibility:** The nature of this type of therapy demands responsibility and accountability on the part of the prescriber, as well as the patient/client. Patient/clients suspected of being incapable of such responsibility will not be considered to be appropriate candidates for this therapeutic option. NCPMS accepts and will abide by the responsibilities imposed to our practice by the following entities: (1) Federation of State Medical Boards; (2) North Carolina Medical Board; (3) North Carolina Controlled Substance Act, Article 5, Chapter 90; (4) U.S. Code, Title 21, Controlled Substance Act; and (5) The Drug Enforcement Administration. As part of fulfilling this responsibility, NCPMS has developed, and will enforce, this "Pain Program Medication Policy". It is imperative for the non-medical community to understand that this responsibility is a "two way street". NCPMS believes that if a medical practice complies with all regulatory agencies and yet a client manages to abuse the system by way of misrepresentation, no justice is served by blaming the medical practice for the harm caused by the client's misuse or abuse. Because of this, NCPMS wants to clearly state that it is the client/patient's responsibility to know and abide by the terms of this policy. Should it be impossible for the client/patient to bear this responsibility, because of the nature of his/her medical condition and inability to care for themselves, then it up to the Estate Administrator/Executor and/or the individual with the "Power of Attorney" to accept and carry this responsibility. In either case, because statistically the client/patient will spend more time with their family, away from the NCPMS healthcare provider, it is imperative that those around the client/patient share the responsibility, not of the therapy itself, but of the monitoring of such therapy, understanding the concept that a healthcare provider is incapable of correcting problems, if he/she is not informed of their existence.

**Article 03.04**     **Consent for Chronic Opioid/Opiate Therapy:** This Consent must be read and signed before any opioid/opiate medications are prescribed. This is a document where the patient is informed of the risks, responsibilities, and complications specifically associated with this type of therapy. After carefully evaluating those risks, the patient will then decide if he/she wants to proceed with the requested therapy. Signing this document indicates the patient's willingness to accept all of the stipulated responsibilities and risks mentioned in the document. In addition, signing the document provides NCPMS with the patient's consent to proceed with the therapy. Patients are required to take the consent home to study it and to obtain legal counsel if required, before signing it. Once signed, the document is self renewable, on a yearly basis. This consent will go into effect the minute it is signed. This consent will remain in effect for the duration of the patient's care with this type of therapy. The consent, and therefore the opioid/opiate therapy, can be terminated by the patient by providing NCPMS with a written request for termination. Having a signed "Informed Consent" does not mean that NCPMS or its affiliates are obligated in any way to provide this type of therapy, however, not having a signed consent would preclude NCPMS from providing this type of therapy.

**Article 03.05**     **Therapy Agreement:** This Agreement must be read and signed before any medications are prescribed. It contains important information pertinent to the patient's responsibilities in terms of the use of pain medications. Patients are required to take the agreement home to study it and to obtain legal counsel if required, before signing it. Once signed, the document is self renewable, on a yearly basis. This agreement will go into effect the minute an opioid/opiate medication prescription is written by this program or its affiliates. This Agreement

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will remain in effect for the duration of the patient's care with this type of therapy. The Agreement, and therefore the opioid/opiate therapy, can be terminated by the patient by providing NCPMS with a written request for termination. Having a signed "Medication Agreement" does not mean that NCPMS or its affiliates are obligated in any way to provide this type of therapy, however, not having a signed agreement would preclude NCPMS from providing this type of therapy.

- Article 03.06**     **State and Federal Laws and Regulations:** Patients are expected to follow State and Federal Laws and Regulations at all times.
- Article 03.07**     **Information Completeness and Accuracy:** Acceptance into our practice is contingent upon a commitment to providing us with up to date, complete and accurate information. The results of the Urine Drug Screening Test (UDST) must be consistent with the substance use information provided by the patient. In addition, the provided information on the patient's questionnaires must be complete and accurate.
- Article 03.08**     **Medication Policy Acceptance and Compliance:** Treatment with controlled substances is contingent upon acceptance of and compliance with all stated policies and procedures of this practice.
- Article 03.09**     **Family Agreement:** Patient's family must agree to therapy and to share the monitoring responsibility, as well as risks. Any internal disagreement must be solved before therapy can be initiated.
- Article 03.10**     **Submit to Evaluation for risks of addiction:** Addiction risk assessment although not perfect, is useful to establish an appropriate monitoring plan for each patient. NCPMS has taken the administrative decision to require a formal psychological substance dependence evaluation from all patients age 60 or younger, requesting treatment with controlled substances. (Based on age-related statistical risks.)
- Article 03.11**     **Accurate and up to date address and contact information:** (Telephone numbers, Cell phone, Fax, e-mail address, etc.) It is absolutely necessary for safety purposes, as well as to comply with appropriate documentation.
- Article 03.12**     **History of Drug or Substance Abuse or Misuse:** Patients found to have a history involving substance abuse, misuse, history of drug diversion, drug violations or legal problems involving drugs will not be considered for this program. Patients discharged from other pain management programs or medical practices will be evaluated on a case by case basis. Patients found to be hiding or omitting such information will not be considered for admission into the program.
- Article 03.13**     **Drug Holiday Compliance:** Drug Holidays are an integral part of our medication tolerance management strategy. Patients may be required to submit to a Drug Holiday before we take over their medication management. Patients unwilling or who believe to be incapable of adherence to plan, are recommended to consider other alternative practices, as other programs may have management strategies more suitable to their needs.
- Article 03.14**     **Drug Testing Compliance:** It is a requirement of our program that patients submit to unannounced drug tests. These may be conducted using a number of available techniques. This is an integral part of our monitoring and acceptance to practice process. Patients unwilling to provide us with a testing sample on the very first visits, may forfeit their candidacy for the medication management

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program. Patients that find an excuse not to be tested on the first visit may not be accepted to the opioid/opiate medication program, even if they later provide a sample. Patients found to have tampered with the test will be automatically discharged from the program. This is done because we have encountered cases where patients, upon learning that a drug test is required, avoid providing a sample on the first visit so that they have time to remove the illegal substances from their body, essentially manipulating the test into providing a clean sample.

**Article 03.15** **Prior Medical Records:** In certain cases, prior to starting opioid/opiate therapy, we will require that all medical records be received directly from the prior treating physicians, rather than being brought in by the patients themselves. This is done due to the fact that we have encountered situations where patients have selectively removed information from their records, prior to handing them in.

**Article 03.16** **No Contraindications:** Before commencing or taking over opioid/opiate therapy, all patients will be evaluated for absolute and/or relative contraindications.

- (01) Allergy to opioid (Absolute)
- (02) Co-administration of drug capable of inducing life-limiting drug-drug interaction. (Absolute)
- (03) Active diversion of controlled substances. (Absolute)
- (04) Acute psychiatric instability or high suicide risk. (Relative)
- (05) History of intolerance, serious adverse effects, or lack of efficacy of opioid therapy.
- (06) Meets Diagnostic and Statistical Manual - Version IV (DSM-IV) criteria for current substance use disorder. (Relative)
- (07) Inability to manage opioid therapy responsibly (e.g., cognitively impaired). (Relative)
- (08) Unwillingness or inability to comply with treatment plan. (Relative)
- (09) Unwillingness to adjust at-risk activities resulting in serious re-injury. (Relative)
- (10) Social instability. (Relative)
- (11) Patient with sleep apnea not on Continuous Positive Airway Pressure (CPAP). (Relative)
- (12) Elderly patients. (Relative)
- (13) Chronic obstructive pulmonary disease (COPD) patients. (Relative)

## **SECTION 04 - PRACTICE LIMITATIONS:**

**Article 04.01** **“Nerve” Medicine(s):** Will not be prescribed by our program. If you have problems with your “nerves” (anxiety, depression, nervousness, panic attacks, suicidal ideations, etc.) you need to see a psychologist or a psychiatrist for help. The patient understands that our pain program will not be prescribing medications for the “Nerves”. Specifically, benzodiazepines such as **Valium** (diazepam), **Xanax** (alprazolam), **Ativan** (lorazepam), etc.. If the patient is currently taking these medications, they must continue to be prescribed by the physician that initiated the therapy, or a licensed psychiatrist.

**Article 04.02** **Non-Pain related Medications/Prescriptions:** We will not prescribe, continue to write, or renew any prescriptions for medications that you may be receiving for non-pain related reasons (blood pressure medicines, diabetes medications, asthma medication, nicotine patches, antibiotics, etc.).

**Article 04.03** **Primary Care Medicine:** NCPMS is a specialty practice and as such, will not be engaged in the primary medical care of our patients. This is the primary reason why

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all patients must have a current Primary Care Physician (Family Doctor, General Practitioner, or Internist) before being accepted to our practice.

## **SECTION 05 - WARNINGS:**

- Article 05.01**     **Pregnancy or Lactation:** We strongly discourage taking controlled substances when pregnant or lactating. Taking controlled substances while pregnant may cause fetal abnormalities as well as fetal addiction and perinatal withdrawal syndrome. Patients are urged to check with their Obstetrician, and/or Pediatricians for recommendations.
- Article 05.02**     **Suicidal ideations:** Any patients with suicidal ideations should immediately contact their personal psychiatrist, psychologist, or primary care physician. Should none of these be available, immediately go to your nearest emergency room, or urgent care facility. Other points of contact include the **USA National Suicide Hotlines** at **1-800-784-2433** , or the **NORTH CAROLINA Suicide & Crisis Hotlines** at **(336) 513-4444**.
- Article 05.03**     **Using suicide as a threat:** This will result in immediate discontinuation of all pain medications and mandatory, possibly involuntary, institutionalized in an in-patient psychiatric facility.
- Article 05.04**     **Suicidal attempts:** This is not a psychiatric-based pain program. Suicidal attempts will result in immediate and complete discontinuation of all medications with the potential to be used to harm the patient. Furthermore, the care of the patient will be transferred to a psychiatric-based pain program.
- Article 05.05**     **Addiction Potential:** Opioids/opiates used in analgesia, can be abused and is subject to criminal diversion. Opioids/opiates have the potential to cause both, psychological as well as physiological dependence, leading to addiction. Drug addiction is characterized by compulsive use, use for non-medical purposes, and continued use despite harm or risk of harm. There is a potential for drug addiction to develop following exposure to opioids/opiates. All patients undergoing this type of therapy need to understand and accept this risk before starting treatment. In addition, patients will need to accept that because of this risk, the physician need to have the ability to frequently monitor for signs of addiction, as well as having the ability to stop or discontinue therapy, should it become evident that the patient is displaying some of these signs.
- Article 05.06**     **Withdrawals:** Physical or physiological dependence and tolerance to opioids/opiates are inevitable. Therefore, patients on these medications or therapy should expect to experience withdrawals at some point in their lives, should they choose to undergo this type of treatment. The intensity of withdrawals to opioids/opiates is dependent on the dose of medication used. The higher the dose, the worse the withdrawals. Symptoms can be uncomfortable, but for the most part, withdrawals to opioids/opiates are not lethal.
- Article 05.07**     **Opioid Hyperalgesia:** This is a phenomenon by which opioid/opiate pain medications, rather than helping the patients by decreasing their pain, they make the patient more sensitive and susceptible to it. Ultimately, they increase the patient's pain. This is a fairly recent medical discovery. A great deal of physicians are not aware of it. The only way to test for it is to closely monitor patients and those not responding to therapy as expected, should be submitted to Drug Holidays, where it then may becomes evident that hyperalgesia was present.

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**Article 05.08**     **Short-term and Long-term Side-effects:** Opioids/opiates have both, short-term and long-term side-effects. They affect breathing, gastrointestinal motility, cognitive abilities, and are known to cause permanent hormonal changes. In combination with certain serious medical problems, these medications can greatly increase the patient's risk of death. In addition, these medications when combined with other drugs or substances, can become lethal. This is why patients are required to disclose taking these medications to all healthcare workers treating them, especially those prescribing other treatments or medications. In addition, and for the same reason, patients are required to consult with their pharmacist, before adding any new medications.

## **SECTION 06 - SAFETY:**

**Article 06.01**     **Starting New Medications:** Patients are required to always consult with their pharmacist before taking any new medications. Patients should confirm the dose, medication, and schedule with the pharmacists, before initiating therapy. Patients should also inquire about details on how to take the medication and what to avoid, as well as possible side-effects. Never start any new medication if you are home alone. Patients are required to always notify a family member or friend, so that they can be monitored for adverse or allergic reactions. Should a side-effect or reaction occur, do not take any further doses and immediately call for assistance. If needed, go to the nearest emergency room.

**Article 06.02**     **Intended User:** No one should ever use any prescription medications that were not specifically prescribed for them. In addition, none of our clients/patients are allowed to sell, give away, lend, share, borrow, or use any controlled substances that were not specifically prescribed to them.

**Article 06.03**     **Side-effects or Adverse Events:** Patients and/or family members are required to call our practice in the event the patient begins to experience any side-effects or adverse events to any of our treatments. In the event that the symptoms are perceived to be serious, the patient should be immediately taken to the nearest emergency room. If symptoms are serious, do not wait to contact our practice, that can be done on the way to the hospital or once you have arrived to the emergency department. NCPMS and/or affiliates are available by phone, 24 hours a day, 7 days a week, 365 days a year, for these type of emergencies. NCPMS can be contacted via the hospital operator. This emergency service should never be abused by using it for non-emergency services.

**Article 06.04**     **Driving or Operating Heavy Machinery:** This is strictly prohibited when taking controlled substances. Opioids/opiates may impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Patients are urged to check state laws at their local DMV (Department of Motor Vehicles). Always ask your pharmacist if the medications that you are taking carry such warnings.

**Article 06.05**     **Handling Firearms or other Weapons:** This is strictly prohibited when taking controlled substances. Patients are urged to check firearms state laws.

**Article 06.06**     **Use of Alcohol:** This is strictly prohibited when taking controlled substances. Combining alcohol and pain medications may result in death.

**Article 06.07**     **Avoid Volunteering Private Information:** Do not talk to non-medical personnel or strangers about the medications that you take. There is an ongoing scam, where certain elements of our society look for people willing to make this

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information available, most commonly in pharmacies or even the waiting room of physician's offices. The unsuspecting patient is then either assaulted and the medications taken, or followed home, where they patiently wait for an opportunity to break in and steal the medications.

**Article 06.08**    **Work Limitations:** Opioids/opiates may impair the mental and physical abilities needed to perform potentially hazardous activities. These medications may also cause cognitive impairment affecting decision-making capabilities, which may lead to dangerous or reckless ideas or behavior, which in turn, may result in potentially devastating financial or physical losses. Extreme caution must be exercised by patients choosing to take on the responsibility of working while taking these substances.

**Article 06.09**    **Limitations in Caring for Others:** Opioids/opiates may impair the mental and physical abilities needed to care for others. These medications may also cause cognitive impairment affecting decision-making capabilities, which may lead to the unintentional harming of others. Extreme caution must be exercised by patients choosing to take on the responsibility of caring for others while taking these substances.

**Article 06.10**    **Family Participation:** It is our strong belief that family participation in the patient's care adds another level of safety to the treatment. Because of this, we insist that all patients share the provided information about risks and possible complications with their loved ones. In addition, we strongly recommend and encourage internal family dialogue so as to have everyone in agreement with the therapy. If there are any internal family disagreements with regards to the therapy as a whole, or any parts of it, these will need to be identified and resolved within the family nucleus, before we feel comfortable continuing with treatment.

**Article 06.11**    (SOS) Safety Opioid Steps:

- (01) *Never take any medication that was not intended for you.*** Everybody responds differently to narcotics. What is safe for one person can kill another.
- (02) *Never take pain medicine with alcohol.*** Never mix the two; the combination can be deadly.
- (03) *Never take more doses than prescribed.*** Even after the effects of pain medication seem to have worn off, it is still depressing the respiratory system. The body must develop a tolerance to the respiratory depressant effects before the dose can be increased.
- (04) *Use with other sedative or anti-anxiety medications can be dangerous.*** Combining pain medicines with other sedative drugs, such as benzodiazepines (diazepam/Valium; alprazolam/Xanax; chlordiazepoxide/Librium; clonazepam/Klonopin; clorazepate/Tranxene; estazolam/ProSom; Lorazepam/Ativan; ), can increase the toxicity of the pain medication. Only take other medications if directed by the prescriber.

## **SECTION 07 - PHARMACIES:**

**Article 07.01**    **Mail-in Prescriptions Services and Medication Assistance Programs:** We cannot be responsible for the handling of your prescriptions or your medications by a third party. When using either one of these medication services, be advised that we are not responsible for problems that you may run into when using them. If your prescriptions or medications are lost in the mail, or there is any delay in

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the shipments, we will not be issuing additional prescriptions “to keep you until the medicines arrive”. Also, we will not be “calling them for you”, to speed up the process, or to see what is happening. In addition, there are “Mail-in Prescription Services” that require that a prescription for a 90 day supply be written, instead of one with refills. We believe this to be inappropriate and unsafe, when dealing with controlled substances. Because of this, we will not be writing for such prescriptions. In general, we do not believe “Mail-in Prescription Service Programs” to be appropriate for “Controlled Substances”. If a medication is lost in the mail, we will not be replacing it. We do not accept “U.S. Postal Service Mail loss/rifling report” as proof of loss.

**Article 07.02** **Internet Pharmacies:** Be aware that internet pharmacies may be considered to be an illegal means of obtaining schedule 2 controlled substances. Patients are encouraged to attain legal counsel with regards to current state and federal regulations with regards to this topic.

**Article 07.03** **Multiple Pharmacies:** This is not permitted. Patients must agree to use only one pharmacy to obtain their pain medication. This pharmacy will be of the patient’s own choosing. The patient is responsible for providing us with the name, location and telephone number of the pharmacy of choice.

**Article 07.04** **Changing Pharmacies:** It is the patient’s right to change pharmacies at any time. However, the patient required to immediately provide us with the name, location and telephone number of the new pharmacy. Reason for changing pharmacies is not required.

**Article 07.05** **Illegal Procurement of Controlled Substances:** This is not permitted. Obtaining controlled substances from any source, other than by legally purchasing them from a licensed, legal pharmacy is prohibited. This includes falsifying, altering, acquiring or obtaining possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.

**Article 07.06** **Drug Safety Information:** Patients are responsible and required to obtain drug safety information from their pharmacists. This should include, but not be limited to information on:

- (01)** How to take the medication.
- (02)** Dietary instructions.
- (03)** Precautions.
- (04)** Contraindications.
- (05)** Precautions for Special Populations (Patients with renal failure or impairment, Liver impairment, elderly, etc.)
- (06)** Information on missed doses.
- (07)** Information on side-effects.
- (08)** Drug-to-drug interactions.
- (09)** Interactions with over-the-counter (OTC) supplements.

## **SECTION 08 - OBTAINING SCRIPTS:**

**Article 08.01** **Obtaining Prescriptions or prescription refills:** Prescriptions will be issued only in the clinic, during regular business hours. Nothing will be called in, faxed, or mailed. This is done for the purpose of maintaining adequate control and documentation on the distribution of these controlled substances.

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**Article 08.02**    **After Business Hours, Holidays, and Weekends:** No prescriptions will be written, faxed, or called-in, at these times. Prescriptions will be written only during regular business hours. Therefore, it is the patient's responsibility to keep track of his/her medications in order not to run out of them during those times.

**Business hours are:**

Monday – Thursday from 8:00AM until 3:00PM.

Fridays from 8:00AM until Noon.

**Article 08.03**    **Identification:** Patients may be required to produce a current, valid Photo I.D., before receiving a prescription for a controlled substance. Valid I.D. include only a current Driver's License.

**Article 08.04**    **Telephone Calls:** No prescriptions will be "refilled" or "called in" to any pharmacies over the phone.

**Article 08.05**    **Faxing Prescriptions:** No prescriptions will be faxed.

**Article 08.06**    **Early Refills:** There will be no early refills. Early refills suggest taking more medication than prescribed. This is not allowed. If you believe there is a problem with the monthly amount of pain medication allowed, you will need to request an appointment with your physician to discuss this in person.

**Article 08.07**    **Lost or Stolen Medications or Prescriptions:** These will not be replaced. We do not accept "police reports" as proof.

**Article 08.08**    **Picking-up prescriptions without an appointment:** This practice is not permitted, especially by someone else for whom the medications were not intended. Patients must attend their appointments in order to be assessed for the need to continue taking the medication. Prescriptions will only be handed to the patient for whom they were intended, and only during regular appointments.

**Article 08.09**    **Illegal Procurement of Prescription:** This is prohibited. This includes falsifying, altering, acquiring or obtaining possession of a prescription by misrepresentation, fraud, forgery, deception, or subterfuge.

## **SECTION 09 - HANDLING & STORAGE:**

**Article 09.01**    **Medication Storage:** Patients are responsible for providing safe storage for pain medications. We strongly recommend that controlled substances be kept under lock and key.

**Article 09.02**    **Prescription Handling and Care:** Our responsibility towards the handling and care of your written prescriptions ends the minute you walk out of our facility with your prescriptions. We will not replace or re-write lost or stolen prescriptions. Always obtain a written receipt from your pharmacist if he agrees to store or file them away for you.

**Article 09.03**    **Keep all of your medications away from children.**

**Article 09.04**    **Keep all pain medications (controlled substances) under lock and key,** even if you live alone. Cases have been described where visiting friends and family members have stolen medications on an innocent trip to the bathroom.

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

## **SECTION 10 - MEDICATION USE:**

- Article 10.01**    **Medication Schedule and Dosage:** Medication should be taken only as directed. This is determined by your physician. Patients are **allowed to decrease** their pain medication dosage or intake frequency on their own, if so desired. Patients may even stop their medications if they believe it is causing side effects, it is not effective, or simply would prefer not to be taking it. The opposite is not true. Patients are **NOT allowed to increase** their dose of pain medication, or to decrease the intake frequency without the express written approval of the physician.
- Article 10.02**    **Unsanctioned Dose Escalation:** This practice is prohibited and may lead to discontinuation (stopping) of the medication and possible discharge from the practice/program.
- Article 10.03**    **Medication Changes Over the Phone:** No medication changes will be made over the telephone. This policy applies to refilling prescriptions and starting new medications.
- Article 10.04**    **Starting New Medications:** Patients are required to always consult with their pharmacist before taking any new medications. Please review **Article 06.01 on Section 06** – “Safety”, of this policy.
- Article 10.05**    **Whenever you are given a new medication,** always check with your pharmacist to see if there may be any drug interactions with any of the other medications that you are currently taking. Remember that over-the-counter medications and herbs can also interact with prescription drugs.
- Article 10.06**    **Accessing your medicines:** Always open your bottles over a counter or table, so that if pills fall out, you may be able to collect and use them. Never open the bottle over the commode. We will not replace damaged or lost medications.
- Article 10.07**    **Carry only what you need:** Never carry more medicine than what you will consume during that day. If your medication is lost or stolen, you will be out of it for only one day. Remember, we will not replace lost or stolen medications.
- Article 10.08**    **Know how much you have left:** Always know how much medicine you have left and if you need a refill. It is your responsibility to know when you are running out of medicine.
- Article 10.09**    **Adopt an “Early Warning System”:** We recommend that you put aside, in a separate (well-labeled) container, seven (7) to ten (10) days worth of pain medicine. Then use the remainder, like you normally would. When the primary supply runs out, then you know that you have seven (7) to ten (10) days worth of pain medicine left and that you need to arrange for an appointment to have your medications refilled.
- Article 10.10**    **Get your “Preferred Drug List”:** In order to save you money, we require that you get a copy of your health insurance carrier’s **“Preferred Drug List”**. Always bring this list with you to all appointments. Because patients have different healthcare carriers, and within each carrier there are multiple insurance plans with multiple different benefits, it is virtually impossible for physicians to know what your plan covers. We recommend for each patient to get their list of approved medications, so that we can prescribe an approved medication. This

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

will ultimately save you time and money, by avoiding denials and requests for preapprovals. Keep in mind that these lists change with time. The situation may arise where a pain medication that was working well for you and that you had been taking for years, has now been taken out of the preferred list. These problems are becoming more common due to the government changes in healthcare. These are now problems between you, your insurance carrier, and government representatives. We strongly suggest contacting and notifying them of the problem.

## **SECTION 11 - MONITORING:**

- Article 11.01**     **Drug Screening Test:** By law and by the State's Medical Board, we are required to maintain adequate documentation with regards to our patient's use of controlled substances. Therefore, you will be required to provide urine or blood samples for the purpose of drug screening tests.
- Article 11.02**     **Follow-up appointments:** It is unethical and illegal to prescribe controlled substances without adequate follow-up. Therefore, not keeping your regular appointments constitutes a violation of this follow-up policy, possibly resulting in the discontinuation of the medication.
- Article 11.03**     **Medication Inspection(s):** Always bring your medications and/or empty bottles to all of your appointments. Unannounced pill counts and/or medication inspection will be conducted randomly. Failure to bring your medications for inspection may result in no prescriptions being written until an inspection can be conducted. Depth of inspection is up to the discretion of the evaluating healthcare provider. All medications should be in their original, unaltered containers (Pharmacy Labeled Bottles). Should you not bring your medications, have less than what you are suppose to, or the identification of the medication prove that the medication is not what you were suppose to have, you will be automatically discharged from our program.
- Article 11.04**     **Unused Portion of Prescription:** Discontinued medications should be taken to your appointments for the purpose of being discarded in front of witnesses. This process needs to be properly documented in your medical record. A drug sample may be sent out for analysis and identification. We will not accept video recordings as proof of disposal. Medication hoarding is not permitted under our program.
- Article 11.05**     **Program Questionnaires:** These questionnaires are designed to closely monitor for any possible problems associated with this type of therapy. Effectiveness of this tool is completely dependent on the patients providing complete honest answers. Unwillingness of patients to fully cooperate and comply with this requirement represents sufficient grounds for discontinuation of the controlled substance therapy. Lack of accurate information decreases our ability to properly monitor the therapy, thereby increasing risk and decreasing patient safety.
- Article 11.06**     **Sharing and obtaining information:** Upon requesting our services, the patient agrees to allow his/her pain physician/healthcare provider to share and/or obtain medical and medication related information with/from his/her other past and present treating physicians. This is essential if medication interactions are to be avoided. The patient also agrees to allow the pain physician to freely discuss his/her case with any other physician currently or previously involved in the patient's care. This also includes past and present pharmacy information.

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

**Article 11.07** **Always** bring your medications and/or empty bottles to all of your appointments.

**Article 11.08** **More than one Chronic Pain Patient in the Family:** If more than one member of the family is on therapy using controlled substances, we recommend that all be managed by the same practice. For patients being managed by our program, we require that all family members using Opioid/Opiate therapy be seen on the same day, but in different evaluation rooms. When unable to have all members (with chronic pain) of the family under the same practice, then we require to have those members not treated voluntarily disclose the type of Opioid/Opiate taken.

**Article 11.09** **Red Flags:** These are behaviors or actions associated with, and considered to suggest substance abuse, misuse, or diversion:

- (01) Assertive personality, often demanding immediate action.
- (02) Attempts to use suicide as blackmail to manipulate pharmacotherapy.
- (03) Avoids giving clear answers.
- (04) Claims not to be able to void for Urine Drug Screening Test (UDT).
- (05) Claims to be late for another appointment, when asked to provide UDT sample.
- (06) Conceals obtaining medications from other sources.
- (07) Contends to be a patient of a practitioner who is currently unavailable.
- (08) Cutaneous signs of drug abuse - skin tracks and related scars.
- (09) Defiant statements about medication use.
- (10) Demands to be seen immediately.
- (11) Denies having a regular Primary Care Physician.
- (12) Denies having healthcare insurance.
- (13) Disregards medication safety education provided by program.
- (14) Disregards program rules and regulations.
- (15) Disrespectful statements, comments, or gestures when confronted about inappropriate or unsafe use of medication(s).
- (16) Exaggerates medical problems and/or feigns symptoms.
- (17) Exhibits lack of impulse control.
- (18) Exhibits mood disturbances.
- (19) Exhibits sexual dysfunction.
- (20) Exhibits thought disorders.
- (21) Fails to comply with appropriate safe use of medications.
- (22) Fails to keep appointments for further diagnostic tests.
- (23) Fails to keep regularly scheduled appointments.
- (24) Feigns physical problems.
- (25) Feigns psychological problems.
- (26) Gives conflicting medication history.
- (27) Gives evasive or vague answers to questions regarding medical history.
- (28) Gives medical history with textbook symptoms.
- (29) Has changed the list of medications taken after having been told of UDT.
- (30) Has crossed program boundaries.
- (31) Has had problems when asked to provide UDT samples.
- (32) Has intentionally provided us with inaccurate information for the purpose of obtaining controlled substances.
- (33) Has no interest in diagnosis.
- (34) Has no interest in interventional techniques that could prove to be helpful.
- (35) Has no regular doctor and/or health insurance.
- (36) Has requested to other healthcare providers not to share information with us.
- (37) Has requested us not to share information with other healthcare providers.

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

- (38) Has tampered with Urine Drug Screening Test (UDT).
- (39) Is reluctant to try other alternatives.
- (40) Manages not provide us with UDT sample, despite our request(s).
- (41) Misrepresents or lies about statements made by other providers, for the purpose of obtaining medications.
- (42) Non-physiological responses to interventional treatments.
- (43) Omits, hides, manipulates, distorts, deceits, misinforms, or simply lies about information requested.
- (44) Overly concerned about obtaining controlled substances.
- (45) Pays cash in pharmacies, despite having healthcare insurance drug coverage.
- (46) Refuses a physical exam.
- (47) Refuses to see another practitioner for consultation.
- (48) Reluctance to cooperate.
- (49) Reluctant or unwilling to consider alternative therapies.
- (50) Reluctant or unwilling to cooperate with controlled substance monitoring.
- (51) Reluctant or unwilling to have diagnostic testing.
- (52) Reluctant or unwilling to provide information.
- (53) Reluctant or unwilling to provide reference information.
- (54) Reluctant to provide us with UDT sample.
- (55) Requests a specific controlled substance by name.
- (56) Requests controlled substances with high street value.
- (57) Requests refills more often than originally prescribed.
- (58) Requests that the rules be disregarded or ignored for him or her.
- (59) States allergies or side-effects to non-narcotic analgesics.
- (60) States being allergic to specific non-narcotic analgesics.
- (61) Symptom exaggeration and/or magnification.
- (62) The patient presents with signs and symptoms of narcotic withdrawal.
- (63) Unsafe or inappropriate use of the medication(s), despite warnings.
- (64) Unsanctioned dose escalation.
- (65) Unusual appearance.
- (66) Unusual behavior in the waiting room.
- (67) Unusual knowledge of controlled substances.
- (68) Unwilling to give permission to access past medical records or allow contact with previous providers.
- (69) Use of non-specific, vague complaints.
- (70) Uses claims of lost or stolen prescriptions, in an attempt to get more medications.
- (71) Uses pain medications for reasons other than prescribed (i.e. as sedatives, tranquilizers, or sleep inducers).
- (72) Utilizes a child or an elderly person when seeking pain medication.
- (73) Wants an appointment toward end of office hours.
- (74) Will not give the name of a primary or reference physician.

## **SECTION 12 - MISUSE & ABUSE:**

**Article 12.01**    **Sharing or Lending Medications:** This is unwise, dangerous, and illegal. Medications are to be taken only by the patient for whom they were legally prescribed and intended. We are aware of cases where fatalities have occurred, due to this practice. In case of a fatality, you may be personally liable and held accountable for the other person's death.

**Article 12.02**    **Selling or Distributing:** This is strictly prohibited by State and Federal Law. This is an illegal practice and could carry jail-time.

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

- Article 12.03**     **Obtaining Pain Medications from more than one physician:** This practice is called “Doctor Shopping” and State Law strictly prohibits it. This is an illegal practice and could carry jail-time.
- Article 12.04**     **Hoarding Pain Medications:** This practice is not permitted and may be a sign of addiction and dependency.
- Article 12.05**     **Use of Alcohol:** This is strictly prohibited when taking controlled substances. Combining alcohol and pain medications results in an additive effect that may result in death. The purposeful intake of alcohol with pain medications demonstrate reckless behavior which will result in the immediate cessation of therapy.
- Article 12.06**     **Illegal Drug use:** This is strictly prohibited and may lead to discharge from the program. All substances deemed to be illegal at the federal and/or state level are included under this section. Substances derived from Cannabis (Marijuana) will continue to be included under this section, as long as they remain illegal under state or federal laws.

## **SECTION 13 - STATE AND FEDERAL LAWS:**

- Article 13.01**     **State and Federal Laws and Regulations:** Patients are expected to follow State and Federal Laws and Regulations at all times. “*Ignorantia juris non excusat*” or “*Ignorantia legis neminem excusat*” (Latin for “**ignorance of the law does not excuse**” or “**ignorance of the law excuses no one**”) is a legal principle holding that a person who is unaware of a law may not escape liability for violating that law merely because he or she was unaware of its content. **Presumed knowledge of the law** is the principle in jurisprudence that one is bound by a law even if one does not know of it. It has also been defined as the “prohibition of ignorance of the law”. The doctrine assumes that the law in question has been properly published and distributed, for example, by being made available over the internet, or in readily available and affordable publications.
- Article 13.02**     Please see ***Appendix 01*** for statutes.

## **SECTION 14 - TERMINATION OF THERAPY AND/OR DISCHARGE FROM THE PROGRAM:**

- Article 14.01**     **Reasons for Discharge from program:** The following are some of the reasons for termination of therapy and discharge from the program. These include, but are not limited to:
- (01)** Aggressive, threatening, disruptive, disrespectful, or belligerent behavior towards our staff.
  - (02)** Determination that the patient requires the services of a different specialist. (Psychiatrist, Addictionologist, etc.)
  - (03)** Doctor-Shopping.
  - (04)** Inability or unwillingness to accept responsibility of care.
  - (05)** Inappropriate use of medications: any substance abuse, misuse, or diversion.
  - (06)** Irreparable damage to Physician-Patient relationship.
  - (07)** Non-compliance.
  - (08)** Not paying bills (Outstanding bills).

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- (09) Patient-initiated end of relationship: (moving, dissatisfied, cost, disappointment with results, unmet expectations, disagreement with policies, written notification of termination of consent).
- (10) Prescription tampering or forgery.
- (11) Providing deceptive, inaccurate or incomplete information.
- (12) Tampering with monitoring tests (UDST) or tools (questionnaires).
- (13) Unsafe or reckless behavior.
- (14) Unwillingness to comply with safety regulations or recommendations.

**Article 14.02** **Reasons for termination of therapy:** The following is a list of some of the reasons why therapy may be stopped or discontinued. These reasons include, but are not limited to:

- (01) All reasons listed under **Article 14.01** of this policy.
- (02) Acute psychiatric instability or high suicide risk.
- (03) Allergic reaction(s) to opioid/opiate therapy.
- (04) Any present, or undisclosed past substance abuse, misuse, or diversion.
- (05) Arrest related to opioid or illicit drug or alcohol intoxication or effects.
- (06) Chronic obstructive pulmonary disease (COPD) patients with evidence of worsening symptoms due to opioid/opiate therapy.
- (07) Decreased functional status or quality of life, attributable to therapy.
- (08) Development of addiction to prescribed medications.
- (09) Development of adverse effects to therapy.
- (10) Driving while impaired (DWI) or Driving Under the Influence (DUI) of drugs or alcohol.
- (11) Illegal substance use.
- (12) Illegal use of drugs.
- (13) Inability or unwillingness to comply with medication policy.
- (14) Inability to manage opioid therapy responsibly (e.g., cognitively impaired)
- (15) Intentional overdose or suicide attempt.
- (16) Non-physiological response to opioid/opiate therapy.
- (17) Opioid/opiate abuse, misuse, or diversion. (i.e.: sale or provision of opioids to others).
- (18) Overdose or overuse of opioids/opiates, due to unsafe use of medication.
- (19) Patient with sleep apnea not on Continuous Positive Airway Pressure (CPAP), with evidence of worsening symptoms due to opioid/opiate therapy.
- (20) Patient-initiated end of therapy. (i.e.: request to avoid highly addictive therapies)
- (21) Rapid development of tolerance requiring frequent dose escalation.
- (22) Rapid or ultra-rapid opioid/opiate metabolizer.
- (23) Stealing or "borrowing" drugs from others.
- (24) Suspected development of opioid hyperalgesia.
- (25) Uncooperative, threatening, or belligerent behavior in the clinic.
- (26) Unresponsiveness to opioid/opiate therapy at reasonable doses.
- (27) Unwillingness or inability to comply with treatment plan.
- (28) Unwillingness to adjust at-risk activities resulting in serious re-injury.
- (29) Unwillingness to provide consent for therapy.
- (30) Violations to Pain Program's Medication Policy and/or agreements.

**Article 14.03** **Transfer of Medical Records:** Copies of the patient's medical records can be released to your new physician upon receiving the properly signed release forms.

**Article 14.04** **Referral to another program:** NCPMS will reasonably assist patients with a referral to another program, as long as this does not represent unethical behavior on our part. This means that we would not refer to another program a patient that

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

we would not want referred to ours. Exceptions to this rule are patients being referred to a psychiatric-based program or an addictionologist. We understand that because of their expertise, these programs can accept patients that we would not. Patients are required to get their referrals from their Primary Care Physicians.

## **SECTION 15 - DISCLAIMERS:**

- Article 15.01**     **Promises and/or assurances made by other practices:** NCPMS is not obligated or bound by any promises, statements, inferences, or assurances made by any healthcare practice(s), other than ours. Specifically, NCPMS discourages referring practices from sending patients to our program, telling them that we will take over their medication management. Even more important, we strongly discourage the practice of giving patients enough medication to last, only until they come in to see us. In fact, as stated above, even in those cases where we will eventually be taking over the patient's medication regimen, we do not prescribe any opioids/opiates during their initial evaluation, or until their second scheduled appointment.
- Article 15.02**     **Safety:** Patients that omits, hide, manipulate, distort, deceit, misinform, or simply lie to us about any and all information requested, are taking their lives into their own hands. Accurate and complete information is the only means by which NCPMS can try to keep a patient, their family, and other casually related members of society, out of harm's way.
- Article 15.03**     **Patient's responsibilities and due diligence:** It must be recognized that NCPMS resources are limited. As such, it is impossible for our healthcare provider(s) to be present alongside all of our patients 24 hours a day, day after day. Because of this, it is imperative that all patients/clients and their families understand their role, responsibilities, and participation in the treatment. NCPMS makes available a considerable amount of information material (in several formats, and thru several means of communication) aimed at keeping our patients safe and out of harm's way. However, it is the patient's responsibility to read, learn, and use/follow that information. It is also the patient's responsibility to promptly notify us, if there is a problem. NCPMS and its affiliates, is/are incapable of solving and/or treating a problem, side-effect, or complication, if the patient and/or family neglects to communicate with us.

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

## **APPENDIX 01 – RELATED LAWS AND STATUTES:**

### **NORTH CAROLINA GENERAL STATUTES § 90-95.1. CONTINUING CRIMINAL ENTERPRISE**

(a) Any person who engages in a continuing criminal enterprise shall be punished as a Class H felon and in addition shall be subject to the forfeiture prescribed in subsection (b) of this section.

(b) Any person who is convicted under subsection (a) of this section of engaging in a continuing criminal enterprise shall forfeit to the State of North Carolina:

(1) The profits obtained by the person in the enterprise, and

(2) Any of the person's interest in, claim against, or property or contractual rights of any kind affording a source of influence over, such enterprise

### **NORTH CAROLINA GENERAL STATUTES § 90-108. ARTICLE 5 – NORTH CAROLINA CONTROLLED SUBSTANCE ACT. PROHIBITED ACTS; PENALTIES.**

(a) It shall be unlawful for any person:

(9) To use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(10) To acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(11) To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this Article, or any record required to be kept by this Article;

(13) To obtain controlled substances through the use of legal prescriptions which have been obtained by the knowing and willful misrepresentation to or by the intentional withholding of information from one or more practitioners;

### **NORTH CAROLINA GENERAL STATUTES § 14-2.6 PUNISHMENT FOR SOLICITATION TO COMMIT A FELONY OR MISDEMEANOR**

(a) Unless a different classification is expressly stated, a person who solicits another person to commit a felony is guilty of a felony that is two classes lower than the felony the person solicited the other person to commit, ...

(b) Unless a different classification is expressly stated, a person who solicits another person to commit a misdemeanor is guilty of a Class 3 misdemeanor. (1993, c. 538, s. 6.1; 1994, Ex. Sess., c. 22, s. 13, c. 24, s. 14(b).)

# **NC PAIN MANAGEMENT SERVICES POLICY 002**

## **NORTH CAROLINA GENERAL STATUTES § 14-3 PUNISHMENT OF MISDEMEANORS, INFAMOUS OFFENSES, OFFENSES COMMITTED IN SECRECY AND MALICE, OR WITH DECEIT AND INTENT TO DEFRAUD, ...**

(b) If a misdemeanor offense as to which no specific punishment is prescribed be infamous, done in secrecy and malice, or with deceit and intent to defraud, the offender shall, except where the offense is a conspiracy to commit a misdemeanor, be guilty of a Class H felony.

## **NORTH CAROLINA GENERAL STATUTES § 14-18 PUNISHMENT FOR MANSLAUGHTER**

Involuntary manslaughter shall be punishable as a Class F felony.

## **NORTH CAROLINA GENERAL STATUTES § 14-401.20 DEFRAUDING DRUG AND ALCOHOL SCREENING TESTS; PENALTY**

(a) It is unlawful for a person to do any of the following:

(2) Attempt to foil or defeat a drug or alcohol screening test by the substitution or spiking of a sample ...

(b) It is unlawful for a person to do any of the following:

(1) Adulterate a urine or other bodily fluid sample with the intent to defraud a drug or alcohol screening test.

(2) Possess adulterants that are intended to be used to adulterate a urine or other bodily fluid sample for the purpose of defrauding a drug or alcohol screening test.

## **NORTH CAROLINA GENERAL STATUTES § 90-95. ARTICLE 5 – NORTH CAROLINA CONTROLLED SUBSTANCE ACT. VIOLATIONS; PENALTIES.**

(a) Except as authorized by this Article, it is unlawful for any person:

(1) To manufacture, sell or deliver, or possess with intent to manufacture, sell or deliver, a controlled substance;

(3) To possess a controlled substance.

## Alamance Regional Medical Center

1236 Huffman Mill Road  
Burlington, NC 27215  
Pain Management Centers  
Opioid Informed Consent Form

### Chronic Opioid/Opiate Informed Consent Form

**Purpose:** to legally document the process by which the healthcare provider, **NC Pain Management Services PA (NCPMS)**, has communicated to me the risks and possible complications associated with the treatment with opioids/opiates. Once completed, I will decide whether or not to authorize **NC Pain Management Services, PA (NCPMS)** and its affiliate(s) to proceed with it.

**Diagnostic indications:** Chronic Pain.

**Purpose of Therapy:** To assist in managing the patient's pain.

**Benefits:** Therapy should decrease the patient's pain therefore allowing him/her to be more functional and productive, while at the same time decreasing the visits to healthcare professionals and emergency departments, and decreasing the overall cost of healthcare, due to the uncontrolled pain.

**Risks and benefits of not undergoing this type of therapy:** Some of the possible **risks** of not undergoing this type of therapy include but are not limited to: uncontrolled chronic pain; decrease functionality and productivity due to painful restrictions; possible psychological and physical deterioration. The possible **benefits** of not undergoing this type of therapy include but are not limited to: avoiding side-effects, risks, responsibilities, and possible complications directly associated with the therapy.

#### Possible Alternatives to this therapy:

- Doing nothing.
- Using drugs other than opioids/opiates, such as muscle relaxants, non-steroidal anti-inflammatory medications, membrane stabilizers, etc..
- Using interventional pain management techniques.
- Using implantable devices.
- Corrective surgery.
- Physical therapy.
- Alternative medicine techniques.

**Note:** Some of these alternatives, although possible, are outside of the scope of this practice, or outside of recommended acceptable medical Guidelines.

**Benefits of alternative therapies:** Similar to those of this therapy.

**Risks of alternative therapies:** Each alternative has its own set of risks and possible complications. Attempting to describe each is beyond the scope of this document. Overall, they can be similar to those of this type of therapy, except for those of addiction, which tends to be more common, but not unique, to opioids/opiates.

#### Definitions:

- **Narcotics:** Any of a group of highly addictive analgesic drugs derived from opium or opium-like compounds. Narcotics can cause drowsiness and significant alterations of mood and behavior. The term is often used interchangeable to denote both opioids, and opiates.
- **Opioid:** Opioid is a blanket term used for any drug which binds to the opioid receptors in the central nervous system (CNS). Opioids include all of the opiates as well as any synthesized drug that attaches itself to the CNS or gastrointestinal tract opioid receptors. Synthetic Opioids include: **Methadone**, Pethidine, **Meperidine (Demerol)**, **Fentanyl**, Alfentanil, Sufentanil, Remifentanil, Carfentanil, Pentazocine, Phenazocine, **Tramadol (Ultram or Ultracet)**, and Loperamide.
- **Opiate:** Opiate is an often-misused term. Any drug which affects the opioid receptors is often incorrectly labeled an opiate, however by definition, opiates refer to alkaloids extracted from poppy pods and their semi-synthetic counterparts which bind to the opioid receptors. Basically to be called an opiate one has to either be a natural opioid receptor agonist or start the refining process with one of the natural alkaloid molecules.

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Once chemically altered, such as the process of converting Morphine into Heroin, the drug is then labeled a semi-synthetic opiate or semi-synthetic opioid - the terms can be used interchangeably. This distinction can be a little confusing since Morphine, Codeine and Thebaine are all pure alkaloids that bind to the Opioid receptors, but Papaverine, which is also a naturally occurring alkaloid inside the poppy pod is not an opiate because it does not act on the opioid receptors. Natural Opiates are: Morphine, Codeine and Thebaine. Semi-synthetic opiates (or semi-synthetic opioids) are: Heroin (diamorphine), Oxycodone, Hydrocodone, Dihydrocodeine, Hydromorphone, Oxymorphone, Buprenorphine, Etorphine, Naloxone and Naltrexone.

- **Withdrawals:** Withdrawal syndrome is most commonly used to describe the group of symptoms that occurs upon the abrupt discontinuation/separation or a decrease in dosage of the intake of medications, recreational drugs, and/or alcohol. In order to experience the symptoms of withdrawal, one must have first developed a physical dependence (often referred to as chemical dependency). This happens after consuming one or more of these substances for a certain period of time, which is both dose dependent and varies based upon the drug consumed. Contrary to withdrawals from alcohol or benzodiazepine (VALIUM, ATIVAN, XANAX, etc.), narcotic withdrawals are, for the most part, not lethal. In the case of short acting narcotics, such as morphine, withdrawals can occur 12 to 14 hours after the last dose, reaching their peak at 48 to 72 hours, and disappearing in 7 to 10 days. With longer acting narcotics, such as methadone, withdrawals can begin 24 to 48 hours after the last dose, reaching a peak at the 3<sup>rd</sup> day, and may not begin to decrease until the 3<sup>rd</sup> week. They usually consist of lacrimation, runny nose, yawning, sweating, dilated pupils, loss of appetite, goose bumps, restlessness, irritability, tremors, insomnia, sneezing, weakness, depression, nausea, vomiting, diarrhea, abdominal cramps, chills, bone and muscle pains, increased in respiratory rate, heart rate and blood pressure, muscle spasms, cold and hot flashes, increase in body temperature, anxiety, and a feeling of being ready to “climb up the walls” or “jump out of your skin”. For the most part, withdrawals are more severe for the short-acting narcotics than for the long-acting.
- **Tolerance:** This is what happens when the patient’s medicines are no longer as effective as they use to. Tolerance may develop to the effects of many drugs, especially the opioids, barbiturates, and other CNS (central nervous system) depressants. When this occurs, *cross-tolerance* may develop to the effects of pharmacologically related drugs. Tolerance to a pain medication will be manifested as an increase in pain after the frequent use of the analgesic (pain medication). Tolerance has been described to develop in as short as 10 days. Although this process may take as long as a year in some patients, it is safe to assume that it will occur to everybody who takes this type of medication on a regular basis. A common complaint of patients is that, *“the medications don’t seem to work as well as they use to.”*
- **Physical Dependence:** (Also known as *Physiological Dependence*) Refers to a state resulting from chronic use of a drug that has produced *tolerance* and where physical symptoms of *withdrawal* result from abrupt discontinuation or dosage reduction. Physical dependence can develop from low-dose therapeutic use of certain medications as well as misuse of recreational drugs such as alcohol. The higher the dose used typically the worse the physical dependence and thus the worse the withdrawal symptoms.
- **Addiction:** The concept of drug addiction has many different definitions: According to the current Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), substance dependence is defined as: *“When an individual persists in use of alcohol or other drugs despite problems related to use of the substance, substance dependence may be diagnosed. Compulsive and repetitive use may result in tolerance to the effect of the drug and withdrawal symptoms when use is reduced or stopped. This, along with Substance Abuse are considered Substance Use Disorders....”* The American Society of Addiction Medicine has defined addiction as a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in the individual pursuing reward and/or relief by substance use and other behaviors. The addiction is characterized by impairment in behavioral control, craving, inability to consistently abstain, and diminished recognition of significant problems with one’s behaviors and interpersonal relationships. Like other chronic diseases, addiction involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death. Federal Law defines an “Addict” as “someone who has lost self-control over their own medications”.

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- **Drug Holidays:** Also known as “Short-Term Detoxification”. This is the name given to the period of time during which the opioid/opiate are stopped for the purpose of treating tolerance to the medications. During the Drug Holidays, because of *cross-tolerance*, patients will not be allowed to switch to another opioid/opiate. When returning to the opioid/opiate, at the end of the Drug Holiday, the patient is likely to be started at a lower dose than the dose prior to the Drug Holiday. They should be repeated as often as necessary to allow the patient to control his/her medication tolerance, rather than allowing the medication to control the patient. Drug Holidays are done as outpatients. They can be monitored by physicians, but they are primarily managed by the patients. Because they demonstrate the patient’s ability for self-control, they serve as evidence of non-addiction. The opposite is also true. Patients that do not comply with this requirement. Federal Law defines an “Addict” as “someone who has lost self-control over their own medications”. Following this definition, it then states that “it is illegal for any physician to prescribe narcotics to an ‘addict’.” Because of this, any patients refusing to undergo a “Drug Holiday”, may be considered as having lost self-control over their medications, subsequently triggering the permanent cessation of all controlled substances by the prescribing physician. The other side of that coin is that by complying with the “Drug Holidays”, the patient demonstrates that he/she continues to have self control over their own medicines, and therefore, it makes it legal for the treating physician to continue prescribing the pain medication.

**Directions:** By signing my initials next to each statement, I am certifying that I have read it and that I clearly understand it. (For this following section, placing your initials next to each statement simply means that it has been read and understood.)

- \_\_\_\_\_ **Item 01:** I recognize that **NC Pain Management Services, PA (NCPMS)** does not represent my only choice of pain specialists and that there are other Pain Management Practices in close proximity and within reasonable driving distance.
- \_\_\_\_\_ **Item 02:** I am aware that as a prerequisite to entering this program, I must have an active, current Primary Care Physician (**PCP**) (Family Doctor, General Practitioner, or Internist), in charge of my general medical needs.
- \_\_\_\_\_ **Item 03:** I understand that before I can be prescribed any opioids/opiates, **NC Pain Management Services, PA (NCPMS)** and its affiliate(s), will evaluate the appropriateness of prescribing opioid/opiate medicine(s), sometimes called narcotic analgesic(s), to me for the treatment of my "Chronic Pain". This type of therapy is being considered at my request, because I believe my condition to be serious enough to warrant it, or other treatments have not helped my pain.
- \_\_\_\_\_ **Item 04:** I am aware that I am required to tell my doctor my complete and honest personal drug history and that of my family, to the best of my knowledge.
- \_\_\_\_\_ **Item 05:** I am aware that I need to **always tell my physicians the truth**, all of the truth, and nothing but the truth, and that I should **never omit** anything when it comes to my current and past medical history, including all substances, legal and illegal, that I may be using, or may have used. I have been informed and clearly understand that not **doing so may endanger my life** and/or hinder my physician’s ability to keep me away from harm.
- \_\_\_\_\_ **Item 06:** I am aware that in the event that I no longer want to continue with this type of therapy, all I have to do is to notify my physician.
- \_\_\_\_\_ **Item 07:** I am aware that there are **other types of treatments** that my doctor may want to try, in order to keep my pain and the use of these medications, to a minimum.
- \_\_\_\_\_ **Item 08:** I have been made aware of the fact that as part of the evaluation and monitoring program, **NCPMS** may conduct criminal and medication background checks, as well as psychological and functional screening tests, for the purpose of assessing my case, my particular risks and my compliance.

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- \_\_\_\_\_ **Item 09:** I understand that my physician may need to contact and communicate with any of my prior and/or current healthcare professionals, family members, pharmacies, legal authorities, or regulatory agencies, to obtain or provide information about my care or actions, *if the NCPMS' physician feels it is necessary.*
- \_\_\_\_\_ **Item 10:** I am aware that the use of opioid/opiate medications has certain **risks associated with it**, including, but not limited to, **addiction**, overdose, **death**, sleepiness or drowsiness, cognitive impairment, constipation, nausea, itching, vomiting, dizziness, allergic reaction, slowing of breathing rate, slowing of reflexes or reaction time, and possibility that the medicine will not provide complete pain relief.
- \_\_\_\_\_ **Item 11:** I am aware that some of these medications can be **harmful and even lethal**, when taken inappropriately.
- \_\_\_\_\_ **Item 12:** I am aware that these medications can be **lethal when ingested by a minor** and that I am responsible for the medication's safe keeping, storage, and handling.
- \_\_\_\_\_ **Item 13: (Males only)** I am aware that chronic opioid use has been associated with low testosterone levels in males. This may effect my mood, stamina, sexual desire and physical and sexual performance. I understand that my doctor may check my blood to see if my testosterone level is normal.
- \_\_\_\_\_ **Item 14: (Females Only)** If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to delivery while taking these medicines, the baby will be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that my child will have a birth defect while I am taking an opioid.
- \_\_\_\_\_ **Item 15:** I am aware that even if I do not notice it, my reflexes and reaction time might still be affected by the use of these medications.
- \_\_\_\_\_ **Item 16:** I am aware that I should never be involved in any activity that may be dangerous to me or someone else, if I feel drowsy or if I am not thinking clearly. I understand this to mean that **I should not drive, operate heavy machinery, or handle any weapons, while under the influence and effects** of these type of medications. Other activities that I should avoid may include, but are not limited to: working in a dangerous environment, or around unprotected heights, or being responsible for other individuals who are unable to care for themselves.
- \_\_\_\_\_ **Item 17:** I am aware that becoming addicted to opioid/opiate pain medications is possible. I am aware that **addiction** is defined as the use of a substance even if it causes harm, having cravings for a drug, or feeling the need to use a drug, despite the consequences. I am also aware that the development of addiction is much more common in a person who has a family or personal history of addiction.
- \_\_\_\_\_ **Item 18:** I have been informed and understand that **I will develop physical dependence** to these medications, as a result of using them. I understand that physical dependence is not the same as addiction. I am aware physical dependence means that if I markedly decrease or stop my medication, I will experience a withdrawal syndrome. This means that I may develop any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawals can be very uncomfortable.
- \_\_\_\_\_ **Item 19:** I have been informed that there is a condition associated with the use of opioids/opiates, known as "**Opioid Hyperalgesia**". I understand this to be a condition where the pain medication actually makes me experience more pain by making me more susceptible to it. I am also aware that if I develop this, I will need to be taken off of these type of medications.

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- \_\_\_\_\_ **Item 20:** I have been informed and understand that **I will develop tolerance** to these medications. I understand this to mean that with time, I will get use to them and they will no longer be effective in controlling my pain. I am aware that **tolerance** means that I may require more medicine to get the same amount of pain relief. If it occurs, increasing doses may not always help and may cause unacceptable side effects. I am aware and understand that tolerance and/or failure to respond well to opioids may cause my doctor to choose another form of treatment.
- \_\_\_\_\_ **Item 21:** I understand that **NCPMS** uses “**Drug Holidays**” rather than “**Opioid Rotation**” to treat Tolerance and/or diagnose “**Opioid Hyperalgesia**”. I am aware that this is an integral part of this program’s medication management.
- \_\_\_\_\_ **Item 22:** I understand a “**Drug Holiday**” to be a period of no less than 14 consecutive days, during which I will take myself completely off of all opioid/opiate medication, with the permission and approval of my pain physician, for the purpose of counteracting the effects of tolerance. I am aware that this is usually done as an outpatient, and that during this period I will experience withdrawals.
- \_\_\_\_\_ **Item 23:** I am aware that combining these medications with certain other substances, such as **alcohol** or illegal drugs can cause undesirable effects, such as respiratory depression and death.
- \_\_\_\_\_ **Item 24:** I am also aware that combining these medications with other substances, including prescription drugs or antibiotics can result in serious complications (including death) and therefore, I am responsible for always consulting my pharmacist about possible **drug-to-drug interactions**, including with over-the-counter medications.
- \_\_\_\_\_ **Item 25:** I am aware that certain other medicines such as nalbuphine (Nubain™), pentazocine (Talwin™), buprenorphine (Buprenex™), and butorphanol (Stadol™), may reverse the action of the medicine I am using for pain control. Taking any of these other medicines while I am taking my pain medicines can cause bad flu-like symptoms, called “**withdrawal syndrome**” or “**abstinence syndrome**”.
- \_\_\_\_\_ **Item 26:** I am aware that I should **never take more pain medicine than prescribed**, without the express written consent of my pain management physician. In addition to the risk of being discharged from the program, I also understand that doing so can result in my **death**, due to **overdosing**.
- \_\_\_\_\_ **Item 27:** I am aware that I am responsible for **keeping these medications under lock and key**, in a safe place, away from the reach of children and everyone else but me, even if I live alone.
- \_\_\_\_\_ **Item 28:** I am aware that I will need to **tell my doctor about all other medicines** and treatments that I am receiving.
- \_\_\_\_\_ **Item 29:** I am aware that I should **never solicit or accept** any other **pain medication(s), from any other source(s)**, other than from this pain program, without the specific written consent of my pain management physician. I also understand that this means that I am responsible for notifying all other healthcare providers involved in my care that I have agreed to receive pain medications from **NCPMS only**. Furthermore, I am aware that obtaining pain medications from more than one physician constitutes “**Doctor Shopping**”, which is illegal in the state of North Carolina.
- \_\_\_\_\_ **Item 30:** I am aware and agree to follow my doctor's recommendations to go into a “**Drug Holiday**”, as described in my orientation package.
- \_\_\_\_\_ **Item 31:** I am aware that **NCPMS’** medication monitoring program requires frequent, unannounced drug screening tests.
- \_\_\_\_\_ **Item 32:** I understand that “**inconsistent**” or “**unexpected**” **drug screening tests results**, and/or tampering with the test will lead to immediate secession of therapy and dismissal from the program.

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- \_\_\_\_\_ **Item 33:** I understand that failure to comply with **NCPMS' "Medication Policy"** may result in the immediate discontinuation of the controlled substances been prescribed, as well as possible discharge from the program.
- \_\_\_\_\_ **Item 34:** I am also aware and understand that failure to follow my doctor's orders will result in my discharge from the program. I also understand that if this occurs, my doctor will not be responsible for referring me to another program or doctor.
- \_\_\_\_\_ **Item 35:** I have been made aware of the **reasons for termination of therapy**. These include, but are not limited to: unsafe use of medications and/or behavior; non-compliance due to inability to do so; development of addiction; suicidal risks; having adverse reactions, uncontrollable side-effects, or non-physiological responses to the therapy; lack of efficacy; resolution of the pain; and desire to discontinue therapy.
- \_\_\_\_\_ **Item 36:** In addition, I have also been made aware of the **reasons for termination of therapy, and/or patient-physician relationship, with possible discharge from the practice**. These include, but are not limited to: unsafe use of medications and/or behavior; non-compliance due to unwillingness (losing medications; not bringing medications to appointments; non-compliance with safe storage practices; non-compliance with medication policy; not following treatment Agreements; and/or not keeping scheduled appointments, tests, or consults); not following State and/or Federal statutes/Laws/regulations associated with controlled substances.
- \_\_\_\_\_ **Item 37:** I understand that signing this document does not mean that my pain physician is obligated in any way to prescribe or continue prescribing any of these medications to me.
- \_\_\_\_\_ **Item 38:** I understand that this document is self renewable, on a yearly basis.
- \_\_\_\_\_ **Item 39:** I understand that it is my responsibility to keep my family informed of the risks associated with this therapy and the fact that they will need to assist and participate in the responsibility of monitoring my use or misuse of these substances.
- \_\_\_\_\_ **Item 40:** Furthermore I understand that under the rules of this program, it is felt that for my own safety and that of others, it is strongly recommended and preferred that I share the entire content of this document with my family, as well as the responsibilities stipulated herein.
- \_\_\_\_\_ **Item 41:** I understand that once I begin to get opioid/opiate prescriptions from the **NCPMS** program, I am not to get any more narcotics from any other practices, including during emergency room visits. In addition, I understand that I should always inform my physician of all medications that I am taking, including herbal remedies, since opioid medications can interact with over-the-counter medications and other prescribed medications, especially cough syrup that contains alcohol, codeine or hydrocodone.
- \_\_\_\_\_ **Item 42:** I understand that by voluntarily signing below, I acknowledge the above information, accept the risks and responsibilities of this type of therapy, and I give **NC Pain Management Services, PA (NCPMS)** and its affiliate(s) my consent to treat me and my pain with opioids/opiates, and if necessary, to discontinue therapy.

**Directions:** This following section is to be signed only if you have completely read the above risks and responsibilities, understand them, and are willing to accept those and give permission for the therapy. This consent section will need to be signed before any opioid/opiate pain medications are prescribed by this program or its affiliates.

**I hereby certify that I have read this form or have had it read to me, that I understand all of it, and that I have had a chance to have all of my questions answered to my satisfaction. By voluntarily signing this form, I accept the risks and responsibilities associated with this type of therapy, and I give NC Pain Management Services, PA**

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**(NCPMS)** and its affiliate(s) my consent to treat me and my pain with opioids/opiates, and if necessary, to discontinue therapy. I agree that should I decide to terminate this agreement, I will do so in writing.

Patient's Name \_\_\_\_\_ Date of birth \_\_\_\_/\_\_\_\_/\_\_\_\_

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

**Receipt of Medical Information**

I acknowledge having received and being responsible for reading the content of the "**Medication Policy**" handout.

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

**Family Acknowledgement**

I hereby certify being the elected family representative (executor/administrator of the estate). By voluntarily signing this form, I acknowledge that the above signed patient and family member has shared the above information with the family, allowing us to be aware of the risks and responsibilities associated with this type of therapy.

Family Representative's Name \_\_\_\_\_ Relationship: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

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### Chronic Opioid/Opiate Medication Agreement Form

**Purpose:** to clearly establish the treatment boundaries for the prescription of opioids/opiates.

**Directions:** By signing my initials next to each statement, I am certifying that I have read it, that I clearly understand it, and that I agree to follow it.

- \_\_\_\_\_ **Item 01:** I agree to have an active and current Primary Care Physician (**PCP**) (Family Doctor, General Practitioner, or Internist), at all times.
- \_\_\_\_\_ **Item 02:** I agree to **fully cooperate**, participate, and answer any evaluations, questionnaires, tests, and consults that NCPMS may believe to be necessary for my care, and medication monitoring.
- \_\_\_\_\_ **Item 03:** I agree to tell my doctor my complete and honest personal drug history and that of my family, to the best of my knowledge.
- \_\_\_\_\_ **Item 04:** I agree to **tell my doctor about all other medicines** and treatments that I am receiving.
- \_\_\_\_\_ **Item 05:** I agree to **always tell** my physicians **the truth**, all of the truth, and nothing but the truth, and **never to omit** anything when it comes to my current and past medical history, including all substances, legal and illegal, that I may be using, or may have used.
- \_\_\_\_\_ **Item 06:** I agree to **allow NCPMS to conduct** criminal and medication background checks, as well as psychological and functional screening tests, for the purpose of assessing my case, my particular risks and my compliance.
- \_\_\_\_\_ **Item 07:** I agree to **allow my physician to contact** and communicate with any of my prior and/or current healthcare professionals, family members, pharmacies, legal authorities, or regulatory agencies, to obtain or provide information about my care or actions.
- \_\_\_\_\_ **Item 08:** I agree to **NCPMS'** medication monitoring program and its frequent, unannounced drug screening tests.
- \_\_\_\_\_ **Item 09:** I agree to submit myself to random drug testing.
- \_\_\_\_\_ **Item 10:** I agree to comply with **NCPMS' "Medication Policy"**.
- \_\_\_\_\_ **Item 11:** I agree to abide by the rules of this program.
- \_\_\_\_\_ **Item 12:** I agree to notify **NCPMS** if I no longer want to continue with this type of therapy.
- \_\_\_\_\_ **Item 13:** I agree **not to** call requesting medication refills over the phone.
- \_\_\_\_\_ **Item 14:** I agree to request refills of my medications only during my regular appointment.
- \_\_\_\_\_ **Item 15:** I agree **not to** request prescriptions or refills after normal business hours, nights, holidays, or weekends.
- \_\_\_\_\_ **Item 16:** I agree to always bring my medications to the appointments.
- \_\_\_\_\_ **Item 17:** I agree never to share, give, lend, or sell any of my medication to anyone.
- \_\_\_\_\_ **Item 18:** I agree to always check with my pharmacist whenever I am given a new medication.

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- \_\_\_\_\_ **Item 19:** I agree to **keep** these medications **away from the reach of children** and other adults.
- \_\_\_\_\_ **Item 20:** I agree to be responsible for the medication's **safe keeping, storage, and handling**.
- \_\_\_\_\_ **Item 21:** I agree to notify my physician of any **side effects or adverse reactions** that I may be experiencing from the medications.
- \_\_\_\_\_ **Item 22: (Females only)** I agree to notify NCPMS if I became **pregnant**, or are planning to become pregnant.
- \_\_\_\_\_ **Item 23:** I agree to never be involved in any activity that may be dangerous to me or someone else, such as driving, operating heavy machinery, handling any weapons, working in a dangerous environment, or around unprotected heights, or being responsible for other individuals who are unable to care for themselves, **while under the influence and effects** of these type of medications.
- \_\_\_\_\_ **Item 24:** I agree to notify my physician, if I suspect that I have become addicted to these medications.
- \_\_\_\_\_ **Item 25:** I agree to undergo "**Drug Holidays**" when requested by my physician.
- \_\_\_\_\_ **Item 26:** I agree never to combine these opioids/opiate medications with other substances, such as **alcohol** or alcohol containing medications (cough syrups), or illegal drugs/substances.
- \_\_\_\_\_ **Item 27:** I agree to be responsible for always consulting my **pharmacist** about possible **drug-to-drug interactions**, when taking other medications such as antibiotics, dietary supplements, "Medical Food", and any other over-the-counter medications.
- \_\_\_\_\_ **Item 28:** I agree to inform all of my healthcare providers that I am receiving opioid/opiate narcotics from **NCPMS**, and reminding them not to prescribe any medications that would contain similar drugs, or may interact with my medications.
- \_\_\_\_\_ **Item 29:** I agree **never take more pain medicine than prescribed**.
- \_\_\_\_\_ **Item 30:** I agree to **keep these medications under lock and key**, in a safe place, away from the reach of children and everyone else but me, even if I live alone.
- \_\_\_\_\_ **Item 31:** I agree **never solicit or accept** any other **pain medication(s), from any other source(s)**, other than from this pain program.
- \_\_\_\_\_ **Item 32:** I understand that signing this document does not mean that my pain physician is obligated in any way to prescribe or continue prescribing any of these medications to me.
- \_\_\_\_\_ **Item 33:** I understand and agree to this document being self renewable, on a yearly basis.
- \_\_\_\_\_ **Item 34:** I agree to responsible for keeping my family fully informed of the risks associated with this therapy and the fact that they will need to assist and participate in the responsibility of monitoring my use or misuse of these substances.
- \_\_\_\_\_ **Item 35:** I agree not to get any more narcotics from any other practices, including during emergency room visits, once I begin to get opioid/opiate prescriptions from **NCPMS**.
- \_\_\_\_\_ **Item 36:** I understand that by voluntarily signing below, I acknowledge the above information, accept the risks and responsibilities of this type of therapy, and I give **NC Pain Management Services, PA (NCPMS)** and its affiliate(s) my consent to treat me and my pain with opioids/opiates, and if necessary, to discontinue therapy.

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**I hereby certify that I have read this form or have had it read to me, that I understand all of it, and that I have had a chance to have all of my questions answered to my satisfaction.** By voluntarily signing this form, I agree and accept the responsibilities associated with this type of therapy. I also understand that failure to comply with the above regulations may result in the immediate discontinuation of the controlled substances been prescribed, as well as possible discharge from the program. I understand that this Agreement contains the entire agreement of the parties and supersedes and replaces all prior agreements between the parties and such other agreements shall be null and void and of no further force or effect. I also understand that this document is self renewable, on a yearly basis. I agree that should I decide to terminate this agreement, I will do so in writing. This agreement will go into effect when pain medications are prescribed by this program or its affiliates.

Patient's Name \_\_\_\_\_ Date of birth \_\_\_\_/\_\_\_\_/\_\_\_\_

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

# NC PAIN MANAGEMENT SERVICES POLICY 002

## APPENDIX 04 - NARCOTICS (OPIOIDS/OPIATES) INFORMATION

### Description

Narcotic (*nar-KOT-ik*) analgesics (*an-al-JEE-zicks*) are used to relieve pain. Some of these medicines are also used just before or during an operation to help the anesthetic work better. Codeine and hydrocodone are also used to relieve coughing. Methadone is also used to help some people control their dependence on heroin or other narcotics. Narcotic analgesics may also be used for other conditions as determined by your doctor. Narcotic analgesics act in the central nervous system (CNS) to relieve pain. Some of their side effects are also caused by actions in the CNS. If a narcotic is used for a long time, it may become habit-forming (causing mental or physical dependence). Physical dependence may lead to withdrawal side effects when you stop taking the medicine. These medicines are available only with your medical doctor's or dentist's prescription. For some narcotics, prescriptions cannot be refilled and you must obtain a new prescription from your medical doctor or dentist each time you need the medicine. In addition, other rules and regulations may apply when methadone is used to treat narcotic dependence.

### Proper Use of This Medicine

To take *long-acting morphine and oxycodone tablets* :

*These tablets must be swallowed whole. Do not break, crush, or chew them before swallowing. Take this medicine only as directed by your medical doctor or dentist. Do not take more of it, do not take it more often, and do not take it for a longer time than your medical doctor or dentist ordered. This is especially important for young children and elderly patients, who are especially sensitive to the effects of narcotic analgesics. If too much is taken, the medicine may become habit-forming (causing mental or physical dependence) or lead to medical problems because of an overdose. If you think this medicine is not working properly after you have been taking it for a few weeks, do not increase the dose. Instead, check with your doctor.*

**Dosing** - The dose of these medicines will be different for different patients. *Follow your doctor's orders or the directions on the label.* The following information includes only the average doses of these medicines. *If your dose is different, do not change it unless your doctor tells you to do so.* The number of capsules or tablets, depends on the strength of the medicine. Also, *the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the narcotic you are taking, whether or not you are taking a long-acting form of the medicine, and the reason you are taking the medicine.*

**Missed dose** - If your medical doctor or dentist has ordered you to take this medicine according to a regular schedule and you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. *Do not double doses.*

**Storage** - To store this medicine: Keep out of the reach of children. Overdose is very dangerous in young children. Store away from heat and direct light. Do not store tablets or capsules in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down. Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

### Additional Information

Once a medicine has been approved for marketing for a certain use, experience may show that it is also useful for other medical problems. Although not specifically included in product labeling, morphine by injection is used in certain pediatric patients with the following medical conditions: Pain, during mechanical ventilation, neonatal Pain, postoperative, neonatal. Other than the above information, there is no additional information relating to proper use, precautions, or side effects for these uses.

### Before Using This Medicine

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For narcotic analgesics, the following should be considered:

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**Allergies** - Tell your doctor if you have ever had any unusual or allergic reaction to any of the narcotic analgesics. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

**Pregnancy** - Although studies on birth defects with narcotic analgesics have not been done in pregnant women, these medicines have not been reported to cause birth defects. However, hydrocodone, hydromorphone, and morphine caused birth defects in animals when given in very large doses. Buprenorphine and codeine did not cause birth defects in animal studies, but they caused other unwanted effects. Butorphanol, nalbuphine, pentazocine, and propoxyphene did not cause birth defects in animals. There is no information about whether other narcotic analgesics cause birth defects in animals. Too much use of a narcotic during pregnancy may cause the baby to become dependent on the medicine. This may lead to withdrawal side effects after birth. Also, some of these medicines may cause breathing problems in the newborn infant if taken just before delivery.

**Breast-feeding** - Most narcotic analgesics have not been reported to cause problems in nursing babies. However, when the mother is taking large amounts of narcotics, the nursing baby may become dependent on the medicine. Also, butorphanol, codeine, meperidine, morphine, opium, and propoxyphene pass into the breast milk.

**Children** - Breathing problems may be especially likely to occur in children younger than 2 years of age. These children are usually more sensitive than adults to the effects of narcotic analgesics. Also, unusual excitement or restlessness may be more likely to occur in children receiving these medicines.

**Older adults** - Elderly people are especially sensitive to the effects of narcotic analgesics. This may increase the chance of side effects, especially breathing problems, during treatment.

**Other medicines** - Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking a narcotic analgesic, it is especially important that your health care professional know if you are taking any of the following:

- Carbamazepine (e.g., Tegretol) Propoxyphene may increase the blood levels of carbamazepine, which increases the chance of serious side effects.
- Central nervous system (CNS) depressants or
- Monoamine oxidase (MAO) inhibitor activity (isocarboxazid [e.g., Marplan], phenelzine [e.g., Nardil], procarbazine [e.g., Matulane], tranylcypromine [e.g., Parnate] (taken currently or within the past 2 weeks) or
- Tricyclic antidepressants (amitriptyline [e.g., Elavil], amoxapine [e.g., Asendin], clomipramine [e.g., Anafranil], desipramine [e.g., Pertofrane], doxepin [e.g., Sinequan], imipramine [e.g., Tofranil], nortriptyline [e.g., Aventyl], protriptyline [e.g., Vivactil], trimipramine [e.g., Surmontil]) The chance of side effects may be increased; the combination of meperidine (e.g., Demerol) and MAO inhibitors is especially dangerous.
- Naltrexone (e.g., Trexan) Narcotics will not be effective in people taking naltrexone.
- Rifampin (e.g., Rifadin) Rifampin decreases the effects of methadone and may cause withdrawal symptoms in people who are dependent on methadone.
- Zidovudine (e.g., AZT, Retrovir) Morphine may increase the blood levels of zidovudine and increase the chance of serious side effects.
- **Strong CYP3A inhibitors** (Cause  $\geq$  5-fold increase in AUC of sensitive CYP3A substrate):
  - atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, lopinavir/ritonavir, saquinavir/ritonavir, telithromycin
- **Moderate CYP3A inhibitors** (Cause  $\geq$  2 but  $<$  5-fold increase in AUC of sensitive CYP3A substrate)
  - aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, grapefruit juice, verapamil
- **Weak CYP3A inhibitors** (Cause  $\geq$  1.25 but  $<$  2-fold increase in AUC of sensitive CYP3A substrate)
  - Cimetidine

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- **CYP2D6 Substrates:**
  - Beta Blockers:, Carvedilol, S-metoprolol, Propafenone, timolol.
  - Antidepressants:, Amitriptyline, clomipramine, desipramine, imipramine, paroxetine.
  - Antipsychotics:, Haloperidol, perphenazine, risperidone\_9OH, thioridazine, zuclopenthixol, alprenolol, amphetamine, aripiprazole, atomoxetine, bufuralol, chlorpheniramine, chlorpromazine, codeine (\_O-desMe), debrisoquine, dexfenfluramine, dextromethorphan, duloxetine, encainide, flecainide, fluoxetine, fluvoxamine, lidocaine, metoclopramide, methoxyamphetamine, mexiletine, minaprine, nebivolol, nortriptyline, ondansetron, oxycodone, perhexiline, phenacetin, phenformin, promethazine, propranolol, sparteine, tamoxifen, tramadol, venlafaxine.
- **CYP2D6 Inhibitors:** inhibitors may slow metabolism, raising the serum level (SL), extending the duration of its effects, and possibly causing methadone-related toxicity such as oversedation and/or respiratory depression.
  - Bupropion, fluoxetine, paroxetine, quinidine, duloxetine, terbinafine, amiodarone, cimetidine, sertraline, celecoxib, chlorpheniramine, chlorpromazine, citalopram, clemastine, clomipramine, cocaine, diphenhydramine, doxepin, doxorubicin, escitalopram, halofantrine, histamine H1, receptor antagonists, hydroxyzine, levomepromazine, methadone, metoclopramide, mibefradil, midodrine, moclobemide, perphenazine, ranitidine, red-haloperidol, ritonavir, ticlopidine, tripeleminamine.
- **CYP2D6 Inducers:** Inducers increase the activity of enzymes involved in metabolism, accelerating the drug's breakdown, and increasing its rate of clearance, abbreviating the duration of effects, lowering serum level (SL), and possibly precipitating opioid-withdrawal syndrome.
  - dexamethasone
  - rifampin

**Other medical problems** - The presence of other medical problems may affect the use of narcotic analgesics. Make sure you tell your doctor if you have any other medical problems, especially:

- Alcohol abuse, or history of, or
- Drug dependence, especially narcotic abuse, or history of, or
- Emotional problems. The chance of side effects may be increased; also, withdrawal symptoms may occur if a narcotic you are dependent on is replaced by buprenorphine, butorphanol, nalbuphine, or pentazocine.
- Brain disease or head injury or
- Emphysema, asthma, or other chronic lung disease or
- Enlarged prostate or problems with urination or
- Gallbladder disease or gallstones. Some of the side effects of narcotic analgesics can be dangerous if these conditions are present
- Colitis or
- Heart disease or
- Kidney disease or
- Liver disease or
- Underactive thyroid. The chance of side effects may be increased
- Convulsions (seizures), history of Some of the narcotic analgesics can cause convulsions

## Precautions While Using This Medicine

If you will be taking this medicine for a long time (for example, for several months at a time), your doctor should check your progress at regular visits.

Narcotic analgesics will add to the effects of alcohol and other CNS depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies, or colds; sedatives, tranquilizers, or sleeping medicine; other prescription pain medicines including other narcotics; barbiturates; medicine for seizures; muscle relaxants; or anesthetics, including some dental anesthetics. *Do not drink alcoholic beverages, and check with your medical doctor or dentist before taking any of the medicines listed above, while you are using this medicine.*

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This medicine may cause some people to become drowsy, dizzy, or lightheaded, or to feel a false sense of well-being. *Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or are not alert and clearheaded.*

Dizziness, light-headedness, or fainting may occur, especially when you get up suddenly from a lying or sitting position. Getting up slowly may help lessen this problem.

Nausea or vomiting may occur, especially after the first couple of doses. This effect may go away if you lie down for a while. However, if nausea or vomiting continues, check with your medical doctor or dentist. Lying down for a while may also help relieve some other side effects, such as dizziness or light-headedness, that may occur.

Before having any kind of surgery (including dental surgery) or emergency treatment, tell the medical doctor or dentist in charge that you are taking this medicine.

Narcotic analgesics may cause dryness of the mouth. For temporary relief, use sugarless candy or gum, melt bits of ice in your mouth, or use a saliva substitute. However, if dry mouth continues for more than 2 weeks, check with your dentist. Continuing dryness of the mouth may increase the chance of dental disease, including tooth decay, gum disease, and fungus infections.

If you have been taking this medicine regularly for several weeks or more, *do not suddenly stop using it without first checking with your doctor.* Your doctor may want you to reduce gradually the amount you are taking before stopping completely, in order to lessen the chance of withdrawal side effects.

*If you think you or someone else may have taken an overdose, get emergency help at once.* Taking an overdose of this medicine or taking alcohol or CNS depressants with this medicine may lead to unconsciousness or death. Signs of overdose include convulsions (seizures), confusion, severe nervousness or restlessness, severe dizziness, severe drowsiness, slow or troubled breathing, and severe weakness.

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention. *Get emergency help immediately if any of the following symptoms of overdose occur:*

Cold, clammy skin, confusion, convulsions (seizures), dizziness (severe) , drowsiness (severe), low blood pressure, nervousness or restlessness (severe) , pinpoint pupils of eyes, slow heartbeat, slow or troubled breathing, weakness (severe)

Also, check with your doctor as soon as possible if any of the following side effects occur:

*Less common or rare*

Dark urine (for propoxyphene only), fast, slow, or pounding heartbeat, feelings of unreality , hallucinations (seeing, hearing, or feeling things that are not there), hives, itching, or skin rash , increased sweating (more common with hydrocodone, meperidine, and methadone), irregular breathing, mental depression or other mood or mental changes, pale stools (for propoxyphene only), redness or flushing of face (more common with hydrocodone, meperidine, and methadone), ringing or buzzing in the ears, shortness of breath, wheezing, or troubled breathing, swelling of face, trembling or uncontrolled muscle movements, unusual excitement or restlessness (especially in children), yellow eyes or skin (for propoxyphene only)

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

*More common*

Dizziness, light-headedness, or feeling faint, drowsiness, nausea or vomiting

*Less common or rare*

Blurred or double vision or other changes in vision, constipation (more common with long-term use and with codeine) , decrease in amount of urine, difficult or painful urination, dry mouth, false sense of well-being, frequent urge to urinate, general feeling of discomfort or illness, headache, loss of appetite, nervousness or restlessness, nightmares or unusual dreams, redness, swelling, pain, or burning at place of injection, stomach cramps or pain, trouble in sleeping, unusual tiredness or weakness

After you stop using this medicine, your body may need time to adjust. The length of time this takes depends on the amount of medicine you were using and how long you used it. During this period of time check with your doctor if you notice any of the following side effects:

Body aches, diarrhea, fast heartbeat, fever, runny nose, or sneezing, gooseflesh, increased sweating, increased yawning, loss of appetite , nausea or vomiting, nervousness, restlessness, or irritability, shivering or trembling , stomach cramps, trouble in sleeping, unusually large pupils of eyes, weakness

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

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## ADVERSEREACTIONS

### Major hazards

- Respiratory depression
- Circulatory depression
- Respiratory arrest
- Shock
- Cardiac arrest

### Most frequent

- Lightheadedness
- Dizziness
- Sedation
- Nausea
- Vomiting
- Sweating

### Central Nervous System

- Euphoria
- Dysphoria
- Weakness
- Headaches
- Insomnia
- Agitation
- Disorientation
- Visual disturbances

### Gastrointestinal

- Dry mouth
- Anorexia
- Constipation
- Biliary tract spasms

### Cardiovascular

- Facial flushing
- Bradycardia
- Palpitations
- Faintness
- Syncope

### Genitourinary

- Urinary retention or hesitancy
- Antidiuretic effect
- Reduced libido and/or potency

### Allergic

- Pruritus
- Urticaria
- Skin rashes
- Edema
- Hemorrhagic urticaria (rarely)

### Hematologic

- Reversible thrombocytopenia

## NOTICE:

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The information about drugs contained in this website is general in nature and is intended for use as an educational aid. It does not cover all possible uses, actions, precautions, side effects, or interactions of these medicines, nor is the information intended as medical advice for individual problems or for making an evaluation as to the risks and benefits of taking a particular drug. Side effects contained herein, although possible, maybe extremely rare. Always consult your physician to assess your particular risks.

## ADDITIONAL INFORMATION

Once a medicine has been approved for marketing for a certain use, experience may show that it is also useful for other medical problems. In certain cases this would mean that the medication may not have FDA approval for a certain use, for which your physician may know it to be appropriate. FDA approval for a specific indication is usually given to those drugs for which the parent pharmaceutical company has decided to invest money in conduct inefficacy and safety studies, for the use of the medicine on that particular indication. Occasionally, the condition may be rare and the investment to profit ratio for the pharmaceutical may not warrant their interest in pursuing that indication.

## BRAND NAMES:

### In the U.S.

Astramorph PF	MS/S
Buprenex	Nubain
Cotanal-65	Numorphan
Darvon	OMS Concentrate
Darvon-N	Oramorph SR
Demerol	OxyContin
Dilaudid	PP-Cap
Dilaudid-5	Rescudose
Dilaudid-HP	RMS Uniserts
Dolophine	Roxanol
Duramorph	Roxanol 100
Hydrostat IR	Roxanol UD
Kadian	Roxicodone
Levo-Dromoran	Roxicodone Intensol
Methadose	Stadol
M S Contin	Talwin
MSIR	Talwin-Nx
MS/L	
MS/L Concentrate	

## BRAND NAMES:

### In Canada

Darvon-N	M S Contin
Demerol	MSIR
Dilaudid	Nubain
Dilaudid-HP	Numorphan
Epimorph	Oramorph SR
Hycodan #	OxyContin
Kadian	Pantopon
Leritine	Paveral
Levo-Dromoran	PMS-Hydromorphone
M-Eslon	PMS-Hydromorphone Syrup
Morphine Extra-Forte	Robidone
Morphine Forte	642
Morphine H.P.	Statex
Morphitec	Statex Drops
M.O.S.	Supeudol
M.O.S.-S.R.	Talwin

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**Other commonly used names are:**

dextropropoxyphene

dihydromorphinone

levorphan

papaveretum

pethidine

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## Appendix 05 – List of Drugs Capable of Interaction with Opioids/Opiates

**Introduction:** Opioids/Opiates can interact with other substances at the pharmacodynamic and/or pharmacokinetic level.

<b>Class: Benzodiazepines</b>	
<b>Effect:</b> All can potentiate or increase the side- effects of opioids/opiates, while decreasing their analgesic effects, leading to increased consumption with overdose and death. These medications also stimulate overconsumption of food and fluids. In addition, benzodiazepines are usually prescribed for anxiety, however, even small doses of opioids will block this anxiolytic effect. In other words, taking benzodiazepines and opioids together will increase their side-effects and eliminate their benefits.	
Generic Name	Brand Name
Alprazolam	Helex, Ksalol, Xanax, Xanor, Tafil, Alprox, Frontal (Brazil)
Bratazenil	N/A
Bromazepam	Lexaurin, Lexotanil, Lexotan, Lexomil, Somalium, Bromam
Chlordiazepoxide	Librium, Tropium, Risolid, Klopoxid
Cinolazepam	Gerodorm
Clonazepam	Klonopin, Rivotril, Iktorivil
Clorazetape	Tranxene
Cloxazolam	Olcadil (Brazil)
Diazepam	Valium, Pax (South Africa), Apaurin, Apzepam, Stesolid, Vival, Apozepam, Hexalid, Stedon, Valaxona
Estazolam	ProSom
Fludiazepam	Erispan
Flunitrazepam	Rohypnol, Fluscand, Flunipam, Ronal, Rohydorm (Brazil)
Flurazepam	Dalmadorm, Dalmane
Flutoprazepam	Restas
Halazepam	Paxipam
Ketazolam	Anxon
Loprazolam	Dormonoct
Lorazepam	Ativan, Temesta, Tavor, Lorabenz
Lormetazepam	Loramet, Noctamid, Pronoctan
Medazepam	Nobrium
Miadzolam	Dormicum, Versed, Hypnovel, Dormonid (Brazil)
Nimatazepam	Erimin
Nitrazepam	Mogadon, Alodorm, Pacisyn, Dumolid
Nordazepam	Madar, Stilny
Oxazepam	Seresta, Serax, Serenid, Serepax, Sobril, Oxascand, Alopam, Oxabenz, Oxapax
Phenazepam	феназепам
Pinazepam	Domar
Prazepam	Lysanxia, Centrax
Premazepam	N/A
Quazepam	Doral
Temazepam	Restoril, Normison, Euhypnos, Temaze, Tenox
Tetrazepam	Mylostan
Triazolam	Halcion, Rilamir

<b>Class: Opioids/Opiates</b>	
<b>Effect:</b> All can potentiate or increase the effects of other opioids/opiates, leading to overdose and death. Extreme care must be taken with cough medicines, most of which contain codeine, hydrocodone, or dextromethorphan.	
Generic Name	Brand Name
Benzylmorphine	Peronine

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Buprenorphine	Buprenex, Suboxone, Subutex, Butrans
Codeine	Actifed with Codeine, Airacof, Ala-Hist AC, Allerfrin with Codeine, Allfen CD, Allfen CDX, Alphen, Ambenyl, Ambifed CD, Ambifed CDX, Ambifed-G CD, Ambifed-G CDX, Ambophen, Antituss AC, Aprodine with Codeine, Ascomp with Codeine, Biotussin, Bitex, Bromanate DC, Bromanyl, Bromotuss with Codeine, Bromphen DC, Bron-Tuss, Brontex, BroveX CB, BroveX CBX, Brovex PBC, Brovex PBCX, C Tussin, Calcidrine, Capital and Codeine, Chemdal Expectorant, Cheracol with Codeine, Cheratussin, Cheratussin DAC, Co-Histine, Co-Histine DH, Cocet, Codafed, Codafen, Codahistine, Codahistine DH, Codegest, Codehist DH, Codeprex, Codimal PH, Codrix, Colrex, Combiflex ES, Conex, Cophene-X-P, Cotab A, Cotab AX, Cotabflu, Cycofed, Cycofed Expectorant, Cyndal, Decohistine, Decohistine DH, Deconsal C, Demi-Cof, Deproist, Dex-Tuss, Diabetic Tus with Codeine, Diabetic Tussin C, Dicomal-PH, Dihistine, Dihistine DH, Dimetane DC, Duraganidin NR, EZ III, Efasin Expectorant SF, Empirin with Codeine, EndaCof DC, Endacof AC, Endacof C, Endal CD, Endal Expectorant, Enditussin Expectorant, Endotuss, ExeClear-C, Fioricet with Codeine, Fiorinal with Codeine, Fiortal with Codeine, Gani-Tuss NR, Gencofed, Gencofed Expectorant, Giltuss Ped-C, Glydeine, Gua PC, Guai-Co, Guaiatussin AC, Guaiatussin DAC, Guaifen AC, Guaifen C, Guaifen DAC, Guiatuss AC, Guiatuss DAC, Guiatussin DAC, Guiatussin with Codeine, Halotussin AC, Halotussin DAC, Iophen, KG-Fed, KG-Fed Expectorant, Liquihistine CS, M-Clear WC, M-End PE, M-End WC, M-Phen, Mar-cof BP, Mar-cof CG, Margesic #3, Maxifed CD, Maxifed CDX, Maxifed-G CD, Maxifed-G CDX, Maxiflu, Maxiphen CD, Maxiphen CDX, Medent C, Myphetane DC, Mytussin AC, Mytussin DAC, Naldecon CX, Nalex AC, Neo AC, Nortuss-NX, Notuss AC, Notuss DC, Notuss PE, Notuss-NXD, Novadyne DH, Novadyne Expectorant, Novagest, Novahistine Expectorant, Nucochem, Nucodine, Nucodine Expectorant, Nucofed, Nucofed Expectorant, Nucotuss, Peditacof, Pedituss, Pentazine VC, Pentazine with Codeine, Phenaphen with Codeine, Phenco-Care, Phenergan VC with Codeine, Phenergan with Codeine, Phenflu, Phenhist, Phenhist DH, Phenylhistine DH, Phenylhistine Expectorant, Phrenilin with Caffeine and Codeine, Poly CS, Poly-Histine CS, Poly-Tussin AC, Polytine CS, Pro Clear AC, Pro Red AC, Pseudodine C, Pyregesic, Quindal, Robafen AC, Robichem AC, Robitussin AC, Robitussin DAC, Rolatuss, Romilar AC, Ryna C, Ryna CX, Soma Compound with Codeine, Statuss, Sudatuss SF, Suttar, T Koff, TL-Hist CD, TL-Hist CM, Triacin C, Triafed & Codeine, Triaminic Expectorant with Codeine, Trifed C, Trihist CS, Tusnel C, Tussar, Tusshistine CS, Tussi Organidin, Tussiden C, Tussirex, Tusso C, Tylagesic, Tylenol #2, Tylenol #3, Tylenol #4, Tylenol with Codeine, Uni-Multihist CS, Vanacof, Vopac, Z Tuss AC, Zodyl AC, Zodyl DAC, Zodyl DEC, Zotex C
Desomorphine	Dihydrodesoxymorphine, Permonid
Dextromethorphan	Robitussin, NyQuil, Dimetapp, Vicks, Coricidin, Delsym, (Inhibits the antinociceptive effects of nicotine).
Dextropropoxyphene or Propoxyphene	Algaphan, Darvon, Darvocet-N, Di-Gesic, Capadex, Lentogesic, Di-Antalvic, coproxamol, Doloxene
Diacetylmorphine	Heroin
Dipropionylmorphine	N/A
Ethylmorphine	codethyline, dionine, Indalgin, Cocillana, Cosylan, Feco Syrup, Solvipect Comp
Fentanyl	Sublimaze, Actiq, Durogesic, Duragesic, Fentora, Onsolis, Instanyl, Matrifen, Innovar
Hydrocodone	Alor, Ambi 5/15/100, Anaplex-HD, Atuss HD, Azdone, BPM-PE-HC, Bromplex-HD, Brovex-HC, Canges-HC, Codal-DH Syrup, CodiCLEAR DH, Cytuss-HC NR, Detussin, Dicomal-DH, Donatussin DC, Donatussin MAX, Drituss HD, Drocon-CS, Dytan-HC, EndaCof-Plus, Endal HD, Entuss-D JR, Excof, Excof-SF, H-C Tussive-NR, Histex-HC, Histinex HC, Histussin D, Histussin-HC, Hycodan, Hycotuss Expectorant, Hydex PD, Hydrocodone CP, Hydrocodone HD, Hydro-

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	DP, Hydromet, Hydrotropine, Hy-KXP, Hyphed, HyTan, Ibudone, Lorcet, Lortab, Lortuss HC, Marcof Expectorant, Max-HC, Mintex-HC, Nalex-DH, Narcof, Nariz HC, Norco, Notuss PD, Notuss, Novasus, Panasal, Phenylephrine HD, Poly-Tussin XP, Procof D, Prolex DH, Protuss, Protuss-D, P-V-Tussin Syrup, Reprexain, Rolatuss with Hydrocodone, Ru-Tuss with Hydrocodone, S-T Forte, Statuss Green, Trimal DH, Tri-Vent-HC, Tusdec-HC, Tusnel-HC, Tussafed-HCG, Tussafin, Tussgen, TussiCaps, Tussigon, Tussinate, Tussionex Pennkinetic, Tussplex, Vanacon, VasoTuss-HC, Vetuss HC Syrup, Vicodin, Vicoprofen, Vi-Q-Tuss, Zotex HC, Z-Tuss 2, Zymine HC.
Hydromorphone	Dilaudid, Exalgo, Dilaudid-HP, Hydromorph Contin, Dilaudid Cough Syrup, Hydal, Sophidone, Hydrostat Hydromorfan, Hydromorphan, Laudicon, Hymorphan, Opidol, Palladone, Jurnista
Methadone	Symoron, Dolophine, Amidone, Methadose, Physeptone, Heptadon, Phy, Levo-Polamidone, Polamidone, Heptanone, Heptadone, Heptadon
Morphine	MS Contin, MSIR, Avinza, Kadian, Oramorph, Roxanol, Kapanol, Embeda
Nicomorphine	Vilan
Oxycodone	Combunox, Dazidox, Depalgos, Endocet, Endocodone, Endodan, Endone, ETH-Oxydose, Eucodol, Eukodol, Lynox, Magnacet, Narvox, OxyContin, Oxyfast, Oxy-IR, OxyNorm, Percocet, Percodan, Percodan, Percolone, Perloxx, Primlev, Proladone, Roxicodone, Roxiprin, Roxycet, Targin, Taxadone, Tylox, Xolox
Oxymorphone	Opana, Opana ER, Numorphan, Numorphan HCl
Pethidine or Meperidine	Demerol, isonipeacaine, lidol, pethanol, piridosal, Algil, Alodan, Centralgin, Dispadol, Dolantin, Mialgin, Petidin Dolargan, Dolestine, Dolosal, Dolsin, Mefedina
Tapentadol	Nucynta
Thebaine	
Tramadol	Ultram, Ultram ER, Tramal, Ultracet, Trexol, Tramacet, Adolonta, Nobligan, Ryzolt, Sinergix, Tradol, Tradonal, Ultradol, Veldrol, Zaldiar, Zytram, Zytrim

### Class: MAO inhibitors

**Effect:** Certain combinations can be lethal. They can trigger a **Noradrenergic Syndrome** (Hypertensive Crisis) and/or **Serotonin Syndrome** (Hyperpyrexia crisis). They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity.

Generic Name	Brand Name
Asagiline	Azilect
Furazolidone	Furoxone, Dependal-M (used as an antibacterial – treatment of cholera and giardiasis)
Isocarboxazid	Marplan
Isoniazid	Laniazid, Nydrazid
Isoniazid rifampin	Rifamate, Rimactane
Linezolid	Zyvox, Zyvoxid, Zyvoxam, (an oxazolidinone antibiotic)
Moclobemide	Aurorix, Manerix
Pargyline	Eutonyl
Phenelzine	Nardil
Procarbazine	Matulane (US), Natulan (Canada), Indicarb (India) (used as a cancer drug)
Selegiline	Eldepryl, Emsam
Tranlycypromine	Parnate
St. John's Wart	St. John's Wart

### Class: Antibiotics

**Effect:** All can potentiate or increase the effects of opioids/opiates, leading to overdose and death. They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity.

Generic Name	Brand Name
Azithromycin	Zithromax
Ciprofloxacin	Cipro

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Clarithromycin	Biaxin
Erythromycin	Erythrocin, E-Mycin, Ery-Tab (Increases side-effects)
Itraconazole	Sporanox
Ketoconazole	Nizoral
Metronidazole	Flagyl
Rifampicin	Rifampin (Decreases analgesic-effects)
Telithromycin	Ketek
Voriconazole	Vfend

### Class: Antiviral Agents

**Effect:** They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity.

Generic Name	Brand Name
Abacavir	Ziagen
Amprenavir	Agenerase
Atazanavir	Reyataz
Didanosine	Videx
Efavirenz	Sustiva
Fosamprenavir	Lexiva, Telzir
Indinavir	Crixivan
Lopinavir	Kaletra
Nelfinavir	Viracept
Nevirapine	Viramune
Ritonavir	Norvir
Saquinavir	Invirase, Fortovase
Stavudine	Zerit
Zidovudine	Retrovir

### Class: Antifungals

**Effect:** They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity. They slow down the hepatic metabolism of opioids (i.e.: fentanyl, alfentanil, etc.)

Generic Name	Brand Name
Abafungin	Abasol
Bifonazole	Canespor
Butoconazole	N/A
Clotrimazole	Canesten, Lotrimin
Econazole	Spectazole, Ecostatin, Pevaryl, Ecostatin Vaginal Ovules, Endix-G, Ecosone, Vivicome Cream
Fenticonazole	Falvin, Fenizolan, Fentiderm, Fentigyn, Fentizol, Gynoxin, Laurimic, Lomexin, Micofulvin, Mycodermil, Mycofentin, Terlomexin.
Fluconazole	Diflucan, Trican, Alfumet
Isavuconazole	N/A
Isoconazole	N/A
Itraconazole	Sporanox
Ketoconazole	Nizoral, Sebizole
Miconazole	Oravig, Desenex, Micatin, Monistat-Derm, Daktarin, Decocort, Daktacort, Miconazex, Monistat, Femizol or Gyno-Daktarin
Nefazodone	Serzone, Nefadar
Omoconazole	N/A
Oxiconazole	Oxistat, Oxizole
Posaconazole	Noxafil, Posanol
Ravuconazole	N/A
Sertaconazole	Ertaczo, Dermofix
Sulconazole	Exelderm

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Terconazole	N/A
Tioconazole	N/A
Voriconazole	VFEND

### Class: Antacids

**Effect:** They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity.

Generic Name	Brand Name
Cimetidine	Tagamet
Ranitidine	Zantac
Metoclopramide	Maxolon, Reglan, Degan, Maxeran, Primperan, Pylomid, Cerucal, Pramin

### Class: Anticonvulsants

**Effect:** They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity. They can all precipitate withdrawals.

Generic Name	Brand Name
Carbamazepine	Biston, Calepsin, Carbatrol, Epitol, Equetro, Finlepsin, Sirtal, Stazepine, Telesmin, Tegretol, Teril, Timonil, Trimonil, Epimaz, Carbama, Carbamaze, Amizepin, Hermolepsin, and Degranol
Fosphenytoin	Cerebyx, Prodilantin
Mephenytoin	Mesantoin
Phenobarbital	Luminal,
Phenytoin	Phenytek, Dilantin, Dilantin Kapseals, Dilantin Infatabs, Eptoin, Epanutin, Дифенин, Diphenin, Dipheninum
Primidone	Mysoline, Prysoline, Apo-Primidone, Liskantin, Desitin, Resimatil, Mylepsinum, and Sertan

### Class: Barbiturates

**Effect:** They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity.

Generic Name	Brand Name
Butalbital	Axocet, Bucet, Bupap, Cephadyn, Dolgic, Phrenilin, Phrenilin Forte, Sedapap, Fioricet, Esgic, Esgic-Plus, Axotal, Fiorinal, Fiormor, Fiortal, Fortabs, Laniroif,
Mephobarbital	Mebaral
Methohexital	Brevital
Pentobarbital	Nembutal
Phenobarbital	Luminal
Thiamylal	Surital
Thiopental	Sodium Pentothal, thiopental, thiopentone sodium, or Trapanal

### Class: Antidepressants (SSRIs)

**Effect:** All can **inhibit CYP2D6**, thereby decreasing opioid/opiate metabolism, leading to accumulation and overdose. They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity. Specifically Tramadol can precipitate seizures and serotonin syndrome/Toxidrome.

Generic Name	Brand Name
Citalopram	Celexa, Cipramil, Cipram, Dalsan, Recital, Emocal, Sepram, Seropram, Citox, Cital
Dapoxetine	Priligy
Escitalopram	Lexapro, Cipralext, Seroplex, Esertia
Fluoxetine	Prozac, Fontex, Seromex, Seronil, Sarafem, Ladose, Motivest, Fluctin, Fluox, Depress, Lovan
Fluvoxamine	Luvox, Fevarin, Faverin, Dumyrox, Favoxil, Movox
Indalpine	Upstene (discontinued)
Paroxetine	Paxil, Seroxat, Sereupin, Aropax, Deroxat, Divarius, Rexetin, Xetanor, Paroxat, Loxamine

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Sertraline	Zoloft, Lustral, Serlain, Asentra
Zimelidine	Zelmid, Normud (discontinued)

<b>Class: Tricyclic Antidepressants</b>	
<b>Effect:</b> All can <b>inhibit CYP2D6</b> , thereby decreasing opioid/opiate metabolism, leading to accumulation and overdose. They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity. They increase blood levels of opioids.	
<b>Generic Name</b>	<b>Brand Name</b>
Amineptine	Survector, Maneon, Directim – (Norepinephrine-dopamine reuptake inhibitor)
Amitriptyline	Elavil, Tryptizol, Laroxyl, Sarotex, Lentizol
Amitriptylinoxide	Amioxid, Ambivalon, Equilibrin
Butriptyline	Evadyne
Clomipramine	Anafranil
Demexiptiline	Deparon, Tinoran
Desipramine	Norpramin, Pertofrane
Dibenzepin	Noveril, Victoril
Dimetacrine	Istonil, Istonyl, Miroistonil
Dosulepin/Dothiepin	Prothiaden
Doxepin	Adapin, Sinequan
Imipramine	Tofranil, Janimine, Pramnil
Imipraminoxide	Imiprex, Elepsin
Iprindole	Prondol, Galatur, Tetran – (5-HT <sub>2</sub> receptor antagonist)
Lofepramine	Lomont, Gamanil
Melitracen	Deanxit, Dixeran, Melixeran, Trausabun
Metapramine	Timaxel
Nitroxazepine	Sintamil
Nortriptyline	Pamelor, Aventyl
Noxiptiline	Agedal, Elronon, Nogedal
Opipramol	Insidon, Pramolan, Ensidon, Oprimol – (σ receptor agonist)
Pipofezine	Azafen/Azaphen
Propizepine	Depressin, Vagran
Protriptyline	Vivactil
Quinupramine	Kevopril, Kinupril, Adeprim, Quinuprine
Tianeptine	Stablon, Coaxil, Tatinol – (Selective serotonin reuptake enhancer)
Trimipramine	Surmontil – (5-HT <sub>2</sub> receptor antagonist)

<b>Class: Phenothiazines</b>	
<b>Effect:</b> They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity. Known to cause <b>extrapyramidal side effects (EPSE)</b> .	
<b>Generic Name</b>	<b>Brand Name</b>
Chlorpromazine	Thorazine, Chlor-PZ, Klorazine, Promachlor, Promapar, Sonazine, Chlorprom, Chlor-Promanyl, Largactil
Fluphenazine	Prolixin, Permitil, Modecate, Moditen
Levomepromazine in Germany and Methotrimeprazine in America	Nozinan, Levoprome
Mesoridazine	Serentil
Methylene blue	
Perphenazine	Trilafon, Etrafon, Triavil, Phenazine
Prochlorperazine	Compazine, Stemetil
Promazine	Sparine
Thioridazine	Mellaril, Novoridazine, Thioril

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Trifluoperazine	Stelazine
Triflupromazine	Stelazine, Clinazine, Novaflurazine, Pentazine, Terfluzine, Triflurin, Vesprin

### Class: Antiemetics

**Effect:** All can **inhibit CYP2D6**, thereby decreasing opioid/opiate metabolism, leading to accumulation and overdose. They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity. Known to cause **extrapyramidal side effects (EPSE)**.

Generic Name	Brand Name
Alizapride	Litican, Plitican, Superan, Vergentan (Dopamine antagonist)
Chlorpromazine	Thorazine, Largactil (Dopamine antagonist)
Dolasetron	Anzemet (5-HT <sub>3</sub> Serotonin receptor antagonist)
Domperidone	Motilium, Motillium, Motinorm, Costi (Dopamine antagonist)
Droperidol	Droleptan, Dridol, Inapsine (Dopamine antagonist)
Granisetron	Kytril, Sancuso (5-HT <sub>3</sub> Serotonin receptor antagonist)
Haloperidol	Aloperidin, Bioperidolo, Brotopon, Dozic, Duraperidol, Einalon S, Eukystol, Haldol, Halosten, Keselan, Linton, Peluces, Serenace, Serenase, Sigaperidol. (Dopamine antagonist)
Metoclopramide	Reglan (Dopamine antagonist)
Mirtazapine	Remeron (5-HT <sub>3</sub> Serotonin receptor antagonist)
Ondansetron	Zofran (5-HT <sub>3</sub> Serotonin receptor antagonist)
Palonosetron	Aloxi (5-HT <sub>3</sub> Serotonin receptor antagonist)
Prochlorperazine	Compazine, Stemizine, Buccastem, Stemetil, Phenotil (Dopamine antagonist)
Promethazine	Phenergan, Promethegan, Romergan, Fargan, Farganesse, Prothiazine, Avomine, Atosil, Receptozine, Lergigan (H <sub>1</sub> histamine receptor antagonists) (Dopamine antagonist)
Tropisetron	Navoban (5-HT <sub>3</sub> Serotonin receptor antagonist)

### Class: Cardiovascular

**Effect:** They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity.

Generic Name	Brand Name
Diltiazem	Adizem, Altiazem, Angiozem, Angizem, Angizem CD, Cardizem, Cartia XT, Dilatam, Dilatem, Dilcardia, Dilcontin SR in India (Sustained Release), Dilt-CD, Diltelan, Dilttime, Dilt-XR, Dilzem, Dyalec, Filazem, Herben, Progor, Tiamate, Tiazac, Tiazac XC, Tildiem, Tildiem in particular in Europe, Vasmulax, Vasocardol & Vasocardol CD, in Australia, Viazem, Zandil, Zemtrial
Verapamil	Isoptin, Verelan, Verelan PM, Calan, Bosoptin, Covera-HS

### Class: Antihistamines (H<sub>1</sub> histamine receptor antagonists)

**Effect:** All can **inhibit CYP2D6**, thereby decreasing opioid/opiate metabolism, leading to accumulation and overdose. They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity.

Generic Name	Brand Name
Cyclizine	Valoid, Marezine, Marzine, Emoquil
Dimenhydrinate	Dramamine, Driminate, Gravol, Gravamin, Vomex, Vertirosan, Viabom, Dramin, Daedalon, Antimo
Diphenhydramine	Benadryl, Dimedrol, Nytol, Unisom, Tylenol PM, Midol PM and Advil PM
Hydroxyzine	Vistaril, Atarax, Equipose, Masmoran, Paxistil, Alamon, Aterax, Durrax, Tran-Q, Orgatrax, Quiess, Tranquizine
Meclizine	Bonine, Bonamine, Antivert, Postafen, Sea Legs, Emesafene
Promethazine	Phenergan, Promethegan, Romergan, Fargan, Farganesse, Prothiazine, Avomine, Atosil, Receptozine, Lergigan, Pentazine, Promacot

### Class: Antipsychotics

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**Effect:** All can **inhibit CYP2D6**, thereby decreasing opioid/opiate metabolism, leading to accumulation and overdose. They can interact with the pharmacokinetics of the opioids, potentially causing side-effects and toxicity.

Generic Name	Brand Name
Amisulpride	Solian
Aripiprazole	Abilify
Asenapine	Saphris
Chlorpromazine	Thorazine, Largactil
Chlorprothixene	Cloxan, Taractan, Truxal
Clopenthixol	Sordinol
Clozapine	Clozaril
Droperidol	Droleptan
Flupenthixol	Depixol, Fluanxol
Fluphenazine	Prolixin - Available in decanoate (long-acting) form
Haloperidol	Haldol, Serenace
Iloperidone	Fanapt
Levomepromazine	Levomepromazine (Nozinan)
Mesoridazine	Serentil
Olanzapine	Zyprexa
Paliperidone	Invega
Pericyazine	Neulactil
Perphenazine	Trilafon
Pimozide	Orap
Prochlorperazine	Compazine
Promazine	Sparine
Promethazine	Phenergan
Quetiapine	Seroquel
Risperidone	Risperdal
Sertindole	Serdolect, and Serlect
Thioridazine	Mellaril, Melleril
Thiothixene	Navane
Trifluoperazine	Stelazine
Triflupromazine	Vesprin
Ziprasidone	Geodon
Zotepine	Nipolept, Losizopilon, Lodopin, Setous
Zuclopenthixol	Cisordinol, Clopixol, Acuphase

**Disclaimer:** This is not a complete list. There are over-the-counter medications, as well as illegal substances that have not been included. For further information, always consult your pharmacist. In anesthesiology and Pain Management, unlike most medical disciplines, pharmacodynamic drug interactions are frequently produced by design. Not all drugs listed here may cause clinically significant drug interactions, however, caution and vigilance must be exercised when considering using these medications in addition to narcotic opioids/opiates.

**APPENDIX 5 – PHARMACOKINETIC INTERACTIONS: CYP2D6 LIGANDS**

<b>Selected inducers, inhibitors and substrates of CYP2D6</b>		
<p><b>Effects: Cytochrome P<sub>450</sub> 2D6</b> (abbreviated <b>CYP2D6</b>), is an important enzymes involved in the metabolism of certain opioids/opiates. <b>Inhibitors</b> will lead to the accumulation of the opioid/opiate, possibly leading to overdose, while <b>inducers</b> will cause the rapid elimination of the medication, with subsequent decreased effects. A <b>substrate</b> is a molecule upon which an enzyme acts, thereby, when present, competing against other substrates. Opioid/opiate “pro-drugs” would act differently.</p>		
<b>Substrates</b>	<b>Inhibitors</b>	<b>Inducers</b>
<p><b>Major:</b></p> <ul style="list-style-type: none"> <li>• beta-blockers                             <ul style="list-style-type: none"> <li>○ metoprolol</li> <li>○ carvedilol</li> <li>○ timolol</li> </ul> </li> <li>• debrisoquine (antihypertensive)</li> <li>• Class I antiarrhythmics                             <ul style="list-style-type: none"> <li>○ flecainide</li> <li>○ lidocaine</li> <li>○ propafenone</li> <li>○ encainide</li> <li>○ mexiletine</li> </ul> </li> <li>• All tricyclic antidepressants, e.g.                             <ul style="list-style-type: none"> <li>○ imipramine</li> <li>○ amitriptyline</li> <li>○ etc.</li> </ul> </li> <li>• Most SSRIs (antidepressant), e.g.                             <ul style="list-style-type: none"> <li>○ fluoxetine</li> <li>○ paroxetine</li> </ul> </li> <li>• venlafaxine (SNRI antidepressant)</li> <li>• <b>opioids</b> <ul style="list-style-type: none"> <li>○ <b>codeine</b></li> <li>○ <b>tramadol</b></li> <li>○ <b>oxycodone</b></li> </ul> </li> <li>• antipsychotics, e.g.                             <ul style="list-style-type: none"> <li>○ haloperidol</li> <li>○ risperidone</li> <li>○ perphenazine</li> <li>○ thioridazine</li> <li>○ zuclopenthixol</li> <li>○ remoxipride</li> <li>○ aripiprazole</li> </ul> </li> <li>• dextromethorphan (antitussive)</li> <li>• ondansetron (antiemetic)</li> </ul> <p><b>Minor:</b></p> <ul style="list-style-type: none"> <li>• alprenolol (beta-blocker)</li> <li>• atenolol (beta-blocker)</li> <li>• mianserin (tetracyclic antidepressant)</li> </ul>	<p><b>Strong:</b></p> <ul style="list-style-type: none"> <li>• SSRIs                             <ul style="list-style-type: none"> <li>○ citalopram</li> <li>○ fluoxetine</li> <li>○ paroxetine</li> </ul> </li> <li>• Some other antidepressants                             <ul style="list-style-type: none"> <li>○ bupropion</li> <li>○ duloxetine</li> </ul> </li> <li>• terbinafine (antifungal)</li> <li>• quinidine (class I antiarrhythmic agent)</li> <li>• MDMA (recreational empathogen)</li> <li>• hyperforin (St. Johns Wort)</li> </ul> <p><b>Weak:</b></p> <ul style="list-style-type: none"> <li>• buprenorphine (in opioid addiction)</li> </ul> <p><b>Unspecified:</b></p> <ul style="list-style-type: none"> <li>• amiodarone (antiarrhythmic)</li> <li>• dronedarone (antiarrhythmic)</li> <li>• antihistamine (H1-receptor antagonists)                             <ul style="list-style-type: none"> <li>○ chlorphenamine</li> <li>○ diphenhydramine</li> </ul> </li> <li>• antipsychotic                             <ul style="list-style-type: none"> <li>○ haloperidol</li> <li>○ perphenazine</li> <li>○ thioridazine</li> <li>○ zuclopenthixol</li> <li>○ risperidone</li> </ul> </li> <li>• celecoxib (NSAID)</li> <li>• cimetidine (H2-receptor antagonist)</li> <li>• clomipramine (tricyclic antidepressant)</li> <li>• chloramphenicol (laevomycetin)</li> <li>• <b>cocaine</b> (stimulant)</li> <li>• doxorubicin (chemotherapeutic)</li> </ul>	<p><b>Strong:</b></p> <ul style="list-style-type: none"> <li>• Piperidines and derivatives (pharmacokinetics modifiers)                             <ul style="list-style-type: none"> <li>○ glutethimide (piperidinedione derivative)</li> </ul> </li> </ul> <p><b>Moderate:</b></p> <ul style="list-style-type: none"> <li>• carbamazepine</li> </ul> <p><b>Unspecified:</b></p> <ul style="list-style-type: none"> <li>• dexamethasone (glucocorticoid)</li> <li>• rifampicin (bactericidal)</li> </ul>

## APPENDIX 5 – PHARMACOKINETIC INTERACTIONS: CYP2D6 LIGANDS

<ul style="list-style-type: none"><li>• phenformin (antidiabetic)</li><li>• tropisetron (5-HT<sub>3</sub> receptor antagonist)</li><li>• amphetamine (in ADHD, narcolepsy)</li><li>• chlorphenamine (antihistamine)</li><li>• metoclopramide (dopamine antagonist)</li><li>• tamoxifen (SERM)</li><li>• vinca alkaloids (anti-mitotic, anti-microtubule)<ul style="list-style-type: none"><li>○ vincristine</li></ul></li></ul>	<ul style="list-style-type: none"><li>• metoclopramide (antiemetic, prokinetic)</li><li>• <b>methadone</b> (analgesic and anti-addictive)</li><li>• moclobemide (antidepressant)</li><li>• quinidine (Class I antiarrhythmic)</li><li>• ranitidine (H<sub>2</sub>-receptor antagonist)</li><li>• ranolazine (antianginal)</li><li>• ritonavir (antiretroviral)</li><li>• doxepin (tricyclic antidepressant, anxiolytic)</li><li>• halofantrine (in malaria)</li><li>• imipramine (tricyclic antidepressant)</li><li>• levomepromazine (antipsychotic)</li><li>• pimozide (antipsychotic)</li><li>• thioridazine (antipsychotic)</li></ul>	
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**APPENDIX 5 – PHARMACOKINETIC INTERACTIONS: CYP3A4 LIGANDS**

<b>Selected inducers, inhibitors and substrates of CYP3A4</b>		
<p><b>Effects: Cytochrome P<sub>450</sub> 3A4</b> (abbreviated <b>CYP3A4</b>), is an important enzymes involved in the metabolism of certain opioids/opiates. <b>Inhibitors</b> will lead to the accumulation of the opioid/opiate, possibly leading to overdose, while <b>inducers</b> will cause the rapid elimination of the medication, with subsequent decreased effects. A <b>substrate</b> is a molecule upon which an enzyme acts, thereby, when present, competing against other substrates. Opioid/opiate “pro-drugs” would act differently.</p>		
<b>Substrates</b>	<b>Inhibitors</b>	<b>Inducers</b>
<p><b>Major:</b></p> <ul style="list-style-type: none"> <li>• immunosuppressants                             <ul style="list-style-type: none"> <li>○ ciclosporin</li> <li>○ sirolimus</li> <li>○ tacrolimus</li> </ul> </li> <li>• Chemotherapeutic                             <ul style="list-style-type: none"> <li>○ anastrozole</li> <li>○ cyclophosphamide</li> <li>○ docetaxel</li> <li>○ doxorubicin</li> <li>○ erlotinib</li> <li>○ etoposide</li> <li>○ ifosfamide</li> <li>○ paclitaxel</li> <li>○ tamoxifen</li> <li>○ teniposide</li> <li>○ vinblastine</li> <li>○ vindesine</li> <li>○ gefitinib</li> </ul> </li> <li>• azole antifungals                             <ul style="list-style-type: none"> <li>○ clotrimazole</li> <li>○ ketoconazole</li> <li>○ itraconazole</li> </ul> </li> <li>• macrolide                             <ul style="list-style-type: none"> <li>○ clarithromycin</li> <li>○ erythromycin</li> </ul> </li> <li>• tricyclic antidepressants                             <ul style="list-style-type: none"> <li>○ amitriptyline</li> <li>○ clomipramine</li> <li>○ imipramine</li> </ul> </li> <li>• SSRIs                             <ul style="list-style-type: none"> <li>○ citalopram</li> <li>○ escitalopram</li> <li>○ fluoxetine and norfluoxetine</li> <li>○ sertraline</li> </ul> </li> <li>• buspirone (anxiolytic)</li> <li>• venlafaxine (SNRI)</li> <li>• antipsychotics                             <ul style="list-style-type: none"> <li>○ Aripiprazole</li> <li>○ haloperidol</li> <li>○ Risperidone</li> <li>○ Ziprasidone</li> </ul> </li> <li>• <b>opiate analgesics</b> <ul style="list-style-type: none"> <li>○ alfentanil</li> <li>○ codeine</li> </ul> </li> </ul>	<p><b>Strong / moderate:</b></p> <ul style="list-style-type: none"> <li>• protease inhibitors                             <ul style="list-style-type: none"> <li>○ ritonavir</li> <li>○ indinavir</li> <li>○ nelfinavir</li> </ul> </li> <li>• macrolide antibiotics                             <ul style="list-style-type: none"> <li>○ erythromycin</li> <li>○ telithromycin</li> <li>○ clarithromycin</li> </ul> </li> <li>• chloramphenicol (antibiotic)</li> <li>• azole antifungals                             <ul style="list-style-type: none"> <li>○ fluconazole</li> <li>○ ketoconazole</li> <li>○ itraconazole</li> </ul> </li> <li>• nefazodone (antidepressant)</li> <li>• bergamottin (constituent of <b>grapefruit juice</b>)</li> <li>• aprepitant (antiemetic)</li> <li>• verapamil (calcium channel blocker)</li> </ul> <p><b>Weak:</b></p> <ul style="list-style-type: none"> <li>• cimetidine (H<sub>2</sub>-receptor antagonist)</li> <li>• buprenorphine (analgesic)</li> <li>• cafestol (in <b>unfiltered coffee</b>)</li> </ul> <p><b>Unspecified:</b></p> <ul style="list-style-type: none"> <li>• amiodarone (antiarrhythmic)</li> <li>• ciprofloxacin (antibiotic)</li> <li>• ciclosporin (immunosuppressant)</li> <li>• diltiazem (calcium channel blocker)</li> <li>• imatinib (anticancer)</li> <li>• echinacea (immunostimulator)</li> <li>• enoxacin (antibacterial)</li> <li>• ergotamine (in migraine)</li> <li>• metronidazole (antibacterial)</li> <li>• mifepristone (abortifacient)</li> <li>• norfloxacin (antibiotic)</li> <li>• tofisopam (anxiolytic)</li> <li>• non-nucleoside reverse</li> </ul>	<p><b>Strong:</b></p> <ul style="list-style-type: none"> <li>• anticonvulsants, mood stabilizers                             <ul style="list-style-type: none"> <li>○ phenytoin (anticonvulsant)</li> <li>○ carbamazepine</li> <li>○ oxcarbazepine</li> </ul> </li> <li>• barbiturates                             <ul style="list-style-type: none"> <li>○ phenobarbital</li> </ul> </li> <li>• non-nucleoside reverse transcriptase inhibitors                             <ul style="list-style-type: none"> <li>○ efavirenz</li> <li>○ nevirapine</li> <li>○ etravirine</li> </ul> </li> <li>• rifampicin (bactericidal)</li> <li>• modafinil (stimulant)</li> <li>• hyperforin (constituent of St John’s Wort)</li> <li>• cyproterone (antiandrogen, progestin)</li> </ul> <p><b>Weak:</b></p> <ul style="list-style-type: none"> <li>• dexamethasone (anti-inflammatory, immunosuppressant)</li> <li>• felbamate (anticonvulsant)</li> <li>• glucocorticoids (blood glucose increase, immunosuppressive)</li> <li>• griseofulvin (antifungal)</li> <li>• pioglitazone (hypoglycemic)</li> <li>• primidone (anticonvulsant)</li> <li>• topiramate (anticonvulsant)</li> <li>• troglitazone (hypoglycemic)</li> </ul>

## APPENDIX 5 – PHARMACOKINETIC INTERACTIONS: CYP3A4 LIGANDS

<ul style="list-style-type: none"> <li>(analgesic, antitussive, antidiarrheal)             <ul style="list-style-type: none"> <li>○ fentanyl</li> <li>○ methadone (analgesic, anti-addictive)</li> </ul> </li> <li>• <b>benzodiazepines</b> <ul style="list-style-type: none"> <li>○ alprazolam</li> <li>○ clonazepam</li> <li>○ flunitrazepam</li> <li>○ midazolam</li> <li>○ triazolam</li> <li>○ pimozide</li> </ul> </li> <li>• statins             <ul style="list-style-type: none"> <li>○ atorvastatin</li> <li>○ lovastatin</li> <li>○ simvastatin</li> </ul> </li> <li>• calcium channel blockers             <ul style="list-style-type: none"> <li>○ amlodipine</li> <li>○ diltiazem</li> <li>○ felodipine</li> <li>○ nifedipine</li> <li>○ verapamil</li> </ul> </li> <li>• amiodarone (antiarrhythmic)</li> <li>• PDE5 inhibitors             <ul style="list-style-type: none"> <li>○ sildenafil</li> </ul> </li> <li>• kinins (vasodilators, smooth muscle contractors)</li> <li>• sex hormones agonists and antagonists             <ul style="list-style-type: none"> <li>○ estradiol (estrogen)</li> <li>○ ethinylestradiol (hormonal contraceptive)</li> <li>○ finasteride (antiandrogen)</li> <li>○ levonorgestrel (female sex hormone, oral contraceptive)</li> <li>○ mifepristone (antiprogesterone, anti-implantation agent)</li> <li>○ testosterone (androgen)</li> <li>○ toremifene (SERM)</li> </ul> </li> <li>• Astemizole (H1 antagonist, antipruritic)</li> <li>• warfarin (anticoagulant)</li> </ul>	<ul style="list-style-type: none"> <li>transcriptase inhibitors             <ul style="list-style-type: none"> <li>○ delavirdine</li> <li>○ efavirenz</li> <li>○ nevirapine</li> </ul> </li> <li>• gestodene (hormonal contraceptive)</li> <li>• mibefradil (in angina pectoris)</li> <li>• protease inhibitors             <ul style="list-style-type: none"> <li>○ saquinavir</li> </ul> </li> <li>• SSRIs             <ul style="list-style-type: none"> <li>○ fluoxetine/norfluoxetine</li> <li>○ fluvoxamine</li> </ul> </li> <li>• star fruit</li> <li>• piperine</li> <li>• milk thistle</li> </ul>	<ul style="list-style-type: none"> <li>• rifabutin (in tuberculosis)</li> </ul>
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## APPENDIX 5 – PHARMACOKINETIC INTERACTIONS: CYP3A4 LIGANDS

<p><b>Minor:</b></p> <ul style="list-style-type: none"><li>• protease inhibitors<ul style="list-style-type: none"><li>○ indinavir</li><li>○ ritonavir</li><li>○ saquinavir</li><li>○ nelfinavir</li></ul></li><li>• Mirtazapine (NaSSA)</li><li>• nefazodone (antidepressant)</li><li>• pimozide (antipsychotic)</li><li>• reboxetine (antidepressant)</li><li>• zopiclone (hypnotic)</li><li>• non-nucleoside reverse transcriptase inhibitors<ul style="list-style-type: none"><li>○ nevirapine</li></ul></li><li>• budesonide (glucocorticoid)</li><li>• donepezil (acetylcholinesterase inhibitor)</li><li>• proton pump inhibitors<ul style="list-style-type: none"><li>○ omeprazole and esomeprazole</li></ul></li><li>• glibenclamide (antidiabetic)</li><li>• cisapride (5-HT<sub>4</sub> receptor agonist)</li><li>• terfenadine (H<sub>1</sub>-receptor antagonist)</li><li>• barbiturates<ul style="list-style-type: none"><li>○ phenobarbital</li></ul></li><li>• carbamazepine (anticonvulsant, mood stabilizing)</li><li>• dextromethorphan (antitussive)</li><li>• digoxin (Antiarrhythmic)</li><li>• ergot alkaloids (circulation, neurotransmission)</li><li>• ivabradine (in angina pectoris)</li><li>• lidocaine (local anesthetic, antiarrhythmic)</li><li>• montelukast (leukotriene receptor antagonist)</li><li>• ondansetron (5-HT<sub>3</sub> antagonist)</li><li>• paracetamol (analgesic, antipyretic)</li><li>• quinidine (class I antiarrhythmic)</li><li>• quinine (antipyretic, anti-smallpox, analgesic)</li></ul>		
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**APPENDIX 5 – PHARMACOKINETIC INTERACTIONS: CYP3A4 LIGANDS**

<ul style="list-style-type: none"><li>• theophylline (stimulant)</li><li>• valproate (anticonvulsant, mood-stabilizing)</li><li>• tetrahydrocannabinol (psychoactive)</li></ul>		
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