

Developing a Safe Opioid Treatment Plan for Managing Chronic Pain

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- Read the enclosed course.
- Complete the questions at the end of the course.
- Return your completed Evaluation to NetCE by mail or fax, or complete online at www.NetCE.com. (If you are a physician or Florida nurse, please return the included Answer Sheet/Evaluation.) Your postmark or facsimile date will be used as your completion date.
- Receive your Certificate(s) of Completion by mail, fax, or email.

Faculty

Mark Rose, BS, MA, LP, is a licensed psychologist in the State of Minnesota with a private consulting practice and a medical research analyst with a biomedical communications firm. Earlier healthcare technology assessment work led to medical device and pharmaceutical sector experience in new product development involving cancer ablative devices and pain therapeutics. Along with substantial experience in addiction research, Mr. Rose has contributed to the authorship of numerous papers on CNS, oncology, and other medical disorders. He is the lead author of papers published in peer-reviewed addiction, psychiatry, and pain medicine journals and has written books on prescription opioids and alcoholism published by the Hazelden Foundation. He also serves as an Expert Advisor and Expert Witness to law firms that represent disability claimants or criminal defendants on cases related to chronic pain, psychiatric/substance use disorders, and acute pharmacologic/toxicologic effects. Mr. Rose is on the Board of Directors of the Minneapolis-based International Institute of Anti-Aging Medicine and is a member of several professional organizations.

Faculty Disclosure

Contributing faculty, Mark Rose, BS, MA, LP, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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The division planners and director have disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

Audience

This course is designed for physicians, pharmacists, nurses, and physician assistants involved in the care of patients prescribed opioids to treat pain.

Accreditations & Approvals



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Special Approvals

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Course Objective

The purpose of this course is to provide the information necessary for clinicians to formulate a opioid treatment plan for chronic pain that takes into consideration the risks and benefits of these agents and minimizes the potential for abuse.

Learning Objectives

Upon completion of this course, you should be able to:

1. Discuss characteristics of appropriate and inappropriate opioid prescribing and contributory factors to both.
2. Compare opioid abuse risk assessment tools and the utility of risk stratification.
3. Outline the appropriate periodic review and monitoring of patients prescribed opioid analgesics, including the role of urine drug testing.
4. Describe necessary components of patient/caregiver education for prescribed opioid analgesics, including guidance on the safe use and disposal of medications.

Pharmacy Technician Learning Objectives

Upon completion of this course, you should be able to:

1. Identify appropriate and inappropriate opioid prescribing and the role of risk assessment tools.
2. Describe the importance of periodic review and monitoring of patients prescribed opioids and necessary components of patient/caregiver education for prescribed opioids, including guidance on the safe use and disposal of medications.



Sections marked with this symbol include evidence-based practice recommendations. The level of evidence and/or strength of recommendation, as provided by the evidence-based source, are also included so you may determine the validity or relevance of the information. These sections may be used in conjunction with the course material for better application to your daily practice.

INTRODUCTION

Opioid analgesics can be highly effective in relieving physical and psychological pain, but some patients are highly susceptible to opioid reward effects. A minority of patients may experience an initial response to opioid therapy of euphoria, stimulation, or intense well-being, and this response is associated with an increased risk for the development of opioid use disorder [17; 18].

Healthcare professionals should know best clinical practices in opioid prescribing, including the associated risks of opioids, approaches to the assessment of pain and function, and pain management modalities. The goals of pain treatment include reasonably attainable improvement in pain to decrease suffering and to increase function; improvement in pain-associated symptoms, such as sleep disturbance, depression, and anxiety; screening for side effects of treatment; and avoidance of unnecessary or excessive use of medications [1]. Pharmacologic and nonpharmacologic approaches should be used on the basis of current knowledge in the evidence base or best clinical practices. Patients with moderate-to-severe chronic pain who have been assessed and treated, over a period of time, with non-opioid pharmacologic or nonpharmacologic pain therapy without adequate pain relief are considered to be candidates for a trial of opioid therapy. The treatment plan should always be individualized for the patient and begun as a trial for a defined period of time (usually no more than 30 days) before embarking on a definitive course of treatment [1].

All patients with pain have a level of risk that can only be roughly estimated initially and modified over time as more information is obtained. There are ten essential steps of opioid prescribing for chronic pain to help mitigate any potential problems [2]:

- Diagnosis with an appropriate differential
- Psychological assessment, including risk of substance use disorders

- Informed consent
- Treatment agreement
- Pre- and post-treatment assessments of pain level and function
- Appropriate trial of opioid therapy with or without adjunctive medication
- Reassessment of patient levels of pain and functioning
- Regular assessment with the 5 A's (i.e., analgesia, activity, adverse effects, aberrant behaviors, and affect)
- Periodically review pain diagnosis and comorbid conditions, including substance use disorders
- Documentation

INFORMED CONSENT AND TREATMENT AGREEMENTS

The initial opioid prescription is preceded by a written informed consent or “treatment agreement” [1]. This agreement should address potential side effects, tolerance and/or physical dependence, drug interactions, motor skill impairment, limited evidence of long-term benefit, misuse, dependence, addiction, and overdose. Informed consent documents should include information regarding the risk/benefit profile for the drug(s) being prescribed. The prescribing policies should be clearly delineated, including the number/frequency of refills, early refills, and procedures for lost or stolen medications.

The treatment agreement also outlines joint prescriber and patient responsibilities. The patient agrees to using medications safely, refraining from “doctor shopping,” and consenting to routine urine drug tests (UDTs). The prescriber’s responsibility is to address unforeseen problems and prescribe scheduled refills. Reasons for opioid therapy change or discontinuation should be listed. Agreements can also include sections related to follow-up visits, monitoring, and safe storage and disposal of unused drugs.

It is important to remember that treatment agreements are only one aspect of developing a safe opioid use plan. The evidence to support the use of such agreements to decrease the misuse of opioids is relatively weak, with little or no proof of improvements in adherence or patient care [19].

CONSIDERATIONS FOR NON-ENGLISH-PROFICIENT PATIENTS

For patients who are not proficient in English, it is important that information regarding the risks associated with the use of opioids and available resources be provided in their native language, if possible. When there is an obvious disconnect in the communication process between the practitioner and patient due to the patient's lack of proficiency in the English language, an interpreter is required. Interpreters can be a valuable resource to help bridge the communication and cultural gap between patients and practitioners. Interpreters are more than passive agents who translate and transmit information back and forth from party to party. When they are enlisted and treated as part of the interdisciplinary clinical team, they serve as cultural brokers who ultimately enhance the clinical encounter. In any case in which information regarding treatment options and medication/treatment measures are being provided, the use of an interpreter should be considered. Print materials are also available in many languages, and these should be offered whenever necessary.

INITIATING A TRIAL OF OPIOID THERAPY

Opioid therapy should be presented as a trial for a pre-defined period (e.g., ≤ 30 days). As noted, the goals of treatment should be reasonable improvements in pain, function, depression, anxiety, and avoidance of unnecessary or excessive medication use [1]. The treatment plan should describe therapy selection, measures of progress, and other diagnostic evaluations, consultations, referrals, and therapies.

In opioid-naïve patients, start at the lowest possible dose and titrate to effect. Dosages for opioid-tolerant patients should always be individualized and titrated by efficacy and tolerability. The need for frequent progress and benefit/risk assessments during the trial should be included in patient education. Patients should also have full knowledge of the warning signs and symptoms of respiratory depression.

Prescribers should be knowledgeable of federal and state opioid prescribing regulations. Issues of equianalgesic dosing, close patient monitoring during all dose changes, and cross-tolerance with opioid conversion should be considered. If necessary, treatment may be augmented, with preference for nonopioid and immediate-release opioids over extended-release/long-acting (ER/LA) opioid formulations. Taper opioid dose when no longer needed [3].

PERIODIC REVIEW AND MONITORING

When implementing a chronic pain treatment plan that involves the use of opioids, the patient should be frequently reassessed for changes in pain origin, health, and function [1]. This can include input from family members and/or the state prescription drug monitoring program. Prescription drug monitoring programs are one of the most effective measures for reducing opioid analgesic diversion and abuse, but their efficacy is undermined by inconsistent use [19]. During the initiation phase and during any changes to the dosage or agent used, patient contact should be increased. Decisions regarding the continuation, modification, or termination of opioid therapy for pain should be based on evaluation of the patient's progress and the absence of substantial risks or adverse events [1]. At every visit, chronic opioid response may be monitored according to the 5 A's [4]:

- Analgesia
- Affect (i.e., patient mood)

- Activities of daily living
- Adverse or side effects
- Aberrant drug-related behaviors

ASSESSMENT DURING ONGOING OPIOID THERAPY

Signs and symptoms that, if present, may suggest a problematic response to the opioid and interference with the goal of functional improvement include [4]:

- Excessive sleeping or days and nights turned around
- Diminished appetite
- Inability to concentrate or short attention span
- Mood volatility, especially irritability
- Lack of involvement with others
- Impaired functioning due to drug effects
- Use of the opioid to regress instead of re-engaging in life
- Lack of attention to hygiene and appearance
- Escalation of pain and/or pain medication dose
- Increasing number of medications prescribed to treat the side effects of opioids

The decision to continue, change, or terminate opioid therapy is based on progress toward treatment objectives and absence of adverse effects and risks of overdose or diversion [1]. Satisfactory therapy is indicated by improvements in pain, function, and quality of life. Brief assessment tools to assess pain and function may be useful, as may UDTs. Treatment plans may include periodic pill counts to confirm adherence and minimize diversion.

VIGIL

VIGIL is the acronym for a five-step risk management strategy designed to empower clinicians to appropriately prescribe opioids for pain by reducing regulatory concerns and to give pharmacists a framework for resolving ambiguous opioid analgesic prescriptions in a manner that preserves legitimate patient need while potentially deterring diverters.

The components of VIGIL are:

- **Verification:** Is this a responsible opioid user?
- **Identification:** Is the identity of this patient verifiable?
- **Generalization:** Do we agree on mutual responsibilities and expectations?
- **Interpretation:** Do I feel comfortable allowing this person to have controlled substances?
- **Legalization:** Am I acting legally and responsibly?

The foundation of VIGIL is a collaborative prescriber/pharmacist relationship [5; 6].

Current Opioid Misuse Measure

The Current Opioid Misuse Measure (COMM) is a 17-item patient self-report assessment designed to help clinicians identify misuse or abuse in patients with chronic pain. Unlike the ORT and the SOAPP-R, the COMM identifies aberrant behaviors associated with opioid misuse in patients already receiving long-term opioid therapy [7]. Sample questions include: In the past 30 days, how often have you had to take more of your medication than prescribed? In the past 30 days, how much of your time was spent thinking about opioid medications (e.g., having enough, taking them, dosing schedule)?

Pain Assessment and Documentation Tool

Guidelines by the FSMB and the Joint Commission stress the importance of documentation from both a healthcare quality and medicolegal perspective. Research has found widespread deficits in chart notes and progress documentation with patients with chronic pain receiving opioid therapy, and the Pain Assessment and Documentation Tool (PADT) was designed to address these shortcomings [8]. The PADT is a clinician-directed interview, with most sections (e.g., analgesia, activities of daily living, adverse events) consisting of questions asked of the patient. However, the potential aberrant drug-related behavior section must be completed by the physician based on his or her observations of the patient.

The Screening, Brief Intervention, and Referral Tool (SBIRT)

The Screening, Brief Intervention, and Referral Tool (SBIRT) is used for early identification and intervention for patients with substance use disorders, including opioid use disorder. Annual universal screening (S) identifies patients that may need intervention. For those who screen positive, a brief intervention (BI) questionnaire determines the level to which the patient may need intervention and allows practitioners to focus on education and awareness of health effects, with an emphasis of healthy behavioral change. The items assess the extent of problems related to drug use in several areas, including drug use-related functional impairment. The last part, referral to treatment (R), helps facilitate access to treatment and additional resources [9].

PSEUDOADDICTION

Patients with inadequately treated pain can develop pseudoaddiction, characterized by aberrant drug-seeking behaviors that mimic opioid use disorder but are driven by desperation for pain relief. In these patients, aggressive complaints of needing higher dosing, openly obtaining opioid analgesics, deception, stockpiling unused medication, and unsanctioned dose escalations resolve with adequate pain control [20; 21].

This phenomenon is essential to understand. Many risk mitigation measures fail to consider this as a possibility, and rigid adherence without closer assessment may lead to further withholding of pain treatment from patients already distressed by pain.

INVOLVEMENT OF FAMILY MEMBERS

Family members of the patient can provide valuable information that better informs decision making regarding continuing opioid therapy. Family members can observe whether a patient is losing control of his or her life or becoming less functional or more depressed during the course of opioid therapy. They can also provide input regarding positive or negative changes in patient function, attitude, and level of comfort. The following questions can be asked of

family members or a spouse to help clarify whether the patient's response to opioid therapy is favorable or unfavorable [4]:

- Is the person's day centered around taking the opioid medication? Response can help clarify long-term risks and benefits of the medication and identify other treatment options.
- Does the person take pain medication only on occasion, perhaps three or four times per week? If yes, the likelihood of addiction is low.
- Have there been any other substance (alcohol, tobacco, or drug) abuse problems in the person's life? An affirmative response should be taken into consideration when prescribing.
- Does the person in pain spend most of the day resting, avoiding activity, or feeling depressed? If so, this suggests the pain medication is failing to promote rehabilitation. Daily activity is essential, and the patient may be considered for enrollment in a graduated exercise program
- Is the person in pain able to function (e.g., work, do household chores, play) with pain medication in a way that is clearly better than without? If yes, this suggests the pain medication is contributing to wellness.
- Does this patient smoke? Smoking increases pain and reduces the effectiveness of opioids.

URINE DRUG TESTING

UDTs may be used to monitor adherence to the prescribed treatment plan and to detect unsanctioned drug use [1]. They should be used more often in patients receiving addiction therapy, but clinical judgment is the ultimate guide to testing frequency (**Table 1**) [10]. Although there is a general consensus in pain management guidelines for the use of UDTs prior to initiating and during opioid therapy, evidence supporting the benefits of UDTs in improving patient care is weak [11].

MONITORING FREQUENCY ACCORDING TO PATIENT RISK			
Monitoring Tool	Patient Risk Level		
	Low	Medium	High
Urine drug test	Every 1 to 2 years	Every 6 to 12 months	Every 3 to 6 months
State prescription drug monitoring program	Twice per year	Three times per year	Four times per year

Source: [10] Table 1

Initially, testing involves the use of class-specific immunoassay drug panels [1]. If necessary, this may be followed with gas chromatography/mass spectrometry for specific drug or metabolite detection. It is important that testing identifies the specific drug rather than the drug class, and the prescribed opioid should be included in the screen. Any abnormalities should be confirmed with a laboratory toxicologist or clinical pathologist. Immunoassay may be used point-of-care for “on-the-spot” therapy changes, but the high error rate prevents its use in major clinical decisions unless liquid chromatography is coupled with mass spectrometry confirmation.

Urine test results suggesting opioid misuse should be discussed with the patient using a positive, supportive approach. The test results and the patient discussion should be documented.



EVIDENCE-BASED
PRACTICE
RECOMMENDATION

According to the American Society of Interventional Pain Physicians, presumptive urine drug testing should be implemented at initiation of opioid therapy, along with subsequent use as adherence monitoring, using in-office point of service testing,

followed by confirmation with chromatography/mass spectrometry for accuracy in select cases, to identify patients who are noncompliant or abusing prescription drugs or illicit drugs. Urine drug testing may decrease prescription drug abuse or illicit drug use when patients are in chronic pain management therapy.

(<https://painphysicianjournal.com/current/pdf?article=NDIwMg%3D%3D&journal=103>. Last accessed October 27, 2021.)

Level of Evidence: III (Evidence obtained from at least one relevant, high-quality nonrandomized trial or observational study with multiple moderate- or low-quality observational studies)

Ethical Concerns with UDTs

It is important to appreciate the limitations of UDTs. Healthcare providers are increasingly relying on UDTs as a means to reduce abuse and diversion of prescribed opioids. This has led to a proliferation in diagnostic laboratories that offer urine testing. With this increase have come questions of whether these business interests benefit or hinder patient care, what prescribers should do with the information they obtain, the accuracy of urine screens, and whether some companies and clinicians are financially exploiting the UDT boom [12]. Despite wide endorsement and making intuitive sense, there is little empirical confirmation that UDTs reduce prescription opioid abuse [19].

A random sample of UDT results from 800 patients with pain treated at a Veterans Affairs facility found that 25.2% were negative for the prescribed opioid and 19.5% were positive for an illicit drug/unreported opioid [13]. However, a negative UDT result for the prescribed opioid does not necessarily indicate diversion; it may indicate the patient halted its use due to side effects, lack of efficacy, or pain remission. The increasingly stringent climate surrounding clinical decision-making regarding aberrant UDTs is concerning. In many cases, a negative result for the prescribed opioid or a positive UDT serves as the pretense to terminate a patient rather than an impetus to guide him or her into addiction treatment or an alternative pain management program [12].

In principle, and ideally in practice, UDTs are a worthwhile element of effective pain management and pharmacovigilance when used to enhance the diagnostic and therapeutic objectives of pain therapy. However, immunoassay screens have high false-positive and false-negative rates and only provide qualitative information about a select number of drug classes [11].

As a side note, cannabis use by chronic pain patients receiving opioid therapy has traditionally been viewed as a treatment agreement violation that is grounds for termination of opioid therapy. However, some now argue against cannabis use as a rationale for termination or substantial treatment and monitoring changes, especially considering the increasing legalization of medical use at the state level [14]. In addition, there is a substantive and growing body of research confirming cannabis efficacy (and opioid-sparing effects) in chronic pain conditions, including neuropathic pain, cancer pain, fibromyalgia, and headache pain [22; 23; 24; 25; 26].

PATIENT AND CAREGIVER EDUCATION

SAFE USE OF OPIOIDS

Patients and caregivers should be counseled regarding the safe use and disposal of opioids. As part of its mandatory Risk Evaluation and Mitigation Strategy (REMS) for ER/LA opioids, the U.S. Food and Drug Administration (FDA) developed a patient counseling document with information on the patient's specific medications, instructions for emergency situations and incomplete pain control, and warnings not to share medications or take them unless prescribed [3]. This has since been replaced with the Patient Counseling Guide from the Opioid Analgesics REMS Program Companies (RPC), a collaboration of companies to implement a single shared REMS. An updated copy of the Patient Counseling Guide may be accessed online at https://www.opioidanalgesicrems.com/Resources/Docs/patient_counseling_document.pdf [29].

When prescribing opioids, clinicians should provide patients with the following information and instructions [3; 29]:

- Product-specific information
- Taking the opioid as prescribed
- Importance of dosing regimen adherence, managing missed doses, and prescriber contact if pain is not controlled
- Warning and rationale to never break or chew/crush tablets or cut or tear patches prior to use
- Warning and rationale to avoid other central nervous system depressants, such as sedative-hypnotics, anxiolytics, alcohol, or illicit drugs
- Warning not to abruptly halt or reduce the opioid without physician oversight of safe tapering when discontinuing
- The potential of serious side effects or death
- Risk factors, signs, and symptoms of overdose and opioid-induced respiratory depression, gastrointestinal obstruction, and allergic reactions
- The risks of falls, using heavy machinery, and driving
- Warning and rationale to never share an opioid analgesic
- Rationale for secure opioid storage
- Warning to protect opioids from theft
- Instructions for disposal of unneeded opioids, based on product-specific disposal information

DISPOSAL OF OPIOIDS

There are no universal recommendations for the proper disposal of unused opioids, and patients are rarely advised of what to do with unused or expired medications. According to the Office of National Drug Control Policy, most medications that are no longer necessary or have expired should be removed from their containers, mixed with undesirable sub-

stances (e.g., cat litter, used coffee grounds), and put into an impermeable, nondescript container (e.g., disposable container with a lid or a sealed bag) before throwing in the trash [16]. The FDA recommends that most opioid medications, including oxycodone/acetaminophen (Percocet), oxycodone (OxyContin tablets), and transdermal fentanyl (Duragesic Transdermal System), be flushed down the toilet instead of thrown in the trash [16]. Disposal by flushing down the toilet provides immediate and definitive elimination of safety hazards from intentional use or accidental exposure involving opioid products. All transdermal patch opioid products should be flushed down the toilet after folding in half by adhesive side against adhesive side [27]. Patients should be advised to flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so. Flushing unused medications has been the subject of controversy, with some state governments and boards recommending against the practice due to pollution concerns and effects on waterways and wildlife [28].

The American Medical Association recommends the following three steps to promote the safe storage and disposal of opioids [15]:

- Educate patients about the safe use of opioids, including not sharing prescriptions with others.
- Remind patients that medications should be stored out of the reach of children and in a safe place—preferably locked—to prevent other family members and visitors from taking them.
- Talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications. The preferred option is that unwanted or unused pills, liquids or other medications should be disposed of in a local “take-back” or mail-back program or medication drop box at a police station, pharmacy, or authorized collection site. Contact your state law enforcement agency or visit <https://www.dea.gov> to determine if a program is available in your area.

CONSULTATION AND REFERRAL

It is important to seek consultation or patient referral when input or care from a pain, psychiatry, addiction, or mental health specialist is necessary. Clinicians who prescribe opioids should become familiar with opioid addiction treatment options (including licensed opioid treatment programs for methadone and office-based opioid treatment for buprenorphine) if referral is needed [1].

Ideally, providers should be able to refer patients with active substance abuse who require pain treatment to an addiction professional or specialized program. In reality, these specialized resources are scarce or non-existent in many areas [1]. Therefore, each provider will need to decide whether the risks of continuing opioid treatment while a patient is using illicit drugs outweigh the benefits to the patient in terms of pain control and improved function [14].

MEDICAL RECORDS

Documentation is a necessary aspect of all patient care, but it is of particular importance when opioid prescribing is involved. All clinicians should maintain accurate, complete, and up-to-date medical records, including all written or telephoned prescription orders for opioid analgesics and other controlled substances, all written instructions to the patient for medication use, and the name, telephone number, and address of the patient’s pharmacy [1]. Good medical records demonstrate that a service was provided to the patient and that the service was medically necessary. Regardless of the treatment outcome, thorough medical records protect the prescriber.

DISCONTINUING OPIOID THERAPY

The decision to continue or end opioid prescribing should be based on a joint discussion of the anticipated benefits and risks. An opioid should be discontinued with resolution of the pain condition, intolerable side effects, inadequate analgesia, lack of improvement in quality of life despite dose titration, deteriorating function, or significant aberrant medication use [1].

Clinicians should provide physically dependent patients with a safely structured tapering protocol. Withdrawal is managed by the prescribing physician or referral to an addiction specialist. Patients should be reassured that opioid discontinuation is not the end of treatment; continuation of pain management will be undertaken with other modalities through direct care or referral.

CONCLUSION

Opioid analgesic medications can bring substantial relief to patients suffering from pain. However, the inappropriate use, abuse, and diversion of prescription drugs in America, particularly prescription opioids, has increased dramatically and has been identified as a national public health epidemic. Whenever opioids are necessary to manage chronic pain, healthcare professionals should take steps to ensure that these agents are used safely and appropriately.

Implicit Bias in Health Care

The role of implicit biases on healthcare outcomes has become a concern, as there is some evidence that implicit biases contribute to health disparities, professionals' attitudes toward and interactions with patients, quality of care, diagnoses, and treatment decisions. This may produce differences in help-seeking, diagnoses, and ultimately treatments and interventions. Implicit biases may also unwittingly produce professional behaviors, attitudes, and interactions that reduce patients' trust and comfort with their provider, leading to earlier termination of visits and/or reduced adherence and follow-up. Disadvantaged groups are marginalized in the healthcare system and vulnerable on multiple levels; health professionals' implicit biases can further exacerbate these existing disadvantages.

Interventions or strategies designed to reduce implicit bias may be categorized as change-based or control-based. Change-based interventions focus on reducing or changing cognitive associations underlying implicit biases. These interventions might include challenging stereotypes. Conversely, control-based interventions involve reducing the effects of the implicit bias on the individual's behaviors. These strategies include increasing awareness of biased thoughts and responses. The two types of interventions are not mutually exclusive and may be used synergistically.

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Evidence-Based Practice Recommendations Citation

Manchikanti L, Kaye AM, Knezevic NN, et al. Responsible, safe, and effective prescription of opioids for chronic non-cancer pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician*. 2017;20:S3-S92. Available at <https://painphysicianjournal.com/current/pdf?article=NDIwMg%3D%3D&journal=103>. Last accessed October 27, 2021.