Prescribing Controlled Substances, Drug Diversion, and Best Practices, 3hr

3.00 Contact Hours

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Outcomes

≥ 92% of participants will understand the Federal and State laws regarding controlled substance prescribing and monitoring.

Objectives

After completing this continuing education course, the participant will be able to:

1. Discuss the accepted best practices for assessing patients' risk for addiction and misuse of controlled substances.
2. Identify State and Federal laws applicable to prescribing, managing, and monitoring the controlled substances in their practice.
3. Obtain the necessary tools to design and implement a suitable direct system of managing, monitoring, and discontinuing controlled substance use for patients' pain issues.
4. Document in compliance with State and Federal law.
5. Discriminate treatment for specific pain types.
6. Discuss tools for identifying the risk of diversion, addiction, and misuse.
7. Describe the treatment of patients with acute, sub-acute, and chronic pain for whom nonpharmacological and non-controlled pain medications have not been fully effective.
8. Access billing codes to get reimbursed for the time spent assessing patients' risk for addiction, diversion, and misuse of controlled substances.
9. Identify three ways controlled substances can be diverted.
10. Explore patient-provider communication.

DISCLAIMER: THIS COURSE DOES NOT INCLUDE PRESCRIBING CONTROLLED SUBSTANCES FOR PREGNANCY AND LABOR OR PAIN MANAGEMENT IN MINORS (LESS THAN 18 YEARS OLD).

All medication information listed here was adapted from PDR.net and Drugs.com.

Introduction

Opioid and other controlled substance addiction, diversion, and overdose continue to be problematic for patients, healthcare providers, and law enforcement and is a complex medicolegal issue. Attempting to control the epidemic of overdose deaths, increasing addiction, and diversion of controlled substances prescribed, many states require individual providers to receive specific training in different areas of prescribing controlled substances. These areas include diversion, patient use monitoring, and abuse risk assessment. State and Federal laws require providers to satisfy many specific conditions to be able to provide controlled substances for their patients suffering with acute and chronic pain or mental health illnesses (Lampe, et al., 2023). Prescription pharmaceutical adjuvants to mental healthcare therapies may also be regulated. Often, providers respond to these labor and time-intensive criteria by referring their chronic pain patients to pain management providers or clinics and their mental health patients to psychiatry for prescriptions after the first limited prescription of controlled substances. Pain management providers and mental health clinicians have built their specialty by prescribing controlled substances needed to maintain safe and effective treatments for mental illness. This includes the minutiae of medico-legal documentation, required uses of the patient drug monitoring programs, and managing patient communications. This has changed the primary care landscape of mutual trust, which was the norm, among other things.

Glossary

- Substance Abuse is the “Intentional use of the opioid for a non-medical purpose, such as euphoria or altering one’s state of consciousness” (Kalkmana et al., 2022).
- Addiction is a “Pattern of continued use with experience of, or demonstrated potential for, harm” (Kalkmana et al., 2022).
- Appropriate opioid analgesic prescribing involves providing pain control while minimizing toxicity, use disorder, or the risk of use disorder and implementing safeguards to reduce drug diversion (Preuss et al., 2022).
- Alcohol use disorder (AUD) is a medical condition characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences (DSM V-5, 2022).
- Cannabinoids-products are used either as the natural marijuana plant or isolated from the constituents of the marijuana/hemp plant.
- Controlled substance is a drug or other substance the government tightly controls because it may be abused or cause addiction.
- The Drug Abuse Screening Test (DAST10) is a 10-question screening tool administered by a clinician or self-administered.
- DAST-20 A 10-item, yes/no self-report instrument designed to provide a short tool for clinical screening and treatment evaluation can be used with adults and older youth.

- Iatrogenic harm is unintentionally induced by a physician or surgeon, medical treatment, or diagnostic procedures (Merriam-Webster, n.d.).
- Opioid-tolerant patients are those taking, for at least one week, ≥ 60 mg oral morphine a day, ≥ 25 mcg transdermal fentanyl per hour, ≥ 30 mg oral oxycodone a day, ≥ 8 mg oral hydromorphone a day, ≥ 25 mg oral oxymorphone a day, ≥ 60 mg oral hydrocodone a day, or an equivalent dose of another opioid (PDR, n.d.).
- Inappropriate opioid analgesic prescribing is non-prescribing, inadequate, excessive, or continued prescribing despite evidence of the lack of effective opioid analgesic treatment (Preuss et al., 2022).
- Misuse is “Opioid use contrary to the directed or prescribed pattern of use, regardless of the presence or absence of harm or adverse effects” (Kalkmana. et al.,2022).
- Medical morphine equivalent (MME).
- Naloxone Narcan®, Kloxxado® Is an opioid antagonist that can quickly reverse an overdose of opioid drugs (NIDA, 2022).
- The opioid Risk Assessment Tool (ORT) is over 20 years old.
- Pain neuroscience education (PNE) teaches about pain mechanisms, causing the brain to stop overreacting and becoming constantly hyper-stimulated at the cerebral cortex level. This, in turn, reduces cerebral threat perception, which decreases the activation of pain systems in the brain. This is for pain like fibromyalgia.
- Pain is an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage (Raja et al., 2022).
- Acute pain duration <1 month.
- Sub-acute pain duration 4-12 weeks.
- Chronic pain duration > three months.
- Acute, chronic pain is when a “flare-up” of “old” pain is usually due to a new insult to an old injury.
- Neuropathic pain- sometimes called nerve pain. This is caused by the somatosensory nervous system's primary lesion(s).
- Visceral pain is induced by organs, such as the gallbladder, stomach, or bladder (a deep aching).
- Nociceptive pain is normally expected from an injury to tissues and Inflammatory pain. Activation and sensitization of the nociceptive pain pathway by the body’s inflammation mediators released at the injury site, such as bradykinins (usually sharp, caused by movement or intermittent to constant sharp aching).
- Computerized statewide pharmaceutical monitoring database programs (PDMP) differ in each state and country.
- Prescription diversion is giving or selling, or loss due to theft of all or part of a prescription for controlled medications to anyone other than for whom it is prescribed.
- Urine drug test (UDT).
- Screener and Opioid Assessment for Patients with Pain (SOAPP).
- Substance use disorder (SUD) DSM-5 criteria are a maladaptive pattern of substance use leading to clinically significant impairment or distress. (Hartney,2022).

Opioid intoxication, per the DSM-5:

- Opioids are often taken in more significant amounts or longer than intended. There is a persistent desire or unsuccessful efforts to reduce or control opioid use. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects. Craving, or a strong desire to use opioids. Recurrent opioid use fails to fulfill major role obligations at work, school, or home. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids. Important social, occupational, or recreational activities are given up or reduced because of opioid use. Recurrent opioid use in situations in which it is physically hazardous Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids (DSM-5 2022).

Tolerance is either one of the following:

1. A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
2. Markedly diminished effect with continued use of the same amount of an opioid (DSM-5 2022).

Either of the following manifests withdrawal:

1. The characteristic opioid withdrawal syndrome.
2. The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms (DSM-5 2022).

Why must I know about the drug diversion risk for sales or abuse?

Understanding the diversion of drugs helps to see the bigger picture in the epidemic of opioid and other controlled substance prescribing environments. There is a greater likelihood that providers will ameliorate it at the primary care level if they know the facts and follow the FDA, CDC, and the VA's recommendations with a higher degree of care and discernment.

With any patient, there can be a risk of addiction (even with pain present), diversion, abuse, or misuse of controlled substances. While unfortunate, the actions of the bad actors and the epidemic of complex medico-legal disasters have outweighed the patients' needs due to legitimate pain and mental health. Stringent guidelines and laws have been implemented to stem the tide of illicit activities. This has been successful, but in a limited way (Manchikanti et al., 2022).

Providers willing to comply with all the detailed rules and regulations involved must avoid seeming untrusting or suspicious as they fulfill their obligation to "Do no harm." According to Goldstick et al. (2022), providers have reacted to the extreme in the face of very restrictive guidelines published by the CDC in 2016. The CDC did not intend this reaction, and thus they wrote new guidelines in 2019, which include the warning not to overreact and thereby harm patients (iatrogenic harm) who are justifiably in need (Dowell et al., 2022; Salvatore et al.,2022).

According to Manchikanti et al. (2022):

- The 2016 CDC opioid guidelines were aimed at primary care providers. However, many state boards mandated them by law, resulting in tremendous needless suffering and exacerbating the illicit opioid epidemic with the causation of needless deaths. These guidelines not only restrict opioid prescriptions but also have restricted all interventional techniques to reduce access and send patients to the streets for illicit opioids.

Providers were concerned about being on the right side of the law and were attempting to protect their hard-earned licenses. Providers already have the situation of trying to discern "real need" from manipulation attempts to gain controlled substances for diversion (Preuss, 2022). Provider trust may continue to be an issue when a provider requires a patient to sign a patient responsibility contract allowing urine drug testing (UDT) and pill counting. UDT is put in place to identify the need to work with a patient who is using other (illegal) drugs and, at the same time to find that the patient is indeed consuming at least some of the prescribed medications. Patients may be "self-medicating" other illegal controlled substances, such as street drugs, which may be dangerous. These patients will need help to discern this and a medication change to eliminate the need to self-medicate. Pill counting is a time-consuming measure that may be a relatively accurate way to discern whether a patient has been diverting medications. Still, it is not a perfect way to assess risks alone (Gill et al., 2022).

Studies are needed to design newer tools, and many computer-assisted tools were in development as late as 2022 but are not available to the providers at the clinic or community level (Wei-Hsuan et al., 2022). Hospitals are equipping themselves against diversion perpetrated by staff providers using computer-driven algorithm software, which can be built into the medication dispensing workstations (Shaw, 2022).

What is Patient-Provider Communication?

Regarding the prescribing, monitoring, and finally discontinuing controlled medications, communication, and education with the patients must be performed and documented to maintain strict conformation to states' requirements. During your initial patient-provider communications, you should touch on the kind of pain your patient is describing and which medications are best for reducing and relieving that type of pain.

Education should include the side effects, dosage, safety information (such as safe, locked storage), and signs of overdose. CDC encourages that naloxone be prescribed with dosage instructions when opioids are prescribed. Overdose of naloxone is rare, but depending on the level of opioid dose, repeated consecutive doses could be uncomfortable for the habituated patient (Dowell et al., 2022). The patient and family members or caregiver should be warned to call 911 immediately after a naloxone dose, as the dose should be managed moment-by-moment by a medical professional as soon as possible.

After the clinician determines that a controlled substance will be prescribed, there is yet more work for the provider to do. Due to the unintended tragic situation caused by the industry's overreaction to the CDC 2016 guidelines, Manchkanti et al. (2022) reported increased illegal drugs for pain and (presumably) mental health issues. There was a concurrent increase in suicides among people with severe chronic

pain issues when providers discontinued chronic controlled substances. Many tapering/ or weaning-off plans were either unsupported or not implemented (2022). Provider-to-patient trust became an issue.

First, discovering the patient's personal, religious, social, and cultural pain constructs are legitimate assessments for pain management. Assessing the patient's cognitive ability as it relates to expressing pain and understanding issues to avoid is also particularly important. With a nonverbal patient, the provider must look for signs and question family members about the patient's pain history. All these things are part of patient/ provider communication.

The patient sets pain goals to discover a place to begin tapering off the medications without leaving the patient in severe pain or with severe mental health issues. Pain goals may include:

- Getting the most pain relief with the least amount of side effects.
- Improving the quality of life in the long term as well as the short term.
- Safely returning to work without side effects of pain medications.

The provider should also be alert to psychological improvements and quality of life changes. It is also a tool that the clinician can use to teach that it may not be possible to eliminate all pain (as a goal) in a patient's body. Sometimes, especially in subacute or chronic pain, the best a patient and provider can hope for is to keep pain to a reasonable level (a goal chosen by the patient) and remediate it with non-pharmacological means. Decisions between the patient and the provider must be made about whether weaning off the drug is the goal or if specialized medical or mental healthcare is the goal. Prescriptions can be written for temporary relief while the patient gets established with a specialist in the field they require. The patient must be taught about medication safety and keeping controlled substances at home. The danger of child overdose cannot be stressed strongly enough. In a retrospective study by Champagne-Langabeer et al. (2022), during the three years ending in 2017, almost 60,000 children were in emergency departments (ED in the US for opioid use and overdoses. The mean age was 11.3, the greater part of the girls. In addition, most of the children were from the South. Sadly, 68.5 percent of these visits were from opioid overdoses. Overall, infants were in the second-largest opioid accident group to appear in EDs across the United States during this period. Over 9000 children have died since the turn of the century because of opioid accidents (Champagne-Langabeer et al., 2022). The rate of prescription opioid overdose among adolescents has also been increasing in recent years. In 2022, there were an estimated 1,800 deaths from prescription opioid overdoses among adolescents. This number is more than double the number of deaths from prescription opioid overdoses among adolescents in 2002. This is evidence that locked, safe, and out-of-reach controlled substance storage in the home is critical. These statistics also indicate the need for naloxone prescriptions with opioid medications for patient and family safety (NIDA, 2022).

What is meant by the diversion of controlled substances?

Theft of opioids and other controlled substances is a major way drugs are diverted from their intended use. Hence a locked cabinet is the best solution. Parents are not often willing to believe their minor children or other family members in an extended family household would

steal medications; however, 50 percent of 12 to 17-year-olds have reported they stole medications from family members in the previous 12 months before the study (2021 National, 2022). According to the National Institute on Drug Abuse (NIDA), an estimated 2.5 million adolescents aged 12 to 17 used prescription opioids for nonmedical purposes in 2022. This number has been steadily increasing in recent years, and it is now more than double the number of adolescents who used prescription opioids for nonmedical purposes in 2002 (SAMHSA, 2022).

A 2017 Substance Abuse and Mental Health Services Administration (SAMHSA) study found that 10.6% of adults aged 18-25 reported using a prescription pain reliever without a prescription in the past year. Of these, an estimated 2.1 million adults reported having obtained their prescription pain relievers from a friend or family member, and an estimated 500,000 adults reported having obtained their prescription stimulants from a friend or family member. Theft by parents of children prescribed controlled substances for various conditions, from ADHD to pain (SAMHSA, 2017). Pharmacy misappropriation, robbery of legitimate drug transport from manufacturers, stealing prescription ordering supplies from medical offices, and stealing from hospitals and other health facilities by healthcare workers and others, including hospices. The patients from all the facilities mentioned above are part of the diversion picture. Since diversion may also come from inadequate disposal of "leftover drugs," there are ways to prevent this. We must not overprescribe to satisfy the "as needed" quantities. Our patients react to leftover, labor, time, and financially intensive medications by "saving" them for the future. This becomes problematic if used without supervising the overall health picture shared with others. Now the patient is an illicit provider and an illegal pharmacy. A child or a pet could ingest that medication or be stolen, used, and sold. Proper disposal of these leftover medications becomes imperative. DEA Drug Take Back boxes are at pharmacies nationwide. To search for year 'round take back location here.

How can I decide who qualifies for controlled substances to treat their pain or mental health needs?

Using the criteria set for substance abuse disorder in the DSMV 5-TR, providers are expected to determine whether a patient will likely abuse, divert, or get addicted to a controlled substance prescription. Multiple screening tools are available for identifying drug or alcohol abusers, such as ORT and SOAAP. DAST10 and DAST20 are designed to identify drug or alcohol abuse in adults and adolescent abusers, respectively.

- SOAPP
- ORT
- DAST-10
- DAST-20

These tools are primarily patient self-screening tests that can also be administered by trained nurses and are intended to be used in concert with the providers' advanced education and intrinsic good judgment. It is unclear why the substance abuser or the drug dealer would be

honest and forthcoming while filling out one of these tools. That is why there are several red flags you can watch for that will be covered later.

A prescription drug monitoring program (PDMP) is an electronic database that tracks controlled substance prescriptions in a state. They can provide health and legal authorities with timely information about providers' prescribing and patient behaviors that contribute to the epidemic and facilitate a nimble and targeted response (CDC, 2021). PDMPs track controlled substance prescriptions from physicians, nurse practitioners, and physician assistants. They also track pharmacists who fill controlled substance prescriptions.

What do I need to know about pain?

According to Niculescu et al. (2019), pain is so real that there are genetic serum biomarkers for its presence and severity. Sadly, they report that suicidality shares some markers with severe pain. Pain has been described throughout human history as an enemy, a threat to sanity, and a lover. There are many ways to accept pain occurring in our bodies, but accepting pain in others is much more difficult. We tend to minimize other people's pain, and according to studies, we are minimizing based on our subjective criteria, with little thought for the patient's subjective report. Depending upon our biases, we may even judge pain in others by their age, gender, apparent financial status, and racial appearance (Keister et al., 2021). As each patient's pain is different and specific to them, there is no one-size-fits-all dosage of pain medication. Pain tolerance is not only different for different people, but it also changes throughout the lifespan (Mullins et al., 2022).

There is a syndrome in patient management called opioid-induced hyperalgesia (OHI), where the medication causes more pain than it relieves. Hyperalgesia is the body feeling a heightened level of pain. Allodynia is the sensation of pain related to a stimulus that ordinarily does not cause pain, such as a light touch or a cool breeze. Allodynia and hyperalgesia can also be leftovers of OIH. The best thing you can do for OIH is reduce the level of pain medication and titrate it to a similar morphine milligram equivalent (MME) in another opioid. The treatment for hyperalgesia is an NMDA receptor agonist such as methadone or ketamine, and for allodynia, pregabalin or another nerve pain medication. People at high risk for allodynia are migraine sufferers, with women at greater risk than men. The culprit for allodynia for both men and women is nerve damage.

What does bias have to do with best practices of controlled substance prescribing?

It is reported in several studies that there is a bias toward prescribing opioid pain relievers to people who are married, white, and of a mature (50-65 years) age as a preference (Keister, 2021). Dr. Carmen Green reports that women of color are improbable to have their pain treated or even assessed properly (Healthy Women, 2020). Even in the case of Sickle Cell Disease (SCD), a widely understood disease process that causes pain by its very mechanism, it is undertreated and given less than sterling care. With more than 90% of SCD patients in America being of African descent, it is an easy-to-study bias phenomenon (Marr, 2022). Boring et al. (2022) report that there is a bias that women and people of color overrate their pain. Still, their study shows that this is not true, showing that women and people of color often minimize their pain due to fears of not being believed and that we all discount or minimize the pain of others. This is a complex issue

psychologically, but it may be sufficient to be aware of our biases and do our best to realize that other people are more likely to be telling the subjective truth about their pain and treat it to effect (Boring et al., 2022).

How does this look in the clinic?

You will encounter two common situations at least once and probably much more often in primary care.

Clinical Case Study #1

Thomas is a 34-year-old Hispanic man who drives a forklift in his job at a large manufacturer. He has complained of continuing lower back pain for the last two weeks. He reports pain in his lower back, "in the middle," radiating to his right hip and down his leg. He reports that even walking is painful (an 8 or 9 on a 0-10 scale), and he cannot rest at night due to the pain. He is currently only taking Lisinopril 10mg daily and a multivitamin. After several assessments, you suspect sciatica caused by a herniated disc. The patient reports that he does not get relief from his pain with ibuprofen or acetaminophen and wants something that will "work." He wants to know if he can get hydrocodone. He had it before his dentist. You explain that you need to have him fill out a few forms, as you are not set up to deliver care beyond one or, at most, two prescriptions for a limited number of pills.

He reminds you that he has been your patient for several years and that you know him. He is a hard worker and does not want to "get high." He wants to get back to work driving a forklift. You explain that hydrocodone/Apap is not for use with operating heavy machinery and that you can give him enough time to get an appointment with a spine specialist. You ask your nurse, who has been trained to use a risk of diversion tool, to fill out the ORT with him, as well as give a personal responsibility contract with the name of the drug and prescriber name for Thomas to fill out with his name and sign, that he will not misuse or divert any of his prescribed schedule II/III medications. You ask Thomas what his goal for his pain level is, and he replies, "Well, I would love a zero, but if I could get it down to a two or a three. So, the goal is not to return to driving a forklift at work or any other heavy equipment until he gets a release from the physical therapist.

These forms will be added to his chart along with your written pain management plan, and in the meantime, you contact the state prescription monitoring program via computer to determine that he has not been going to any other doctors in your state to get pain medication prescriptions filled. You find that he has not filled any prescriptions at any pharmacy for pain medications in the searchable past. You prescribe Hydrocodone/ Apap 5/500, 1-2 tablets PO q 4-6 hours, PRN pain for three days in the quantity of 24 with the maximum dosage of 8 per day, no refills. You also prescribe Tizanidine 4mg, twice daily, PO for muscle tightness, the quantity of 20, with one refill. And a Naloxone nasal spray kit quantity one.

You add a letter of excuse for a doctor's appointment and FMLA forms for his job. He is reminded that taking these medications and driving heavy machinery would be unsafe. He will take home a letter for light duty and not operate heavy machinery. He is given a referral for an orthopedic surgeon and advised to go to the ER for pain if he finds he needs more than eight pills a day due to the adverse effect on the CNS and significant respiratory depression. He is also referred to a pain management physician to fill the gap until the orthopedist and a referral

for Physical Therapy can see him. He is trained by the nurse via a safety booklet from the DEA about the safe storage and disposal of controlled substances and taught how to use the Naloxone nasal spray for an overdose of opioids. He is given an inside folder with all these materials and the poison control center number.

The next time you see Thomas, he has seen the pain specialist, the orthopedist, and a physical therapist and now does not take any pain medications. He says his back "acts up" if he forgets to do his stretches before straining at work or home. He declined to have surgical intervention as his stretching and therapy have made his intermittent pain tolerable at a one or a two on a 0-10 scale. He thanks you for not thinking he was a "druggie" and helping him out in his time of need.

Clinical Case Study #2

Anne, age 62, white female, is a new patient in your office, you happen to see her checking in, and she is pleasant towards the office staff. She reports she does not have an ID at the front desk as her "house burnt down," she must get her documents for this state since she just moved here. She comes to you complaining of pain in her leg from an old motor vehicle accident (MVA). She reports that she just moved into the area from a nearby state and that her physician from the previous state of residence, who usually helps her when this pain "flares up," has retired. She has no medical records either because "They also burnt up in the fire."

When you ask where the pain is and what her pain level is on a scale of 0-10, she reports, "It is always an 8 or 9, unless I stay on it too much, then it is off the scale" She holds her right thigh as she speaks. When you ask what surgical procedure(s) were performed during the MVA, she states she does not remember because she was young, which all occurred in another state. She has filled out the pain map, and the patient consents to care and UDTs on refills monthly. You note the pain is marked on the right thigh area over the mid-thigh laterally and is marked 8-10 on the pain scale. Reviewing her current medications, you see that she takes a daily statin and a hormone replacement medication regularly. As you look at her stated allergies, you note she has listed tramadol, ibuprofen, and codeine. When you ask about her reactions to these drugs, she says she gets a rash and "nearly died from codeine" because she could "not stop throwing up for at least a week."

During the gait exam, she reports that she cannot stand too long, but walks, bends over, and stands on each foot alone well, with good hip alignment. You ask the patient to get up onto the table so that you can listen to her heart and further examine her. You look down at the forms she has filled out so that you can still see her out of the side of your eye. You note she is quick to walk to the table and pull out the step to climb up onto the table without any noticeable objective signs of pain. On assessing her reflexes, you can see normal reflexes. When you tap the Achilles tendon and ask if that hurts, she affirms, "Oh yes, all that hurts. Every time you do anything, it hurts." Again, you see no signs of objective pain, such as overly reactive reflexes, grimaces, or sudden intake of breath. You know that chronic pain is not as obvious as acute pain, or even as much as acute on chronic pain as in a flare-up of chronic pain, as she is describing. While discussing your plan to help her pain and attempting to set some goals with her regarding her pain in the future, she informs you that her "old" doctor always prescribed "Oxy IR" since nothing else seems to work for her.

She takes the folder of pain management materials. She says, “Oh yeah, I have all this stuff at home somewhere.” When you mention physical therapy, she expresses disdain for it and says she tried therapy three or four times already, which never helps for more than a day. When you bring up the possible need for a CT of the femur (as she was holding her thigh earlier), she seems to begin to be frustrated by the interview, saying, “Look, I already had all of this kind of stuff done and all I need is for you to do like they figured out to do, and give me something for my pain”! You attempt to soothe her and excuse yourself to get a prescription pad. When you check the patient drug monitoring service, you can see that she has no reports of filled prescriptions in your state in the last year. You look at the ORT and see that she scored without risk of diversion. Still, you feel uncomfortable. However, you must still attempt to “Do no harm.”

You obtain the name of a pain management clinic that you trust from your referrals desk, knowing that they have been accepting new patients, and you prescribe celecoxib 200 mg PO BID Q #60. You gave her this medication because she stated that allergy to Ibuprofen is unlikely to react to a Cox 2 inhibitor NSAID. You tell her this and give her a referral to a pain management physician, explaining that your office is not equipped to prescribe controlled substances on a chronic “as needed” basis. You remind her to go to the ER if her pain becomes unbearable. She takes the prescription and the referral. She pays her bill in cash and leaves the office without further ado. You observe she has no limp and is not holding her thigh in the parking lot. She does not call back or respond to calls from your office for a follow-up visit after this appointment.

In this case, you used the ORT tool and your advanced training, instincts, and better judgment to determine that the patient exhibited some common signs of drug-seeking for diversion or abuse.

Red Flags

- Claims to be from out of state, with or without documentation or without identification, which is reported as stolen, or they cannot get a new one.
- The patient has a convoluted but uncheckable story about injury and previous care with no medical records.
- Has reported allergies to pain medications with lower levels of abuse potential.
- Shows no objective signs of pain when the patient is unaware of being observed.
- Requests a specific drug and displays an unusual familiarity with exam room equipment.
- Refuses or avoids other non-pharmacological treatments and or imaging requests.
- A patient with a history of “lost” medications, e.g., “I spilled it into the sink which had water in it.”

What are some specific pharmacological and non-pharmacological treatments and medications for adult use?

The selected medications below are listed for your information. However, controlled pain medications are not the chosen treatments according to the CDC, the FDA, and the VA. These agencies recommend that nonopioid and non-pharmacological therapies be used for sub-

acute (flare-ups) and chronic pain treatment (Dowell et al.,2022; US Department of Veterans Affairs, 2022). Nonpharmacological treatments could be said to fall into five groups:

- Metabolic: dietary supplements, herbs, vitamins, and minerals, weight loss.
- Stress Reduction: Yoga, Meditation, Acupressure, Massage.
- Device Assisted: Acupuncture, Transcranial or direct magnetic stimulation, neurofeedback, chiropractor.
- Exercise: Tai Chi, Qigong, stretching, physical therapy, PNE with physical therapy.
- Psychosocial: PNE, support groups, volunteering.

Some of these non-pharmacological areas overlap and are used in combination with each other and with non-controlled and controlled pain relief medications. Patients should be strongly encouraged to participate in one or more as this is more effective for increasing the quality of life and decreasing awareness of pain and discomfort than medications alone (CDC, 2022; VA, 2022)

Noncontrolled pain medications

Antiepileptics:

Neurontin/gabapentin is used for nerve pain, antineuralgic, anticonvulsant, muscle relaxant. The usual adult dose for postherpetic neuralgia is an initial dose: 300 mg orally on day one, 300 mg orally two times a day on day two, then 300 mg orally three times a day on day three. Titrate up as needed for pain relief; the maximum dose is 1800mg daily in divided doses. Gabapentin/ Neurontin Off-label uses are diabetic neuropathy, trigeminal neuralgia, fibromyalgia, and complex regional pain syndrome. In these cases, starting between 100-300 mg three times daily and titrating up to 2400-3600 mg divided daily is common.

Pregnancy and breastfeeding warning, in monotherapy, no problems were seen. However, in the event of more than one drug used with Neurontin and in rat studies, teratogenicity was seen. Neurontin does cross the placenta and breast milk.

A half-life of 5-7 hours should be used with caution in the elderly (fall risk, prolonged metabolism, COPD (respiratory depression), and renal impairment (mostly renal excretion).

Moderate to major drug-drug interactions are multiple, and some are counterintuitive, for example, pseudoephedrine, azelastine, and antacids. Different forms of gabapentin are not interchangeable. Immediate-release tablets should not be broken for more than 28 days due to a change in efficacy. While taking gabapentin, a person should be observed for signs of suicidal ideations for at least 24 weeks. Gabapentin may potentiate opioids and can be used during the tapering of alcohol addiction. Side effects (SE) include somnolence and dizziness, which may affect driving, and the ability to judge driving skills may also be altered. Avoid abrupt discontinuation as the seizure threshold has been artificially lowered (PDR.net, n.d.). Tapering in administration of large doses should not be more than 100mg twice daily for at least a week (Thakkar et al., 2022).

Pregabalin/Lyrica is an antiepileptic used for nerve pain such as fibromyalgia, post-herpetic neuralgia, diabetic neuropathies, and spinal cord injuries resulting in pain. Monitor the patient for changed psychological status and changes in behavior, such as new or increased depression, suicidal ideation, and actions at the beginning of and continuing throughout therapy. Family members should be made aware of the possibility of suicidal thoughts and actions.

The dosage for fibromyalgia should not exceed 450 mg per day as higher doses were not more effective. Tapering should not be done over less than a week. Do not give over 300 mg daily for other nerve pain listed as higher doses were less effective. Off-label use: trigeminal neuralgia, prescribe the same dose as other nerve pain treatments above. They also treat generalized anxiety disorder at a maximum of 600 mg daily in divided doses. Dose changes are needed with decreased creatinine clearance rates. Pregabalin is removed up to 60% by hemodialysis. See prescribing information on further reductions related to hemodialysis.

Common side effects are vision changes, unsteadiness, clumsiness, dizziness, drowsiness, and trouble thinking. Pregabalin may increase the chances of cancers such as hemangiosarcoma and may increase bleeding. Also, myopathy and diabetic ulcers may be seen. Pregabalin should not be used with Actos due to weight gain, fluid retention, and peripheral edema. This could lead to exacerbating or causing heart failure. Patients with the New York Health Association class III or IV should not combine these medications.

Animal studies indicated there could be issues during pregnancy with the growth and survival of the fetus at over 75 times the normal human dose. Not for breastfeeding. Men may have 50% reduced sperm production up to about seven months after discontinuing pregabalin. Sperm morphology was normal in all cases.

Antidepressants:

Antidepressants are Serotonin-norepinephrine Reuptake inhibitors (SNRIs duloxetine, venlafaxine, and Pristiq, Tricyclic antidepressants (TCAs), amitriptyline, clomipramine, desipramine, imipramine, and nortriptyline. According to Ferrier et al. (2023), antidepressant medications are used for several pain issues (2023). In a study of over 25,000 people (156 different trials), Ferrier et al. (2023) discovered that for nine types of chronic pain presentations, fibromyalgia, migraine headaches, chronic back pain, post orthopedic surgery pain, IBS, and neuropathic pain, SNRIs gave moderate relief in just 26% of cases, 74% of the trials reviewed showed little or inconclusive evidence of efficacy, where TCAs were shown to be moderately effective in neuropathic pain only.

These antidepressant drugs were not interchangeable for any type of pain. Selective Serotonin Reuptake Inhibitors (SSRIs) were not shown to be effective in the trials. Antidepressants of these types have dizziness, fatigue, nausea, constipation, decreased libido, and normal weight gain, except Pristiq, which decreases appetite and has side effects of ED. The side effects may be less serious than those found with opiates. However, they are less effective and are not used for moderate to severe pain. A provider will need to weigh these options carefully with the patient in the cases where these drugs might be useful.

NSAIDS:

Non-selective NSAIDs are for mild to moderate pain and inflammation.

- Diclofenac/Voltaren 50mg TID PO is the common Rx. SE: Indigestion, GI upset and cramps, fluid retention. Also available as a topical medication over the counter for arthritic pain.
- Ibuprofen-Advil/Motrin This drug is available in many forms and is sometimes included in opiate formulations (Oxycodone/ibuprofen). SE: Indigestion, GI upset and cramps, dizziness.
- Indomethacin, Ketoprofen, Ketorolac, Meloxicam.
- Cox 2 selective NSAID.
- Celecoxib.

The adverse effects of NSAIDs are gastrointestinal, hepatic, renal, cardiac, and hematological. NSAIDs inhibit the creation of prostaglandins. Prostaglandins protect gastric mucosa, renal function, and kidney preservation. Cardiac disorders are seen with NSAIDs also, with diclofenac being the drug most implicated in myocardial infarction, atrial fibrillation, and thromboembolic events. Because NSAIDs increase aminotransferase levels, liver damage, though rarer, can happen, especially with diclofenac. Since there is antiplatelet activity with NSAIDs, hematologic issues may occur for those with compromised coagulation. Aspirin can cause problems with hyperreactive lung issues in asthmatics. NSAIDs are not recommended during the third trimester of pregnancy. Monitor patients with chronic use if they have renal hepatic or hematologic dysfunction. Educate patients to avoid toxic levels and minimize side effects. (Ghlichloo & Gerriets, 2022).

Antipyretic Analgesic:

Acetaminophen is not an anti-inflammatory medication; there is no blood thinning effect or GI upset as seen in NSAIDs, and it is often used for mild, moderate, or severe pain, as a single drug or in combination with opioids or other drugs such as caffeine, aspirin, dihydrocodeine, butalbital. Side effects are rare and sometimes included in opiate formulation medications (hydrocodone/Apap). Doses range from 325mg-1000 mg. every 4-6 hours as needed for pain up to 4000mg daily for adults and seniors. Acetaminophen is available in liquids, rectal suppositories, IV solutions, oral powders, and effervescent, extended, and intermediate-release tablets.

Acetaminophen is liver-toxic for adults at >4g/day. Overdoses can be fatal due to liver failure. It should be stored away from children and pets. Alcoholic, hepatic diseased, hypovolemic, and malnourished patients are at increased risk for hepatotoxicity with acetaminophen. With stable liver disease, proper dosing is not toxic. Reduced doses for adults and seniors less than 110 pounds are recommended. In the patient with osteoarthritis pain, 1300 mg every eight hours is recommended. Renal impairment dosage intervals are increased to 8 hours (PDR, n.d.).

Controlled Pain Medication

Controlled pain medications are commonly used in pain management and psychiatry.

Rules and regulations for controlled substances vary by state and federal law in the U.S. Schedule II-controlled substance prescriptions cannot be refilled and expire after six months. Schedule III or IV prescriptions may not be filled or refilled more than six months after the

written date or refilled more than five times, whichever comes first. Schedule V controlled substances may be refilled as authorized. Laws may vary by state. A complete list of scheduled drugs is available at Drugs of Abuse: A DEA Resource Guide.

Drug Schedules

Schedule I

The list of Schedule I includes marijuana, heroin, and LSD. We will discuss only the one currently being used for pain medication.

There are forty-six states where all forms of medical marijuana are legal: (Anderson & Rees, 2023). This is a controversial moment in the history of Marijuana legalization by the states because the drug is still classified as Schedule I by the Federal government. The VA and Federal Bureau of Prisons do not allow marijuana for their patients. If they have marijuana show up on a drug test, they will be penalized (VA, 2022). There is currently no consensus on what or when a change might be made, as marijuana could be reclassified (rescheduled), or perhaps as it is legal for recreational use in many states, it might be decriminalized federally (Celeste & Thompson-Dudiak, 2021).

Schedule II

These medications/drugs have the strictest regulations when compared to other prescription drugs because they are the most likely to be abused, diverted, or addicting. They include hydromorphone, meperidine, methadone, morphine, and oxycodone.

Morphine is used to treat soft tissue pain but also has been used to treat arthritis when other medications have failed. It is initially supplied as an oral solution, 10 to 20 mg PO every 4 hours as needed. Titrate the dose as needed to achieve adequate analgesia.

Initially, tablets, 10 to 20 mg PO every 4 hours as needed. Titrate the dose to achieve adequate analgesia—IV solutions 2 to 10 mg IV every 4 hours as needed.

Embeda® a combination with naltrexone for the opioid naïve patient, 20 mg/0.8 mg PO every 24 hours. Titrate the dosage every 1 to 2 days as needed to control pain. Do not dose more frequently than every 12 hours. Extended-release forms of morphine, such as MS Contin, should only be used for opioid-tolerant patients accustomed to ingesting over 400mg/day. MS Contin should not be crushed or chewed as this and concurrent alcohol use will disrupt the extended time release mechanisms. They are leading to overdose and potentially death. This medication is contraindicated in all forms in patients with GI obstruction or acute post-operative pain.

Morphine in selected forms should be used cautiously for patients with variable respiratory diseases such as COPD, obstructive asthma, hepatic or renal dysfunction, brain injury, increased intracranial pressure, or severe hypotension. Use with caution in the elderly, alcoholic, morbidly obese, Addison's disease, seizure disorders, benign prostatic hyperplasia, debilitation, pancreatitis, and cardiovascular disease. With appropriate dosage titration, there is no maximum dose of morphine (PDR, n.d.). To discontinue long-acting morphine preparations, taper the dose by 25% to 50% every 2 to 4 days. Significant opioid withdrawal symptoms may indicate the need to pause or slow the taper.

Hydromorphone/Dilaudid is a semisynthetic, phenanthrene opioid agonist. For the treatment of persistent, severe pain that requires an extended treatment period with a daily opioid and for which alternative treatments are inadequate. Give 2 to 4 mg PO every 4 to 6 hours as needed, initially. Titrate the dose to achieve adequate analgesia. Administer doses around the clock for chronic pain. A supplemental dose of 5% to 15% of daily usage may be administered every 2 hours as needed. With appropriate dosage titration, there is no maximum dose of hydromorphone.

For use in moderate to severe hepatic or renal disease of hydromorphone, reduce the first dose to 50% and 75%, respectively. The longer the duration of previous opioid therapy, the longer the taper may take. Common tapers involve a dose reduction of 5% to 20% every four weeks; a faster taper may be appropriate for some patients. Significant opioid withdrawal symptoms may indicate the need to pause or slow the taper. Opioids may be stopped, if appropriate, when taken less often than once daily. Advise patients that there is an increased risk for overdose on abrupt return to a previously prescribed higher dose; provide opioid overdose education and consider offering naloxone. Monitor patients closely for anxiety, depression, suicidal ideation, and opioid use disorder, and offer support and referral as needed (PDR, n.d.).

Fentanyl is supplied as a sublingual, transmucosal, and nasal spray, transdermal patches, sublingual tablets, buccal lozenge, transmucosal lozenge, intramuscular injections, transmucosal tablets, IV injections, and electrically controlled transdermal patch. Different preparations of fentanyl are not interchangeable from microgram to microgram, even if administered via the same route. With the most popular clinic-level form, the transdermal 72-hour patch, providers should use a conversion table from other opiates used in the previous 24 hours to MME's then convert to fentanyl micrograms per hour.

Patients may use short-acting opioid agonists for the first 24 hours after stopping all other opiates at fentanyl patch initiation. For titrating the dose upward, the first time, from the lowest dose used, wait for a total of 24 hours after initialization of the patch. After that, the provider should wait six days to increase further. If the patient uses 45 mg per day of extra short-acting morphine, consider increasing the fentanyl patch to 12.5 micrograms in fentanyl patches to reach optimal dosage. Some severe pain issues may require patches to be changed every 48 hours instead of 72 hours to maintain optimal pain coverage. Education should be performed regarding exposures to new or used patches by other adults, children, or pets, as 30 to 85% of fentanyl may still be available in the used patches due to the product formulation.

Fatalities have occurred from children applying used patches during play or ingesting them. Consider not allowing children to watch the application of patches. Disposal of used patches is done by folding the patch so that the adhesive ends are together and flushing it down the toilet if you cannot use an acceptable drug take-back site. If ingested, it may be fatal for children or pets. Never cut patches to reduce dosage, as this exposes the medication, causing toxic levels to the person managing it. Patches may be covered with a “breathable” clear dressing or taped around the edges with skin-friendly medical tape to prevent accidental dislodgement. Patients should rotate areas to apply patches. Completely avoid using heat or heating pads on patches, as toxicity could result.

The fentanyl patch is meant for transdermal use. Any other use of this preparation could lead to overdose or death via decreased respiratory drive and fentanyl toxicity. There is no maximum dose of fentanyl in this form. Avoid using it in severe hepatic and renal impairment.

Decrease the first dose by 50% in mild to moderate hepatic or renal impairment. Patients who have overdosed should be transported via EMS and hospitalized for observation (PDR, n.d.).

Hydrocodone/Apap is a semisynthetic opiate agonist and a non-salicylate analgesic. Hydrocodone and acetaminophen are synergistic hybrids. As with all opiates, use caution with patients suffering from any process or disease that predisposes them to CNS depression or other breathing issues such as COPD, obesity, acute or severe asthma, or cor-pulmonary. The usual dosages of hydrocodone/ acetaminophen can cause apnea and decrease respiration drive in this population. Consider nonopioid medications for these patients. Monitor patients carefully for decreased respiratory reserve due to altered breathing patterns in patients with impaired consciousness. Also, recent or concurrent use of CYP 453A4 inhibitors can increase the respiratory depression effect due to increased serum blood levels available (PDR, n.d.).

Opioid use requires an experienced clinician knowledgeable about the use of opioids, including the use of extended-release and long-acting opioids and how to mitigate the associated risks. All opiates have similar side effect profiles. From most to least severe, they cause all the obvious symptoms of CNS depression, such as decreased level of consciousness, increased respiratory depression, nausea, vomiting, constipation, slow gastric transit, and dry mouth. Unfortunately, hormonal and immunological dysfunction can happen with chronic use, physical dependence, tolerance, and rarely hyperalgesia. According to the American Gastroenterological Association, the most common side effect is constipation that results from opiate-induced changes in the stomach, the intestines (large and small), the rectum, anus, and anal sphincter tone, is different from the usual causes of constipation and require special attention with specific treatment (Sizar, 2022).

Due to decreased gastric transits, stool bulking agents are not recommended for opioid-induced constipation (Sizar et al., 2022). Just as Narcan is prescribed for an overdose at the time of opioid initiation, education regarding maintaining regular bowel movements by increased water intake, exercising, and using laxatives should also be performed (PDR, n.d.).

Schedule III

Schedule III drugs have a lower misuse and addiction potential than I and II. Medications in this category are often used for pain control or anesthesia. Drugs in this category may cause physical dependence but more commonly lead to psychological dependence. Examples of Schedule III substances include ketamine, opioid analgesics in this schedule include products containing not more than 90 mg of codeine per dosage unit, and buprenorphine/naloxone oral film.

Schedule IV

These drugs are considered to have less likelihood of dependence and abuse. Carisoprodol is a centrally-acting skeletal muscle relaxant and salicylate analgesic.
Carisoprodol is used for musculoskeletal conditions such as muscle spasms. Carisoprodol has a mild anxiolytic effect. Maximum is two tablets PO 4 times daily. This is equivalent to 1,600 mg of carisoprodol and 2,600 mg of aspirin daily. Use it with caution in debilitated elderly patients. Limit to 2-3 weeks as it has not been studied for long periods and is usually given in acute muscle pain situations. Most

side effects of these medications come from the aspirin portion due to increased blood thinning. Avoid opioid preparations, which may increase CNS depression (PDR, n.d.).

Tramadol is an opiate sometimes used for patients experiencing intractable pain because of its impact on peripheral pain pathways, partial inhibition of serotonin reuptake, and low affinity for opioid receptors. This is thought to result in less sedation, respiratory depression, and potential for tolerance; however, constipation can still be problematic because of anticholinergic adverse effects. Caution should be exercised in administering tramadol to epileptic patients because this drug is known to lower the seizure threshold. In addition, tramadol should not be combined with morphine, selective serotonin reuptake inhibitors, tricyclic antidepressants (TCAs), or anticonvulsants because it can precipitate serotonin syndrome. Doses may need to be reduced in patients with renal failure (PDR, nd.).

Schedule V

Medications containing codeine must have less than 200 mg of codeine per 100 mL (cough syrups). Tylenol #3® and Tylenol #4®. Tylenol #3® and Tylenol #4® are an oral combination of analgesics, which include an opioid agonist. The combination is available as a liquid of 120 mg of acetaminophen per 12 mg of codeine in five ml. Oral tablets of Tylenol #3® are 300 mg of acetaminophen per 15 mg of codeine. Tylenol #4 is 300 mg per 30 and 300 mg per 60 mg daily. This is commonly used for mild to moderate pain where opioids are appropriate. Over 60 mg of codeine and one dose is not considered beneficial and raises the side effects profile. Adults and seniors' maximum dose is 4000 mg of acetaminophen with 360 mg of codeine for the tablets and the liquid. Codeine as an opiate has all the same side effects and adverse effects as other opioids. This medication may mistakenly be less protected from children, pets, or other adults because of the Tylenol® name. Tylenol #3 and Tylenol #4 are acetaminophen mixed with codeine. Acetaminophen alone should only be given during pregnancy if the benefit to the mother outweighs the risk to the baby. Codeine is not recommended during labor due to decreased CNS and decreased contractions. Opioids do cross the placenta and breast milk and will decrease CNS. Naloxone may be needed to reverse increased respiratory depression in neonates if the mother takes the medication regularly. Regular use during pregnancy may cause neonatal opioid withdrawal syndrome (NOWS) at birth.

Patients with respiratory dysfunction should not use this medication. If patients have hepatic or severe renal disease, dosing should be altered by longer intervals between doses and reduced dosages. Consider the lowest dose for the shortest time needed, as with all controlled substances. Monitor these patients for hypotension, respiratory depression, and sedation. Remember to taper according to the amount taken and the time used. There are many drug-to-drug interactions, the most notable being other opioids, benzodiazepines, and MAOIs. Review drug lists carefully before prescribing.

Muscle relaxants

Tizanidine/Zanaflex, a Centrally acting muscle relaxant similar chemically to clonidine, works about as well as baclofen. Give 2 mg PO every 6 to 8 hours as needed up to a maximum of 6 mg in 24 hours, initially. You may increase the dose by 2 to 4 mg/dose every 1 to 4 days until a satisfactory reduction of muscle tone is achieved. Max: 36 mg/day. Single doses of more than 16 mg have not been studied. To discontinue, reduce the dose by 2 to 4 mg/day, particularly in persons who have been receiving high doses for long periods like 20 to 36 mg/day for nine

weeks or more, or who are receiving concomitant opioids, to minimize the risk of withdrawal and rebound hypertension, tachycardia, and hypertonia. Abrupt discontinuation of tizanidine may result in withdrawal adverse reactions, including rebound hypertension, tachycardia, and hypertonia. To minimize the risk of withdrawal, particularly in patients who have been receiving high doses for long periods like 20 to 28 mg/day for nine weeks or longer, or who may be on concomitant treatment with narcotics, decrease the dose slowly, 2 to 4 mg/day (PDR, n.d.).

Tizanidine causes dry mouth. It may cause orthostatic hypotension, especially in the elderly. Avoid tizanidine in hepatic dysfunction and use it cautiously in pregnancy. It may be secreted in breast milk because it is lipid-soluble (PDR, n.d.).

Cyclobenzaprine/ Flexeril-a muscle relaxant for acute musculoskeletal pain, maximum dose of 10 mg three times a day after a start of 5 mg three times a day. PDR.net recommends two to three weeks as the maximum length of use. The extended-release product is 15 mg per day and is not recommended for the geriatric population due to the drug's substantial increase in plasma concentrations and half-life. A low dose of 1 to 4 mg at bedtime is being used for fibromyalgia patients' sleep needs and pain reduction. However, evidence for this is weak. They may have cross hypersensitivity with TCA's as they are chemically related, and because they are cyclobenzaprine should not be used in patients with seizure disorders. It is not to be used for hyperthyroid patients due to the risk of cardiac events and depression, nor with MAOI. Serotonergic drugs tramadol, bupropion, SNRIs, meperidine, or Verapamil, may cause serotonin syndrome.

Interactions and adverse reactions are many, especially in a predisposed population such as patients with multiple comorbidities. It should not be used for intrathecal radiographic contrast administration; therefore, discontinue it 48 hours before and 24 hours after myelography. Patients should avoid prolonged UV exposure due to increased chances of sunburn. According to the Beers Criteria, cyclobenzaprine is an inappropriate medication for seniors due to strong anticholinergic activity and an almost twofold increase of plasma concentration in the elderly. This leads to weakness, sedation, and falls.

Side effects are many, usually noted early in treatment. Patients should be monitored for palpitations, confusion, and blurred vision. Later in administration, patients may see seizures, constipation, cardiac arrhythmias, and gastric and genital urinary symptoms. Rare but notable side effects could be NGO edema. Mild side effects such as xerostomia, drowsiness, dizziness, headache, GI disturbances, and fatigue may be seen. For more information online for this and all medications profiled here, go to www.pdr.net (PDR, n.d.).

Opioid agonist/antagonist

Naloxone is an opioid antagonist, a derivative of oxymorphone employed for reversing the central nervous system and respiratory depression caused by opioid overdose.
Auto-injectors and nasal formulations are available to treat or prevent an overdose outside of the healthcare setting. Naloxone nasal insufflation may be used in adults, children, and even infants at both the 4 and 8mg doses.

Medicaid, Medicare, and most insurance cover Naloxone. There are free Naloxone programs nationwide and prescription cards that can reduce the costs of prescribed Naloxone to about $20.00 per kit. It should be remembered that as an opioid antagonist, it can precipitate a

complete and sudden opioid withdrawal crisis for the patient. In the pain patient, too much Naloxone can also remove all analgesic effects of the opioid being reversed. This can be extremely dangerous, even fatal, for an opioid-addicted infant and extremely uncomfortable for the opioid-addicted in other age groups. Think severe instant withdrawal, a trip to the hospital to combat this may be necessary. The half-life of the nasal spray is comparable to the injection at about 2 hours. When given for fentanyl overdose, it may have to be repeated as fentanyl and other synthetic drugs, such as carfentanil related to fentanyl, are 10,000 times stronger than morphine. Naloxone should be used cautiously with patients taking buprenorphine and Cobistat concurrently with HIV protease inhibitors (PDR, 2023). As of this writing, Naloxone has been made an over-the-counter medication by the FDA.

Buprenorphine is prescribed for patient support while tapering off opioid addiction and can be combined with naloxone to make a medication called Suboxone®. Buprenorphine/naloxone combo is available dose is 2 to 8 mg tabs, taken twice daily. Babies born to mothers using opioids are likely to experience withdrawal with the combination drug. This medication is not low-priced at up to $350.00 a month and $450.00 a month as Suboxone® Medicare and Medicaid prices differ. It is a weaker pain medicine but cannot be combined with other opioid medications due to increased respiratory depression and changes in opioid metabolism. It may be used with NSAIDs, nerve blocks, regional anesthetics, and antiepileptics.

The provider must monitor for missed doses as they could be for illicit drug use. Monitor LFTs and warn patients that used as an IV drug damages the liver—considered safer at higher doses (24mg/day max) which may be required for off-label pain use. Compared to methadone, buprenorphine is safer and easier to wean a patient off of opioids than methadone. There are no special clinics needed. Methadone treatment is often lifelong, whereas suboxone treatment lasts 90 to 180 days. If combined with any CNS depressant respiratory depression may result (Pruess, 2022). Weekly meetings should be considered to reeducate family members on the signs and symptoms of toxicity and warn the patient not to mix with CNS depressants.

Medications with a strong CYP 450-dependent inhibitor, such as ketoconazole and protease inhibitors, may increase serum levels of buprenorphine. On the other hand, strong inducers of the enzyme, like barbiturates and some antiseizure medications, may decrease the levels of buprenorphine. Since the half-life is about 70 hours, it can be dosed every other day when a therapeutic serum level is reached. A long dry-out period is observed after methadone, fentanyl patch, long-acting morphine, or oxycodone preparation usage of up to 72 hours. With short-acting opioids like immediate-release oxycodone or heroin, just 6 to 12 hours is needed. To avoid sudden severe withdrawal symptoms from methadone, delay buprenorphine until the dose of methadone is decreased to 30 mg daily. Then a 72-hour dry-out is recommended. It does cross the placenta and is excreted in breast milk. It is a category C drug for pregnancy. The benefits are considered to outweigh the risks of opioid use during pregnancy. Specialized training is required to learn how to use buprenorphine effectively, maintain documentation, and patient monitoring. A DEA number is required to prescribe it (PDR, n.d.).

Methadone is structurally unrelated to morphine, and Methadone is a Schedule II synthetic opiate agonist. Used in medically supervised opiate withdrawal and maintenance programs; also effective for relieving severe or chronic pain. For the treatment of opiate dependence, prescribers must register and comply with the Narcotic Addict Treatment Act (NATA) [21USC 823(g)]. It is available as Methadone Hydrochloride/Methadone Oral Sol: 1mL, 10mg. This is the most commonly used form. With appropriate dosage titration, there is no

maximum dose of methadone. Consider the loss of opioid tolerance for anyone who has not taken opioids for more than five days. With renal or hepatic dysfunction, start low and titrate slowly as metabolism is notoriously unstable. With mild to moderate renal function, a CrCl 30 to 50 mL/minute administer dosage every 6 to 8 hours. For a CrCl 10 to 30 mL/minute: Administer dosage every 8 to 12 hours. For a CrCl less than 10 mL/minute: Administer dosage every 12 to 24 hours.

Methadone is well known for "stacking up" in the elderly, meaning the metabolism is reduced and the prolonged half-life merges to the point that the dosages may overlap, causing an overdose. Monitor them closely for CNS depression. In case of an overdose, naloxone should be administered. Because methadone has a long half-life, it is necessary to provide a prolonged infusion or multiple doses of naloxone. Patients who have overdosed should be transported via EMS and hospitalized for observation (PDR, n.d.).

Benzodiazepine Antagonist

Flumazenil/ Romazicon Is not available commercially in an intranasal spray. Therefore, the overdosed patient must be transported immediately to the hospital for care. It treats benzodiazepine overdose, reverses benzodiazepine-induced sedation, and antagonizes the actions of zolpidem. It does not reverse the actions of barbiturates, opiate agonists, or tricyclic antidepressants. The initial dose is 0.2 mg IV. The dose may be repeated after 45 seconds if the desired level of consciousness is not achieved and subsequently at 1-minute intervals until a maximum of 4 doses have been administered. The dose is 1 mg total over 5 minutes. Observe the patient for at least two hours after administration for signs of re-sedation and hypoventilation. Repeat the regimen at 20-minute intervals, up to a maximum of 3 mg/hour. If this occurs, up to a maximum of 5 mg IV total cumulative doses for suspected benzodiazepine overdose. If the patient continues to be unresponsive at this dose, the cause of sedation is not likely to be benzodiazepines. The maximum dose for reversal of conscious sedation is 1 mg IV (PDR, n.d.).

How is pain assessed for opioid prescription cases?

Pain is assessed the same in every case. It is the details that matter here. Ask where it hurts and mark the pain map meticulously as a baseline. Document further using a pain assessment tool like the PQRST model, PEG, or 1-10 scale. The Baker-Wong scale has only five faces and is often used for children. The benefits of this scale are that it works no matter the patient's age or language. Be sure to provide a patient-friendly professional interpreter and tools if the patient speaks a different language at home. The following are website examples of a pain map, assessment tools, and scales.

- Pain Map
- PQRST Pain Assessment
- PEG scale
- 1-10 pain scale
- Wong-Baker Scale

Get a complete social, family, and health history, including diseases or co-morbidities. Find out if they have seen other providers for this pain, what was tried, did that help, and has the pain changed. Knowledge is power. The more you know about this patient and the past, present, and future, the better you will help them and yourself.

Modified PEG tool

If the pain is not specifically trauma related, is it a product of diseases such as Sickle Cell disease (SCD), MS, or Diabetes Imaging studies are in order once you have eliminated obvious physiologic reasons for pain: injury, trauma, metabolic, or polypharmacy. Insurance companies require a certain order of imaging tests, or the patient must pay out of pocket. Usually, radiographs are followed by CT scans, and finally, MRIs can be done. Insurance companies are poor decision-makers regarding what should be done and when. You will help your patient by preauthorizing tests. While different pains can all be assessed in about the same manner and treated differently, eventually, we can use pharmacogenetics as a more personalized prescription.

Doctors and scientists have already discovered DNA useful to determine whether some drugs might be metabolized better by some people due to genetic expression and enzymes that either promote or inhibit metabolism. The CYP 450 and the CYP 46B4 are enzymes responsible for many pharmaceutical metabolic actions, including opioids and other pain-alleviating drugs. These are expressed well, moderately, or not in different people.

What kind of drugs should I prescribe for the different types of pain?

Many patients have a combination of types of pain. A severe injury or trauma patient might experience soft tissue and visceral and nerve pain. Bone fractures, burns, and crushing injuries are similarly complex to treat. Then there are the most common patient complaints of disease-related pain, headaches, back pain, orthopedic sprains, and tears. Soft tissue pain is considered inflammatory pain that benefits from NSAIDS. For nerve pain, Consider TCAs or antiseizure medication such as Neurontin. Are there labs or imaging needed to discern the cause of visceral pain? Treating the source of the pain is always the desirable answer if etiology can be identified. Consider over-the-counter anti-inflammatories such as Naprosyn Sodium or Ibuprofen, non-anti-inflammatory acetaminophen, or a combination product.

Non-cancer disease pain like sickle cell disease is chronic with acute or chronic flares. This pain may require opioids such as MS Contin, with an immediate release “backup” such as Oxy IR. For diseases and disorders such as arthritis, irritable bowel disease, ulcerative colitis, sciatica, migraines, fibromyalgia, and rheumatoid arthritis, to list a few, NSAIDs with non-pharmacological adjuncts are just as successful (V.A. 2022). Cancer pain is often treated with long-acting or extended-release opioids.

How do I get my patients off controlled substances safely?

The CDC and Goldstick et al. (2022) have made mention of the previous 2016 controlled substance guidelines being followed so strictly that patients were harmed by being tapered too quickly off opioid pain medications and not being given adequate support during the process

(Dowell et al.,2022), (Goldstick et al., 2022).

Tapering is the deliberate reduction of controlled substance dosage and lengthening intervals between doses. You can use tapering algorithms to help your patients stop taking these problematic medications. No perfect tapering algorithm fits every unique physical and psychological situation because every patient's mind, spirit, and body are unique. Research shows that out of almost 14,000 patients who tapered off opioids over one year, they continued to have pain, overdose, and increased mental health crisis issues, even suicide up to two years after the tapering started (Fenton et al., 2022). The United States Department of Veteran's Affairs (VA) has given provider advice for tapering: reducing opioid medications in the chronic opioid user taking more than 50 MMEs per day should not exceed 5-20% of the total daily dose per month (VA, 2019). This amount may help a patient to reduce or discontinue the opioid drug, keeping in mind that the patient must be educated that they cannot suddenly return to the original dose as they will no longer have the tolerance for it. It will precipitate an overdose (Fenton et al., 2022).

According to Fenton et al. (2022), 15.3% of patients in their meta-review successfully discontinued opioid use and had fewer mental health issues. According to the same study, however, the other 74% of the patients continued to need opioid pain medications at a reduced rate, and a few eventually increased the dosage they were taking (Fenton et al., 2022). This complex study led to several conclusions over and above these. The main gist of the study is that the dangers of opioids do not end with tapering the medications, and the patient should be followed and supported up to two years after initialization of the tapering efforts. The provider may need to consider keeping the pain goals fluid.

In today's medical practices, most providers lack consistent electronic calendar reminders and the time to achieve these needs. Providers must keep this at the forefront of their communications with the patient at every visit. Educating the patient regarding the need for extra follow-up, rotating medications, and starting non-pharmacological therapies early may help to alleviate or reduce these mental health crises. Unfortunately, not all patients can be discontinued from pain medications and maintain a decent quality of life.

Per the CDC:

You can refer specifically to DSM-5 Criteria A and B for opioid withdrawal syndrome:

- Either of the following:
  - Cessation of or reduction in opioid use that has been heavy and prolonged for several weeks or longer; or
  - administration of an opioid antagonist after a period of opioid use
- Three or more of the following, developing within minutes to several days after Criterion A:
  - dysphoric mood
  - nausea or vomiting
  - muscle aches
  - lacrimation or rhinorrhea
  - pupillary dilation, piloerection, or sweating

- diarrhea
- yawning
- fever
- or insomnia (2022).

What about hospice and end-of-life patient pain?

Pain in hospice patients varies from patient to patient. Pain in this population is treated in ways that could not be employed for non-terminal disease pain. In the past, methadone, morphine, oxycodone, and fentanyl have all been used in nearly every formulation, from oral and sublingual tablets, capsules, lollipops, injections, automatic pumps, oral films, and transdermal patches. The medication dosages are titrated up to the level of effect, which will keep the dying patient from suffering from symptoms of uncontrolled pain while dying. The dosages are often extraordinarily high compared to a patient who is expected to live longer than six months.

In this situation, there is no need for limits concerning addiction or the need to taper the patient from the medications in the future. There is still the possibility of overdose as the metabolism slows at the end of life, and there is a need to be cognizant of that. Also, there is a certain amount of drug diversion by family, visitors, and medical personnel (Cagle, 2020). Again safe, locked storage of these medications should be in place, regardless of the inconvenience to the patient, providers, and caregivers. Pain medication in terminal cancers and other life-ending disease processes is multilayered and ever-changing due to the complexities of physiological changes.

All this takes time. How do I equitably bill for this?

Billing codes for this do exist. For Calendar Year (CY) 2023 Medicare Physician Fee Schedule Final Rule, go here.

Medicare is using the following codes, Pain Management bundle codes effective January 01, 2023:

- Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by a physician or other qualified healthcare professional, per calendar month.
- When using G3002, 30 minutes must be met or exceeded. In other words, the code includes assessment, diagnosis, and monitoring of the patient's pain, including working with other clinicians to manage treatment and lead to better outcomes. However, this code only describes the first 30 minutes of chronic pain management care.
- Providers who spend more than 30 minutes with the patient can report the new add-on code: G3003: Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified healthcare professional per calendar month, listed separately in addition to code for G3002. When using G3003, 15 minutes must be met or exceeded. Because G3003 is considered an add-on code, providers can only report it if they spend more than 30 minutes on CPM (Kim, 2023).

Billing codes designed for the AMA: Evaluation and Management (E&M) codes are ever-changing. For a complete sheet, go here. For the complete document with accompanying grids and in-depth instructions, go here.

Can you summarize all this?

As a healthcare provider/prescriber, it is inescapable that you decide a patient's motivation when coming to you with pain or mental health issues in each unique case. You will be expected to try to discover if a patient is an unfortunate human being who needs your expertise or has addiction issues, with multiple substance abuse like alcohol, cannabinoids, or opioids, and plans to divert, sell, or give away the controlled substances you prescribe. In order to "Do no harm," there are multiple steps to prescribing controlled substances as mandated by law in your state.

This includes requiring your patients to consent to and submit to urine drug testing and pill counting, educating them about safe storage, preventing overdose, an emergency treatment for overdose, and the need to be alert to theft by family or others. Maintain all the tools and consent with your specific documentation in the patient's chart. It is a good idea for providers to perform a self-assessment for bias against or toward race, gender, age, or ethnic group regarding willingness to prescribe opioid vs. non-opioid pain medications.

Written treatment agreements between prescribers and patients when controlled substances are used help guide the conversation between patient and prescriber. It discusses expectations, the risks, and the monitoring that will occur to limit the complications of controlled substances (Table 1).

Table 1: Points Commonly Seen in Opioid Agreements

- Early refills will generally not be given.
- Patient will not seek controlled substances from another provider.
- Patient will use only one pharmacy.
- Permission for the prescriber to speak freely with other healthcare providers, pharmacists, and family members regarding opioid use.
- Patient will submit to urine drug testing.
- The patient will safeguard the medications.
- Common side effects of the medication will be discussed.

Thankfully, there are billable codes for every minute, and within reason, you must devote yourself to this pain management plan with each patient. Eventually, it is up to you to decide if you want to maintain your pain patients or if referring them to a pain specialist would be

more time and cost-effective. Does the patient's pain require more expertise for longer than you are willing to manage? Mental health patients decide whether they prefer mental health or purely medical professionals for their special needs.

Resources

- DEA Takeback Program. Visit Resource.
- Commonly encountered drug interactions with NSAIDs. Contributed from the Public Domain (Wikipedia User: COP2013G02). Visit Resource.
- ClinCalc, Equivalent Opioid Calculator. Visit Resource.
- Calculation of Oral Morphine Equivalents (OME). Visit Resource.
- NIDA. Visit Resource.
- National Opioids Crisis: Help and Resources. Visit Resource.
- The Rural Communities Opioid Response Program. Visit Resource.
- CDC. Visit Resource.
- Risk Evaluation, mitigation strategies, patient communication guide and CEs. Visit Resource.
- Suboxone patient assistance plans. Visit Resource.

Implicit Bias Statement

CEUFast, Inc. is committed to furthering diversity, equity, and inclusion (DEI). While reflecting on this course content, CEUFast, Inc. would like you to consider your individual perspective and question your own biases. Remember, implicit bias is a form of bias that impacts our practice as healthcare professionals. Implicit bias occurs when we have automatic prejudices, judgments, and/or a general attitude towards a person or a group of people based on associated stereotypes we have formed over time. These automatic thoughts occur without our conscious knowledge and without our intentional desire to discriminate. The concern with implicit bias is that this can impact our actions and decisions with our workplace leadership, colleagues, and even our patients. While it is our universal goal to treat everyone equally, our implicit biases can influence our interactions, assessments, communication, prioritization, and decision-making concerning patients, which can ultimately adversely impact health outcomes. It is important to keep this in mind in order to intentionally work to self-identify our own risk areas where our implicit biases might influence our behaviors. Together, we can cease perpetuating stereotypes and remind each other to remain mindful to help avoid reacting according to biases that are contrary to our conscious beliefs and values.

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