

Controlled Substances: Opioids for Pain Management

Clinical Practice Guideline MedStar Health

These guidelines are provided to assist physicians and other clinicians in making decisions regarding the care of their patients. They are not a substitute for individual judgment brought to each clinical situation by the patient's primary care provider-in collaboration with the patient. As with all clinical reference resources, they reflect the best understanding of the science of medicine at the time of publication, but should be used with the clear understanding that continued research may result in new knowledge and recommendations.

RATIONALE

While opioids remain an essential medication class for the management of acute and chronic pain, there is increasing awareness of and attention to their risks. Opioids are the most common prescription medications that are misused or diverted. According to the 2017 National Survey on Drug use and Health, at least 11.4 million Americans age 12 and older misused opioid pain relievers in the prior year, with hydrocodone containing products representing the opioids most likely to be misused. Further, even when taken as prescribed, any person who takes opioids for more than 30 days is at increased risk of opioid addiction. The purpose of this guideline is to improve awareness, both to providers and patients, of opioids risks and benefits, and will help to preserve the ability of providers to safely prescribe chronic opioid therapy where such therapy is appropriate.

DEFINITIONS

Acute Vs. Chronic Pain

A commonly used definition of *acute* pain is pain lasting less than 30 days, and a commonly used definition of *chronic* pain is pain lasting more than three months. However, these definitions are arbitrary and not essential for deciding on treatment strategies. Symptoms and causes of the two types of pain may overlap and pathophysiological factors can be independent of duration. Therefore, this division between acute and chronic pain based on duration may be problematic.

Acute pain is of sudden onset, is felt immediately following injury, is severe in intensity, but is usually short-lasting. It arises as a result of tissue injury stimulating nociceptors and generally disappears when the injury heals.

Chronic pain is continuous or recurrent pain that persists beyond the expected normal time of healing. Chronic pain may begin as acute pain and persist for long periods or may recur due to persistence of noxious stimuli or repeated exacerbation of an injury. Chronic pain may be neuropathic, musculoskeletal, inflammatory or compressive in origin. Chronic pain may also arise and persist in the absence of identifiable pathophysiology or medical illness. Chronic pain can negatively affect all aspects of daily life, including

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physical activities, school attendance, sleep patterns, family interactions and social relationships and can lead to distress, anxiety, depression, insomnia, fatigue or mood changes, such as irritability and negative coping behavior. As pain is an outcome of an interaction of many factors, the patient as a whole must be considered when evaluating the clinical features of pain. Therefore, a holistic approach may be required to relieve pain.

Pain Medication (analgesics) – medication whose primary function is to relieve pain and is divided into two groups: 1) opioids and 2) non-opioids. Opioids are used in treatment of acute and chronic pain and are indicated for severe pain or when moderate pain is disabling, when non-opioid therapy has failed, or the need for more aggressive intervention is needed.

Indications for chronic opioid use: While there is a risk of harm from any medication, the risk of harm is increased with opioids. This risk exists for the patient who is prescribed opioids, and for family members who intentionally or unintentionally have access to these medications. While it is important to identify and treat pain, it is important to balance potential benefit against risk. Because the potential for risk increases with chronic use, prescribers should exercise additional caution when prescribing opioids for chronic use. Opioids are indicated for chronic pain when: (a) pain is moderate to severe, and/or disabling; (b) aggressive intervention is warranted, or; (c) non-opioid therapy has been tried, and has failed to adequately control pain.

Physical dependence – using opioids daily for a few weeks may result in a physical dependence that manifests itself with withdrawal symptoms when stopped.

Opioid tolerance – patients are considered opioid tolerant when they have received 60 mg of morphine equivalents or more for greater than one week. Tolerance is required for certain opioid products (e.g., transdermal fentanyl) and reflects the ability to tolerate doses above that of an opioid-naive patient.

Analgesic tolerance – means that the same dose of opioid gives less pain relief (in the absence of disease progression or other external factors). There is wide individual variability during opioid therapy.

Addiction – addiction is the use and/or craving of a drug despite harm to one's quality of life, health, or social relations. A personal history of addiction or family history of addiction disorder may increase the risk. Nicotine use (in any form) increases this risk.

Withdrawal symptoms – withdrawal symptoms may include runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, body aches and/or flu like feeling. These symptoms may last 7-10 days or longer but are rarely life threatening. Certain medical conditions will also increase this risk and will need to be monitored more carefully.

Side effects of opioids – Common side effects include constipation, nausea, itching, hives, drowsiness, loss of appetite, upset stomach, sweating, and dizziness. Less common side effects

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include difficulty urinating, feeling slowed down, sexual dysfunction, irregular menses, confusion, increased sensitivity to pain, increased pain with increased opioid dose, muscle twitching, sadness, depression, irregular heartbeat, and sleep apnea. Tolerance to many side effects from opioids can be recognized between days 3-5 of regular dosing, except for constipation. Management of select side effects:

- Constipation-- Patients on daily opioid therapy should be prescribed an appropriate bowel regimen (e.g., Senna, 2 tabs daily). Contributory factors (dehydration, tricyclic antidepressants, metabolic abnormalities) should be addressed and corrected if possible. If constipation persists, a stepwise approach can be taken:
 - Conventional laxatives
 - o Lubiprostone
 - Peripherally acting mu-opioid receptor antagonists (PAMORAs) such as methylnatrexone, naldemedine and naloxegol. These agents should be used with caution in patients with known or suspected lesions in the intestinal wall to prevent perforation.
- Pruritus—The mechanism of pruritus is uncertain but may be mediated through central mu-opioid receptors. Treatment options include non-sedating antihistamines, diphenhydramine, paroxetine, gabapentin and opioid rotation.
- Drowsiness and mental clouding—Ruling out contributing structural or metabolic abnormalities is important as is re-evaluating the dose or choice of opioid. Consideration can be given to adding an adjuvant analgesic in an attempt to achieve an opioid sparing effect. Finally, psychostimulants can be considered.

OPTIMAL OPIOID PRESCRIBING

MedStar Health endorses the CDC recommendations for prescribing opioids for chronic pain.¹

CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care

Determining When to Initiate or Continue Opioids for Chronic Pain

- 1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
- 2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

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3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

- 4. When starting opioid therapy for chronic pain, clinicians should prescribe immediaterelease opioids instead of extended-release/long-acting (ER/LA) opioids.
- 5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
- 6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
- 7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

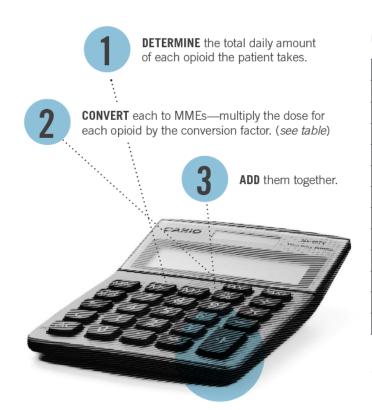
- 8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
- 9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
- 10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- 11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

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12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

* All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.

Calculating morphing milligram equivalents (MME)



Calculating morphine milligram equivalents (MME)

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.

USE EXTRA CAUTION:

- Methadone: the conversion factor increases at higher doses
- Fentanyl: dosed in mcg/hr instead of mg/day, and absorption is affected by heat and other factors

https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

Do not use the calculated dose in MMEs to determine

dosage for converting one opioid to another-the new opioid should be lower to avoid unintentional overdose

caused by incomplete cross-tolerance and individual

differences in opioid pharmacokinetics. Consult the

Special Populations:

medication label.

CAUTION:

1. The elderly—elderly patients have increased sensitivity to both the therapeutic and the adverse effects (constipation, urinary retention, dry mouth and sedation) of opioid pain

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medications. They also are more likely to have impaired kidney function. Consequently, starting doses should be lower and escalation should be slower than for younger patients.

- 2. Patients with chronic kidney disease or chronic liver disease—opioids should be used cautiously, with attention to dose and route of excretion.
- 3. Pregnant patients—according to the 2012 ACOG Committee Opinion on Opioid Abuse, Dependence, and Addiction, 1% of pregnant women reported nonmedical use of opioid containing pain medication. Opioid dependent pregnant women should be co-managed by the obstetrician and addiction medicine specialist. General principles of care include avoidance of abrupt discontinuation of opioids, use of methadone or buprenorphine for opioid assisted treatment, and vigilance for the neonatal abstinence syndrome in the neonate.

DOCUMENTATION

The patient's medical record should include the diagnosis causing chronic pain as well as a discussion of risks, benefits, alternatives and goals of therapy. It is important for the patient to realize that this medication is not designed to completely eliminate his/her pain but rather to reduce the pain so that the patient is able to perform activities of daily living as well as engage in social activities to improve quality of life.

Consideration should be given to assessing risk of opioid misuse using one of the available screening tools (SOAPP, Opioid Risk Tool).

The Current Opioid Misuse Measure (COMM) tool may be useful in identifying aberrant behaviors suggestive of opioid misuse in patients receiving long-term opioid therapy.

Note that chronic pain management is optimally achieved through the relationship of the patient with a single provider who knows him/her well. Episodic care with providers who do not have a true relationship with the patient (such as in the ED) is not an effective means of achieving true management of chronic pain.

All patients who are prescribed chronic opioid therapy and/or are at increased risk of opioid addiction as determined by the provider (even if prescribed short term opioid therapy) must sign a Controlled Substances Agreement. MedStar Health considers the Controlled Substances Agreement mandatory for all patients who are prescribed 90 days or more of continuous opioid therapy.

All Controlled Substance Agreements should be reviewed and renewed annually if opioid therapy is ongoing.

A violation of the Controlled Substance Agreement may result in discontinuation of opioid medication (abrupt or rapid taper as clinically appropriate) and/or termination of the patient from the provider's practice.

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Unannounced random urine or serum toxicology screens may be requested to determine compliance with this agreement and the opioid treatment regimen. This may include screens for illegal substances. Refusal of this testing may lead to a rapid weaning schedule to discontinue the opioid medication and/or prompt termination from this practice.

The patient must receive a copy of the signed Controlled Substance Agreement. The original signed Controlled Substance Agreement should be filed or scanned into the patient's chart. A copy of this guideline should be available to the patient on request.

The patient agrees to keep his/her opioid prescription closely safeguarded from others, and especially from children, who are at increased risk of harm and death from ingestion. The patient must also understand that he/she may not share, sell, trade, exchange his/her opioid medication for money, goods, services, etc., or permit others to have access to his/her opioid medications, and these opioid medications must be secured at all times from wrongful access.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16-45 yrs	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Screening totals		

Opioid Risk Tool

Interpretation: Low risk for future opioid abuse: ≤ 3 Moderate risk for opioid abuse: 4-7 High risk for opioid abuse: ≥ 8

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Current Opioid N	Isuse.	vieasure			
In the past thirty days:	Never	Seldom	Sometimes	Often	Very often
How often have you had trouble with	0	1	2	3	4
thinking clearly or had memory problems	Ŭ	-	-	5	•
How often do people complain that you are					
not completing necessary tasks?(i.e., doing					
things that need to be done, such as going to					
class, work or appointments)					
How often have you had to go to someone					
other than your prescribing practitioner to get					
sufficient pain relief from medications?(i.e.,					
another practitioner, the Emergency Room,					
friends, street sources)					
How often have you taken your medications					
differently from how they are prescribed?					
How often have you seriously thought about					
hurting yourself?					
How much of your time was spent thinking					
about opioid medications (having enough,					
taking them, doing schedule, etc.)?					
How often have you been in an argument?					
How often have you had trouble controlling					
your anger (e.g., road rage, screaming, etc.)?					
How often have you needed to take					
medications belonging to someone else?					
How often have you been worried about how					
you're handling your medications?					
How often have others been worried about					
how you're handling your medications?					
How often have you had to make an					
emergency phone call or show up at the					
clinic without an appointment?					
How often have you gotten angry with					
people?					
How often have you had to take more of					
your medication than prescribed?					
How often have you borrowed pain					
medication from someone else?					
How often have you used your pain medicine					
for symptoms other than for pain (e.g., to					
help you sleep, improve your mood, or relive					
stress)?					
How often have you had to visit the					
Emergency Room?					

Current Opioid Misuse Measure (COMM)

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Interpretation: Score of 9 or more—negative predictive value 95%, positive predictive values 66%. This tool is most useful in identifying patients at low risk for abusing or misusing opioids.

Prescribing naloxone

Prescribing naloxone is an important intervention to reduce fatalities from opioid overdoses. Please see the MedStar Health guideline for detailed information.

http://starport.medstar.net/msh/_layouts/15/WopiFrame.aspx?sourcedoc=/msh/Ambulatory%20 Guidelines/Prescribing%20naloxone%20in%20the%20outpatient%20setting--Oct%202019--Final%20(002).pdf&action=default

Drug Diversion

Drug diversion is defined as the unlawful distribution or use of prescription drugs in a manner not intended by the prescriber. Drug diversion can result in addiction, overdose and even death. Methods for prescription drug diversion may include the following:

- patients selling legally obtained prescription drugs
- patients altering a prescription to obtain an unlawful quantify of medication
- patients forging prescriptions
- patients obtaining medications under false pretenses

Clues that a patient may be diverting medication include reluctance to permit an appropriate physical exam, refusing to give permission to obtain prior medical records, exaggerated or feigned symptoms, very specific medication requests or new patients who claim to be traveling to your area and "forgot" their controlled substances.

Steps to prevent drug diversion include:

- Always perform a complete history and physical.
- Obtain information from prior practitioners
- Document thoroughly when prescribing or choosing not to prescribe controlled substances
- Minimize controlled substance prescribing
- Use controlled substance agreements
- Query the appropriate prescription drug monitoring program
- Electronically prescribe controlled substances
- Protect paper prescription pads from theft
- Refer patients with extensive pain management needs to pain management.

Regulatory issues

CMS has finalized new polices, effective January 2019, for Medicare Part D beneficiaries.

• Opioid naïve patients—initial opioid prescription fills limited to no more than 7 days for acute pain

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- Chronic opioid users—implement real-time safety edits for chronic opioid users at the time of dispensing
- Opioid care coordination—implement a care coordination edit when the cumulative MME per day across all prescriptions reaches or exceeds 90 MME. A hard safety edit may be implemented at doses reaching 200 MME.
- High risk opioid users—beneficiaries may be required to obtain frequently abused drugs from selected pharmacies or prescribers after case management and notice to the beneficiary.
- Opioid users also taking duplicative or key potential drugs—implement soft safety edits to alert the pharmacist to duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

Beneficiaries who are long term care residents; hospice care, palliative care or end of life care recipients; or being treated for active cancer-related pain are excluded.

Prescription Drug Monitoring Programs:

Regulations related to the prescription drug monitoring programs in Washington, DC, Maryland and Virginia are as follows:

DC

Prescribers in the District of Columbia are encouraged but not required to access the PDMP. Prescribers who intend to access the PDMP must notify patients that the PDMP will be accessed either by posting a sign in a visible location or by providing a written notice.

Maryland

All prescribers in the State of Maryland must access the PDMP before beginning a new course of treatment with an opioid or benzodiazepine or when a course of treatment extends beyond 90 days. Exceptions include the following:

- Prescriptions extending for three days or less
- Prescriptions extending for 14 days or less following surgery, fractures, significant trauma or childbirth
- Prescriptions for cancer treatment or cancer-related pain
- Patients receiving treatment in an inpatient unit of a hospital, diagnosed with a terminal illness, part of a general hospice program or residing in a nursing home, long term care, developmental disability or assisted living facility

Prescribers must document in the patient's medical record that the information from the PDMP was requested and assessed.

<u>Virginia</u>

All prescribers authorized to prescribe opioids in the Commonwealth of Virginia must be registered with the PMP. At the time of initiating a course of opioid treatment anticipated to last 7 or more days or prior to prescribing medications for opioid use disorder, the

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prescriber shall access the PMP to determine what, if any, other controlled substances are being prescribed to the patient. Exceptions include opioids prescribed to patients receiving hospice or palliative care, patients receiving opioids in a hospital or at hospital discharge, or patients residing in a nursing home or assisted living facility using a single source pharmacy. Prescribers must notify patients that the PMP will be accessed either by posting a sign in a visible location or by providing a written notice.

The prescription drug monitoring programs in DC, VA and MD all share information with each other and many other states.

Tapering Opioid Medications

PLANNING OPIOID TAPERING

Opioid tapering involves six steps:

- 1. Assessing risks vs. benefits of tapering
- 2. Determining the total oral MMEs and tapering speed
- 3. Determining the order of tapering specific opioid medications if more than one prescribed.
- 4. Planning treatment to proactively manage withdrawal symptoms from tapering opioid medication(s).
- 5. Planning treatment options to manage pain through non-opioid and non-medication options
- 6. Planning the frequency of following up with the patient during the taper

Assessing risks vs. benefits of tapering

- a. The clinician must weigh the risks vs. benefits of continued opioid therapy by considering these factors ³⁴⁻³⁶:
- b. Patient initiates dosage reduction
- c. There is suspicion about substance use disorder
- d. The patient experiences an overdose or a serious adverse event
- e. The patient has medical comorbidities that increase their risk (mental health disorders, pregnancy, sleep apnea, lung disease, liver disease, etc.)
- f. The patient shows early warning signs for overdose risk
- g. There is suspicion about drug diversion
- h. The patient has been treated with opioids for prolonged period and benefit/harm ratio is unclear
- i. There is absence of clinically meaningful improvement in pain and function (e.g., at least 30% improvement on 3-item PEG scale [average Pain, Enjoyment of life, General activity])

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- j. There is concomitant use of benzodiazepines
- k. The patient requires higher dosages but there is no evidence of benefit

Determine total opioids prescribed and tapering speed

Opioid tapers can be completed over several months to years, depending on the opioid dose. The clinician must first calculate the total number of Oral MMEs. Once the total and individual doses of Oral MMEs by prescription are calculated, the clinician must then choose with the patient at what speed the opioids should be tapered. Of note, the current VA Guidelines recommend tapering patients if total MMEs exceed 90.

Slower taper speeds involve dose reduction by approximately 5-20% every 4 weeks, with pauses in taper as needed. Slower taper speeds are recommended when:^{34,38}

- The patient is on relatively higher doses of opioid
- The patient has been on opioid medications for a longer duration of time
- When safety permits, gradual taper is more often tolerated
- It is feasible to complete the tapering over several months to years

Standard taper speeds involve dose reduction by approximately 10% every 4 weeks.

Faster taper speeds involve dose reduction by approximately **10-20% every week.** Faster taper speeds are recommended when: ^{34,38}

- The patient is not adherent to the treatment plan
- There is an escalation of high-risk medication-related behaviors
- There is suspicion of drug diversion or illegal activities

Rapid taper speeds involve dose reduction by **20-50% of the first dose,** followed by **reduction of 10-20% every day.**

Determining the order of tapering specific opioid medications if more than one prescribed

If patients are receiving both long-acting and short-acting opioids, determine which formulation is to be tapered first based on: ^{34,38}

- patient safety,
- medical history,
- mental health conditions and
- patient preference (tapering both formulations simultaneously may be appropriate)
- It is recommended to first taper long-acting opioids, followed by short-acting opioids.

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Plan early treatment of withdrawal symptoms

Early Symptoms	Late Symptoms	Prolonged Symptoms
(hours to days)	(days to weeks)	(weeks to months)
 Anxiety/restlessness Rapid short respirations Runny nose, tearing eyes, sweating Insomnia Dilated reactive pupils 	 Runny nose, tearing eyes Rapid breathing, yawning Tremor, diffuse muscle spasms/aches Piloerection Nausea, vomiting, and diarrhea Abdominal pain Fever, chills Increased white blood cells if sudden withdrawal 	 Irritability, fatigue Bradycardia Decreased body temperature Craving Insomnia

Patients may experience several withdrawal symptoms during opioid tapering, including:³⁵

Withdrawal symptoms are not life-threatening and can be minimized with slower tapers. Early symptoms generally resolve within 5-10 days after initiating the opioid taper. However, some symptoms may resolve slower depending on the half-life of the opioid medication (e.g., methadone). Symptoms such as fatigue, mental functioning, pain, and well-being generally improve over time.³⁴

Medication therapy can be used to proactively manage withdrawal symptoms when beginning patients on an opioid taper. These medications are especially useful during faster tapers.³⁸

Considerations with managing opioid withdrawal:

- o Do NOT treat withdrawal symptoms with an opioid or benzodiazepine
- o Use short-term oral medications to manage withdrawal symptoms

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Indication	Treatment Options
Autonomic symptoms (sweating, tachycardia, myoclonus)	 First line Clonidine 0.1 – 0.2 mg oral every 6 – 8 hours; hold dose if blood pressure < 90/60 mmHg (0.1 – 0.2 mg 2 – 4 times daily is commonly used in the outpatient setting) Recommend test dose (0.1 mg oral) with blood pressure check 1 hour post dose; obtain daily blood pressure checks; increasing dose requires additional blood pressure checks Re-evaluate in 3 – 7 days; taper to stop; average duration 15 days Alternatives Baclofen, gabapentin, tizanidine
Anxiety, dysphoria, lacrimation, rhinorrhea	 Hydroxyzine 25 – 50 mg 3 times a day as needed Diphenhydramine 25 mg every 6 hours as needed*
Myalgias	 NSAIDs (e.g., naproxen 375 – 500 mg twice daily or ibuprofen 400 – 600 mg 4 times daily)** Acetaminophen 650 mg every 6 hours as needed Topical medications like menthol/methyl salicylate cream, lidocaine cream/ointment
Sleep disturbance	 Trazodone 25 – 300 mg orally at bedtime
Nausea	 Prochlorperazine 5 – 10 mg every 4 hours as needed Promethazine 25 mg orally or rectally every 6 hours as needed Ondansetron 4 mg every 6 hours as needed
Abdominal cramping	 Dicyclomine 20 mg every 6 – 8 hours as needed
Diarrhea	 Loperamide 4 mg orally initially, then 2 mg with each loose stool, not to exceed 16 mg daily Bismuth subsalicylate 524 mg every 0.5 – 1 hour orally, not to exceed 4192 mg/day

*Avoid for persons > 65 years' old

**Caution in patients with risk of GI bleed, renal compromise and cardiac disease

*Clonidine patches recommended

Plan treatment of the patient's pain with non-opioid medications

There are several non-opioid medication and non-medication options that can help manage the patient's pain during opioid tapering.³⁹

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Low back pain

Self-care and education in all patients; advise patients to remain active and limit bedrest

Nonpharmacological treatments: Exercise, cognitive behavioral therapy, interdisciplinary rehabilitation

Medications

- First-line: acetaminophen, non-steroidal anti inflammatory drugs (NSAIDs)
- Second-line: Serotonin and norepinephrine reuptake inhibitors (SNRIs)/tricyclic antidepressants (TCAs)

Migraine

Preventive treatments

- Beta-blockers
- TCAs
- Antiseizure medications
- · Calcium channel blockers
- Non-pharmacological treatments (Cognitive behavioral therapy, relaxation, biofeedback, exercise therapy)
- Avoid migraine triggers

Acute treatments

- Aspirin, acetaminophen, NSAIDs (may be combined with caffeine)
- Antinausea medication
- Triptans-migraine-specific

Neuropathic pain

Medications: TCAs, SNRIs, gabapentin/pregabalin, topical lidocaine

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Osteoarthritis

Nonpharmacological treatments: Exercise, weight loss, patient education

Medications

- · First-line: Acetamionphen, oral NSAIDs, topical NSAIDs
- Second-line: Intra-articular hyaluronic acid, capsaicin (limited number of intra-articular glucocorticoid injections if acetaminophen and NSAIDs insufficient)

Fibromyalgia

Patient education: Address diagnosis, treatment, and the patient's role in treatment

Nonpharmacological treatments: Low-impact aerobic exercise (e.g., brisk walking, swimming, water aerobics, or bicycling), cognitive behavioral therapy, biofeedback, interdisciplinary rehabilitation

Medications

· FDA-approved: Pregabalin, duloxetine, milnacipran

• Other options: TCAs, gabapentin

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Planning the frequency of following up with the patient during the taper

The frequency of following up with the patient depends on the speed of the tapering plan. The VA/DoD recommends this follow-up schedule:³⁴

Follow up	Slowest Taper	Slower Taper	Faster Taper	Rapid Taper
	(over years	(over months)	(over weeks)	(over days)
When	1 to 4 weeks after starting taper then monthly before each reduction	1 to 4 weeks after starting taper then monthly before each reduction	Weekly before each dose reduction	Daily before each dose reduction or if available offer inpatient admission
How	Clinic and/or	Clinic and/or	Clinic and/or	Hospital, clinic or
	telephone	telephone	telephone	telephone
What	Patient function, pain intensity, sleep, physical activity personal goals, and stress level			

Patients at high risk for decompensation during taper due to comorbid medical conditions or evidence of aberrant behaviors during the taper, may do better with a clinic visit than a telephone visit.

<u>Clinician Resources</u>

Prescription Drug Monitoring Programs

https://namsdl.org/wp-content/uploads/Model-Prescription-Monitoring-Program-PMP-Act.pdf

http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm

https://crisphealth.org/wp-content/uploads/2018/05/PDMP-Legislation-Fact-Sheet-_Version-V_May-1-2018.pdf

https://dchealth.dc.gov/service/prescription-drug-monitoring-program

https://www.dhp.virginia.gov/PractitionerResources/PrescriptionMonitoringProgram/

Milligram Morphine Dose Calculator

http://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm

MedConnect Resources and Documentation Tools Opioid Review component in provider view:

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Displays prescription, calculated MME per day and per total prescription as well as whether an opioid treatment agreement is on file, whether more then 3 opioids have been prescribed in the past 30 days, whether concurrent opioids and benzos are being prescribed, and whether there is documentation of a prior overdose.

Dpioid Review						ll Visits Last 30 days 🕤
Missing Opioid Treatment Agreement: Yes More than 3 Opioid Rx in the last 30 days: No Coprescribed Opioid and Benzo: Yes Previous Overdose: No						
Acute Opioid Administrations (0) o Morphine mg Equivalent View Details						
Prescribed and Documented Opioids (1) 60 Daily Morphine mg Equivalent						
Туре	Date	Status	Dispense Quantity	Refills	MME Day	MME Total
ů.	OCT 05, 2020	Prescribed	120 tab		60	1800
	tails quivalent	tails quivalent Type Date	tails quivalent Type Date Status	tails quivalent Type Date Status Dispense Quantity	tails quivalent Type Date Status Dispense Quantity Refills	s: No Coprescribed Opioid and Benzo: Yes Previous Overdose: No tails quivalent Type Date Status Dispense Quantity Refills MME Day

Opioid Risk Tool:

Adhoc \rightarrow Additional assessments \rightarrow Opioid risk tool

COMM:

Adhoc→Primary care→COMM

Controlled Substance (Narcotic) Agreement order:

Permits ad hoc printing from within patient's chart and allows the order to be used for tracking and data collection purposes

Opioid Risk Alert:

Fires when an opioid prescription containing 50 MME's or more is ordered and permits a naloxone order to be added at the discretion of the clinician.

Review Opioid Risks
Cerner The following details of the second s
National Guidelines suggest consideration of offering Naloxone and overdose prevention education to both patients and the patients' household members when ordering acetaminophen-HYDROcodone for the following risks:
Opioid Rx MME greater than 50: New Rx MME per day: 40 Total MME per day: 80
More than 50% of Rx remaining: acetaminophen-HYDROcodone 325 mg-5 mg oral tablet, 2 tab, PO, 4x/day, not to exceed 8 tablets/day, 180 tab, 0 Refill(s), 10/19/2020
Risk Factors on Problem List: Depression - SLEEP APNEA -
Alert Action:
O Cancel prescription
O Continue prescription
Add orders for:
naloxone 1 mg/mL injectable solution -> Spray one-half of syringe (1mL) into each nostril upon signs of opioid overdose. May repeat x1, if no response after 3 minutes, See Instructions, # 2 ea naloxone 4 mg/0.1 mL nasal spray -> 4 mg = 1 spray, For suspected opioid overdose, administer a single spray of Naloxone nasal spray into one nostril, Soln-Nasal, Inhale-nasal, As Indicated, PRN opiate reversal, Opiate overdose Indication: naloxone 04 mg/mL injectable solution -> 0.4 mg = 1 mL, For suspected opioid overdose, inject 1mL intramuscularly into shoulder or thigh, may repeat after 3 minutes if no or minimal response, Inj, IM, q3min, PRN opiate reversal, # 2 ea, 2 Refill(s), Indicated, PRN opiate reversal, PRN opiate reversal, # 2 ea
OK
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Prescribing opioids

https://www.cdc.gov/drugoverdose/pdf/TurnTheTide_PocketGuide-a.pdf

Strategies to engage with patients during prescribing, management, and tapering of opioids: <u>https://depts.washington.edu/fammed/sixbuildingblocks/wp-</u> <u>content/uploads/sites/12/2018/02/Principles-and-language-suggestions-for-talking-with-</u> <u>patients.pdf</u>

Communicating with empathy:

https://depts.washington.edu/fammed/improvingopioidcare/wpcontent/uploads/sites/12/2020/07/Empathic-Communication-Resources_2020-07-28.pdf

Schedule to assess management of opioids:

https://depts.washington.edu/fammed/improvingopioidcare/wpcontent/uploads/sites/12/2019/09/Suggested-opioid-management-assessment-schedule-wattribution.pdf

- Evidence for complementary and alternative medicine for chronic pain: <u>https://depts.washington.edu/fammed/improvingopioidcare/wp-</u> <u>content/uploads/sites/12/2019/09/Complementary-and-Alternative-Medicine-for-</u> Chronic-Pain 2018-08-13-w-attribution.pdf
- Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review https://effectivehealthcare.ahrq.gov/products/nonpharma-treatment-pain/research-2018
- State of the evidence for complementary health approaches for chronic pain: <u>https://www.nccih.nih.gov/health/providers/digest/complementary-health-approaches-for-chronic-pain-science</u>

Becoming a buprenorphine-waivered clinician:

https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphinewaivered-practitioner

Follow-up appointments:

http://www.theacpa.org/wp-content/uploads/2017/08/ACPA-Follow-Up-V-5.pdf

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Patient Resources

Opioid Treatment Programs

https://www.samhsa.gov/medication-assisted-treatment

Buprenorphine Physician Locator

https://www.samhsa.gov/medication-assisted-treatment/physician-programdata/treatment-physician-locator

Safe disposal of opioids

FDA's <u>Disposal of Unused Medicines: What You Should Know</u> FDA's Drug Disposal: Drug Take Back Locations

US Pain Foundation

Main Website: <u>https://uspainfoundation.org/</u>

Living with Chronic Pain – treatments, self-management, complementary therapy, emotional well-being

https://uspainfoundation.org/living-with-pain/

Pain Connection: Support Groups - https://painconnection.org/

Share your Story: <u>https://uspainfoundation.org/get-involved/share-your-story/</u> Resources: <u>https://uspainfoundation.org/resources/</u>

American Chronic Pain Association

- a. Main Website: https://www.theacpa.org/
- b. Video: Four Flat Tires: [provided on ACPA website or on YouTube] i.<u>https://www.theacpa.org/acpa-car-with-four-flat-tires/</u> ii.https://www.youtube.com/watch?v=W vffF50E3c

SAHMSA Website

a. Support/Helpline: <u>https://www.samhsa.gov/find-help/national-helpline</u> i.1-800-662-HELP (4357)

ii.Find Treatment: https://findtreatment.samhsa.gov/

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References

- 1. CDC Guideline for Prescribing Opioids for Chronic Pain United States, 2016: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
- 2. <u>https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report</u>
- 3. http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm
- 4. http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm
- 5. ACOG Committee Opinion. Opioid Abuse, Dependence, and Addiction in Pregnancy. Number 523. May 2012.
- 6. https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf
- 7. https://nhms.org/sites/default/files/Pdfs/SOAPP-14.pdf
- 8. American Academy of Pain Medicine, (2013). Use of opioids for the treatment of chronic pain. Retrieved from http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf
- American Academy of Pain Medicine, (2013). Chronic pain medical treatment guidelines. Retrieved from <u>http://www.dir.ca.gov/dwc/DWCPropRegs/MTUS_Regulations/MTUS_ChronicPainMed</u> <u>icalTreatmentGuidelines.pdf</u>
- 10. American Academy of Pain Medicine, (2013). Acute pain and cancer pain. Retrieved from http://www.painmed.org/files/acute-cancer-pain-statement.pdf
- 11. American Academy of Pain Medicine, American Pain Foundation, Ntaional Hospice and Palliative Care Organization (2013). Recommendations to physicians caring for Katrina disaster victims on chronic opioids. Retrieved from
 http://www.academy.a

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http://www.painmed.org/files/emergency-recommendations-opioid-patients.pdf
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- 12. American Academy of Pain Medicine, (2013). Eight opioid safety principles for patients and caregivers. Retrieved from http://www.painmed.org/files/eight-opioid-safety-practices-for-patients-and-caregivers.pdf
- 13. American Academy of Pain Medicine, (2013). Monitoring scheduled meds. Retrieved from http://www.monitoringscheduledmeds.com/
- 14. National Institute on Drug Addiction, (2013).
- 15. American Academy of Pain Medicine, (2013). Ethics charter. Retrieved from http://www.painmed.org/files/ethics- charter.pdf
- 16. Portenoy, Russell et al. Prevention and management of side effects in patients receiving opioids for chronic pain. UpToDate Sept 2020.
- Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. Gastroenterology 2019; 156:218.
- American Journal of Drug and Alcohol Abuse, (2010). Introduction to behavioral addictions. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3164585/ or http://dx.doi.org/10.3109%2F00952990.2010.491884
- 19. Center for Disease Control (CDC), 2014). Drug diversion. Retrieved from http://www.cdc.gov/injectionsafety/drugdiversion/index.html
- Dougall, A.L., Gatchel, R.J. (2013). Common risk factors & avoidance techniques for Medicine. Doi: 10.2217/9781780843483.

Initial Approval Date and <u>Reviews:</u> Sept 2014, Oct 2016, Oct 2018, Oct 2020 Most Recent Revision and Approval Date: October 2020 © Copyright MedStar Health, 2012

- 21. Green, C.R., Hart-Johnson, T., (2010). Cancer pain: An age based analysis. Pain 1525-1536. DOI: 10:1111/j.1526-4637. 2010.00957.x
- 22. Katz, C., El-Gabalawy, R., Keyes, K.M., Martins, S.S., Sareen, J., (2013). Risk factors for prescription opioid use and abuse and dependence: results from a longitudinal nationally representative sample. Drug and Alcohol Dependence. September 2013, 132 (1-2).
- Lewis, E.T., Combs, A., Trafton, J.A., (2010). Reasons for under-use of prescribed opioid medications by patients in pain. Pain Medicine. June 2010, 11 (6), 861-871. DOI: 10.1111/j. 1526-4637. 2010.00868.x
- 24. Shugarman, L.R., Asch, S.M. Meredith, L.S., Sherbourne, C.D., Hagenmeier, E., Cohen, A., Rubernstein, L.V., Goebel, J., Lanto, A., Lorenz, K.A., (2010). Factors associated with clinician intention to address diverse aspects of pain in seriously ill outpatients. Pain Medicine. September 2010, 11 (9), 1365-1372. DOI: 19.1111/j. 1526-4637. 2010.00884.x
- Terrell, K.M., Castelluccio, P., Kronenke, K., McGrath, R.B., Miller, D.K., (2010). Analgesic prescribing for patients who are discharged from an emergency department. Pain Medicine. July 2010, 11 (7), 1072-1077. DOI: 10. 111/j. 1526-4637. 2010.00884x
- 26. Von Korff, M.R., (2013). Long term use of opioid s for complex chronic pain. Best practice & research Clinical Rheumatology. October 2013, 27 (5), 663-672.
- 27. Wallace, L.S., Wexler, R.K., Miser, W.F., McDougle, L., Haddox, J.D., (2013). Journal of Pain Research. September 5, 2013, 6, 663-681. Doi: 10.2147/JPR.S50715.
- 28. World Health Organization, 2008. WHO treatment guideline on non-malignant pain in adults.
- 29. Cole, Eliot. Recognizing and Preventing Medication Diversion. Family Practice Management 2001; 37-41.
- 30. Kristof, Tina. Methods, Trends and Solutions for Drug Diversion. IHSS Foundation. February 8, 2018.
- 31. <u>https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaid-integrity-education/provider-education-toolkits/downloads/prescriber-role-drugdiversion.pdf</u>
- 32. Commonly Used Terms. https://www.cdc.gov/drugoverdose/opioids/terms.html. Accessed October 16, 2020.
- 33. Treede R-D, Rief W, Barke A, et al. A classification of chronic pain for ICD-11. Pain. 2015;156(6):1003-1007.
- 34. US Department of Veterans Affairs. Opioid Taper Decision Tool. 2016:1-16. https://vaww.portal2.va.gov/sites/ad/SitePages/Home.aspx%0Ahttps://vaww.portal2.va.g ov/sites/ad/SitePages/Home.aspx%0Ahttps://www.pbm.va.gov/PBM/AcademicDetailing Service/Documents/Pain_Opioid_Taper_Tool_IB_10_939_P96820.pdf.
- 35. Department of Veteran Affairs, Department of Defense. Tapering and Discontinuing Opioids.; 2017.
- 36. Centers for Disease Control and Prevention. Pocket Guide: Tapering Opioids for Chronic Pain. Guideline for Prescribing Opioids for Chronic Pain.; 2016.

Initial Approval Date and <u>Reviews:</u> Sept 2014, Oct 2016, Oct 2018, Oct 2020 Most Recent Revision and Approval Date: October 2020 © Copyright MedStar Health, 2012

- Dowell D, Compton WM, Giroir BP. HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics.; 2019. doi:10.1001/jama.2019.16409
- 38. US Department of Veteran Affairs, US Department of Defense. VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. 2017:1-198. www.tricare.mil.
- 39. Centers for Disease Control and Prevention. Nonopioid Treatments for Chronic Pain Principles of Chronic Pain Treatment. 2016. https://www.cdc.gov/drugoverdose/pdf/alternative_treatments-a.pdf.
- 40. Centers for Disease Control and Prevention. Calculating Total Daily Dose of Opioids for Safer Dosage. Centers Dis Control Prev. 2017:2. <u>https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-</u> <u>a.pdf%0Awww.cdc.gov/drugoverdose/prescribing/guideline.html</u>.

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Controlled Substance Agreement

The purpose of this contract is to protect your ability to obtain controlled substances and to protect our ability to provide them to you while maintaining a safe, controlled treatment plan.

1. I understand that the possible complications of this particular medicine may include:

Opioid pain meds	□ Anti-anxiety meds	□Sedatives/Hypnotics	\Box ADHD meds
Addiction	Addiction	Addiction	Addiction
Sleepiness	Sleepiness	Sleepiness	Trouble sleeping
Slowed breathing	Slowed breathing	Slowed breathing	Weight loss
Death from overdose	Death from overdose	Death from overdose	Death from overdose
particularly if used	particularly if used	particularly if used	
with benzodiazepines	with alcohol	with alcohol	
Trouble urinating	Falls, particularly in	Falls, particularly in	Headache
	the elderly	the elderly	
Nausea	Cognitive	Nightmares	Abdominal pain
	difficulties,		
	particularly in the		
	elderly		
Itching or hives	Impaired functioning	Hallucinations	Hallucinations
Constipation which	Sleep disturbance,	Agitation	Cardiac symptoms
may be severe	particularly in the		including elevated
enough to require	elderly		blood pressure, rapid
medical attention			heart rate and sudden
			cardiac death
Sexual problems		Headache	

- 2. I understand that if I am not taking the medication as prescribed that this could result in a dangerous situation such as coma, organ damage, or even death. I understand and agree to take the-medication only as prescribed by my provider.
- 3. I also understand that if I run out of my medication or if my medication is stopped suddenly, I could have withdrawal symptoms which can be very uncomfortable, dangerous or even life-threatening.

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- 4. I understand that all of my refills will be obtained at this office during regular office hours, and that no refills will be available during evenings or on weekends. There will be no "emergency" refills.
- 5. I understand that I must keep my medication in a safe and secure place at all times so that the medication is not lost or stolen, and understand that I am responsible for making sure that the medicine lasts the appropriate amount of time. I understand that I will not receive additional pain medicine ahead of time. I understand and agree that I will keep my medication away from children and others who might take it by mistake and be harmed.
- 6. I agree not to share, sell, trade, give medication for money, goods, or services, etc. or allow others to have the ability to get to these medications and they must be out of reach at all times from improper access but most important it must be kept safe from children. I agree not to alter my medication in any way (crushing, chewing, injecting, insufflation).I also agree that I will not use illegal controlled substances including but not limited to cocaine, heroin, marijuana, crystal meth, ecstasy, ketamine or other mood changing drugs and/or alcohol. I understand that the use of these medications by someone other than me is illegal and can result in overdose and/or death, especially by children.
- 7. I agree that while I am in the United States of America, I will get my prescriptions from this office only and agree that I will not attempt to get medications from another healthcare provider without notifying my provider within three business days.
- 8. I agree, upon request, to bring all unused pills to my follow up appointments for pill counts and understand that I may be tested unannounced (blood and/or urine) to make sure that I am taking my medications as prescribed. I also understand that if I do not go for blood or urine testing or fail to submit to a blood or urine test upon request by my provider, it is also considered a failed drug test.
- 9. I understand that I have been advised and understand that I should not drive a motor vehicle or operate machinery that could put my life or someone else's life at risk until I get used to the way the medication may affect me. While taking this medication, I will follow this same care when and if my dose of controlled substance (opioid pain medication) is increased.
- 10. Women If I become pregnant, there are known and unknown risks to the unborn child which can include addition and/or withdrawal at birth and could be life threatening to an infant. I must inform my practitioner right away if I am pregnant or think I am pregnant.
- 11. I know that my provider and drug store must follow any state or federal laws about misuse, sale, and other diversion of my pain medication.

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- 12. I permit my provider to share this agreement with my chosen drug store, emergency room, hospital, and other providers who are treating me to better organize my care, and I agree to give up my right of privacy or confidentiality with this agreement.
- 13. I understand and permit my provider and drug store to cooperate fully with any city, state, or federal law enforcement agency in the investigation of any possible misuse, sale, or other diversion of my pain medication.
- 14. I also give my permission for other providers, emergency departments, or drug stores to report violations (breaking) of this agreement to my prescribing provider
- 15. I understand that any violation of this agreement may result in one or more of the following:
 - a. Rapid tapering off of medications and no further prescriptions after they are tapered off
 - b. A referral to the appropriate specialist (pain specialist, psychiatrist, etc) with enough medication coverage to last only until the first appointment takes place
 - c. A referral for substance abuse treatment
 - d. Notification of violation of this Controlled Substance Agreement to my pharmacy and the State database for the Prescription Drug Monitoring Program
 - e. Notification of violation of this Controlled Substance Agreement to my insurance company
 - f. Termination from my practitioner's practice along with a notification of this termination to all MedStar facilities and practices in accordance with applicable laws and regulations.
- 16. I agree to fill and refill ALL of my prescriptions only at the pharmacy that I have chosen below. A change of pharmacy must be made in person with the prescribing provider or by phone discussion with the prescribing provider, and a note will be sent of this controlled substance agreement to the new drug store as well as notice of ending of service notice to the old drug store.

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AGREEMENT

I understand I have the right to complete management of my symptoms, to have my questions answered regarding treatment, to participate in a discussion of different treatment options, and to receive compassionate and timely care. I understand that my provider will act in my best interest and provide full, accurate, and complete information so that I may make an educated decision regarding my care. I also understand that any exceptions to this document must be documented by my provider in this agreement.

I have had the opportunity to read this contract or have it read to me. The contract has been fully explained to me, and I understand all its terms. I agree to follow the rules in this contract and understand that any violation of this contract will result in ending of therapy with a controlled substance and possibly an ending of the provider-patient relationship in accordance with applicable laws and regulations. All of my questions and concerns regarding treatment have been answered to my satisfaction, and copies of these documents have been given to me. I understand I have the right and power to sign this agreement and accept all of its terms.

l agree to use (pharmacy)	
located at	
to fill prescriptions for all of my controlled substand must be changed, I will notify my provider at my reg conversation.	
Patient Name	_ Date of Birth
Patient Signature	_ Date
Prescribing Provider Signature	
Drug prescribed	
Amount	Frequency
Refills	-

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