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# Prescribing Guidelines for Pennsylvania

# OPIOID DISPENSING GUIDELINES

Pharmacists provide care to patients in various settings, from community stores to clinics and hospitals. Regardless of the location, pharmacists will dispense medications for several pain conditions. According to the Drug Enforcement Agency (DEA), pharmacists have a corresponding responsibility to that of the provider to ensure all medications are being used for a legitimate medical purpose. Ultimately, the safe and appropriate use of medications forms the backbone of the profession. Opioid pain medication has tremendous benefit, but also carries high risk for several issues including but not limited to respiratory depression, constipation, hyperalgesia, diversion, abuse, addiction, arrest and death.

These guidelines are focused on several key areas that can impact pharmacists of any practice setting. Focal points include assessing the appropriateness of opioid pain medication at the point of dispensing, recognition of “red flags” on prescriptions as well as high risk medication combinations, available resources for those with a substance use disorder, and methods to prevent diversion from the emergency department. The purpose of

these guidelines are to aid pharmacists in ensuring that dispensed opioid pain medication is both safe and appropriate for each patient. This is only to act as a supplement to and not replacement for the clinical and professional judgment of a pharmacist.

These guidelines are divided into three sections. First is a general overview on pain therapy. This section focuses on types of pain, assessment, and medication therapy management information. The second section acts as a checklist to ensure all dispensed medications are safe and appropriate for the patient in the community and hospital setting. The third section focuses on resources available to the pharmacist, patient and family for assistance with substance use disorder

## SECTION I - GENERAL OVERVIEW ON PAIN THERAPY

### ASSESSING AND TREATING PAIN

**Pain can be broken down into two distinct qualities[1,2,3]**

1. When inquiring as to specific pain pathologies, most patients will define the quality of pain into one of two categories. The first is known as nociceptive pain and is usually described as sore, aching, tight or twisting. This is a common pain with known etiologies to the patient, such as arthritis, muscle spasms, and traumatic injury. This type of pain is usually felt more towards the morning, or after long periods of rest. The best types of medication used to treat this type of pain would be NSAIDs, muscle relaxants, acetaminophen and, at times, opioids.
2. The second type of pain is known as nerve based and is usually described as burning, tingling, stabbing, stinging, numbing, or electric. Unlike nociceptive pain, patients may be unaware as to how this pain developed. Commonly, there would be inflammation or impingement on a nerve, or actual damage to the nerve that would result in this condition. Nerve based pain can be present throughout the day and is especially felt at night. The best medication classes for this type of pain include anti-convulsants and antidepressants. Keep in mind that these types of medications need to be at the right dose for an appropriate amount of time in order for the patient to experience the full benefit. This is in stark contrast to the medications used for nociceptive pain, which can be effective with a single dose in a short period of time.

**Pain Assessment and the PQRST-U**

A proper pain assessment is crucial to better understanding not only medication selection, but also the need for adjunctive therapies to manage the physical, emotional, and/or spiritual needs of the patient.

The common pain assessment tool is known as the “PQRST-U” method shown on page 3.[4]

# PQRST-U

| Assessment Question | Explanation |
|---|---|
| **P**alliative/ Aggravating Factors | What makes the pain better and what makes the pain worse? This can be medications, activities, non-pharmacologic therapies and alternative therapies. |
| **Q**uality | What does the pain feel like? This is the most important question as it best determines the type of pain and appropriateness of the current medication regimen |
| **R**adiation | Does the pain travel (as in sciatica) as it may represent a different type of pain requiring alternative therapies |
| **S**everity/Sleep | What is the intensity of the pain on a scale? High medication use with high level of pain should act as a red flag to lack of efficacy. Also, it is important to track hours of sleep a night. Chronic pain highly effects quality of sleep, causing mostly insomnia. With fatigue and sedation being common adverse effects of several pain medications, knowing when to dose these based on sleep is important for patient centric care. |
| **T**ime | What time of day does the pain hurt the most? Coupling this information to the amount of sleep a patient gets lends to better timing of medication use throughout the day. Should the patient experience pain more in the morning, taking medication prior to bed will help prevent this. Pain experienced in the afternoon/evening should result in medication being taken earlier in the day. |
| **You** | How does the pain affect you? Question to find the impact pain is having on emotions, relationships, feelings of self-worth, family life. This is important as extreme emotional pain can impede medication therapy efficacy. This can open the door for the patient to be referred to a psychologist or social worker for cognitive behavioral therapy. |

## Opioid Medications Require Appropriate Monitoring for Safety and Efficacy[5]

- Opioid pain medication can be a very effective option for both acute and chronic pain. Ultimately, the goal of opioid therapy is to aid in the development and completion of physical and emotional therapies. While the patient is progressing through their prescribed non-pharmacologic therapies, work with the provider to wean the patient to the lowest effective dose of opioids.
- Opioid pain medication can be broken down into two distinct classes based on duration of action. Short acting medications (immediate release forms of oxycodone, morphine sulfate, hydrocodone) are mostly used as initial opioid therapy, especially in acute situations. For chronic pain, short acting opioids are commonly seen for treatment of breakthrough, or episodic pain. Long acting (oxycodone extended-release, morphine sulfate extended-release, fentanyl patches, methadone) should never be used as initial therapy due to a high risk of respiratory depression. These should only be considered when a patient is on a stable dose of short acting opioids in an effort to improve baseline coverage and decrease pill burden. Occasionally, patients will be on both long and short acting opioids at the same time. If an assessment finds that the patient is taking high amounts of short acting and asking for more, then increasing the long acting is the most appropriate option. Providing better baseline coverage can result in improved pain control and less use of short acting medications.

**Opioid Tolerance Development**

| Medication | Dose/Time |
|---|---|
| **Oral Morphine** | 60 mg/day |
| **Transdermal Fentanyl** | 25 mcg/hour |
| **Oral Oxycodone** | 30 mg/day |
| **Oral Hydromorphone** | 8 mg/day |
| **Oral Oxymorphone** | 25 mg/day |

**Note:** Patients are considered opioid tolerant when on these doses or an equianalgesic dose of another opioid for at least one week

***Pharmacists should always question immediate past medication use at these doses prior to dispensing a new prescription for a long acting opioid

## High doses of opioid medication does not necessarily result in improved pain control[5,7,8,9]

- Several guidelines and hospital systems recommend that doses of opioid medication should not exceed 120 mg of morphine or morphine equivalent per day. Doses over this limit should indicate a call to the provider. Currently, the Pennsylvania Medical Society prescribing guidelines recommend 100 mg per day as the max dose. In order to determine a total daily dose, simply add the strengths of all long and short acting opioid taken daily.
- Taking doses over the recommend amount may result in an increased risk of opioid induced hyperalgesia, a phenomenon where higher doses of pain medications lead to increased pain. The best method of treatment is to reduce the amount of opioid that a patient is taking.

## Developing a weaning schedule prior to contacting a provider will result in improved care coordination for the patient[5,7,8,9]

- Weaning opioid medication too rapidly can result in signs of withdrawal such as sweating, tremor, flu like symptoms, anxiety, restlessness, and insomnia. Though not deadly, opioid withdrawal is extremely uncomfortable, but patients will recover in time. Progressing at a slow rate reduces the risk of developing these symptoms. Should these signs present, the rate should be decreased to allow more time between each dose reduction. Opioid withdrawal is not a sign of addiction; it is a common reaction to discontinuing opioids after a given period of time. Recommend a 10% reduction in total daily dose secondary to the half-life of the medication. Common products are listed in the following table.

| Medication | Wean Rate Examples Reduce by 10% every: |
|---|---|
| **Oxycodone and Morphine Extended Release*** | 3 days |
| **Fentanyl Patch** | 9 days |
| **Methadone** | 14 days |
| ***it is possible to wean immediate release products faster due to a shorter half-life. See individual package inserts for product specific information** | |

- It is possible that as people begin to wean that they will need emotional and psychological assistance; consider a recommendation to see a counselor. Once a wean is complete or near complete the use of other appropriate medication can be considered.

## Recently, methadone has risen in popularity as a treatment for chronic pain[4,6]

- Methadone is a very useful agent against nerve based pain as well as nociceptive pain. Unfortunately, methadone has a negative reputation of only being used to treat opioid addiction. Though it is commonly used for this purpose, methadone has been rising in popularity for its use in pain management. Methadone can be prescribed by any physician or other eligible prescriber working within his/her scope of practice. When used for opioid detoxification, methadone is dispensed in a registered treatment facility. Only buprenorphine/naloxone can be prescribed, along with a special DEA number, and used for outpatient detoxification. Placing “for pain” in the sig code allows the use of methadone for chronic pain management.
- Methadone does come with its own monitoring parameters. Unlike other commonly used opioids, methadone is known to cause arrhythmias. For patient safety, it is recommended that an EKG be obtained at baseline, 4 weeks, 6 months, and yearly. At the point of dispensing, the patient should be asked if he/she has received this recently. It is also important that the pharmacist conduct a thorough chart review to look for other agents that can prolong the QTc interval, leading to higher risk of arrhythmia when used in combination with methadone. Example agents include: tri-cyclic antidepressants, citalopram 40 mg in the elderly, and long term use of antibiotics among others.
- Determining an appropriate dose of methadone is difficult as there is no clear cut conversion that is widely accepted. Though various models exist, a common thread is that no starting dose should exceed 30 mg daily. When attempting to convert, be aware that a methadone dose can only be determined from a

morphine dose. A common and conservative conversion is using a 10:1 ratio, where each 10 mg of morphine is 1 mg of methadone. When converting back to morphine, a common approach is using a 1:3 ratio where every 1 mg of methadone is 3 mg of morphine. Unlike other opioids, you do not have to compensate for incomplete cross tolerance once converted. With other options available, it is good practice to double check with a provider if a methadone dose appears excessive to you.

**Recognizing opioid equivalencies is essential in determining if a conversion was calculated correctly[4]**

| Drug | PO (mg) | IV (mg) |
|---|---|---|
| **Morphine** | 30 | 10 |
| **Buprenorphine** | 0.4 | 0.3 |
| **Codeine** | 200 | 100 |
| **Fentanyl*** | -- | 0.1 |
| **Hydrocodone** | 30 | -- |
| **Hydromorphone** | 7.5 | 1.5 |
| **Oxycodone** | 20 | 10 |
| **Oxymorphone** | 10 | 1 |
| **Tramadol** | 120 | 100 |
| *Please refer to the package insert for dosing conversions of the fentanyl patch | | |

## SECTION II - CHECKLISTS FOR PHARMACISTS

### A Systematic Approach to Recognizing and Resolving Red Flags

When filling a prescription, regardless of practice setting, following this checklist can help the pharmacist ensure that the patient is receiving medication that is both safe and appropriate while mitigating the risk of diversion. The following are tools to assist pharmacists in making appropriate decisions regarding the dispensing of controlled substances. Each on its own is not necessarily a sole indicator of potential medication misuse and/or diversion.

- ✓ **Verify the legitimacy of the patient, the provider and the prescription.**
  - Utilize VIGIL: the foundation of VIGIL is a collaborative prescriber/pharmacist relationship[10,11] VIGIL is the acronym for a 5-step risk management strategy designed to empower clinicians to appropriately prescribe opioids for pain by reducing regulatory concerns and to give pharmacists a framework for resolving ambiguous opioid analgesic prescriptions in a manner that preserves legitimate patient need while potentially deterring diverters.
    - **V**erification: Is this a responsible opioid user?
    - **I**dentification: Is the identity of this patient verifiable?
    - **G**eneralization: Do we agree on mutual responsibilities and expectations?
    - **I**nterpretation: Do I feel comfortable allowing this person to have controlled substances?
    - **L**egalization: Am I acting legally and responsibly?

- Patient validation
  - Patient not known to the pharmacy.
    - Obtain a valid government issued photo ID and document on back of the prescription.
  - Patient has insurance but insists on paying cash.
  - Patient's address is out of pharmacy's normal trading area.
  - Utilizing multiple prescribers.
  - Only prescriptions for controlled substances in profile.
  - Early refills on controlled substances, especially multiple times for lost or vacation supply.
  - Patient uninformed to therapy or has unrealistic expectations.
  - Check Prescription Monitoring Program when applicable.

- Prescriber validation
  - Prescriber writes for the same or similar medications in the same strength and quantity for many or multiple patients particularly without regard to the patient's age, sex, height, weight, or other existing medical conditions.
  - Prescriber writes for the same "cocktail" or combination of drugs.
    - Opioid + Muscle Relaxant + Benzodiazepine
  - Prescriber writes for excessive quantities.
  - Prescriber is located outside the pharmacy's typical geographical area.
  - Prescriber writes a prescription outside their normal scope of practice.
    - Is the provider Board Certified in pain management or addiction medicine?
  - Well known that the prescriber does not take insurance.
  - Patients from a particular prescriber come in groups.

- Prescription validation
  - Forgeries – irregularities on face of prescription.
  - Patient drops off at times when difficult to reach the prescriber (evenings or weekends).
  - Contains misspellings.
  - Contains atypical abbreviations or directions fully written out.
  - Internet printout, preprinted or stamped, prescriber's handwriting too legible, different colored inks or handwriting, eraser marks.
  - Missing state or Federal requirements for a controlled substance prescription.
  - Contains writing or markings that would indicate it was turned away or filled previously by another pharmacy.

- Should you discover an issue and decide to use your professional judgment to not dispense, a pharmacist should:
  - Address in a calm, controlled manner.
  - Be respectful and never accuse the patient of doing something wrong.
  - Report to authorities when a prescription is confirmed by the prescriber as fraudulent or forged, contact the local police.

- ✓ **Ensure the medication, dose and quantity is both safe and appropriate for the patient and condition.**
  - Are the amounts prescribed consistent with the indication?
    - Prescribed solely for provider convenience
    - Prescribed for the financial advantage of a third party payer
  - Is the patient experiencing nerve based pain and receiving appropriate therapy with adjunctive agents?
  - Is the patient receiving non-pharmacologic therapy appropriate for their pain condition?
    - Physical therapy
    - Psychological therapy for emotional issues secondary to pain

- ✓ **Determine if the prescription will introduce drug-drug interactions with other new or already existing prescriptions.**
  - Be aware of the "Holy Trinity" of oxycodone + carisoprodol + alprazolam
    - Question other medication combinations within these classes
  - Tramadol + zolpidem + trazodone, especially in the elderly
  - Sedative-hypnotics + benzodiazepines
  - Bupreorphine + benzodiazepines
  - Switching from Suboxone back to Subutex in a maintenance regimen

- ✓ **Determine if the patient has a medication use agreement with the provider and your pharmacy.**
  - If the patient is unsure, contact the provider and ask if he/she is willing to provide you, the pharmacist, a copy
  - Store copy in a secure, HIPAA compliant manner

- ✓ **Provide appropriate patient education and support.**[12]
  - Product-specific information
  - Taking the opioid as prescribed
  - Importance of dosing regimen adherence, managing missed doses, and prescriber contact if pain is not controlled
  - Warning and rationale to never break or chew/crush tablets or cut or tear patches prior to use
  - Warning and rationale to avoid other central nervous system (CNS) depressants, such as sedative-hypnotics, anxiolytics, alcohol, or illicit drugs
  - Warning not to abruptly halt or reduce the opioid without physician/prescriber oversight of safe tapering when discontinuing
  - The potential of serious side effects or death
  - Risk factors, signs, and symptoms of overdose and opioid-induced respiratory depression, gastrointestinal obstruction, and allergic reactions
  - The risks of falls, using heavy machinery, and driving
  - Warning and rationale to never share an opioid analgesic
  - Rationale for secure opioid storage
  - Warning to protect opioids from theft

- Instructions for disposal of unneeded opioids, based on product-specific disposal information

✓ **Contact the provider with any concerns.**
- Pharmacists are challenged to increase their knowledge of current clinical guidelines and, when faced with situations that do not pass the "smell test," to actively engage the prescriber in conversation about the plan of care so that patients deserving of pain relief receive it and individuals with abuse and misuse issues are not enabled but directed to appropriate intervention.

✓ **When in doubt – COMMUNICATE WITH THE PRESCRIBER – not just office staff**
- Have all pertinent information available prior to placing the call:
  - Possible drug interactions
  - Maximum dosing guidelines
  - Dispensing history if available (e.g. early refills, multiple prescribers, multiple pharmacies)
- Ask for clarification on indication and expected length of treatment.
  - DOCUMENT THE INFORMATION in a readily accessible, but HIPAA-compliant place
- Ask if a "pain contract" exists for the patient
  - Would the physician/prescriber be willing to provide a copy to you, the pharmacist?
  - Ensure that the contract is stored in a readily accessible, but HIPAA compliant place.
- Explain in clear and concise terms, your concerns; maintain appropriate clinical context without sounding judgmental.
  - We may not be privy to the psycho-social factors influencing a patient's condition or need for pain management.
- Offer to provide feedback to the physician/prescriber on patient compliance and adherence
  - Ask what mode of future communication would be most acceptable to the prescriber.
  - Ask how often the prescriber would like to receive feedback from you.
  - FOLLOW THROUGH!

## Procedures to prevent over-prescribing of controlled substances from the emergency department and at hospital discharge

✓ **Acute pain secondary to trauma or other event**
- Perform chart review to determine substance abuse potential.
  - Frequent ED visits, early refill requests, reports of lost/stolen prescriptions.
- Use opioids for pain control only after considering whether non-opioid therapy would be more appropriate or not.
- When acute pain under control, non-opioid alternatives should be used as outpatient if possible.
- Provider may prescribe appropriate amount of opioids to treat the acute episode and allow patient to follow up with primary care physician or pain specialist
  - Generally 2-3 days' worth of medication is sufficient.
- Refer patient to appropriate provider for follow-up.
- Do not prescribe long-acting opioids from the ED.

- Exception could be considered for those with terminal illness who do not wish to be admitted to hospital. Those individuals should be provided a quantity of medication sufficient to last until able to follow up with PCP or connect with hospice.

✓ **Chronic pain**
- Manage based on clinical judgment or in accordance with medication use agreement (MUA) if one exists.
- Patient is not permitted to use the ED as a means to not abide by their MUA or follow up with their outpatient provider.
- Utilize Opioid Risk Tool (ORT) or other assessment tool as necessary.
- Avoid outpatient opioids if a chart review demonstrates a pattern of non-compliance with prior follow-up recommendations.
- Refer patient to outpatient provider to better manage chronic pain if appropriate.
- Providers should not write for opioid prescription refills for patients with an MUA or provide replacement medication for lost/stolen prescriptions.
- If there is potential for withdrawal until patient is able to see their outpatient pain management provider, patient may be provided care for symptomatic relief
  - Antiemetic or antidiarrheal

✓ **Acute on Chronic Pain**
- If the patient is under an MUA, ED physician or other hospital provider should speak with patient's outpatient provider prior to dispensing any opioid treatment or notify the outpatient provider as soon as possible.
- Take into consideration any information in patient's chart that indicates pattern of abuse or non-compliance.
- If opioid therapy is warranted, issue only enough medication to give patient time to follow up with primary care provider or pain specialist, generally 2-3 days' worth.

✓ **Ways pharmacists can help**
- Store medications in automated pharmacy dispensing system and require passcodes to access medication.
- Track medication dispensing via appropriate paperwork or computer system.
- Utilize "to-go" packets of pain medications that have a limited quantity of medication to provide patient until their outpatient follow up.
- Limit dispensing of medication directly from the hospital to hours when patient's pharmacy is not open.
- Pharmacist should review prescription to ensure DEA requirements are met.
  - Patient's name and address, provider's name and address, DEA number, drug name, strength, dosage form, quantity, directions for use, number of refills if applicable.

## SECTION III – AVAILABLE RESOURCES

### WHERE CAN PATIENTS AND FAMILY MEMBERS GO FOR INFORMATION ON TREATMENT OPTIONS?

- ✓ Pharmacists can assist a patient or family to seek help for a substance use disorder. The pharmacist can screen, identify, and refer a patient or a family member to treatment.

- ✓ **SBIRT** (**S**creening, **B**rief **I**ntervention and **R**eferral to **T**reatment) is a comprehensive, integrated, public health approach to the delivery of early intervention and treatment services for persons with substance use disorders, as well as those who are at risk of developing these disorders.
  - **Screening** quickly assesses the severity of substance use and identifies the appropriate level of treatment.
  - **Brief intervention** focuses on increasing insight and awareness regarding substance use and motivation toward behavioral change.
  - **Referral to treatment** provides those identified as needing more extensive treatment with access to specialty care.

- ✓ Trying to locate appropriate treatment for a loved one, especially finding a program tailored to an individual's particular needs, can be a difficult process. However, there are some resources to help with this process. For example, NIDA's handbook *Seeking Drug Abuse Treatment: Know What to Ask* offers guidance in finding the right treatment program. Numerous online resources can help locate a local program or provide other information, including:

**Online Resources:**

1. Pennsylvania Department of Drug and Alcohol Programs Let's Work Together https://apps.ddap.pa.gov/GetHelpNow/Index.aspx

2. The Substance Abuse and Mental Health Services Administration (SAMHSA) maintains a Web site (www.findtreatment.samhsa.gov) that shows the location of residential, outpatient, and hospital inpatient treatment programs for drug addiction and alcoholism throughout the country. This information is also accessible by calling 1-800-662-HELP.

3. The National Suicide Prevention Lifeline (1-800-273-TALK) offers more than just suicide prevention—it can also help with a host of issues, including drug and alcohol abuse, and can connect individuals with a nearby professional.

4. The National Alliance on Mental Illness (www.nami.org) and Mental Health America (www.mentalhealthamerica.net) are alliances of nonprofit, self-help support organizations for patients and families dealing with a variety of mental disorders. Both have State and local affiliates throughout the country and may be especially helpful for patients with comorbid conditions.

5. The American Academy of Addiction Psychiatry and the American Academy of Child and Adolescent Psychiatry each have physician locator tools posted on their Web sites at aaap.org and aacap.org, respectively.

6. Faces & Voices of Recovery (facesandvoicesofrecovery.org), founded in 2001, is an advocacy organization for individuals in long-term recovery that strategizes on ways to reach out to the medical, public health, criminal justice, and other communities to promote and celebrate recovery from addiction to alcohol and other drugs.

7. The Partnership at Drugfree.org (drugfree.org) is an organization that provides information and resources on teen drug use and addiction for parents, to help them prevent and intervene in their children's drug use or find treatment for a child who needs it. They offer a toll-free helpline for parents (1-855-378-4373).

8. The American Society of Addiction Medicine (asam.org) is a society of physicians aimed at increasing access to addiction treatment. Their Web site has a nationwide directory of addiction medicine professionals.

9. NIDA's National Drug Abuse Treatment Clinical Trials Network (drugabuse.gov/about-nida/organization/cctn/ctn) provides information for those interested in participating in a clinical trial testing a promising substance abuse intervention; or visit clinicaltrials.gov.

10. NIDA's DrugPubs Research Dissemination Center (drugpubs.drugabuse.gov) provides booklets, pamphlets, fact sheets, and other informational resources on drugs, drug abuse, and treatment.

11. The National Institute on Alcohol Abuse and Alcoholism (niaaa.nih.gov) provides information on alcohol, alcohol use, and treatment of alcohol-related problems (niaaa.nih.gov/search/node/treatment).

12. Alcoholics Anonymous (www.aa.org) is an international fellowship of men and women who have had a drinking problem. It is nonprofessional, self-supporting, multiracial, apolitical, and available almost everywhere. There are no age or education requirements. Membership is open to anyone who wants to do something about his or her drinking problem.

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