Guideline Scope and Washington State Law

**What is the definition of the patient population?**

Adult patients who are already on chronic opioid therapy (COT) for the treatment of chronic non-malignant pain. COT is defined as a minimum 70-day supply of opioids dispensed in the previous 3 calendar months. Hospice and palliative care patients are excluded.

**What is my legal responsibility when it comes to COT?**

This is governed by the Washington State Administrative code (WAC) and administered by the Medical Quality Commission (MQAC). These regulations establish requirements for patient evaluation, treatment planning, informed consent, a written treatment plan, prescribing, management in episodic care settings and consultation with pain management specialists. Kaiser Foundation Health Plan of Washington’s updated COT guideline is consistent with the regulations, and providers adhering to the guideline will be compliant with the law.

You can scroll forward and backward to see other pain WACs

**Do I have to apply the guideline to ALL of my patients on COT?**

Yes.

**Do I have to abide by all of the guideline content?**

The guidelines are intended to provide a MINIMUM standard of care, and are based on the legal requirements defined by Washington State Administrative code (WAC). It is not acceptable to choose a lower frequency of monitoring than dictated by the guideline risk categories, except in rare cases when there is a good clinical reason (safety), and it has been carefully documented.
Risks of Opioid Medications

Everything always flip-flops in medicine. Just a decade ago, we were being told pain was the fifth vital sign and that we were undertreating pain. What’s different now?

Medical evidence accumulates over time. In the 1980s and 90s pain guidelines were developed based on expert opinion, and numerous assumptions were made. Since that time a huge amount of evidence has accumulated regarding the risks of chronic opiate use, while very little evidence has become available regarding its benefits. Evidence will continue to accumulate in the coming years, but it is unlikely to override the risks that we are now aware of. So pain guidelines will continue to change, but it is highly unlikely we will ever find evidence to support the approach we took to pain years ago.

For more on the historical context of the opioid crisis, see:
- Opioid Prescribing, Podcast, 3/15/2016
- The opioid epidemic: It's time to place blame where it belongs. Blog post, 4/6/2016

Opioids are fairly safe medications, right? Some patients have been on them for decades, even at high doses, and never had a problem. So aren't opioids low-risk?

There is no "safe" dosage of opioid medication, and serious opioid-related risks increase sharply with higher doses.

<table>
<thead>
<tr>
<th>Serious risks and side effects</th>
<th>In a group of 100 people, how many would experience this side effect?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid overdose</td>
<td>Less than 1, but increases with dosage</td>
</tr>
<tr>
<td>Addiction or misuse of opioids</td>
<td>5–30</td>
</tr>
<tr>
<td>Depression or anxiety</td>
<td>unknown</td>
</tr>
<tr>
<td>Constipation</td>
<td>30–40</td>
</tr>
<tr>
<td>Hormonal effects, including:</td>
<td>25–75</td>
</tr>
<tr>
<td>• Lower sex drive</td>
<td></td>
</tr>
<tr>
<td>• Erection problems (impotence)</td>
<td></td>
</tr>
<tr>
<td>• Infertility</td>
<td></td>
</tr>
<tr>
<td>• Osteoporosis (can weaken bones, increasing risk for fracture)</td>
<td></td>
</tr>
<tr>
<td>Sedation (feeling sleepy or sluggish) - can cause difficulty driving or thinking clearly</td>
<td>15</td>
</tr>
<tr>
<td>Problems with sleep and breathing problems during sleep</td>
<td>unknown</td>
</tr>
</tbody>
</table>
Why did the FDA issue a boxed warning for opioid and benzodiazepine labeling in 2016?

The new “black box” warning is based on two recently published FDA studies that found:

- A 41% increase in concurrent prescribing of opioids and benzodiazepines between 2002 and 2014
- A near tripling in rates of emergency department use and overdose deaths that involved both drugs between 2004 and 2011
- Patients taking the drugs concurrently had almost four times the risk of fatal overdose as those taking only an opioid

For more information, see: http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm

Risk Mitigation

How will pain be managed in acute settings to reduce harm and prevent a transition to COT?

- Opioids should not be prescribed for non-specific back pain, headaches, or fibromyalgia.
- Opioid prescriptions should be written for the lowest necessary dose and for the shortest duration. Three days or less will often be sufficient; more than seven days will rarely be needed. (CDC 2016)
- Opioid use beyond the acute phase is rarely indicated.

Urgent Care will provide appropriate therapy of all acute exacerbations or new pain, which may or may not include opioids. Urgent Care will notify the PCP when there are concerns of abuse, non-compliance, diversion, etc. Urgent Care will also use the prescription monitoring program (PMP) website.

What is naloxone, and what is its role in the care of patients on COT?

Naloxone is an opioid antagonist that may be used to reverse the symptoms of opioid depression (including respiratory depression) after a known or suspected opioid overdose. Naloxone should be prescribed to patients (and their family members) who are taking opioid therapy > 40 mg MED per day or have other risk factors for opioid overdose. Kaiser Foundation Health Plan of Washington’s preferred naloxone product is Narcan nasal spray.

_Naloxone does not replace emergency medical care._

See also:

Opioid overdose prevention education: www.stopoverdose.org

Other Resources for Treating Chronic Pain

What other resources are available at Kaiser Foundation Health Plan of Washington for treating patients with chronic pain?

Non-opioid approaches to chronic pain include:

- Exercise
- Physical therapy
- Cognitive behavioral therapy (patients can self-refer through Behavioral Health Access)
- Mindfulness meditation
- Sleep hygiene
- Living Well with Chronic Conditions workshops
- “Living Better with Chronic Pain” video from Healthwise (requires member log-in)
COT Care Plans

At what point should the clinician start a patient on a COT care plan?
When a patient is using opioid pain medication daily or nearly daily, when it is anticipated that a patient will be prescribed opioids for greater than 3 months, or when a patient has been prescribed opioids for greater than 3 months.

When should a patient get an updated COT care plan?
A patient’s care plan should be updated at every COT monitoring visit using opioidcareplan, and included in the After Visit Summary—at least every 3 months for patients in the high-risk category, 6 months for medium-risk, and 12 months for low-risk. This is to ensure clear communication of the medication plan to the patient, document clear informed consent, and provide treatment recommendations.

What is the difference between an opioid care plan and an opioid treatment agreement?
All COT patients need a care plan. While a provider and COT patient may choose to create a signed treatment agreement, it is not required.

Sharing Opioid Safety Concerns with the Team

What if a provider is covering for an absent provider and the patient wants opioid medication that the covering provider is not comfortable with?
A covering clinician is prescribing under his or her own DEA license and must be comfortable before prescribing the medication in question and should use his/her own discretion to agree/not agree with the plan. A conversation with the PCP and perhaps the clinic chief may be in order if there is a consistent worrisome pattern or concern with a provider's prescribing practices.

What should a team member do if they are concerned about the safety of a patient's care plan, or if they think a care plan is not in compliance with the guideline and can’t find documentation to explain it in the chart?
Clinic leaders need to encourage every provider to speak up and bring concerns like these to their attention. A conversation for better understanding of the care plan would be in order, and how to have what can sometimes be a very sensitive conversation is at the discretion of the clinic leader.

Risk Stratification and Dosing

How do I properly risk-stratify patients taking opioids for chronic non-cancer pain?
Choose the HIGHEST risk/monitoring category that applies to the patient based on morphine equivalent dose (MED) and risk factors. Low-dose patients taking benzodiazepines or Z-drugs (such as zolpidem) should be in the HIGH-intensity monitoring group, for example. COT lists should not show a patient in one group based on MED yet assigned to a lower-intensity group by a PCP.

How do I calculate a morphine equivalent dose (MED)?
http://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm
What if I need help with a taper schedule?
Tapering patients off of opioids requires a great deal of individualization, as no two patients experience pain or the symptoms of withdrawal in the same way. However, there are several good resources to assist you in creating a taper schedule for your patient.

- The COT safety guideline has general recommendations for tapering your patient off of opiates in Table 3 on page 10.

Urine Drug Screening

Why do I have to do urine drug screens on all patients?
There is a high level of inconsistency (40–50%) in what people say they are taking and what is in their urine, regardless of the prescribed opioid dose.

Universal testing as a precaution for all patients is a best practice. Testing based on clinical suspicion is likely to miss a number of patients who may be non-adherent to treatment, and patients may perceive it as discriminatory. Urine drug testing identifies patients who are adherent to treatment; additionally, prospective studies have shown that 9–16% of patients had urine drug test results concerning for possible substance use disorder.

Which urine drug screen should be ordered?
Urine drug screen for pain management is the appropriate test to monitor adherence to opioid therapy. Additional confirmation testing may need to be ordered in addition to this test for patients being treated with fentanyl.

What if the results of a UDS are unexpected? For example, if they are positive for alcohol or stimulants, benzodiazepines, barbiturates, or opioids; if medication is missing; if sample is adulterated or dilute, or no UDS has been done?

1. Ensure that confirmation results are consistent with positive screen results.
2. Check to make sure that the patient had filled a prescription such that he/she should have provided an appropriate sample.
3. Check to make sure that the results are not due to an expected metabolite of the prescribed medication.
4. Discuss the results with the patient to try to understand why the unexpected results may have occurred.
5. Take appropriate steps to ensure treatment is safe and appropriate per guideline recommendations (e.g., dosage adjustment or tapering), or consult with Addiction Medicine if there is concern about a substance use disorder.

If a patient fails to comply with a request for a UDS and the refill authorization comment indicates that a UDS is needed, the pharmacy will not dispense the medication until the UDS is “in process.”
Referrals

When should a COT patient be referred to a pain specialist?
The mandatory consultation threshold for adults is 120 mg MED (oral). Physicians may also refer patients
for additional evaluation and treatment as needed to achieve treatment objectives, provided the reason
for referral has been documented.

A physician is not required to consult with a pain management specialist when he or she has documented
adherence to all standards of practice as defined in the pain WACs or when:

- The patient is following a tapering schedule;
- The patient requires treatment for acute pain (including hospitalization) with a temporary
  escalation in opioid dosage and is expected return to or below their baseline dosage level; or
- The physician documents the patient’s pain and function is stable and the patient is on a non-
  escalating dosage of opioids.

What treatment is available for Kaiser Foundation Health Plan of Washington patients with opioid
use disorder?
Patients with opioid use disorder have a range of treatment options available, including:

- Transition to agonist maintenance treatments: methadone maintenance from an opioid treatment
  program, or treatment with buprenorphine/naloxone by a DEA-waivered physician. These are the
  most effective treatments for opioid use disorder.
- Antagonist medication treatment with oral or injectable naltrexone, which can be started after
  patients have fully withdrawn from opioids.
- Psychosocial treatments. These may be provided by chemical dependency counselors in
  outpatient or residential settings.

Patients may access these treatments by provider- or self-referral to Behavioral Health Access.

When should a patient be referred to Addiction Medicine?
There are numerous symptoms and behaviors—not just physical dependence—that raise concern about
the possibility of addiction. A positive response to the one-question screen and a positive Substance Use
Disorder Symptom Checklist should prompt referral or virtual consultation. Consider a referral if patients
have aberrant medication use or other behaviors that raise concern for a possible substance use disorder
concurrent with chronic pain.

Tools for Informing Patients

What information can I share with patients about the new guidelines and chronic opioid
medication risks?
Choosing Wisely patient handout, Avoid Opioids for Most Long Term Care: Advice from Experts

- Spanish:  http://consumerhealthchoices.org/wp-content/uploads/2016/05/ChoosingWiselyOpioidsBrochure-
  ES.pdf

The CDC offers some excellent one-pagers for patients about the national guideline:
http://www.cdc.gov/drugoverdose/prescribing/patients.html

The Surgeon General’s website on the opioid crisis contains numerous patient stories from all over the
country:  http://turnthetiderx.org
Disposal of Opioid Medication

What should I tell patients to do with unused opioid products?
Patients may safely and responsibly dispose of their unused and unwanted opioids (and other medications) through:

• Medication disposal units in all the King County Kaiser Permanente pharmacies that can accept controlled substances. These units can be used by both Kaiser Permanente members and non-members.
• Collection receptacles maintained by a law enforcement agency or other authorized collector. Search for an authorized collection location: https://www.deadiversion.usdoj.gov/pubdispsearch
• Take-back events overseen by law enforcement agencies.

See www.takebackyourmeds.org for more information.

Why can't the pharmacy just take them and destroy them?
Until recently, federal law has not allowed pharmacies to take back unused controlled substances, even when they have medication disposal programs in place. In 2010 Congress passed the Secure and Responsible Drug Disposal Act, which allowed the DEA to set up a process for the disposal of controlled substances by pharmacies. However, strict regulations, high costs, and potential liability issues have prevented large-scale controlled substance take-back programs from being created. As of 2016, only Kaiser Permanente pharmacies in King County have medication disposal units that can accept controlled substances. We expect that more pharmacies, in both the community and Kaiser Permanente, will create opportunities for patients to safely dispose of their controlled substances in the future.

For more information, see this FDA page on medication disposal: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186188.htm

Is There More I Can Do?

I am committed to opioid medication safety for my patients. Is there more I can do to help with our national opioid crisis?
Yes! Check out the U.S. Surgeon General’s Turn the Tide Rx initiative, at http://turnthetiderx.org