
**APF Position Statement on Washington State Interagency Guideline on
Opioid Dosing for Chronic Non-Cancer Pain: An Educational Pilot to
Improve Care and Safety with Opioid Treatment
May, 2007**

The American Pain Foundation has been following the initiative in the State of Washington to take proactive steps to curb abuse and diversion of opioid analgesics by creating a new pain treatment guideline as a means to protect public safety (i.e., the Agency Medical Directors' Group's Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain). We recognize the significant public health crisis of prescription drug abuse and fully support initiatives offering solutions that have a real chance of success. However, such solutions need not come at the expense of legitimate consumers and should not have to undermine appropriate patient care, directly or indirectly.

The American Pain Foundation is concerned that this guideline in its current form is not an effective response to the abuse and diversion issue and will have the unintended consequence of denying access to appropriate care of patients with chronic severe pain. We are in agreement that in the ideal world every pain patient receiving long-term opioid treatment should have a thorough, thoughtful and complete specialty evaluation. However, it is not at all clear what such a pain specialist is; even if it were possible to define such an expert, it is doubtful that there would be enough of them to do the job (even in urban centers). Therefore, it is a well intentioned plan that places impossible requirements on patients and prescribers; it essentially is a formula for failure with high probability for producing obstacles to care and, subsequently, harming patients with legitimate medical conditions. As a result, we strongly advise that the impact of the Opioid Dosing guidelines be reconsidered. Our concerns are based on the following considerations:

1. The identification of a pain specialist is problematic.
 - a. The American Board of Medical Specialties recognizes pain medicine as a subspecialty of Anesthesiology, Neurology, Psychiatry and Physiatry, rather than a general specialty certification. The training of pain specialists varies according to their chosen general specialty. This does not guarantee that the vast majority has been prepared to be the arbiters of safe and effective opioid prescribing and giving them this role is neither feasible nor appropriate.



- b. According to Portenoy, et al, (J Pain, 2007), there are about 2,500 board certified pain specialists in the whole country which accounts for an estimated 6 board certified pain specialists for every 100,000 patients. As with most specialties, more providers are located in urban or university settings. Therefore, fewer providers are available to serve the rural and underserved populations.
 - c. Approximately 29% of pain specialists practice only one treatment modality. Due to the current reimbursement structure, interventional pain medicine is more lucrative as compared to conservative medical management of pain or the more effective model of multi-modal management. Many pain specialists, one-third as cited by Portenoy, do not provide a service that oversees ongoing pharmacotherapy.
 - d. Board certification is not a minimum requirement before a physician can claim to be a pain specialist. This holds true for nurse practitioners and physicians' assistants as well. Therefore, referring to a qualified specialist is challenging at best.
2. Who will pay for these referrals?
- a. Third party payer reimbursement for the medical management of pain in many cases is not available. Though there is a recommendation to establish a form of reimbursement for the pain specialty referral, it needs to match the required time for assessment, reassessment, monitoring, titrating and re-adjustment of the pain treatment plan. What management plan would be followed for transitioning of treatment options and monitoring of withdrawal, when/if appropriate? For those with co-morbidities of addictive disease or mental illness, will their treatment needs be reimbursed or denied? If these issues are ignored, the economic and care burden will fall on the patient, the prescriber's practice setting or emergency departments and health clinics.
 - b. Nationally, there is an overall deficit in pain providers to meet the needs of over 76 million Americans living with chronic pain, according to a recent CDC report. It is not known whether populated cities in Eastern and Western Washington State have adequate numbers of pain specialists, but access to pain care for those living in rural/remote settings is severely limited. Often the primary care provider is the only treatment option for these citizens. If a referral is required that is based solely on a predetermined dosing amount, what distance will each affected patient be required to travel and at what personal expense?



3. The guideline sets a limit on how much morphine (or morphine equivalent) can be prescribed by non-pain specialists.
 - a. Prescribing for serious pain conditions is based on the principle that the dose should be individualized and based on the consideration of degree of pain relief, improvement of function, and impact of side effects. The opioid upper dosing threshold recommended is an arbitrary “ceiling,” as there are no scientific data to support that more than 120 mg morphine equivalents per day represents an unusual or unreasonable dose. In fact, a randomized controlled trial conducted by Raja, et al. (*Neurology* 2002; 59: 1015-1021) demonstrated that 120mg was about one standard deviation below the mean dose used to treat post-herpetic neuralgia in elderly patients without prior exposure to opioids. Such treatment was associated with pain reduction, improvement in function with no evidence of abuse behavior and no adverse effects on cognition. We certainly would support research to that investigates the effects of dosing, and whether dosing by primary care providers was associated with increased risks of abuse problems. As it stands, however, the dosing ceiling proposed is unsupported scientifically and clinically. The proposed threshold is arbitrary and discriminatory.
 - b. There is presently no clear guideline about the dosages of morphine equivalents when other opioids are in use. In order for the guidelines to be clear, they would have to specify the maximum dose for each opioid that is used. This in itself invites problems as the dosing equivalents in fact vary greatly from patient to patient. Expecting primary care providers to be able to keep track of the guidelines for each opioid will lead to the easier option of simply avoiding the use of this class of medications altogether.
 - c. While drug abuse is a major societal problem in America, there is no evidence that targeting healthcare providers with these arbitrary and burdensome practice guidelines will have an impact on this problem. At this point, no data are available to show that interfering with the clinical decision-making of typical physicians or other prescribers contributes greatly to reducing abuse and diversion. Governmental interference in the doctor’s office risks lowering the availability of effective care, and promises to increase the regulatory burdens on providers. Restricting healthcare practice can have a devastating effect on patient care.
4. The proposed guideline will likely increase provider fear of using their best clinical judgments to treat patients.
 - a. Physicians and other healthcare providers will interpret this restrictive policy to mean that caring for pain patients who require opioid therapy will trigger great



regulatory or legal surveillance than other areas of healthcare practice.

- b. The average practitioner will simply adopt the approach of, “I am not going to take chances,” which would lead to greater undertreatment of patients with chronic severe pain.
5. This action increases the stigma on pain patients.
- a. The guidelines are discriminatory in nature. What other patient population is required to be referred for their medical disorder due solely to a predetermined dosing requirement?
 - b. This action further encourages patients with pain to be seen as drug abusers or potential abusers. Research shows that the risk of addiction in the pain population is no different than the average population without pain. Evidence shows that high risk behaviors of diversion, misuse and abuse continue to be primarily an adolescent/young adult problem. Sources for diversion mostly stems from theft at the supply line or from family and friends (PPSG; ONDCP). Why are providers and pain patients the targets of corrective action?

It is the opinion of the American Pain Foundation that the proposed guideline, though well intentioned, is setting a dangerous precedent based on arbitrary standards. In addition, as an attempt to curb abuse and diversion, this policy is misdirected. According to the recent report from the Pain and Policies Group from the University of Wisconsin, an important and knowable source of diversion comes from pharmacy theft, independent of the physician-patient relationship, and we do not know the extent that diversion comes from the provider or the patient with pain. Further study is required to understand better the source of abuse and diversion of prescription pain medications.

We urge the policy leaders for the State of Washington reconsider the promulgation of this guideline, even as an educational effort, until there is sufficient clarification and identification of “pain specialists.” If the use of the guideline is to continue, we recommend that a pilot study be conducted that includes the addition of prospective quality monitoring programs that are created to evaluate the impact of the unintentional consequences on clinical practice and access to care that most likely will ensue. These outcomes should be reported in a timely fashion and on a regular basis to key policy leaders and the general public of the State of Washington.