

Exhibit A

Interagency Guidelines on Opioid Dosing for non-Cancer Pain



Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: *an educational pilot to improve care and safety with opioid treatment*

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Introduction

This guideline is part of a year-long educational pilot to improve care and safety when treating chronic non-cancer pain with opioids. Sponsored by the Agency Medical Directors' Group (AMDG), the guideline was developed by the Interagency Workgroup on Practice Guidelines¹ in collaboration with actively practicing physicians who specialize in pain management. It is intended as a resource for primary care providers treating patients who receive health care through state agency programs. It does not apply to the treatment of acute pain, cancer pain, or end-of-life (hospice) care.

Providers prescribing opioids should be aware of the delicate balance between the undertreatment and overtreatment of chronic non-cancer pain. Because high dose opioid treatment can be ineffective and/or unsafe, providers must pay ongoing attention to adverse outcomes of chronic opioid use (Ballantyne 2003).

Recent studies indicate an increase in accidental deaths associated with the use of prescription opioids since 1999 (CDC 2005, Franklin 2005, Paulozzi 2006). At the same time, there has been a dramatic increase in the average daily morphine equivalent dose (MED) of the most potent (Schedule II) long-acting opioids (Franklin 2005). In Washington State, the overall number of opioid-related deaths more than doubled between 1995 and 2004, and prescription opioid-related deaths now exceed non-prescription opioid-related deaths. (Sabel 2006).

The purpose of Part I of the dosing guideline is to assist the primary care provider who does not specialize in pain medicine in prescribing opioids for adults in a safe and effective manner when:

- Instituting or transitioning opioid treatment from acute to chronic non-cancer pain;
- Assessing and monitoring opioid treatment for chronic non-cancer pain; and
- Weaning opioids if an opioid trial fails to yield improvements in function as well as pain.

The purpose of Part II of the guideline is to assist primary care providers in treating patients whose morphine equivalent dose (MED) already exceeds 120 mg per day.

¹ Washington State Department of Corrections; Health; Labor and Industries; Social and Health Services; and Health Care Authority

I. Guidelines for initiating, transitioning, and maintaining oral opioids for chronic non-cancer pain

Part I of the dosing guideline will assist the primary care provider who does not specialize in pain medicine in prescribing opioids for adults in a safe and effective manner when:

- Instituting or transitioning opioid treatment from acute to chronic non-cancer pain;
- Assessing and monitoring opioid treatment for chronic non-cancer pain; and
- Weaning opioids if an opioid trial fails to yield improvements in function and pain.

Dosing threshold for pain consultation

In order to improve the quality of care in the state of Washington, the state agencies, in collaboration with the physician panel, reviewed the available evidence and made the following recommendations:

- In general, the total daily dose of opioid should not exceed 120 mg oral morphine equivalents.
- Rarely, and only after pain management consultation, should the total daily dose of opioid be increased above 120 mg oral morphine equivalents.
- Safety and effectiveness of opioid therapy for chronic non-cancer pain should be routinely evaluated by the prescriber.
- Assessing the effectiveness of opioid treatment should entail tracking and documenting both functional improvement and pain relief.
- A specialty consultation may be considered at any time if there is evidence of frequent adverse effects or lack of response to an opioid trial.

| Table 1. Summary of Recommendations | |
|---|--|
| Prescribing opioid doses up to 120mg/day MED: (Cumulative daily dose when using one or more opioids. See Table 2 for specific opioid thresholds.) | Before exceeding 120mg/day MED dose threshold: (Cumulative daily dose when using one or more opioids. See Table 2 for specific opioid thresholds.) |
| <ul style="list-style-type: none"> • No pain management consultation needed if the prescriber is documenting sustained improvement in both function and pain. • Consider specialty consultation² if frequent adverse effects or lack of response is evident in order to address: <ul style="list-style-type: none"> ○ Evidence of undiagnosed conditions; ○ Presence of significant psychological condition affecting treatment; and ○ Potential alternative treatments to reduce or discontinue use of opioids. | <ul style="list-style-type: none"> • Seek pain management consultation³ to address: <ul style="list-style-type: none"> ○ Potential alternative treatments to opioids; ○ Risk and benefit of a possible trial with opioid dose above 120mg/day MED; ○ Assistance with ongoing documentation of improvement in function and pain; and ○ Schedule for follow up with pain management specialist, if necessary. |

² For information on specialty consultations, see page 6.

³ For information on pain management consultations, see page 7.

Morphine equivalent dose calculation

For patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose (see Table 3 on page 11 for MEDs of selected medications). For example, if a patient takes six hydrocodone 5mg / acetaminophen 500mg and two 20mg oxycodone extended release tablets per day, the cumulative dose may be calculated as follows:

- 1) Hydrocodone 5mg x 6 tablets per day = 30mg per day.
- 2) Using the Equianalgesic Dose table on page 11 of this guideline, 30mg Hydrocodone = 30mg morphine equivalents.
- 3) Oxycodone 20mg x 2 tablets per day = 40mg per day.
- 4) Per Equianalgesic Dose table, 20mg oxycodone = 30mg morphine so 40mg oxycodone = 60mg morphine equivalents.
- 5) Cumulative dose is 30mg + 60mg = 90mg morphine equivalents per day.

An electronic opioid dose calculator can be downloaded at www.agencymeddirectors.wa.gov/guidelines.asp.

When to consider prescribing opioids

- Other conservative measures have failed (e.g. NSAIDs, tricyclic antidepressants, antiepileptics and non-pharmacologic therapies) and opioids have not been tried.
- Patient has demonstrated sustained improvement in function and pain level in previous opioid trial.
- Patient has no relative contraindication to the use of opioids (e.g. active alcohol or other substance abuse).

Principles for prescribing opioids

- Single prescriber
- Single pharmacy
- Patient and prescriber sign opioid agreement
- Lowest possible effective dose should be used
- Be cautious when using opioids with conditions that may potentiate opioid adverse effects (including COPD, CHF, sleep apnea, history of alcohol or substance abuse, elderly, or history of renal or hepatic dysfunction).
- Do not combine opioids with sedative-hypnotics, benzodiazepines or barbiturates for chronic non-cancer pain unless there is a specific medical indication for the combination.
- Assess function and pain status routinely (see *Tools for assessing function and pain*, page 5).
- Monitor for medication misuse (for a list of drug-seeking behaviors, see *Reasons to discontinue opioids or refer for addiction management*, page 10).
- Random urine drug toxicology screening to objectively assure compliance (see *Urine drug toxicology screening*, page 6).

Instituting opioid treatment for chronic non-cancer pain

Prior to initiating chronic opioid therapy, the prescriber should comprehensively assess the risks and benefits of treatment. The prescriber is responsible for routinely monitoring the safety and effectiveness of opioid therapy in providing pain relief and improving function.

When instituting opioid therapy, both provider and patient should discuss and agree on:

- Risks and benefits of opioid therapy supported by an opioid agreement;
- Treatment goals and provider's established criteria to evaluate the effectiveness of opioid therapy; and
- A follow-up plan with specific time intervals to monitor treatment.

Treatment goals must include improvements in both function and pain while monitoring for and minimizing adverse effects (see *Principles for prescribing opioids*, page 4).

Depression and anxiety disorders are frequently associated with the use of opioids (Sullivan 2005). Extreme caution should be used, and a specialty consultation is strongly encouraged, prior to prescribing opioids when patients have a history of significant psychological conditions such as conversion disorder, somatization, borderline personality, mood disorder, PTSD, or history of alcohol or other substance abuse.

Transitioning opioid treatment from acute pain to chronic non-cancer pain

- **Acute pain** is self-limiting and lasts from a few days to a few weeks following trauma or surgery.
- **Chronic pain** persists beyond the anticipated healing period for the specific disease condition.

The level of pain during an acute phase does not necessarily and accurately predict the pain level in a chronic phase. Thus, opioid dosing for chronic treatment should be assessed and adjusted accordingly (see *Instituting opioid treatment for chronic non-cancer pain*, page 4).

Tools for assessing function and pain

The key to effective opioid therapy for chronic non-cancer pain is sustained functional improvement (Loeser 1989, Devulder 2005). While there is no universally accepted tool to assess opioid treatment, it is important to use a tool that monitors both function and pain. An assessment of function should consistently measure the same elements to adequately determine the degree of progress. The following are functional assessment tools that may be helpful in monitoring your patient's progress:

- **SF36 Health Survey**
<http://www.npecweb.org/clinicaltoolbox.asp?id=26&selMenu=15,0> (Select quality of life tab, RAND 36 Health Survey)
- **QuickDash** for musculoskeletal disorders of the upper extremities
http://www.dash.iwh.on.ca/assets/images/pdfs/quickdash_q.pdf
- **Quality of Life Scale**
<http://www.npecweb.org/clinicaltoolbox.asp?id=26&selMenu=15,0> (Select quality of life tab)
- **Oswestry Disability Index**
http://www.chirogeek.com/001_Oswestry-Disability-level.htm
- **Neck Disability Index**
http://www.chirogeek.com/001_Neck-Disability-Index.htm
- **Short Musculoskeletal Function Assessment.** (See Swiontkowski et al.)

Assessing effects of opioid treatment

Long-term opioid treatment is associated with the development of tolerance to its analgesic effects (White 2004). Evidence is accumulating that opioid treatment may also paradoxically induce abnormal pain sensitivity, including hyperalgesia and allodynia (Mao 2002, Ossipov 2005, King 2005). Thus, increasing opioid doses may not improve pain control and function.

The prescriber should assess the risks and benefits of their patient's current opioid therapy. This assessment should include:

- Function and pain status (see *Tools for assessing function and pain*, page 5);
- Possible adverse effects of current opioid doses;
- Potential psychological condition affecting treatment;
- Possible drug combinations or conditions that may potentiate opioid adverse effects (such as COPD, CHF, sleep apnea, history of alcohol or substance abuse, advanced age, or history of renal or hepatic dysfunction); and
- Any relative contraindication to the use of opioids (active alcohol or other substance abuse, see *Urine drug toxicology screening*, below).

If function and pain do not improve after a sufficient opioid trial, consider discontinuing opioids (see *Weaning opioids*, page 7). When there is evidence of significant adverse effects from opioid therapy, the provider should reduce the opioid dose and reassess the patient's status.

Otherwise, if no reasons for dose reduction or discontinuation are identified, and the prescriber feels (with support of objective measures of pain and function) that the patient is benefiting from current therapy, continuation would be appropriate. Ongoing therapy, however, entails ongoing assessment. The screening described above should be done on a regular basis to assess progression of therapy as the patient's condition changes over time.

Urine drug toxicology screening

Urine drug toxicology screening can improve the prescriber's ability to safely and appropriately manage opioid treatment. Urine toxicology can verify if the patient is taking the prescribed medications. It can also identify if other psychoactive substances are consumed, but not reported, which may impact the patient's safety, function and treatment. The NIDA 5 (National Institute on Drug Abuse) is the most commonly used basic urine drug test that screens for five common drug classes:

- Cannabinoids (marijuana, hash)
- Cocaine (crack)
- Amphetamines (methamphetamines, speed)
- Opioids (heroin, opium, codeine, morphine)
- Phencyclidine (PCP)

The NIDA 5 does not screen for many other drugs of abuse, such as barbiturates, benzodiazepines, hydrocodone, methadone, oxycodone, propoxyphene, or other synthetic drugs. An expanded urine drug toxicology panel can be ordered to screen for these substances.

Positive results from a urine toxicology screen should be interpreted with caution. Over-the-counter medication may occasionally cause a positive result, particularly in the amphetamines and opioids classes. In some circumstances a positive result may require confirmatory tests and consultation with a certified Medical Review Officer (MRO). To locate a MRO in your area, submit a search at the following website:

http://www.aamro.com/registry_search.html

Specialty consultation

Specialty consultation is recommended for ongoing severe pain symptoms with no improvement in function despite treatment with opioids. Consultation should address possible undiagnosed conditions, psychological conditions affecting treatment, and alternative treatments. The type of consultation obtained should be determined by the patient's presenting signs and symptoms. Consultation may be with, but not limited to, a physician specializing in psychiatry, neurology, anesthesiology, pain, physical medicine and rehabilitation, orthopedics, addiction medicine, rheumatology, or oncology.

Chronic opioid treatment can be challenging in patients with symptoms suggestive of mood, anxiety, and psychotic disorders. Consider psychiatric and/or psychological consultation for intervention if a psychological condition is affecting treatment. Patients with signs of alcohol or other substance abuse should be referred to an addiction specialist (*see Referrals for addiction management or opioid agonist treatment*, page 10).

Pain management consultation

Although pain may be relieved at oral morphine doses up to 120 mg per day, pain relief is not necessarily associated with psychological or functional improvement (Moulin 1996). Because sustained functional improvement is so critical to effective opioid therapy for chronic non-cancer pain, the prescriber should ensure that the patient meets the following conditions before considering a dosage above 120mg/day MED:

- There are no significant psychological issues or evidence of drug-seeking behaviors, AND
- The patient has demonstrated improvement in function and pain level previously at a lower dose.

If these conditions are met, the prescriber may seek a pain management consultation for a possible trial with opioid doses above 120mg/day MED.

Consultation with a specialist does not necessitate transfer of the patient's care or ongoing opioid prescribing. However, the consultant should advise the prescribing provider on a pain management plan that may include alternative treatments to reduce or discontinue use of opioids; adequate explanation of the risks and benefits of a possible trial with opioid dosing above 120mg/day MED; and the need for ongoing documentation of improvement in function and pain.

If you need to find a pain management specialist, you may find it helpful to contact one of the following organizations that offer credentialing or certification in pain medicine:

- American Board of Pain Medicine
- American Board of Anesthesiology with certification of added qualifications in pain management
- American Board of Physical Medicine and Rehabilitation
- American Board of Psychiatry and Neurology

In addition, you can find a non-exclusive list of pain specialists at

www.agencymeddirectors.wa.gov/guidelines.asp

Weaning opioids

Not all patients benefit from opioids, and a prescriber frequently faces the challenge of reducing the opioid dose or discontinuing the opioid altogether. From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1mg/24hrs (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

Recognizing and managing behavioral issues during opioid weaning

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper (Passik 2006).

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation (“You are indifferent to my suffering”)
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary (see *Instituting opioid treatment for chronic non-cancer pain*, page 4).

Part II: Guidelines for optimizing treatment when opioid doses are greater than 120 mg MED per day

Part II of this dosing guideline will assist the provider in optimizing treatment:

- When assessing effectiveness of opioid therapy in patients whose total morphine equivalent dose exceeds 120 mg per day;
- When reducing the total daily opioid dose; and
- When discontinuing opioid therapy.

Assessing effects of opioid doses greater than 120 mg MED per day

As previously stated, ongoing opioid treatment requires ongoing assessment to optimize therapy. This is important in light of the development of hyperalgesia and other abnormal pain sensitivity with chronic high dose opioid treatment. If, after using the guidelines under *Assessing effects of opioid treatment* (page 5), the prescriber feels that current treatment is not benefiting the patient, a dose reduction or discontinuation is warranted. However, if current treatment is benefiting the patient as demonstrated by objective measures of pain and function, it may be appropriate to continue, while establishing a plan to monitor therapy as the patient's condition changes over time (see *Principles for prescribing opioids*, page 4).

How to discontinue opioids or reduce and reassess at lower doses

Treatment with opioids, even at high doses, does not guarantee freedom from chronic pain, and some patients may actually do better on lower doses of opioids (Mao 2002, Ballantyne 2003). A decrease by 10% of the original dose per week is usually well tolerated. Behavioral issues or physical withdrawal symptoms can be a major obstacle to an otherwise beneficial dose reduction (see *Weaning opioids*, page 7, and *Recognizing and managing behavioral issues during opioid weaning*, page 8).

The prescriber should assess the patient's status after discontinuing or reducing the opioid dose to less than 120mg MED per day. If the chosen assessment tool indicates improved patient status, other than subjective pain complaints, or if there is improvement in opioid-related side effects, maintain the patient off opioids or at the new reduced dose and reassess at a later time.

Conversely, if there is evidence of functional and symptomatic deterioration following opioid taper, the prescriber can resume prior dosing or strongly consider consulting with a pain management specialist to evaluate additional therapeutic options.

Referrals to pain centers

A referral for counseling or other support during opioid taper or dose reduction is recommended if there are significant behavioral issues. In addition, a multidisciplinary pain program may be considered when appropriate to address the psychosocial and cognitive aspects of chronic pain together with patients' physical rehabilitation (Guzman 2002).

Recognizing aberrant behaviors during opioid treatment

Patients who exhibit aberrant behaviors may or may not be at risk for opioid abuse. There is no universally accepted screening tool to predict aberrant behaviors with opioid treatment for chronic pain. However, it is important to identify aberrant behaviors as they can affect the medical management of your patients (see *Reasons to discontinue opioids or refer for addiction management*, page 10).

Patients with a co-morbid psychiatric condition or addiction are at higher risk of uncontrolled opioid use despite their attempts to follow the treatment plan (Streltzer 2001, Streltzer 2006, Passik 2006). Prescribers should seek a

consultation with an addiction specialist if there is co-morbid substance dependence or abuse.

Reasons to discontinue opioids or refer for addiction management

- No improvement in function or pain after opioid trial;
- Opioid treatment produces significant adverse effects; or
- Patient exhibits drug-seeking behaviors or diversion:
 - Selling prescription drugs
 - Forging prescriptions
 - Stealing or borrowing drugs
 - Frequently losing prescriptions
 - Aggressive demand for opioids
 - Injecting oral/topical opioids
 - Unsanctioned use of opioids
 - Unsanctioned dose escalation
 - Concurrent use of illicit drugs
 - Failing a drug screen
 - Getting opioids from multiple prescribers

Referrals for addiction management or opioid agonist treatment

A patient who exhibits overt signs of alcohol or substance use disorder as defined in the current edition of the Diagnostic and Statistical Manual of Mental Disorders fourth edition (DSM) should be referred to an addiction specialist for appropriate treatment. Prognosis is poor for patients with a DSM diagnosis of opioid dependence or opioid abuse who do not receive opioid agonist therapy, such as methadone or buprenorphine (Sees 2000, Kakko 2003).

Methadone can only be provided to treat a DSM diagnosis of opioid dependence through a federally licensed opioid treatment program (OTP). A referral for treatment may be made to any one of the licensed OTPs in Washington State:

- <http://www1.dshs.wa.gov/DASA/services/certification/GB.shtml> and click on Appendix Q.

Buprenorphine or buprenorphine/naloxone may also be prescribed by a qualified physician to treat opioid addiction. Any pharmacy can fill a buprenorphine or buprenorphine/naloxone prescription. To find qualified physicians in Washington, access:

- http://buprenorphine.samhsa.gov/bwns_locator/dr_search.htm

Additional resources

- Department of Social and Health Services (DSHS) Tool Kit to help address drug and alcohol issues in Medicaid patients <http://maa.dshs.wa.gov/pharmacy/ToolKit.htm>
- DSHS Division of Alcohol and Substance Abuse at 877-301-4557
- List of providers for pain management consultation www.agencymeddirectors.wa.gov/guidelines.asp
- Collaborative Opioid Prescribing Education (COPE), an online training to improve doctor-patient communications and collaborative goal-setting. COPE training is available for free CME through the University of Washington CME website at: <http://depts.washington.edu/cme/online/course/EN0705>

| Table 2. Dosing Threshold for Selected Opioids* | | | |
|---|---|---|--|
| Opioid | Recommended dose threshold for pain consult (not equianalgesic) | Recommended starting dose for opioid-naïve patients | Considerations |
| Codeine | 800mg per 24 hours | 30mg q 4–6 hours | See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below. |
| Fentanyl Transdermal | 50mcg/hour (q 72 hr) | | Use only in opioid-tolerant patients who have been taking ≥ 60mg MED daily for a week or longer |
| Hydrocodone | 120mg per 24 hours | 5-10mg q 4–6 hours | See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below. |
| Hydromorphone | 30mg per 24 hours | 2mg q 4-6 hours | |
| Methadone | 40mg per 24 hours | 2.5-5mg BID – TID | Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting (LA) opioids. |
| Morphine | 120mg per 24 hours | Immediate-release: 10mg q 4 hours Sustained-release: 15mg q 12 hours | Adjust dose for renal impairment. |
| Oxycodone | 80mg per 24 hours | Immediate-release: 5mg q 4–6 hours Sustained Release: 10mg q 12 hours | See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below. |
| Oxymorphone | 40mg per 24 hours | Immediate-release: 5-10mg q 4–6 hours Sustained Release: 10mg q 12 hours | Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol. |

*Meperidine and propoxyphene products should not be prescribed for chronic non-cancer pain pain.

Acetaminophen warning with combination products

Hepatotoxicity can result from prolonged use or doses in excess of recommended maximum total daily dose of acetaminophen including over-the-counter products.

- Short-term use (<10 days) – 4000 mg/day
- Long-term use – 2500mg/day

Key considerations in dosing long acting opioids

- Monitoring for adequate analgesia and use of “rescue” medications (at least until the long-acting opioid dose is stabilized). All new dosage calculations should include consideration for concurrent utilization of short-acting opioids.
- If the patient is more debilitated, frail and/or has significant metabolic impairments (e.g. renal or hepatic dysfunction), consider starting at the lower end of the conversion dose range.
- Always monitor for adverse effects (nausea, constipation, oversedation, itching, etc.)

Equianalgesic dose table for converting opioid doses

All conversions between opioids are estimates generally based on “equianalgesic dosing” or ED. Patient variability in response to these EDs can be large, due primarily to genetic factors and incomplete cross-tolerance. **It is recommended that, after calculating the appropriate conversion dose, it be reduced by 25–50% to assure patient safety.**

| Table 3. MED for Selected Opioids | |
|-----------------------------------|---|
| Opioid | Approximate Equianalgesic Dose (oral & transdermal) * |
| Morphine (reference) | 30mg |
| Codeine | 200mg |
| Fentanyl transdermal | 12.5mcg/hr |
| Hydrocodone | 30mg |
| Hydromorphone | 7.5mg |
| Methadone | Chronic: 4mg† |
| Oxycodone | 20mg |
| Oxymorphone | 10mg |

*Adapted from VA 2003 & FDA labeling

†Equianalgesic dosing ratios between methadone and other opioids are complex, thus requiring slow, cautious conversion (Ayonrinde 2000)

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Exhibit B

List of Pain Management Specialists published with Interagency Guidelines

Pain Management Specialists Directory

This list is not intended to be an all-inclusive list of pain management specialists in Washington State. The physicians listed below are either certified in Pain Medicine or are recognized in the management of chronic non-cancer pain. If there is not a pain management specialist listed in your area, please consult with a board certified physician who has experience managing chronic non-cancer pain. Typically physicians who are certified in Pain Medicine are also certified in Physical Medicine and Rehabilitation, Anesthesiology, Neurology, or Internal Medicine.

To locate a physician certified in Pain Management by the American Board of Pain Medicine go to www.abpm.org and locate your state.

| Doctor | Address | Phone | Health Care Funding Source * |
|----------------------|---|----------------|--|
| Robert Djergaian, MD | SW Washington Medical Center 400 NE Mother Joseph Place Vancouver, Washington 98668 | (360) 514-3142 | All |
| Marvin Hoffert, MD | 1530 N. 115th Street, #207 Seattle, Washington 98133 | (206) 523-7246 | All |
| Charles Chabal, MD | Evergreen Pain Management Center 12040 NE 128th Street Kirkland, Washington 98034 | (425) 899-2388 | Health Care Authority Corrections Labor & Industries |
| Cong Yu, MD | 1101 Madison, Suite 200 Seattle, Washington 98104 | (206) 386-6000 | All |
| Marian Johnston, MD | 125 N 18th St, Suite B Mount Vernon, Washington 98274 | (360) 336-0123 | Labor & Industries |
| Jean You, MD | Columbia Rehabilitation & Pain 560 Gage Boulevard Richland, Washington 99352 | (509) 627-2848 | All (by provider referral only) |
| John Loeser, MD | University of Washington Department of Neurologic Surgery Box 356470 Seattle, Washington 98195 | (206) 543-3570 | All (only neurosurgical services) |

| | | | |
|---|--|------------------------------|--------------------|
| Bing Manawadu, MD | PO Box 1408 Richland, Washington 99352 | (509) 946-3340 | Labor & Industries |
| Greg Carter, MD | 1809 Cooks Hill Road Centralia, Washington 98531 | (360) 330-8626 | All |
| Jefferey Fitzthum, MD | 1530 N. 115th Street, Suite #305 Seattle, Washington 98133 | (206) 362-2464 | All |
| Andrew Friedman | 1100 9th Street Seattle, Washington 98101-2756 | (206) 625-7373 Ext. 64330 | Labor & Industries |
| Wing C. Chau, MD | 943 Stevens Dr. Richland, Washington 99352 | (509) 943-1211 | All |
| L. Brian Ready, MD, FRCPC | Allenmore Hospital 1901 S. Union Ave., Suite A-244 Tacoma, Washington 98405 | (253) 459-6509 | All |
| Michael Hatzakis, Jr., MD | 1600 116th Avenue NE Suite 202 Bellevue, Washington 98004 | (425) 453-1000 | Labor & Industries |
| Gordon Irving, MD | Swedish Pain Management 1101 Madison Street, Suite 200 Seattle, Washington 98104 | (206) 386-2013 | All |
| * Patients who receive health care funded by either Medicaid, Department of Labor & Industries, Department of Corrections, or Health Care Authority | | | |

Updated: November 15, 2007

Exhibit C

Medical Quality Assurance Commission Guidelines for Management of Pain, Approved 18 April 1996

[PPSG Home](#)[PPSG United States](#)Prepared for internet access by
the University of Wisconsin **Pain & Policy Studies Group**

WASHINGTON

Medical Quality Assurance Commission

Source: Provided by the Board of Medical Examiners and Medical Disciplinary

Approved: April 18, 1996

Medical Quality Assurance Commission

Guidelines for Management of Pain

State of Washington

Approved 4/18/96

BACKGROUND

Substitute Senate Bill 5365 Uniform Disciplinary Act Amendments directed the Secretary of the Department of Health to "...coordinate and assist the regulatory boards and commissions of the health professions with prescribing authority in the development of uniform guidelines for addressing opiate therapy for acute pain and chronic pain associated with cancer and other terminal diseases, or other chronic or intractable pain conditions. The purpose of the guidelines is to assure the provision of effective medical treatment in accordance with recognized national standards and consistent with requirement of public health safety".

The Department of Health convened a group entitled Task Force on Policies for Management of Pain. This task force included representation from the medical, pharmacy, and nurses' associations and commissions; physicians from pain management clinics and private practice; a Washington state Representative; and patients with chronic intractable pain.

INTRODUCTION

There are widespread concerns among patients throughout the state about access to appropriate medical treatment, including opioid therapy, for addressing chronic intractable pain. Similarly, providers express apprehensions about challenges by state disciplinary authorities when prescribing opioid analgesics for indicated medical treatment when serving the legitimate medical needs of pain patients. The under treatment of chronic pain due to concerns about addiction and drug diversion affect the public health, safety and welfare. There is a need for guidance which would: a) encourage appropriate treatment for pain management; b) reduce providers' fear of injudicious discipline; and, c) protect the public from inappropriate prescribing practices and diversion.

PURPOSE STATEMENT

The Secretary of the Department of Health recommends the uniform adoption, by appropriate state regulatory authorities, of the following guidelines when managing pain. It is not the intent of these guidelines to define complete standards of acceptable medical care in the treatment of pain patients. These guidelines are not intended to direct clinical practice parameters. It is the intent that providers will have confidence that these guidelines are the standard by which opioid usage is evaluated.

POLICY STATEMENT

Under generally accepted standards of medical practice, opioids may be prescribed for the treatment of acute or chronic pain including chronic pain associated with cancer and other non-cancer pain conditions. Prescribing opioids requires special consideration. It is the position of the Department of Health that opioids may be prescribed, dispensed, or administered when there is an indicated medical need without fear of injudicious discipline

GUIDELINES FOR OPIOID USAGE

Acute Pain

Opioids are useful for patients with acute pain such as surgery, burn, or trauma. The goal of such treatment is to provide adequate and timely pain management to the patient. Side effects of opioids that are difficult to treat may occur and must be balanced against the benefits of pain relief. The provider should, for any patient who has a history of alcoholism or other drug addictions, carefully monitor medications and when available seek appropriate consultation.

Chronic Pain Associated With Cancer

Chronic pain associated with cancer may often be successfully managed with opioids. If use of opioids is the primary analgesic strategy, adequate doses should be given frequently enough to keep the patient continuously comfortable. Addiction is rare in patients with cancer pain; tolerance and physical dependency are often unavoidable and should not interfere with opioid prescribing. Not all pain in patients with cancer is responsive to opioids; alternative strategies for managing the pain should also be made available.

Other Chronic Pain Conditions

Opioid analgesics can be useful in the treatment of patients with intractable non-cancer pain especially, where efforts to remove the cause of pain or to treat it with other modalities have failed or were not fully successful. The pain of such patients may have a number of different etiologies and may require several modalities. In addition, the extent to which pain is associated with psychological, physical, and social impairment varies greatly. Therefore, the selection for a trial of opioid therapy should be based on a careful assessment of the pain as well as the impairment experienced by the patient. Continuation of opioid therapy should be based on the provider's evaluation of the results of treatment, including the degree of pain relief, changes in psychological, physical, and social functioning, and appropriate utilization of health services. Providers are encouraged to obtain consultation from providers who are knowledgeable in pain management, particularly when managing patients with a history of alcohol abuse or previous chronic opioid use.

DEFINITIONS

1. Addiction - A disease process involving use of psychoactive substances wherein there is loss of

control, compulsive use, and continued use despite adverse social, physical, psychological, or spiritual consequences.

2. Physical Dependence - A physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is not necessarily associated with full blown addiction, and condition does not always equate with addiction.

3. Psychological Dependence - A subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.

4. Tolerance - State in which an increased dosage of a psychoactive substance is needed to produce a desired effect.

5. Withdrawal Syndrome - The onset of a predictable constellation of signs and symptoms following the abrupt discontinuation of, or rapid decrease in, dosage of a psychoactive substance.

6. Acute Pain - An essential biologic signal of the potential for or the extent of injury. It is usually short-lived and is associated with hyperactivity of the sympathetic nervous system; e.g. tachycardia, increased respiratory rate and blood pressure, diaphoresis, and papillary dilation. The concurrent affect is anxiety.

7. Chronic Pain - Pain persistent beyond expected healing time and often cannot be ascribed to a specific injury. Chronic pain may not have a well-defined onset and by definition does not respond to treatment directed at its causes.

8. Intractable Pain in a Non-Cancer Patient - Pain in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts.

GUIDELINES FOR ASSESSMENT AND DOCUMENTATION IN NON-CANCER PAIN

Alternative strategies for managing pain must be explored. If alternative strategies for managing the pain are unsuccessful, long term opioid therapy can be added. The goal is not merely to treat the symptoms of pain, but to devise pain management strategies which deal effectively with all aspects of the patient's pain syndrome, including psychological, physical, social, and work-related factors. Documentation in the patient's medical record should include:

1. History and medical examination - A complete physical examination and comprehensive medical history should be part of the active treatment record including, but not limited to, a review of past pain treatment outcomes and any history of addiction risks to establish a diagnosis and treatment plan.

2. Diagnosis and medical indication - A working diagnosis must be delineated, which includes the presence of a recognized medical indication for the use of any treatment or medication.

3. Written treatment plan with recorded measurable objectives - The plan should have clearly stated, measurable objectives, indication of further planned diagnostic evaluation, and alternative treatments.

4. Informed consent - Discussions of risks and benefits should be noted in some format in the patient's record.

5. Periodic reviews and modifications indicated - At these periodic reviews, the provider should reassess the treatment plan, the patient's clinical course, and outcome goals with particular attention paid to disease progression, side effect and emergence of new conditions.

6. Consultation - The treating provider should be knowledgeable and competent in referring patients to the appropriate specialist if needed and noting in the patient's record the treating providers interpretation of the consultation reports. Additionally, a new patient with evidence of at-risk patterns of opioid usage should be evaluated by a knowledgeable specialist.

7. Records - the provider should keep accurate and complete records documenting the dates and clinical findings for all evaluations, consultations, treatments, medications and patient instructions.

8. Assessment and monitoring - Some patients with chronic pain not associated with cancer may be at risk of developing increasing opioid consumption without objective improvement in functional status. Subjective reports by the patient should be supported by objective observations. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, patient consumption of health care resources, positive answers to specific questions about the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient as observed by the physician.

Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a disease with behavior characterized by psychological dependence and aberrant drug related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or merely because they are being treated with opioids

The physician is responsible for monitoring the dosage of the opioid. Monitoring includes ongoing assessment of patient compliance with drug prescriptions and related treatment plans. Communication between health care providers is essential. The patient should receive long term analgesic medications from one physician and where possible one pharmacy. All providers should be particularly cautious with patients with a history of alcoholism or other drug addiction when prescribing long term opioids. Consults with addiction specialists are recommended.

PATIENT RESPONSIBILITIES

1. It is the patient's responsibility to candidly provide the treatment provider with a complete and accurate treatment history, including past medical records, past pain treatment and alcohol and other drug addiction history.
2. The patient should participate as fully as possible in all treatment decisions.
3. The patient and family members, if available, should inform the prescriber of all drug side effects and concerns regarding prescription drugs.
4. The patient should not use other psychoactive agents, including alcohol, naturopathic products or over-the-counter drugs without agreement of the prescriber.
5. The patient should use the same name when receiving medical care to assure completeness of the

medical record.

6. The patient should demand respect and expect to be believed.
7. The patient should keep an open mind and be willing to work with the treatment provider, including:
 - a. negotiate with the provider to arrive at an acceptable plan of treatment;
 - b. be open in trying alternative treatment strategies; and
 - c. follow the treatment provider's instructions precisely.
8. The patient should, where possible, get all central nervous system medications from one provider. If this is not possible, the patient should inform each provider of all medication he/she is receiving.
9. The patient should, where possible, have all prescriptions filled at a single pharmacy.
10. The patient should not hoard, share, or sell medications.
11. The patient should be aware that providers may, by law, share information with other providers about the patient's care.

Exhibit D

Letter from Dr. Merle Janes to his Pain Patients

Board Certified in Physical Medicine and Rehabilitation
Board Certified in Pain Management
Board Eligible in Electrodiagnostic Medicine
Se Habla Español {Spanish spoken}

Dr. Merle Janes, MD
Valley Rehab and EMG
Mustard ~~Pain~~ Clinic
North 1414 Vercler, Suite #3
Spokane, WA 99216

∞ Specializing in diagnosis and treatment of injuries to nerve, muscle, ligament, and tendon ∞

"Pain in this life might be inevitable, but suffering is optional!"

{509} 927-4252 VOICE

{509} 927-4426 FAX

To my dear patients

March 19, 2008

re: *disengagement from opiate medications prescribing*

I have decided to **stop prescribing** opiate anti-pain medications on a chronic basis.

Therefore, I will not issue either a new or renewal prescription for you for any opiate medication after April 31, about 1 1/2 months from now.

According to my records, you have received this type of prescription from me in the past. Between today and April 31 you **must** choose one of the options below, and *notify me in writing* of what your decision is:

- [1] Switch your opiate medication prescribing to a different doctor.
- [2] Totally wean off of opiate medications by the April 31st date. You can do this either with my assistance or that of a different doctor. There are several possible methods and each has advantages and disadvantages.
- [3] Switch over to Chinese herbs, such as **corydalis** and **angelica**. Herbs are slower-acting than prescription drugs and may not 'cover' your pain as well, but might be worth considering.

Whichever of the above methods you choose, I will continue to endeavor to correct or improve your medical condition(s) using non-drug treatments and methods.

Health, Long Life, and Happiness,

Merle Janes, MD

Exhibit E

**Findings of Fact and Conclusions of Law dated May 22, 2008 re: Alan
Hunt**

**STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION**

| | | |
|----------------------------|---|-----------------------------------|
| In the Matter of: |) | Docket Nos. 06-06-A-1092MD (Lead) |
| |) | 06-09-A-1025MD |
| ALAN N. HUNT, M.D., |) | Master Case Nos. M2007-61837 |
| Credential No. MD00023685, |) | M2006-61838 |
| |) | |
| Respondent. |) | FINDINGS OF FACT, |
| |) | CONCLUSIONS OF LAW |
| |) | AND FINAL ORDER |
| _____ | | |

APPEARANCES:

Respondent, Alan N. Hunt, M.D., per
J.J. Sandlin, Attorney at Law

Department of Health Medical Program, by
Office of the Attorney General, per
Tracy L. Bahm, Assistant Attorney General

COMMISSION PANEL: Theresa Elders, Public Member, Panel Chair
Athalia Clower, PA-C
William Marineau, M.D.

PRESIDING OFFICER: John F. Kuntz, Health Law Judge

The Medical Quality Assurance Commission (the Commission) convened a hearing on February 4 – 8, 2008. The Department of Health issued a Statement of Charges alleging that the Respondent violated the Uniform Disciplinary Act under Docket Nos. 06-06-A-1092MD and 06-09-A-1025MD.¹

¹ These matters were consolidated pursuant to a prehearing order. See Prehearing Order No. 1 dated, November 2, 2006.

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

ISSUES

- A. Whether the Respondent engaged in unprofessional conduct as alleged under RCW 18.130.180(1), (4), and (9)?
- B. If the Department proves, by clear and convincing evidence, that the Respondent engaged in unprofessional conduct, what is the appropriate sanction under RCW 18.130.160?

SUMMARY OF THE PROCEEDING

The Department presented the testimony of: William N. Crowell, Health Care Investigator; Thomas Williamson-Kirkland, M.D.; Tofihg "Tony" Tahvili; Judith A. Brooks; James B. Kirkelie; Gary Munday; and Scott McClendon. The Respondent testified on his own behalf and presented the testimony of Frank Fisher, M.D. The following exhibits were admitted at hearing (except as indicated):

Department Exhibits:

- Exhibit D-1: Patient Records for Patient A1.
- Exhibit D-2: Rite Aid Pharmacy Records related to Patient A1.
- Exhibit D-3: Expert witness T. Williamson-Kirkland, M.D., report dated May 31, 2006, regarding Patient A1.
- Exhibit D-4: Patient Records for Patient B.
- Exhibit D-5: Expert witness T. Williamson-Kirkland, M.D., report dated May 31, 2006, regarding Patient B.
- Exhibit D-6: Patient Records for Patient C.
- Exhibit D-7: Summary of Pharmacy Reports for Patient C.
- Exhibit D-8: Patient Records for Patient D.
- Exhibit D-9: Pharmacy Records related to Patient D.

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

Page 2 of 31

Docket Nos. 06-06-A-1092MD (Lead) & 06-09-A-1025MD
Master Case Nos. M2007-61837 & M2006-61838

- Exhibit D-10: Summary of Pharmacy Records for Patient D.
- Exhibit D-11: Patient Records for Patient E.
- Exhibit D-12: Summary of Pharmacy Records for Patient E.
- Exhibit D-13: Patient Records for Patient F.
- Exhibit D-14: Summary of Pharmacy Records for Patient F.
- Exhibit D-15: Pharmacy Records from Fred Meyer #286 related to Patients C, D, and F.
- Exhibit D-16: Patient Records for Patient G.
- Exhibit D-17: Pharmacy Report for Patient G.
- Exhibit D-18: Pharmacy Report from Safeway #27-0333 related to Patient B and Patient G.
- Exhibit D-19: Patient Record for Patient H.
- Exhibit D-20: An undated letter from the Respondent.
- Exhibit D-21: Letter from the Respondent related to Patient D.
- Exhibit D-22: Letter from the Respondent dated August 25, 2005.
- Exhibit D-23: Letter from the Respondent, dated August 29, 2005, and revised December 20, 2005.
- Exhibit D-24: Letter from the Respondent regarding Patient E dated April 4, 2006.
- Exhibit D-25: Facsimile from the Respondent dated May 8, 2006.
- Exhibit D-26: Facsimile from Pharmacist John Adams to Health Care Investigator Bill Crowell dated August 31, 2006.
- Exhibit D-27: Letter from John Adams to Bill Crowell dated August 31, 2006.
- Exhibit D-28: Letter from John Adams to Bill Crowell dated September 1, 2006.

- Exhibit D-29: Letter from Pharmacist Scott McClendon to Bill Crowell dated September 1, 2006.
- Exhibit D-30: An undated statement from the Respondent.
- Exhibit D-31: Letter from the Respondent dated September 20, 2006.
- Exhibit D-32: Photographs.
- Exhibit D-33: Statement of James Kirkelie dated August 25, 2006.
- Exhibit D-34: Statement of Judy A. Brooks dated August 28, 2008.
- Exhibit D-35: Statement of Tony Tahvili dated August 25, 2006.
- Exhibit D-36: Statement of Gary Munday dated August 25, 2006.
- Exhibit D-37: Oregon Board of Medical Examiners Search Results, effective date of January 24, 2008.
- Exhibit D-38: Denied.²
- Exhibit D-39: Denied.
- Exhibit D-40: Denied.

Respondent's Exhibits

- Exhibit R-1: Denied.
- Exhibit R-2: Withdrawn at hearing.³
- Exhibit R-3: Withdrawn at hearing.
- Exhibit R-4: Withdrawn at hearing.
- Exhibit R-5: Withdrawn at hearing.
- Exhibit R-6: Withdrawn at hearing.

² At hearing, Department Exhibit Nos. D-38, D-39, and D-40 were numbered D-40, D-41, and D-42.

³ Counsel for the Respondent withdrew the remainder of the Respondent's exhibits (those not admitted or denied) on the third day of the hearing.

- Exhibit R-7: Withdrawn at hearing.
- Exhibit R-8: Illustrative format for notepads used by the Respondent.
- R-8A: Memo Pad.
R-8B: Receipt Form.
- Exhibit R-9: Illustrative format for prescription format used by the Respondent.
- Exhibit R-10: Denied.
- Exhibit R-11: Denied.
- Exhibit R-12: Denied.
- Exhibit R-13: Denied.
- Exhibit R-14: Withdrawn at hearing.
- Exhibit R-15: Withdrawn at hearing.
- Exhibit R-16: Denied.
- Exhibit R-17: Withdrawn at hearing.
- Exhibit R-18: Withdrawn prior to the hearing.⁴ See Prehearing Order No. 4, Footnote 1.
- Exhibit R-19: Withdrawn at hearing.
- Exhibit R-20: Lease Agreement entered April 5, 2006, between the Respondent and Retail-K LLC (with attachments); Retail K LLC Agreement with the Respondent dated May 13, 2006.
- Exhibit R-21: Judith Brooks' complaint dated July 5, 2006.
- Exhibit R-22: Denied.

Based on the evidence presented, the Commission enters the following:

⁴ See Prehearing Order No. 4, Footnote 1.