

David Teicheira, MD  
American Boards of Anesthesiology, Internal Medicine, Pain Medicine

April 21, 2014

I agree with the comments posted. They represent thoughtful and experienced opinions.

From my own experience, the biggest problems that will arise will be from the internal inconsistencies, which allow selective interpretation of the guidelines. We can work with guidelines, as long as they are not self-contradictory.

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Robert Gussenhoven, PharmD  
Assistant Professor, Biotechnology Dept.  
University of Alabama at Birmingham

April 21, 2014

This is in response to your call for comments on the guidelines for the use of opioids for work related injuries.

The use of opioids for chronic pain management is misguided. The reviews on chronic opioid use and associated outcomes is partial and inadequate. Numerous studies are showing that chronic use of opiates seldom leads to recovery and that chronic pain management using other methods have less pain and greater functionality. The recommendations by Portenoy and Fine in the '90s to use opiates for chronic pain syndromes were based on limited short term evidence. It is now apparent that chronic opioid use has not led to improved outcomes in what the Institute Of Medicine (IOM) described as the "conundrum of opioids" in the required investigative report on pain management following passage of the ACA.

The issue is that over 100 million Americans have chronic pain syndromes, and almost half with moderate to severe pain are being inadequately treated. Current pain management approaches are not working adequately. In the adverse drug reaction discussion in the guidelines, Opiate Induced Hyperalgesia (OIH) and neuro-endocrine disruption are hardly mentioned. The IOM determined that while opioid costs and abuse issues were costing \$60 billion per year, inadequate pain management resulted in a tenfold cost increase rivaling the military defense budget (\$600 billion).

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When physicians consider the use of opioids they are primarily concerned with addiction and abuse issues. The long term effects on the neuro-endocrine system and OIH are seldom considered because it is difficult to quantify, even though both have been known for over a century. OIH can magnify pain and increase pain upon discontinuation, with at least five mechanisms being postulated. Long term opioid use clearly results in disruption of the HPA and HPG axes and is a significant factor in exacerbating comorbidities such as depression. It is now clear following trends and outcomes in the United States and Denmark that these effects can be quite significant.

The combination of the influences of OIH and neuro-endocrine disruption are clearly synergistic. How patients react will vary based on genetics, pharmacotherapy, life events, and many biodiverse influences. These factors make the identification and management of the adverse effects of opiates following chronic use challenging. I believe encouraging the use of opioids for chronic pain management should be judicious at best considering the difficulty in predictable and reliable outcomes.

The reliance on the use of opioids in chronic pain syndromes is partially driven by the lack of adequate effective alternative choices as identified by the IOM. The use of compounded Non-Systemic Transdermal (NST) pain creams is proving to be valuable in refractive pain syndromes. Prior MTUS regulations gave guidelines for the use of topical preparations for pain management. The IOM also defined the need for comparative effectiveness research (CER) to discern the benefit of various treatment approaches.

There has been considerable abuse of this treatment modality, mostly a result of improper quantity and strength prescribing. The cost analysis has been incorrect as well, with patient utilization declining over time as the peripheral processes contributing to chronicity are being reversed. There are a number of effective cost containment strategies that can be employed. The value is relatively unknown as the evidentiary science and outcomes are just now beginning to emerge, and due to abuses within the system the industry would like to abandon this valuable tool.

It is now known that peripheral mechanisms can influence sensitization (peripheral and central), transduction, transmission, modulation, and chronicity. Safety of this treatment modality is proving to compare very favorably to oral meds. Patient Outcomes Analytics is presenting three posters next week at the APS symposium showing the outcomes achieved and model employed. Their studies demonstrate that the NST creams can be effective for refractive patients with 75% showing a benefit, and 60% of patients showing a reduction in pain of 50% or greater. Results over time are now showing increased benefit and these results are consistent with a placebo controlled double blind RCT that is being prepared for publication.

Sandiford Helm, MD  
The Helm Center for Pain Management

April 21, 2014

I would like to thank the DWC for their effort and skill in creating the Guideline for the Use of Opioids to Treat Work-Related Injuries.

Please accept these comments.

The MED conversion method set out in Appendix F seems unnecessarily complex:

**Appendix F2. Equianalgesic Dose Table for Converting Opioid Doses<sup>22</sup>**

All conversions between opioids are estimates generally based on equianalgesic dosing <sup>22</sup> or ED. Patient variability in response to these EDs can be large, due primarily to genetic factors and incomplete cross-tolerance. <b>It is recommended that, after calculating the appropriate conversion dose, it be reduced by 25–50% to assure patient safety.</b>	
<b>Opioid</b>	<b>Approximate Equianalgesic Dose (oral &amp; transdermal) *</b>
<b>Morphine (reference)</b>	<b>30mg</b>
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)

The current Chronic Pain MTUS offers:

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### Opioid Dosing Calculator

#### Morphine Equivalent Dose (MED) factor:

Codeine - 0.15  
Fentanyl transdermal (in mcg/hr) - 2.4  
Hydrocodone - 1  
Hydromorphone - 4  
Methadone, 41 to 60mg per day - 10  
Methadone, >60mg per day - 12  
Morphine - 1  
Oxycodone - 1.5  
Oxymorphone - 3

The ratios in both documents are the same. It is easier to use the multiplier in the current MTUS than the proposed system.

2. Section 10 defines catastrophic injuries as Catastrophic injuries such as severe burns, crush or spinal cord injury in which significant recovery of physical function is not expected. I suggest adding complex regional pain syndrome and post lumbar laminectomy syndrome to this list.

3. Section 7 states,  
Prescribers should avoid introducing concomitant central nervous system (CNS) depressants to chronic opioid treatment regimens, including benzodiazepines and non-benzodiazepine sedatives, such as carisoprodol

Other sections state,  
Discontinue sedative-hypnotics including anti-histamines (H1-blockers) and/or benzodiazepines before surgery. (Fulton-Kehoe 2013) (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics)

The language in Section 7 is less restrictive and more appropriate. I agree with the Division's concern regarding the concomitant use of opioids and sedative medications. One problem which we face in treating chronic pain is that other practitioners are providing the opioids.

I suggest using the language in Section 7 throughout the Guidelines

4. The Guidelines lower the MED at which heightened concern is triggered from 120 to 80. There is ample evidence to support the 120 figure and I suggest maintaining the current 120 figure:

Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, et al. Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Intern Med.* 2010

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Gomes T, Mamdani MM, Dhalla IA, Paterson JM, Juurlink DN. Opioid dose and drug-related mortality in patients with nonmalignant pain. *Arch Intern Med.* 2011;171:686-91

Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA.* 2011;305:1315-21

5. The guidelines mandate the use of screening tools to screen for depression and for potential opioid and alcohol abuse. The use of screening for opioid and alcohol has been questioned. For example, Phillip Coffin, M.D., in a 2014 editorial in *Annals of Internal Medicine*, states

We have since moved through 3 stages of thinking about opioid medications, from the early hypothesis that treating pain with opioids resulted in addiction among less than 3% of patients (4), to the hope that opioid medication problems were due to “bad apples” who could be weeded out through screening, to a recent recognition that the problem is due to “risky drugs, not risky patients”

We have moved beyond screening to the realization that opioids are risky. The Division's proposed Guidelines reflect this awareness, in large part. The mandate for the use of screening reflects a now out-moded view.

I suggest dropping the requirement for screening for potential opioid and alcohol abuse, for lack of efficacy, and maintaining the screening for depression.

6. Mandating the use of CURES is problematic. There are times when I am unable to log on despite multiple attempts and despite the fact that I can log on later in the day. While use of CURES is important, the inability to log on should be acknowledged as a possible outcome.

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Brenda Ramirez, Claims and Medical Director  
California Workers' Compensation Institute

April 21, 2014

### **Summary of Recommendations**

The Institute urges the Division to consider adopting the ACOEM V.3 Opioid Treatment Guideline (2014) in lieu of the drafted Guideline.

If the Administrative Director does not propose to adopt the ACOEM V.3 Opioid Treatment Guideline (2014), the Institute recommends expanding the guideline review to include the ACOEM

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V.3 Opioid Treatment Guideline (2014) and revising the draft guideline accordingly. The following specific revisions are particularly recommended:

- Replace “should” with “shall” throughout.
- Replace the 80mg/day MED with 50mg/day MED.
- Specify that employees shall be precluded from performing safety sensitive tasks such as driving and operating heavy machinery while taking opioids.
- Consider prohibiting opioid dispensing from physician offices and clinics.
- Require the dispensing physician to consult CURES prior to prescribing opioids to assure that the injured worker has not been prescribed opioids (or had opioids dispensed from) multiple sources and document it in the patient's records.
- Reorder priorities used to determine recommendations so that higher-level medical evidence trumps common recommendations.
- Specify “recommended,” “not recommended” or “no recommendation” and the strength of evidence/consensus for each recommendation status.
- Consider including a closed opioid formulary.

### **Rationale**

#### **Recommendation**

The Institute urges the Division to consider adopting the ACOEM V.3 Opioid Treatment Guideline (2014) in lieu of the drafted Guideline.

#### **Discussion**

The ACOEM V.3 Opioid Treatment Guideline (2014) is the most current guideline available as it was released in February, 2014. This Guideline is peer-reviewed and nationally recognized, and is based on a rigorous review of higher-grade medical evidence and on expert consensus when higher-grade evidence was unavailable or inconsistent. The Guideline is user-friendly and suitable for use by treating physicians and reviewers. It appears to be superior in most or all respects to the other guidelines reviewed, and to the DWC's draft Guideline that is posted for Forum comment.

Adopting a single guideline offers the advantage of internal consistency, as opposed to a guideline that includes recommendations from disparate guidelines based on different standards. It also offers treating physicians and reviewers the efficiency of optional on-line interactive tools.

**Recommendation**

If the Administrative Director does not propose to adopt the ACOEM V.3 Opioid Treatment Guideline (2014), the Institute recommends the Division expand its guideline review to include the ACOEM V.3 Opioid Treatment Guideline (2014) and revise the draft guideline accordingly. The following specific revisions are particularly recommended:

**Discussion**

As noted in Part A. section A5 of the DWC's draft Guideline, "the review was restricted to guidelines available as of December 2013." The Institute encourages the Division to expand the review to include the ACOEM V.3 Opioid Treatment Guideline (2014) which was released in February 2014. It is important to ensure that an Opioid Treatment Guideline adopted by the DWC is as current and complete as possible.

**Recommendation**

Replace "should" with "shall."

**Discussion**

Regulations that say a certain action "should" occur can be ignored with impunity, leaving physicians who inappropriately prescribe opioids free to continue doing so. In the context of utilization review such regulatory language is useless because it cannot be enforced. To prevent inappropriate prescribing of opioids, and assure appropriate prescribing, the terms in opioid treatment guidelines adopted in regulation need to be prescriptive rather than permissive. The purpose of the Medical Treatment Utilization Guideline is not only to suggest good practices to practicing physicians; it determines standards that define what is reasonably required under Labor Code section 4600. In utilization review and independent medical review it is the standard used to protect an injured employee from deleterious and unnecessary medical care and to ensure the provision of appropriate medical care. "Shoulds" and "should nots" impede those responsibilities.

**Recommendation**

Replace the 80mg/day MED with 50mg/day MED.

**Discussion**

According to the available medical evidence, the death rate (hazard ratio) accelerates for morphine equivalent doses (MEDs) above 50 mg per day, as illustrated in Figure 2 in the section on Acute Pain (page 20) in the ACOEM V.3 Opioid Treatment Guideline (2014).

**Recommendation**

Specify that employees shall be precluded from performing safety sensitive tasks such as driving and operating heavy machinery while taking opioids.

**Discussion**

All large epidemiological studies found an increased risk of car accidents for working age adults taking opioids that ranged from 29% to 800%.

**Recommendation**

Consider prohibiting opioid dispensing from physician offices and clinics.

**Discussion**

In 2007, the DWC curtailed differential pricing for repackaged drugs, which are dispensed from physicians' offices, by narrowing a loophole in the pharmacy fee schedule regulations. The effect was an immediate reduction in both the volume and the amounts paid for these drugs.<sup>1</sup> Because financial incentives for dispensing drugs from doctors' offices still exist, it is no surprise that dispensing drugs from physicians' offices is associated with higher drug utilization than dispensing drugs from pharmacies. A 2013 Workers Compensation Research Institute study examined the impact of Florida's ban on physician dispensing of stronger opioids that took effect in July, 2011 and provided evidence that physician dispensing is associated with patients receiving more opioids than necessary.<sup>2</sup>

**Recommendation**

Ensure that opioids are prescribed by a single physician and dispensed from a single pharmacy by requiring the prescribing physician to consult CURES before writing each opioid prescription, except in emergency situations, and document the results of the CURES inquiry in the injured worker's medical record.

**Discussion**

All dispensers of opioids and other Schedule II, III, and IV prescription drugs, including pharmacies, clinics and physicians must provide weekly dispensing reports to the Controlled Substance Utilization Review and Evaluation System (CURES), which is California's Prescription Drug Monitoring Program (PDMP). The program allows pre-registered users including physicians and pharmacists, to access timely patient history on controlled drugs, including opioids.

Physicians can reduce the epidemic of opioid overdoses and diversions by confirming through CURES that patients are not legitimately or surreptitiously obtaining opioids and other scheduled

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<sup>1</sup> Swedlow, A., Gardner, L., Ireland, J. Differences in Outcomes for Injured Workers Receiving Physician-Dispensed Repackaged Drugs in the California Workers' Compensation System. CWCI Research Brief, February 2013.

<sup>2</sup> Thumula, V. Impact of Banning Physician Dispensing of Opioids in Florida. July 2013.

drugs from other physicians and pharmacies. Requiring physicians to check with CURES before writing the prescription, will save lives.

### **Recommendation**

Reorder priorities used to determine recommendations so that higher-level medical evidence trumps common recommendations. Base recommendations on:

1. High-level evidence from high-quality therapeutic studies
2. Moderate-level evidence from therapeutic studies
3. Recommendation common to all/most peer-reviewed and nationally recognized evidence-based guidelines if there is no high- or moderate-level evidence and if recommendation is aligned with goals and objectives identified for this DWC Guideline
4. Recommendation of a major peer-reviewed and nationally recognized evidence-based guideline if there is no high- or moderate-level evidence and if recommendation is aligned with goals and objectives identified for this DWC Guideline

### **Discussion**

Section A5 of the DWC's draft Guideline, states "*Wherever possible, recommendations that were common to all or most of the guidelines reviewed received priority and were adopted as recommendations, even if they were based on expert consensus. ....Where common recommendations were lacking, the following sequential approach was utilized:*

- a. *High-level evidence from high-quality therapeutic studies....*
- b. *If no high-level evidence was available, the recommendations of a major guideline were adopted, even when other guidelines did not replicate these recommendations, as long as they aligned with the goals and objectives identified for this DWC Guideline...*"

Trumping higher-level medical evidence with recommendations from other guidelines is not consistent with Labor Code 5307.27. In Labor Code section 5307.27 the Legislature specifically requires the Administrative Director to create a treatment schedule that incorporates "evidence-based, nationally recognized, peer reviewed standards of medical care." Treatment guidelines cannot be upgraded if additional and/or newer, high-level medical evidence is trumped by existing recommendations from other guidelines.

### **Recommendation**

Specify "recommended," "not recommended" or "no recommendation" and the level of each, based on the strength of evidence/consensus.

**Discussion**

It is necessary to indicate the recommendation status and the strength of evidence/consensus for each status so that the strength of alternative evidence can be properly compared.

**Recommendation**

Consider including a closed opioid formulary.

**Discussion**

When provision of an opioid is determined appropriate in accordance with the Opioid Guideline adopted by the DWC, a closed opioid formulary would be helpful to further determine which specific opioid(s) is/are the most appropriate.

**Recommendation**

Consider requiring the use of one or more specific screening tools.

**Discussion**

Requiring the use of one or more specific screening tools will ensure a thorough screening and evaluation before prescribing opioids.

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Lisa Anne Forsythe, Senior Compliance Consultant  
Coventry Workers' Compensation Services

April 21, 2014

After a review of the proposed opioid guidelines, Coventry Workers' Compensation Services and its pharmacy benefits management program, First Script, would like to offer our support for the proposed DWC Guidelines for the Use of Opioids to Treat Work-Related Injuries (Guidelines).

First and foremost, Coventry/First Script applauds the efforts of the Division and its staff to undertake addressing such a critical issue in compensation care today. The Guidelines represent a significantly positive step in addressing the opioid epidemic, showing both clinical insight and logical application of that clinical knowledge.

In particular, we would like to offer our support for the following specific provisions from among the proposed guidelines:

1. The recommendation for very limited general use of opioids,

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2. Requiring the use of the CURES prescription drug monitoring database, and
3. The targeted use of urine drug screening

All 3 of these provisions are important steps towards ensuring the use of opioids only in clinically appropriate situations.

While Coventry/First Script is aware that the Division may not have had access to the recently published ACOEM guidelines recommending (amongst other things) a benchmark of 50mg MED, revisiting the Division's recommendation of 80mg MED in the future may be warranted, considering that the ACOEM guidelines are now available.

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James Butler, Esq., President  
California Applicants' Attorneys Association

April 21, 2014

Initially, these proposed guidelines are detailed, thoughtful, and very useful for setting forth appropriate parameters for the use of opioids to manage pain for work related injuries. The DWC should be commended for their hard work and effort in drafting these guidelines. CAAA supports the main goal of these guidelines to provide a set of best practices for safe and effective prescribing of opioids to decrease pain, and to promote improved functional restoration to ensure early return to work.

Generally, there is good language in the guidelines but as advocates for injured workers our main concern is with endorsing a humane and medically safe tapering process from long term use of opioids where warranted, and whether these recommendations adequately insure that will happen.

The proposed guidelines require the treating physician to monitor for and document indications for discontinuing opioids, including:

- Resolution of pain or improvement to the point of not requiring opioids within the expected timeframe for the injury being treated.
- Lack of improved function despite adherence to the treatment regimen.

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- Intolerance or severe adverse effects: it is likely that at least some side effects will occur with opioid use. The nature and severity of side effects will determine whether to discontinue the medication.
- Non-compliance, surreptitious medication use, aberrant drug screening results, diversion, consumption of medications or substances when advised to not take simultaneously.

If the patient meets any one of the above four criteria, then the guidelines state that tapering from the medication should be considered.

The guidelines further provide that patients who have been treated for more than two weeks with opioids should have these medications discontinued via tapering rather than by abrupt cessation.

CAA's concern is what happens if the physician doesn't follow the rules requiring monitoring and documentation to justify continued use, but the guideline for cutting off the medication has not been met either. There is no timeframe in the proposed guidelines for the treating physician to document the need for continuous use of the prescribed medication. Therefore, it is suggested that language be added to the final guidelines allowing for a grace period of up to one year to allow the treating physician to provide documentation to justify continuous use of the prescribed opioid, before the medication can be discontinued. If the criteria for continued use is not met within that time period, the injured worker should then be tapered off the medications. The final guidelines should also clearly state that an injured worker can never be cut off their medications without a tapering protocol if the physician does not establish the need for continuous use.

Additionally, decisions regarding a tapering schedule may need to be made on an individual basis. Sometimes slower tapering may be warranted. Some experts suggest that the longer the person has been on opioids, the slower the taper should be. (VA Guidelines 2010)

Lastly, if all attempts to taper are unsuccessful as the patient is unable to tolerate further dose reduction despite the use of appropriate supportive interventions, then in some circumstances opioids may need to be maintained. The final guidelines should address what happens if pain can not be adequately managed with non-opiate medications after a patient has been tapered off opioid medications.

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Steven Suchil, Assistant Vice President/Counsel  
American Insurance Association

April 21, 2014

### I. Introduction

## Division of Workers' Compensation - Opioid Forum Comments

We are supportive of the DWC proposed Guideline, and wish to provide the following comments.

Overall, the best parts of the Guideline are:

- Discouraging the use of opioids in minor injuries.
- Encouraging the use of other therapies before considering opioids.
- Encouraging lowest effective dose, and time limits on opioid use.
- Encouraging the prescription of opioids for use at night and when the patient is not working.
- Listing relative contraindications for the use of opioids.
- Suggesting that current substance abuse, or illicit substance use, would be contraindication to opioid treatment.
- Encouraging education and informed consent.
- Encouraging education about safe storage and disposal of opioids.
- Recommending that central nervous system (CNS) depressants, including antihistamines, benzodiazepines and alcohol, should not be used concurrently with opioids.
- Requiring the use of CURES, treatment agreements and urine drug testing.
- Limiting urine drug testing to baseline plus two to four times yearly.
- Limiting UDT to prescribed and additional opiates, alcohol, amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, fentanyl, methadone and oxycodone.
- Emphasizing the importance of documented functional improvement as a prerequisite to continued opioid use.
- Providing criteria for discontinuation, such as lack of pain reduction, lack of functional improvement, intolerance or severe side effects, or non-compliance.
- Recommending morphine equivalent dose (MED) documentation at every patient visit.
- Recommending opioid weaning semi-annually for injured workers on greater than 80 mg MED.

## II. Comments

Several areas of the proposed Guideline should be improved or clarified:

A. Rest:

Although addressing opioids only - the MTUS addresses chronic pain separately - the Guideline includes rest as a treatment for pain. We note that, however, that rest is considered to be a physical activity elsewhere in the Guideline. Rest should be clearly defined, for example it may be appropriate to rest or immobilize a joint, depending on the clinical situation. The term may be taken to mean bed-rest or inactivity, and such a cure may be worse than the disease.

B. Complementary and Alternative Modalities:

The Guideline recommends complementary and alternative modalities "...such as acupuncture." It is not clear what other treatments may fall into this category. The Guideline does not elaborate, and does not address the requirement for effective, evidence based treatments – this is a concern because it may open a door that providers may exploit. The Guideline should cross-reference the MTUS Chronic Pain Guideline to regarding other modalities.

C. Opioid Discontinuance:

In some places the Guideline is clear and absolute as to when to discontinue opioids, but flexible in other places. For example, the Executive Summary states that, "In order for opioids to be prescribed beyond the acute phase, there should be no contraindicated comorbidities..." In the Abbreviated Treatment Protocol, and elsewhere, the Guideline recommends that the prescriber "consider and document relative contraindications...If these conditions are present, written documentation must be provided to justify the use of opioids."

D. Aberrant Use:

Aberrant use of medications or substances, as evidenced in an inconsistent urine drug test, for example, is indicated as an absolute disqualifier for further opioid prescribing in one section. The Explanation section, however, moves away from this provision.

E. CNS Depressants:

The use of CNS depressants, such as sedatives, hypnotics, H<sub>1</sub> antihistamines, benzodiazepines and alcohol seem to be an absolute contraindication in the Recommendations. Section 7 - Concurrent Use of Benzodiazepines and Other Sedative Hypnotics During Chronic Opioid Treatment - only recommends counseling the patient against using these substances concurrently. Section 7 states:

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If, after careful consideration, the clinical decision is made to prescribe other sedatives or muscle relaxants to patients on chronic opioid treatment, counseling should be provided to stagger dosing to avoid excess sedation and potentially disastrous complications.

Avoiding disastrous complications, including fatal overdose events should be a physician's first priority. This statement seems to contradict one of the three purported goals of the Guideline, which is to prevent and reduce opioid-related long-term disability, morbidity, mortality and substance abuse and misuse.

### F. Urine Alcohol Testing:

Urine alcohol testing, as recommended as part of urine drug testing by the Guideline is not accurate and may not be clinically useful.

### G. ACOEM Opioid Guidelines:

The DWC's proposed Guideline is a review of eight existing guidelines, and is not a de novo review of primary sources. The proposed Guideline was completed before the publication of the new ACOEM Opioid Guidelines (March 2014). The ACOEM Opioid Guidelines is a thorough and evidence-based practice guideline document. We respectfully refer DWC to that document when reviewing and preparing changes to its Guideline.

## III. Comments By Phase

Set forth below are comments on several of the Guideline's key recommendations, by phase.

### A. Acute Phase

#### 1. Relative Contraindications:

The Guideline states that relative contraindications are listed as psychiatric disorders, untreated sleep disorders, drug seeking behaviors, psychotropic medications, PTSD, cognitive impairment, COPD, severe obesity, balance problems or fall risk, osteoporosis and renal failure.

If opioids are used in injured workers with any of these conditions, written justification for their use must be provided in the documentation.

#### 2. CNS Depressants:

The Guideline provides that CNS depressants, including antihistamines, benzodiazepines and alcohol should not be used concurrently with opioids, and should be discontinued prior to prescribing opioids.

Benzodiazepines are very difficult to discontinue and require long weaning periods. The Guideline also includes carisoprodol (Soma) as a CNS depressant. It recommends extreme caution when using central muscle relaxants such as baclofen (Lioresal) or tizanidine (Zanaflex).

### 3. Pain and Function:

The Guideline states that pain and function should be documented at every visit.

This is major step forward from the question, "How's your pain today?" Prescribers should ask an injured worker what they are doing that they could not do at the last visit, or use a function scale, where on a scale of 0 to 10, if 0 means the patient cannot get out of bed, and 10 means the patient is doing everything he or she was doing before the injury, where is the patient at today?

### B. Subacute Phase

#### 1. Non-Opioid Treatments:

The Guideline provides for non-opioid treatments: non-steroidal anti-inflammatory drugs and acetaminophen, cognitive behavioral therapy, activity coaching, graded exercise and treatments such as acupuncture.

As stated above, it is not clear what other "treatments such as acupuncture" may fall into this category. This should be clarified to provide effective, evidence-based treatments.

#### 2. Urine Drug Testing:

The Guideline provides for urine drug testing Baseline within 4 to 6 weeks of opioid treatment onset.

Perhaps there should be an explanation of why such baseline testing should not happen before opioid prescription.

The Guideline further provides that aberrant testing results are a contraindication to continued opioid use.

This is a useful provision - it will allow UR to stop opioid prescribing in the many cases where aberrant results are ignored and opioid prescribing continues.

The Explanation section, however, appears to retreat from the above statement:

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If the initial UDT detects opioids or illicit substances, the results should be documented and considered a relative reason to discontinue opioids. If UDT indicates illicit substance, but after weighing the potential adverse impacts and alternatives opioid treatment still appears the best option, the provider should provide appropriate written documentation explaining why detection of the unexpected substances does not prevent treatment with opioids, particularly chronic opioid therapy. If two-step UDT in a certified laboratory confirms that the patient is not taking the prescribed medications, suggesting possible medication diversion, the clinician should discuss the findings with the patient and discontinue treatment with opioids.

We recommend that the Guideline be clarified as to aberrant results.

### 3. MED Documentation:

The Guideline recommends MED documentation at every patient visit.

This provision is beneficial. It will serve as an educational tool for many prescribers who may not be aware of the concept or who do not use it to gauge patient opioid use.

### C. Chronic Phase

#### 1. Non-Opioid Treatments:

Psychological/behavioral therapy is included along non-opioid treatments.

The Guideline does not mention what type of therapy - acceptance and commitment therapy, cognitive behavioral therapy, or other therapies – would be include, except to recommend referring to the MTUS section on Chronic Pain.

#### 2. Patient Agreement:

The Guideline recommends a patient treatment agreement.

Such an agreement should be required whenever more than two weeks of opioids are used, and this also would be applicable to the subacute and acute periods.

#### 3. Opioid Trial:

The Guideline provides for an opioid trial to assess efficacy and side effects - 90 days or less).

We note that it is rare to start opioids in the chronic phase, and that a trial would be appropriate in those rare cases. Most of the time, the injured workers will have been on opioids from early on.

#### 4. Urine Drug Testing:

The Guideline provides for urine drug testing randomly at least twice per year for all patients, but four times yearly for patients on greater than 80 MED.

The Guideline recommends urine alcohol testing, which is not a standard way of measuring alcohol in the body and is not useful clinically in the context of chronic opioid prescribing.

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John Nelson, Director of Sales, Guidelines  
Disability Guidelines

April 21, 2014

This is to provide feedback on the proposed opioids guideline draft. It is Reed Group's belief that the newly published Opioid Chapter in DisabilityGuidelines™ (formerly MDGuidelines), researched and developed by ACOEM, is the superior content as a thorough and true evidence-based practice guideline. We recommend the CA DWC adopt the ACOEM content as the State standard for opioid prescriptions:

- The majority of the current MTUS is ACOEM published content.
- 1000's of providers, insurers, and UR professionals already subscribe to the ACOE M guidelines and we have integrated MTUS content.
- The new ACOEM Opioid Chapter is made available to all current subscribers of ACOEM and Disability Guidelines with ACOEM free of charge.

The ACOEM Opioid Chapter has been recognized by the vast majority of the Workers' Compensation market as the best recommendation available today:

- Healthsystems Chief Medical Officer, Dr. Robert Goldberg – “The release of the new ACOEM opioids treatment guideline can be the catalyst for workers' compensation payers to implement new strategies and reverse the problematic trend of inappropriate and excessive use of opioids.” –See more at: [http://www.workcompwire.com/2014/03/dr-robert-goldberg-new-evidence-new-opioid-strategies-better-outcomes/?utm\\_source=WCR+Daily+3%2F19%2F14+-+Guideline+Gains%21&utm\\_campaign=WCR&utm\\_medium=email](http://www.workcompwire.com/2014/03/dr-robert-goldberg-new-evidence-new-opioid-strategies-better-outcomes/?utm_source=WCR+Daily+3%2F19%2F14+-+Guideline+Gains%21&utm_campaign=WCR&utm_medium=email)
- Managed Care Matters Principal, Joe Paduda – “Perhaps the best new tool in our armamentarium comes from ACOEM – their opioid guidelines” - See more at: <http://www.joepaduda.com/2014/04/drugs-work-comp-top-issues-are/#sthash.8blcjuds.dpuf>

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The new ACOEM opioids chapter is included in Reed Group's Disability Guidelines™ (formerly MD Guidelines and ACOEM Practice Guidelines) and is titled "ACOEM Opioid Guidelines." Among the chapter's findings and recommendations:

- 80-94% of opioid trials have industry conflicts (funding and/or conflicts of interest in the trials).
- People in safety sensitive jobs should not take opioids. A systemic review found all 12 studies of motor vehicle crashes supported an elevated risk of crashes among drivers taking opioids. Other guidelines currently on the market don't include this warning, and/or do not back it up with scientific review.
- Suggests a 50mg morphine equivalent dose is the appropriate limit. Prior guidance used elsewhere and based mostly on expert opinion has been 100-120mg, possibly allowing fatalities to occur.
- No comparative trial shows that an opioid is superior to another medication (out of 28 trials.)
- Most patients in opioid trials do not tolerate opioids and drop out in various phases of the trials.
- No evidence shows the long-term efficacy of opioids - the longest placebo controlled trial lasted only 4 months

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Mark Sektnan  
Association of California Insurance Companies  
Property Casualty Insurers Association of America

April 21, 2014

We appreciate the Division's efforts towards developing guidelines on the appropriate use of opioids. As you know, this is one of the major public health problems facing both the workers' compensation system and society at large. Numerous studies have shown the widespread use of these types of drugs when there is no medical guideline to support their use. Other studies have shown how overuse of these types of drugs often delays a workers' ability to return to work and in many cases leads to addiction. We believe these guidelines are an important first step in addressing this issue.

We also note that the various groups including the International Association of Industrial Accident Boards and Commissions, the American College of Occupational and Environmental Medicine (ACOEM), National Association of Insurance Commissioners (NAIC), National Alliance for Model State Drug Laws (NAMSDL), and National Council of Insurance Legislators (NCOIL) are also working on developing guidelines. ACOEM, in particular, has recently adopted model

guidelines and we would support the adoption of these guidelines which enjoy the benefit of being updated regularly. Use of these recently adopted guidelines would also ensure no conflict between competing guidelines which can impose implementation problems for insurers.

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Jose Ruiz, Director  
Corporate Claims – Regulatory Division  
State Compensation Insurance Fund

April 21, 2014

In general, the proposed OMTG is a sound guideline for using opioids in pain treatment. We appreciate the work and effort in developing these guidelines. The following recommendations are respectfully submitted with the intent of improving outcomes for all injured workers.

### **Part A: Executive Summary and Introduction**

#### **Accessing Controlled Substance Utilization Review and Evaluation System (CURES)**

COMMENT: OMTG recommends the use of CURES if opioids are prescribed. It is our understanding that CURES is not in “real time” but possibly has a delay of about two to four weeks.

RECOMMENDATION: Indicate use of caution when utilizing CURES due to its possible delay of about two to four weeks.

#### **Opioids for Subacute Pain**

COMMENT: Performing urine drug test (UDT) for chronic opioid use and eliminate this in the subacute stage. We are not clear if there is an added benefit to drug test in the subacute stage.

RECOMMENDATION: Eliminate UDT in the subacute stage, but use UDT in the chronic stage until further research is done on this.

#### **Screening for Risk of Addiction, Adverse Events Using Validated Tools**

COMMENT: Screening patients for risk of addiction and/or adverse events should be conducted when initiating opioid treatment at the acute stage, not just at the chronic stage. Using validated tools, the proactive approach of screening at the early stage would be more effective in preventing risks of substance addiction and adverse events.

RECOMMENDATION: Conduct screening tests for substance addiction and/or adverse events at the acute stage of opioid use.

**Generic vs. Brand**

COMMENT: There is no discussion about the use of generic or brand for opioids. It would be useful information to indicate if there is any difference in effectiveness between brand and generic opioids.

RECOMMENDATION: Discuss the comparison between brand and generic opioids with respect to effectiveness and cost

**Part B: Recommendations**

**1. Opioids for Acute Pain**

**In general, opioids are not indicated for mild injuries**

COMMENT: There are examples of mild injuries such as: acute strains, sprains, tendonitis, myofascial pain, repetitive strain injuries

RECOMMENDATION: The list of examples of mild injuries should be more comprehensive since many readers will assume mild injuries are limited to acute strains, sprains, tendonitis, myofascial pain, repetitive strain injuries and that opioids are indicated in all other cases.

**Short- or Long-Acting Opioids**

COMMENT: There is no discussion about whether short or long-acting opioids are more effective in treating pain in the acute phase.

RECOMMENDATION: Include information about the effectiveness of short- and long-acting opioids in treating pain in the acute phase.

**3. Opioids for Chronic Pain**

**Patient Treatment Agreement**

COMMENT: The guideline is recommending the use of the patient treatment agreement in the chronic stage for opioid use. Such information would be more useful to the patient if given when initiating opioids.

RECOMMENDATION: Recommend the use of patient treatment agreement when initially dispensing opioids to set expectations early

William G. Brose, MD, CEO  
HELP Pain Management

April 20, 2014

See proposed edits in red:

## **A1. Executive Summary and Abbreviated Treatment Protocols**

### ***A1.1 Executive Summary of Proposed “Division of Workers’ Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries” for Inclusion in the Medical Treatment Utilization Schedule***

Opioid misuse remains a national concern due to adverse health impacts and other unintended consequences. Yet, opioids may be useful as an adjunct in the treatment of pain. The Division of Workers’ Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries (Guideline) provides a balance between appropriate treatment of pain among injured workers and safety in the use of opioids for that purpose.

A key difference between occupational and non-occupational guidelines is that a main goal of the former is the restoration of function to ensure early return to work. However, as such guidelines also serve as the primary authority for the future medical treatment of those injured with chronic pain who will not return to work both occupational and non-occupational considerations must be included. This Guideline is based on the best available medical evidence and has three main goals: to

(1) provide a set of best practices and universal precautions for safe and effective prescribing of opioids for acute (lasting up to four weeks), subacute (lasting four to 12 weeks), and chronic (lasting three or more months) pain due to a work-related injury; (2) prevent and reduce opioid-related long-term disability, morbidity, mortality, and substance misuse and abuse; and (3) recommend opioid prescribing practices that promote functional restoration. The intended audience is primary care and specialty

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clinicians, providers of utilization review and independent medical review, and insurers. This Guideline does not address pediatric pain, labor pain, pain immediately following catastrophic injuries, or cancer/end of life pain.

The Guideline is divided into four parts: Part A consists of a summary, abbreviated treatment protocols, and an introduction; Part B contains complete recommendations for patient management and appendices with helpful tools for clinicians; Part C presents findings to support the recommendations; and Part D compiles recommendations from a review of existing opioid use guidelines.

The following are key recommended practices:

- Opioid medications are not the first line of treatment for pain and should not in general be used for mild injuries. Other therapies, such as non-opioid medication, appropriate physical activity, and complimentary/alternative modalities should be used first.
- Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice *and* after determining that other non-opioid pain medications or other therapies will not provide adequate pain relief or are contraindicated for medical reasons. They should only be prescribed at the lowest dose that provides pain relief, for a limited time, and with no refill, prior to re-assessment.
  - Opioids for acute pain treatment should be tapered to zero within two weeks whenever possible.
- If opioids are prescribed, the Controlled Substance Utilization Review and Evaluation System (CURES), California's Prescription Drug Monitoring Program should be accessed. If CURES indicates the simultaneous use of other narcotic medication, opioid use may be contraindicated. What does one do if the CURES system is not available or if information in the system is found incorrect. Does the provider have an obligation to review a verified CURES report to make an initial prescription. Can the guideline specify that there is an obligation to look and if a decision to prescribe is made that discrepancies found on the CURES report need to be addressed in a fashion satisfactory to the physician to support their continued prescribing.
- Central nervous system depressants, including anti-histamines, benzodiazepines, and alcohol, should not be used simultaneously with opioids and should be discontinued before prescribing opioid medication. This statement implies

prescriber control over that other prescription. It is unrealistic to have industrial injury treatment always take precedential position over non-industrial treatment. Either recommend discontinuing or communicate to other prescribers about the risk. I can see a UR physician choosing to interpret this section as permission to deny prescriptions of opioids to a patient who has an industrial injury warranting such prescription but also consuming a benzodiazepine for treatment of established PTSD due to battlefield trauma covered non-indutrially by the VA.

- Patients should be cautioned about the potential adverse effects of opioids, including impacts on alertness. Driving and operation of heavy equipment should be discouraged while on these medications.

- At the time of initial prescription, and at every visit, patients should be advised regarding responsible storage and disposal of opioid medications.
- In order for opioids to be prescribed beyond the acute phase, there should be no contraindicated comorbidities, non-opioid treatments should be continued, urine drug testing should be performed and reveal no aberrant results, and patients should be carefully monitored, both for improvement in pain and function, as well as indications for discontinuing opioids. The clinical monitoring of analgesic adherence integrates the review of PDMP data, UDS results, analgesic use patterns, analgesic response including desired and adverse effects as well as additional evidence of aberrant behaviors. The careful analysis of the impact of clinical information including comorbidities, inconsistent information including UDS or PDMP reporting should be used as a basis for review and revision of prescribing decision including cessation of opioid prescribing.
- Short-acting opioids may be indicated for a limited duration to manage moderate to severe post-operative pain and to obtain sleep, especially in the immediate post-operative period.
- Patients with chronic pain may be candidates for treatment with opioids if pain management and functional improvement have not been achieved with other treatment modalities and the following conditions are met:
  - A comprehensive evaluation is performed.
  - Alternative treatments are considered.
  - Screening identifies patients with high risk of addiction or serious adverse events, substance misuse, and psychosocial factors that may contribute to misuse. Such patients are not good candidates for chronic opioid treatment.

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- Patients are informed about risks, benefits, and alternatives for opioids and a treatment agreement/informed consent is completed.
- Patients undergo urine drug testing prior to initiating an opioid trial.
- A trial is conducted prior to committing to chronic opioid treatment.
- CURES is queried and the results documented; aberrant results are a contraindication to chronic opioid treatment.

- Patients on chronic opioid treatment should be carefully managed, after the following have been documented:
  - Results of questionnaire tools assessing for aberrant behavior, which may indicate the need for discontinuing opioids. The way this is stated suggests that the fixed length fixed format testing alone is sufficient evidence to support cessation of treatment. These tests are intended to be intergrated in to a providers assessment of a patient and should not be used alone to exclude a patient from such treatment in the absence of clinical evaluation and judgement. I see UR interpretation of this including a single abnormality identified on a fixed length fixed format questionnaire as being sufficient grounds to disqualify a patient who have demonstrated functional benefit from opioids from authorization of those medically necessary prescriptions.
  - Results of periodic urine drug testing (at point of care initially and verified by a federally certified laboratory) performed on a random basis during chronic treatment, and if the provider is concerned about misuse, abuse, or diversion. If random testing is to be promoted there needs to be an instruction about how this random testing is defined and can be implemented. Most current testing occurs in a providers' office and is done on either a scheduled or unscheduled basis that may be single blinded to the patient or to both the patient and the provider. But certainly would not be considered random when considering the time of drug consumption. Random suggests that at any time during the period of drug consumption a test could be requested. The practical implementation of this would then be that an injured worker using opioids would need to present to a testing facility within a specified period of time to have the "random" sample obtained. This would create an unknown amount of burden on the facility and the patient in an unpredicable fashion and would reuire new policy and procedure in virtually all medical offices which prescribe

opioids. If the intention here is to have a randomization applied to the scheduled patient appointments so that during any appointment such testing may be performed then this definition of random needs to be contained in the document.

- Clinically meaningful reduction in pain and functional improvement (as defined by the patient and the prescribing physician).
- When titrating the dose of opioids used for treatment of chronic pain to achieve maximal improvement in pain and function, decisions to increase opioids should be made jointly by both the provider and the patient. It is the responsibility of the provider to inform the patient that current evidence shows a dose-related increase in adverse events.
- Although all doses of opioids carry risks, providers should be increasingly vigilant for doses above 80 mg/day morphine equivalent dose (MED), as the known risk of adverse events rises while the evidence for increased benefit remains weak.
- Clinicians should conduct semiannual attempts to wean workers whose dose is above 80 mg/day MED, and who have been on that dose or higher for at least six months, to lower than 80 mg/day MED.
- Clinicians are encouraged to ~~may~~ consult with or refer to a pain specialist based on clinical need:
  - To assess the risk-benefit ratio of using opioids to treat pain in complex patients or those at high risk of adverse effects
  - At the time of a trial of chronic opioid treatment
  - To assist with management of a patient with significant co-morbidities

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- When significant tolerance to opioids is suspected
  - To assist with the management of aberrant behavior or patients who have opioid use disorder
  - To assist with tapering or weaning regimens
  - To assist with the monitoring of analgesic adherence
  - To assist with management of complex issues not listed above.
- Methadone may be indicated for specific types of patients and should be initiated, titrated, and monitored cautiously by providers who have substantial experience with its use and risks.

To the members of MEEAC. Thank you for your work here to offer more detailed guidelines. IF the result is to be achieved a much more clear and less ambiguous language supporting providers who are trying to implement these guides is necessary. The guide are useful but the implementation is an enormous issue. Any ambiguity in language will be interpreted by UR providers in a nihilistic way and further limit evaluation and therapy to injured workers. In addition the cost of implementation to each and every practice treating according to these guidelines is enormous. You have an opportunity to assist those of us trying to assist injured workers in curing and relieving the effects of their injuries by adding language which support provider payment. Please consider adding language like the State of Colorado guidelines that provide for compensation to physicians who are performing this extra work of risk assessment measurement, monitoring, analysis and reporting on this more complex and complicated management of patients.

The language from the Colorado guideline reads, "(b) \_\_\_\_\_ Codes and maximum fees for the authorized treating physician for a written report with all the following review services completed and documented:

(1) \_\_\_\_\_ Ordering and reviewing drug tests

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(2) Ordering and reviewing PDMP results

(3) Reviewing the medical records

(4) Reviewing the injured workers' current functional status

(5) Determining what actions, if any, need to be taken

(6) Appropriate chronic pain diagnostic code (ICD)

Bill using code DoWC Z0765 \$75.00 per 15 minutes

- – maximum of 30 minutes per report

***A1.2 Abbreviated Treatment Protocols***

- **Opioids for Acute Pain (pain lasting up to 4 weeks from onset)**
- **Opioids for Subacute Pain (1–3 Months)**
- **Opioids for Chronic Pain and Chronic Opioid Treatment (3 Months or More)**

**Opioids for Acute Pain (Up to 4 Weeks From Onset)**

**In general, opioids are not indicated for mild injuries, such as**

- Acute strains, sprains, tendonitis, myofascial pain, repetitive strain injuries

**Opioids may be indicated for moderate to severe injuries and post-operative pain.**

**First use non-opioid treatments**

- Pain medications (e.g., acetaminophen, NSAIDS) unless contraindicated, physical activity including rest, range of motion, exercise, physical therapy, and treatments such as acupuncture

**Consider and document relative contraindications**

- Depression, anxiety, personality disorder, untreated sleep disorders, past substance abuse, drug seeking behavior, other psychotropic medications, PTSD, and cognitive impairment
- COPD, severe obesity, balance problems/fall risk, osteoporosis, and renal failure

**If considering opioids:**

- Document nature and extent of injury
- Consult CURES (Controlled Substances Utilization Review and Evaluation System)

**Prescribe limited supply of opioids without refills**

- Start with weaker opioids at the lowest dose producing analgesia and improving function
- Best prescribed at night or when patient is not at work
- Advise not to take sedative-hypnotic medications (e.g., benzodiazepines) or drink alcohol
- Advise about the potential adverse effects of opioid medications

**Track and document levels of pain and function at every visit**

**Monitor for indications for discontinuing opioids (any one of the following)**

- No pain reduction or functional improvement
- Intolerance or severe adverse effects
- Non-compliance

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### **Complete opioid treatment course within 2 weeks whenever possible**

- Use tapering rather abrupt cessation if patient has received opioid treatment for more than two weeks

**For detailed recommendations, see Part B of the**

**Division of Workers' Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries**

### **Opioids for Subacute Pain (1–3 Months)**

With rare exceptions, resolution of pain and resumption of regular function is anticipated 4 weeks after the initial injury, regardless of whether opioids have been used throughout this time period.

#### **Prior to continuing opioid use beyond 4 weeks, providers should:**

##### **Consider and document relative contraindications**

- Depression, anxiety, personality disorder, untreated sleep disorders, past substance abuse, drug seeking behavior, other psychotropic medications, PTSD, and cognitive impairment
- COPD, severe obesity, balance problems/fall risk, osteoporosis, and renal failure

##### **Use non-opioid treatments**

- Pain medications (e.g., acetaminophen, NSAIDs) unless contraindicated, cognitive-behavioral therapy, activity coaching, graded exercise, and treatments such as acupuncture

#### **If considering opioids beyond 4 weeks:**

- Consult CURES (Controlled Substances Utilization Review and Evaluation System)
- Perform urine drug testing (UDT)
- Prescribe lowest dose producing analgesia and improving function

##### **Advise patients on opioids**

- Not to take sedative-hypnotic medications (e.g., benzodiazepines) or drink alcohol
- About the potential adverse effects of opioid medications
- Regarding responsible storage and disposal of opioid medications
- Not to operate a motor vehicle

##### **Track and document levels of pain and function at every visit**

##### **Monitor for indications for discontinuing opioids (any one of the following)**

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- No pain reduction or functional improvement
- Intolerance or severe adverse effects
- Non-compliance revealed by UDT or otherwise evident

**When discontinuing opioids, use tapering rather abrupt cessation**

**For detailed recommendations, see Part B of the  
Division of Workers' Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries**

## **Opioids for Chronic Pain and Chronic Opioid Treatment (3 Months or More)**

Patients with chronic pain (lasting more than 3 months) may be candidates for treatment with opioids if pain management and functional improvement have not been achieved with other treatments.

### **Prior to initiating chronic opioid treatment, document the following in the medical record:**

#### **Perform a comprehensive evaluation and assessment, including UDT**

#### **Prescribe alternative treatments**

- Non-opioid pain medications unless contraindicated, cognitive-behavioral therapy, activity coaching, graded exercise, and treatments such as acupuncture

#### **Screen for risk of addiction, adverse events using validated tools**

- Drug misuse/abuse (e.g., SOAPP-R, ORT)
- Alcohol misuse/abuse (e.g., CAGE-AID, TICS)
- Additional psychosocial factors contributing to substance misuse/abuse (e.g., PHQ-9)

#### **Perform urine drug testing (UDT)**

Complete patient treatment agreement/informed consent

Initiate a trial period of opioid treatment to assess efficacy and side effects (typically 90 days or less)

Check the Controlled Substance Utilization Review and Evaluation System (CURES)

### **Once chronic opioid treatment is underway:**

#### **Titrate to an effective stable dose**

- Use weaker opioids and the lowest effective dose
- Increase vigilance and frequency of monitoring for adverse effects if dose is above 80 mg/day MED

#### **Perform UDT**

- Randomly at least 2 times a year for all patients (on what basis? This is very costly in low risk patients what evidence at we drawing on to set this standard?)
- 4 times a year for patients on doses greater than 80 mg/day MED for more than 6 months. This establishes a ceiling which should not be created: for example when a high risk patient is already taking doses >80MED and efforts at outpatient tapering have not been successful due to patient securing alternative higher risk

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drugs (heroin) and there exists a conflict between UR and PTP requesting structured inpatient Detox resulting in a IMR application which requires 6 months or more to decide. This language will result in a peer reviewer denying the weekly UDT necessary to maintain control of the patient by threat of accountability and simultaneously result in the intrusion of UR into denial of necessary medication which can be tapered successfully but has not been authorize by the carrier.

### **Track and document levels of pain and function at every visit**

#### **Monitor patients on chronic opioid treatment**

- With use of questionnaires and other validated screening tools (e.g., COMM, POMI)
- By using valid methods to track pain and function, and determining clinically meaningful improvement
- With regular face-to-face visits during the maintenance period

#### **Indications to discontinue opioid treatment or reduce dose**

- Patient desire to discontinue
- Resolution of pain
- Severe adverse effects or overdose events
- Lack of documented improvement in pain and function
- Non-adherence to treatment plan
- Consumption of medication or substances advised not to take
- Dose above 80 mg/day MED (semiannual attempts to reduce dose)

**For detailed recommendations, see Part B of the**

**Division of Workers' Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries**

## **A2. Background**

The rapid rise in the use of prescription opioids has been associated with a parallel increase in the number of cases of opioid misuse/abuse and opioid-associated deaths. Coinciding with the rise in opioid use has been an increased awareness of chronic pain as a societal problem. The Division of Workers' Compensation (DWC) Guideline for the Use of Opioids to Treat Work-Related Injuries is an evidence-based guide for using opioids to treat adults with work-related acute, subacute, perioperative, and chronic noncancer pain. A key goal of the DWC Guideline is to provide a balance between appropriate treatment of pain and safety in the use of opioids for those purposes.

Opioid analgesics are widely used to treat severe acute and perioperative pain as well as pain due to cancer and at end of life. However, the use of chronic opioid therapy for noncancer chronic pain remains controversial. (Cheadle 1994; IOM 2011; Noble 2010) While a small number of workers experience "delayed recovery" (persistent debilitation/disability, drug dependence, depression, deconditioning), they account for the majority of total disability burden and costs. Some injured workers may require opioids for the management of their acute or chronic pain. It is not the intention of the DWC Guideline to restrict proper medical use of opioids. However safe and responsible prescribing is necessary to avoid unintended consequences, including prolonged disability and iatrogenic morbidity and mortality.

### ***A2.1 Burden of Pain***

Pain that persists for weeks to years is a public health problem that affects more than 100 million adults in the US and reduces their quality of life. (IOM 2011) The resulting costs to society are at least \$560–\$635 billion per year in direct medical expenses and lost work productivity.

## ***A2.2 Workers' Compensation Context***

Reducing preventable disability is of the highest priority for society in general, as well as medical practitioners, employers, and workers' compensation professionals. While the vast majority of injured workers heal quickly and return to work, a relatively non-catastrophic injury may lead to the loss of a productive life. (Cheadle 1994; Frank 1998; IOM 2011) While a small number of workers develop "delayed recovery" (persistent debilitation/disability, drug dependence, depression, deconditioning), they account for the majority of total disability burden and costs.

Failure to return to work early following an injury is a predictor for long-term and entrenched disability. (Cheadle 1994) Using best practices to heal injury and illness, improve function, and encourage return to work immediately following injury is the most effective way to prevent and reduce prolonged disability. (Wickizer 2011; Bernacki 2003) Preventing the transition from acute and subacute pain to chronic pain in a workers' compensation context should be considered parallel to the goal of preventing long-term disability.

For purposes of the DWC Guideline, acute pain is of sudden onset and is expected to last up to four (4) weeks; in the occupational context, acute pain is linked clearly to a specific event, injury, or illness. Subacute pain is pain that lasts between four (4) and 12 weeks (or one and three months). Chronic pain is defined as pain that lasts more than three (3) months. (IOM 2011) Thus, the actions taken immediately following injury and in the ensuing two to three months are crucial in limiting both preventable disability and chronic pain.

This Guideline has therefore focused on use of opioids in the acute, subacute, and chronic periods as critical decision points. It is important to carefully consider whether and how opioids may be used in the acute and subacute periods, since available

evidence does not always warrant their use. If the evidence-based decision is to prescribe opioids, the following steps must be followed as they are crucial to worker outcomes:

1. Weigh the risks and benefits of treatment at all times
2. Follow documentation, treatment, monitoring, and dosage recommendations described in the DWC Guideline for all pain phases.
3. Using extreme caution, make a transparent and planned decision with the patient's consent whether to proceed from treating acute pain with opioids to treatment of subacute and especially chronic pain with opioids.

### ***A2.3 Evidence of Effectiveness of Opioid Use in the Acute Period***

While there are no high-quality trials to suggest that opioids are superior to other active treatments for the treatment of mild to moderate acute pain, there is evidence that short course treatment may be effective in alleviating severe acute pain. (Franceschi 2008; Gaskell 2009; Kelley 2012; Moore 2011; Toms 2009) However, non-opioid medications such as non-steroidal anti-inflammatory medications are at least equivalent if not superior for mild to moderate pain and may have fewer unwanted side effects than opioids. (Brown 1986; Clark 2007; Ekman 2006; Innes 1998; Li 2008; Lovell 2004; Veenema 2000) However, non-opioid medications also may cause adverse health effects and may not be tolerated by some patients. (Blondell 2013)

### ***A2.4 Evidence of Effectiveness of Long-Term Opioid Use***

Despite the lack of consistent, strong evidence for efficacy, the use of opioids for chronic noncancer pain has greatly increased over the past decade. At the time the

DWC Guideline was written, the question as to the long-term effectiveness and safety of opioids for the treatment of chronic noncancer pain remained unanswered. The evidence as summarized by systematic reviews as well as noted by more contemporary randomized controlled trials (RCTs) is complicated by varying conclusions. These disparate conclusions are sometimes based on the integration of new findings and at other times, on different interpretations of the same data.

Some systematic reviews report that oral opioids are significantly more effective than placebo in treating chronic pain, with declines in pain of 30–50% and significant improvements in measures of functional status. (Furlan 2006; Noble 2010; Kalso 2004; Papaleontiou 2010) A recent systematic review of randomized controlled trials of chronic opioid treatment found modest effects for improved pain, and small, inconsistent effects for improved function. (Furlan 2011) Additionally, a systematic review of pharmacological treatments for chronic low back pain found that “opioids are more effective than placebo with respect to pain and disability, with a much greater effect size for pain than disability.”(White 2011) Most randomized trials are not longer than four weeks, with the longest trials less than three months in duration.

Evidence of effectiveness for a longer time period has only been assessed in observational studies. A systematic review of longer duration observational studies of chronic opioid treatment came to the following conclusion:

*[...] proper management of a type of strong painkiller (opioids) in well-selected patients with no history of substance addiction or abuse can lead to long-term pain relief for some patients with a very small (though not zero) risk of developing addiction, abuse, or other serious side effects. However, the evidence supporting these conclusions is weak, and longer-term studies are needed to identify the patients who are most likely to benefit from treatment. (Noble 2010)*

Furthermore, a recent report offered the following opinion:

*Opioids can be an appropriate means of treating patients with chronic pain, particularly those with moderate to severe pain. Four of the systematic reviews we identified found that oral opioids are significantly more effective than placebo in treating chronic pain, with declines in pain in the range of 30–50%. Use of opioids for chronic pain has also been associated with significant improvements in measures of functional status (such as on SF-36). According to two of these studies, opioids are also more effective at improving pain and functional status than NSAIDs. Nevertheless, the increasing use of opioids has been accompanied by real risks of substance misuse, addiction, diversion, overdose, and death. The Institute of Medicine Report, *Relieving Pain in America*, summarizes the ongoing challenges involved in balancing effective treatment of pain against the known risks associated with opioid therapy and provides specific recommendations for national and other policy audiences. (Nuckols 2012)*

The overall finding of greater effects of chronic opioid treatment on pain, rather than function or disability, is also true of many other treatments for chronic pain, in that reduction in pain is not always associated with improvement in function and reduced disability. (Chou 2010) This highlights the importance of combining pain treatments with efforts aimed at improving function. The DWC Guideline emphasizes the need to balance the use of opioids to treat pain with measures of effectiveness, by monitoring pain, function, and progress towards reduced disability.

Effective treatment of pain involves using multiple modalities and a multidisciplinary approach. For guidance on the effectiveness of treatment for chronic pain with non-opioid therapies, see the DWC Chronic Pain Medical Treatment Guideline. (DWC 2009)

### ***A2.5 Opioid Safety: Overdose, Serious Adverse Events, and Substance Misuse/Abuse***

*Overdose:* Opiate overdose, whether intentional or unintentional, is a risk of opioid prescribing, and is mainly manifested by depressed mental status, decreased respiratory rate and tidal volume, decreased bowel sounds, and pupillary constriction. Hypotension may also accompany opioid intoxication. Patients may exhibit ataxia and audible snoring prior to more severe consequences, including collapse and death. If untreated, opioid overdose can lead to hypothermia, coma, seizure, head trauma, aspiration pneumonia, and rhabdomyolysis. Suppression of respiratory drive is one of the most serious complications, as it is most likely to lead to death.

At pharmacological doses, opioids decrease the ventilatory response to carbon dioxide (CO<sub>2</sub>). In combination with other central nervous system depressants, opioids can induce acute respiratory failure as defined by a decrease in the partial pressure of oxygen in arterial blood (P<sub>a</sub>O<sub>2</sub>). However, different opioids vary in their tendency to induce respiratory failure. For instance, methadone causes a dose-dependent decrease in P<sub>a</sub>O<sub>2</sub> before hypercapnia is evident. It is believed that the different effects of various opioids is dependent on their relative affinity for discrete opioid receptors in the central nervous system (CNS) as well as pharmacokinetic interactions between the opioid and other co-administered drugs.

In addition to suppressing central respiratory drive and response to CO<sub>2</sub>, morphine and related drugs slow respiration by prolonging inspiration and by postponing the spontaneous termination of inspiration ("inspiratory off-switching"). Morphine suppression of phrenic nerve activity can be reversed by cholinergic agents such as physostigmine. It can be proposed that addition of anticholinergic agents in an opioid

regimen may lower the toxic threshold of morphine on such mechanisms and potentially increase morbidity and mortality associated with opioid overdose. (Niwa 2011)

The pharmacokinetics of opioid clearance can vary between patients, and can also be influenced by agents that affect opioid metabolism, such as concomitant medications, herbals and dietary supplements. Genetics, age, gender and other dietary influences can also modify opioid clearance through hepatic metabolism. In overdose, the observed half-life of opioids may increase due to changes in absorption and gastric transit. (Boyer 2012)

*Serious Adverse Events:* According to the US Centers for Disease Control and Prevention (CDC), deaths associated with prescription opioids rose from 4,000 in 1999 to over 14,000 in 2008. (CDC 2011) Moreover, these deaths peaked in the age group of 25–55 years, conferring on this cause of unintentional poisoning death a large burden of premature loss of productive life. (Warner 2011) Additionally, an increasing number of emergency department visits and hospitalizations have been associated with prescription opioids. (Fulton 2013)

In addition to prescribed opioids, in the majority of opioid-associated deaths cases a postmortem exam reveals other drugs, including multiple opioids, antidepressants, and either sedative/hypnotics or benzodiazepines. A published review of national data reports that in about half of deaths involving opioid analgesics, more than one type of drug contributed to the death. Benzodiazepines were most frequently associated with opioid analgesics-deaths; other drugs included cocaine and heroin. (CDC 2009) This finding emphasizes the need to exercise caution in prescribing benzodiazepines and other sedative hypnotics with opioids. (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics)

The most commonly reported adverse effects of opioid use are constipation, nausea,

dyspepsia, headache, fatigue, lethargy, and urinary retention. (Noble 2010) Other major adverse effects of opioids include myocardial infarction, allergic reactions, impairment of executive function, sleep apnea, and death. The safety profile of chronic opioid treatment also includes less common adverse effects such as endocrine disorders, neonatal abstinence syndrome, falls and fractures in the elderly, and a potential increased risk of road trauma. (Elliott 2012) The true incidence of these adverse effects is unknown.

*Substance Misuse and Abuse:* There has been a significant increase in the use of opioids that were not prescribed for a medical reason, with one study estimating that one in 25 opioid prescriptions is used for such non-medical purposes. (Katz 2010) Based on the 2010 National Survey on Drug Use and Health, more than 35 million Americans age 12 and older used an opioid analgesic for non-medical purposes at some time in their life—an increase from about 30 million in 2002. (US DHS2011) Use of prescription opioids for non-medical purposes now surpasses that of other illicit substances—marijuana, cocaine, methamphetamine, and heroin. (US DHS 2006)

Despite the large numbers of patients misusing and abusing prescription opioids, the overall incidence and prevalence of substance abuse and misuse of opioids in patients treated for chronic pain remains unclear, with systematic reviews and retrospective studies reporting varying results. For instance, a recent systematic review found that the median incidence of opioid dependence syndrome was 0.5% (range 0–24%) and median prevalence was 4.5% (range 0–31%). (Minozzi 2013) The study concluded that the “available evidence suggests that opioid analgesics for chronic pain conditions are not associated with a major risk for developing dependence.” However, another review was critical of the methodology of most of the studies attempting to assess substance misuse and abuse rates. (Juurlink 2012) This same review suggests that earlier studies that demonstrated very low rates of substance abuse were particularly flawed. The

authors identified a more contemporary study that found that 35% of longer term opioid users met the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria for a current or previous opioid use disorder. (Boscarino 2011) It is clear that higher-quality studies are needed to more accurately characterize the incidence and prevalence of prescription opioid misuse and abuse.

While the overall incidence and prevalence of opioid misuse is not well understood, certain identified factors do predispose patients to persistent opioid use and higher rates of substance misuse and abuse. One of these factors is psychosocial distress (e.g. depression, anxiety, and post-traumatic stress disorder (PTSD)), and this finding reinforces the importance of assessing these co-morbidities in patients with chronic pain being considered for chronic opioid therapy (See Section 3.3.1, Screening for Risk of Addiction to Opioids or Adverse Events Prior to Initiation of Chronic Opioid Treatment). (Grattan 2012; Martins 2012; Outcalt 2013)

Coinciding with the increases in opioid-associated deaths and opioid misuse and abuse has been a substantial escalation in opioid prescribing and dosage between 2000 and 2010. (Kenan 2012) Opioids are currently the second most widely prescribed class of medications (statins for lowering cholesterol are the first). Indeed, the combination agents containing hydrocodone/acetaminophen (sold under brand names including Vicodin and Norco) are the most prescribed medications in the country at 131 million prescriptions per year. (DEA 2013) This rise in sales of prescription opioids over the past decade has contributed greatly to the observed increases in serious adverse events and opioid substance misuse/abuse. It is a primary goal of the DWC Guideline to significantly reduce the rate of opioid-related adverse events and substance misuse and abuse

### **A3. Scope and Target Audience for Opioid Guideline**

The target audiences for the DWC Guideline are primary care and medical and surgical specialty physicians, including pain specialists, caring for injured workers in the State of California and medical providers who perform utilization review and independent medical review. Employers and insurers will also find the concepts in the document useful. The Guideline is meant to assist in the decision to initiate trials of opioid therapy for patients with acute, perioperative, and chronic pain, and to assist in safer, more judicious and effective use of opioids if they are prescribed on a chronic basis.

A key focus of this DWC Guideline is to seek a balance between appropriate treatment of pain and safety in the use of opioids for that purpose. As noted in the 2011 White House Office of National Drug Control Policy comprehensive action plan on prescription drug abuse, "...any policy in this area must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use." (White House Office 2011)

The DWC Guideline does not address pediatric pain, labor pain, or cancer/end of life pain. Caution should also be exercised in extrapolating these recommendations to the non-workers' compensation population. While some of the concepts applied here are common to all patient populations, a significant difference between occupational and non-occupational guidelines is that a key goal of the former is the restoration of function to ensure early return to work. However, as such guidelines also serve as the primary authority for the future medical treatment of those injured with chronic pain who will not return to work both occupational and non-occupational considerations must be included.

## **B. RECOMMENDATIONS**

Part B of the DWC Guidelines provides complete recommendations for management of patients with acute, subacute, post-operative, and chronic pain, as well as appendices with helpful tools for clinicians. The recommendations in Part B are based on findings from a review of existing guidelines and the literature (found in Part C). References cited in Part B are listed in the Reference section of Part C.

### **1. OPIOIDS FOR ACUTE PAIN (UP TO FOUR WEEKS AFTER INJURY OR PAIN ONSET)**

The term “acute pain” is defined in this guideline as pain lasting up to four weeks from the initial onset of injury.

#### ***1.1. Mild Acute Injuries (musculoskeletal strains and sprains, muscle pain, tendonitis)***

- Opioid medications should not in general be used for mild injuries such as acute onset strains, sprains, muscle pain, and tendonitis, myofascial pain; they are also not indicated for repetitive strain injuries. The following therapies should be utilized first for acute injuries:
  1. Pharmacologic therapy with non-opioid pain medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), unless contraindicated due to history of allergy or severe adverse impact.
  2. Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.
  3. Complementary/alternative modalities, such as acupuncture.

- Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice *and* after determining that other non-opioid pain medications or other therapies will not provide adequate pain relief or are contraindicated for medical reasons. They should only be prescribed at the lowest dose that provides pain relief, for a limited time (e.g., five days) and with no refill, prior to re-assessment. (Cifuentes 12)
- If opioids are prescribed, the Controlled Substance Utilization Review and Evaluation System (CURES), California's Prescription Drug Monitoring Program (PDMP) should be accessed. Consider: If CURES indicates the simultaneous use of other narcotic medication, opioid use is contraindicated at this point. Discrepancies found on the CURES report need to be addressed in a fashion satisfactory to the physician to support their continued prescribing. What does one do if the CURES system is not available or if information in the system is found incorrect. Does the provider have an obligation to review a verified CURES report to make an initial prescription. Can the guideline specify that there is an obligation to look and if a decision to prescribe is made that discrepancies found on the CURES report need to be addressed in a fashion satisfactory to the physician to support their continued prescribing.
- Weaker opioids and the lowest effective dose should be used.<sup>i</sup> Stronger opioids may be considered only if weaker ones are ineffective or not tolerated. The FDA categorizes drugs into five schedules (from I to V). (US FDA CFR Title 21, Chapter 13) Schedule V drugs (weakest) have the lowest potential for abuse and Schedule I drugs (strongest) are considered to have the highest potential for abuse. (US FDA CFR Title 21, Chapter II, Part 1308)
- Patients should be cautioned about the potential adverse effects of opioid medications, including impacts on alertness. Driving and operation of heavy equipment should be

discouraged while on these medications. (See Appendix B, Sample of a Written Opioid Treatment Agreement)

- At the time of initial prescription, patients should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible Storage and Disposal of Opioid Medications)

*Rationale:*

Based on the literature summarized above, there is insufficient evidence that supports the efficacy of opioids in the acute phase for mild injuries. There is quality evidence that use of opioids can lead to adverse outcomes.

***1.2. Moderate to Severe Acute Soft-Tissue Injuries (e.g., severely strained ligaments, severe sprains, moderate trauma, moderate to severe low back pain, moderate to severe radiculopathy)***

A brief course of short acting opioids is an option to provide analgesia for moderate to acute severe pain due to acute soft tissue injuries when pain is uncontrolled by other measures and/or accompanied by functional deficits.

- The clinician should ensure that the following conditions are met prior to prescribing opioids for moderate to severe soft tissue injuries:
  1. Documented moderate to severe soft tissue injury
  2. The following additional treatments, which may be both medically indicated and more effective than opioids, have been initiated and either (a) have failed and/or (b) are contraindicated and/or (c) there are reasonable expectations that only opioids will produce immediate pain relief and sleep immediately following the injury:
    - Pharmacologic therapy with non-opioid pain medications (e.g., acetaminophen, NSAIDs).
    - Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.
    - Complementary/alternative modalities, such as acupuncture.
  3. The CURES database has been checked and the results documented prior to prescribing opioids. If the search indicates the use of other opioids medication and the assessment otherwise supports the use of opioids, only a limited supply should be prescribed at the lowest feasible dose under careful monitored conditions. (See Section 3.3.4, Use of CURES to Ensure Safe and Effective Opioid Use)
  4. Documentation is provided in the medical record that the following conditions are not present. These conditions are a relative contraindication to initiating opioids:

Depression, anxiety, personality disorder, untreated sleep disorders, current or past substance abuse, drug seeking behavior, other psychotropic medications, post-traumatic stress disorder (PTSD), cognitive impairment, chronic obstructive pulmonary disease (COPD), severe obesity, balance problems/fall risk, osteoporosis, and renal failure.

- If these conditions are present, written documentation must be provided to justify the use of opioids.
5. The use of sedative-hypnotics, including anti-histamines (H<sub>1</sub>-blockers) and benzodiazepines, has been discontinued before prescribing opioids. (Fulton-Kehoe 2013) (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics) This implies probable authority for countermanding an order of another provider who may be prescribing for non-industrial purpose. Consider as alternative: Recommendations for discontinuing sedative hypnotics including antihistamines has been provided to the patient and communicated to the provider prescribing these substances so that appropriate informed consent can be provided.
  6. There is no use of illicit substances or other substances that should not be taken concomitantly (e.g., sedating substances, including alcohol and benzodiazepines). (Fulton-Kehoe 2013) Treatment with opioids is contraindicated in individuals using illicit substances. (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics)
    - Clinical practice should include the following:
      1. Initiate opioids as a “trial” to ascertain whether the selected opioid produces functional improvement.
      2. Document clinically meaningful improvement in pain and function (See Section

3.3.7, Monitoring Effectiveness of Chronic Opioid Treatment: Tracking Pain and Function and Determining Clinically Meaningful Improvement)

3. Generally, prescribe opioids at night or when the patient is not at work. (Gomes 13)
4. Weaker opioids and the lowest effective dose should be used. Stronger opioids may be considered only if weaker ones are ineffective or not tolerated. The FDA categorizes drugs into five Schedules (from I to V). (US FDA CFR Title 21, Chapter 13) Schedule V drugs (weakest) have the lowest potential for abuse and Schedule I drugs (strongest) are considered to have the highest potential for abuse. (US FDA CFR Title 21, Chapter II, Part 1308)
5. Prescribe only one opioid at a time. The lowest dose capable of providing analgesia should be used. (Cifuentes 2010; Dersh 2008; Volinn 2009)
  - Doses for opioid-naïve patients should not exceed 80 mg/day morphine equivalent dosage (MED) (See Section 3.3.8, Opioid Titration and Dosing).
  - Prescribe a short course (limited supply, for example 1-2 weeks with no refills) of opioid medication. (Cifuentes 2012)
6. Providers to decrease probability of UR / provider conflict stronger language is necessary. Consider: ~~may consider~~ are encouraged to use using screening tools or recommend consultation with a pain specialist at any point prior to the 4<sup>th</sup> week, if they feel it is warranted. (See Appendix A, Brief, Validated Tools; Section 3.3.1, Screening for Risk of Addiction to Opioids or Adverse Events Prior to Initiation of Chronic Opioid Treatment, Section 3.3.6; and Section 6, Pain Medicine Consultation)
7. Clinicians should monitor for and document indications for discontinuing opioids, including:

- Resolution of pain or improvement to the point of not requiring opioids within the expected timeframe for the injury being treated.
  - Lack of improved function despite adherence to the treatment regimen.
  - Intolerance or severe adverse effects: it is likely that at least some side effects will occur with opioid use. The nature and severity of side effects will determine whether to discontinue the medication.
  - Non-compliance, surreptitious medication use, aberrant drug screening results, diversion, consumption of medications or substances when advised to not take simultaneously.
8. Patients who have been treated for more than two weeks with opioids should have these medications discontinued via tapering rather than by abrupt cessation.
  9. Patients should be cautioned about the potential adverse effects of opioid medications, including impacts on alertness. Driving and operation of heavy equipment should be discouraged while on these medications. (See Appendix B, Written Opioid Treatment Agreement)
  10. At the time of initial prescription, patients should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible Storage and Disposal of Opioid Medications)

*Rationale:*

The physiologic benefits of effective analgesia are well described in these circumstances. The goal is to reduce pain in the first few days following injury. Thereafter, functional restoration is a specific goal for opioid use in this setting. The short and long-term risks of opioid use outweigh the benefits if there is lack of efficacy, evidence of adverse effect, or

inappropriate medication or substance use.

***1.3. Severe Acute Injuries (fractures, crush injuries, major trauma, large burns, other injuries with significant tissue damage) (See also Section 10: Opioid Use in Catastrophic Injuries)***

Opioids are recommended for the treatment of acute, severe pain uncontrolled by other modalities and/or with functional deficits. A brief course may also be indicated for pain following severe injuries. (Blondell 2013)

- The physician should ensure that the following conditions are met prior to prescribing opioids for severe acute injuries:
  1. Documented severe injury
  2. The following additional treatments, which may be more effective than opioids, have been initiated and either (a) have failed and/or (b) are contraindicated and/or (c) there are reasonable expectations that only opioids will produce immediate pain relief and sleep immediately following the injury:
    - Pharmacologic therapy with non-opioid pain medications (e.g., acetaminophen, NSAIDs).
    - Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.
    - Complementary/alternative modalities, such as acupuncture.
  3. The CURES database is checked and the results documented prior to prescribing opioids. If the search indicates that other opioids are being used, the patient should be questioned about the additional medications. If the clinical assessment supports the use of additional opioids, only a limited supply should be prescribed under carefully monitored conditions. (See Section 3.3.4, Use of CURES to Ensure Safe

and Effective Opioid Use)

4. Documentation is provided in the medical record that the following conditions are not present. These conditions are a relative contraindication to initiating opioids: Depression, anxiety, personality disorder, untreated sleep disorders, current or past substance abuse, drug seeking behavior, other psychotropic medications, PTSD, cognitive impairment, COPD, severe obesity, balance problems/fall risk, osteoporosis, and renal failure. If any of these conditions are present, written documentation must be provided to justify the use of opioids.
  5. The use of sedative-hypnotics including anti-histamines (H<sub>1</sub>-blockers) and/or benzodiazepines has been discontinued before prescribing opioids. (Fulton-Kehoe 2013) (See Section, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics) This wording implies authority for altering the prescription of another physician and should be altered. Informed consent about concurrent use should be provided to the patient and communicated to the prescriber of the sedative hypnotic.
  6. There is no use of illicit substances or of substances that should not be taken concomitantly (e.g., sedating medications including alcohol and benzodiazepines). (Fulton-Kehoe 2013) The use of illicit substances is a contraindication to opioid treatment. (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics) Consider altering language: Physician prescribing in the circumstance of such concurrent illicit medication use should identify the awareness of use and a treatment plan to mitigate any danger.
- Clinical practice should include the following:
    1. Opioids should be initiated as a “trial” to ascertain whether the selected opioid produces functional improvement.

2. Document clinically meaningful improvement in pain and function during the acute phase (See Section 3.3.7: Monitoring Effectiveness of Chronic Opioid Treatment: Tracking Pain and Function and Determining Clinically Meaningful Improvement)
3. Generally opioids should be prescribed at night or when not at work.
4. Only one opioid should be prescribed. The lowest dose capable of providing analgesia is preferable.
  - In general, doses for opioid-naïve patients should not exceed 80 mg/day MED. (See Section, 3.3.8, Opioid Titration and Dosing)
5. A short course (limited supply) of opioid medication should be prescribed.
6. Weaker opioids and the lowest effective dose should be used. Stronger opioids may be considered only if weaker ones are ineffective or not tolerated. The FDA categorizes drugs into five Schedules (from I to V). (US FDA CFR Title 21, Chapter 13) Schedule V drugs (weakest) have the lowest potential for abuse and Schedule I drugs (strongest) are considered to have the highest potential for abuse. (US FDA CFR Title 21, Chapter II, Part 1308)
7. Providers ~~may consider using~~ to decrease probability of UR / provide conflict stronger language is necessary. Consider: are encouraged to use screening tools or obtaining a consult with a pain specialist at any point prior to the 4th week if they feel it is warranted. (See Appendix A, Brief, Validated Tools, Section 3.3.1, Screening for Risk of Addiction to Opioids or Adverse Events Prior to Initiation of Chronic Opioid Treatment, Section 3.3.6, and Section 6, Pain Medicine Consultation)
8. A gradual increase in physical activity and activities of daily living should be part of the treatment regimen as the patient progresses.
9. Clinicians should monitor for indications for discontinuing opioids including:

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- a. Resolution of pain or improvement to the point of not requiring opioids within the expected timeframe for the injury being treated.
  - b. Lack of improved function despite adherence to the treatment regimen.
  - c. Intolerance or severe adverse effects: it is likely that at least some side effects will occur with opioid use. The nature and severity of side effects should be considered when deciding whether to discontinue the medication.
  - d. Non-compliance, surreptitious medication use, aberrant drug screening results, diversion, consumption of medications or substances when advised to not take simultaneously.
10. Patients who have been treated for more than two weeks should have opioids discontinued via tapering. (See Section 3.3.8, Opioid Titration and Dosing)
11. Patients should be cautioned about the potential adverse effects of opioid medications, including impacts on alertness. Driving and operation of heavy equipment should be discouraged while on these medications. (See Appendix B, Sample of a Written Opioid Treatment Agreement)
12. At the time of initial prescription, patients should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible Storage and Disposal of Opioid Medications)

### *Rationale:*

The physiologic benefit of the use of opioids for treating pain due to severe acute injuries is well described. The use of opioids to treat pain must be balanced with the need to prevent misuse and adverse effects.

### ***1.4. Opioids for Post-Operative Pain***

Opioid use for a limited duration is recommended for management of post-operative pain management in addition to other treatments, especially during the immediate post-operative period and for moderate to extensive surgical procedures (e.g., arthroplasty, lumbar fusion). (Gaskell 2009; Moore RA 2011; Toms 2007)

- Considerations for prescribing opioids for post-operative pain include the following:
  1. Treatments with other non-opioid medications have failed to provide relief or are contraindicated. Opioids are indicated to obtain sleep for evenings after surgery, and they are also indicated for daytime use to alleviate severe post-operative pain. Non-opioid medications (e.g., NSAIDs, acetaminophen) should be prescribed along with opioid medications.
  2. The CURES database is checked and the results documented prior to prescribing opioids. If the search indicates that other opioids are being used, the patient should be questioned about the additional medications. If the clinical assessment supports the use of additional opioids, only a limited supply should be prescribed under careful monitored conditions. (See Section 9, Managing Perioperative Pain in Workers on Chronic Opioid Treatment Undergoing Elective Surgery)
  3. Patients with more than one of the following conditions should be carefully monitored as inpatients; these conditions are relative contraindications for opioid use following hospital discharge: Anxiety, depression, personality disorder, current or past substance abuse, drug seeking behavior, untreated sleep disorders (particularly sleep apnea), use of other psychotropic medications, post-traumatic syndrome disorder (PTSD), cognitive impairment, cerebrovascular disease, balance problems/fall risk, COPD, chronic hepatitis, cirrhosis, renal failure, severe obesity, and osteoporosis. (Haack 2012)
  4. The use of illicit substances is a contraindication to opioid use following hospital discharge. (Fulton-Kehoe 2013)
- Clinical practice should include the following:

1. Discontinue sedative-hypnotics including anti-histamines (H<sub>1</sub>-blockers) and/or benzodiazepines before surgery. (Fulton-Kehoe 2013) (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics) Consider alternate position reducing conflict of co-morbid condition management by inserting, "Document informed consent of the patient regarding the increased risk of death associated with this concurrent use and communicate this informed consent to the physician prescribing the sedative hypnotic."
2. Post-operative opioid use is recommended at night as needed for pain-interrupted sleep. Use during the daytime may generally be indicated for up to a few days to overcome severe post-operative pain, following which tapering to nocturnal use only should occur as soon as possible.
3. Opioids to control postoperative pain are adjuncts to other treatments such as NSAIDs (used when the risk of bleeding is not a concern), progressive exercises, and other modalities.
4. In general, doses for opioid naïve patients should not exceed 80 mg/day MED. (See Section 3.3.8, Opioid Titration and Dosing).
5. Weaker opioids and the lowest effective dose should be used. Stronger opioids may be considered only if weaker ones are ineffective or not tolerated. The FDA categorizes drugs into five Schedules (from I to V). (US FDA CFR Title 21, Chapter 13) Schedule V drugs (weakest) have the lowest potential for abuse and Schedule I drugs (strongest) are considered to have the highest potential for abuse. (US FDA CFR Title 21, Chapter II, Part 1308)
6. For less extensive procedures, opioid use should not extend beyond two to three weeks.
7. For more extensive surgical procedures, use for up to three months may be considered during recovery. Written documentation should be provided regarding the status of pain and function.

8. For patients treated with opioids for one to three months postoperatively, the opioid use recommendations for management of subacute pain apply (See Section 2.2, Opioids for Subacute Pain). With rare exceptions, only nocturnal use is recommended in the second and third months of post-operative opioid use.
9. If opioids are continued for treatment pain beyond four weeks post-operatively, screening tools for substance (drugs and alcohol) misuse/abuse, as well as psychosocial conditions should be used. (See Section 3.3.1.1, Screening for Drug Misuse/Abuse and Section 3.3.1.2 Screening for Alcohol Misuse/Abuse) If aberrant results are obtained, providers should consider obtaining a consult with a pain specialist (See Section 6, Pain Medicine Consultation) or conducting urine drug screening (See Section 3.3.6, Use of Urine Drug Testing [UDT])
10. Following discharge, patients should have periodic visits to monitor efficacy, adverse effects, compliance and surreptitious medication use. Towards this end, providers should document their assessments and may consider using screening tools, obtaining a consult with a pain specialist or conducting urine drug screening at any point, if they feel it is warranted.
11. Clinicians should monitor for indications for discontinuing opioids, including:
  - a. Resolution of pain or improvement to the point of not requiring opioids within the expected timeframe for the injury being treated.
  - b. Lack of improved function despite adherence to the treatment regimen.
  - c. Intolerance or severe adverse effects. It is likely that at least some side effects will occur with opioid use; the nature and severity of side effects should be considered when deciding whether to discontinue the medication.
  - d. Non-compliance, surreptitious medication use, aberrant drug screening results, diversion, consumption of medications or substances when advised

to not take simultaneously.

12. Patients who have been treated with opioids for more than two weeks should have opioids discontinued via tapering, as opposed to abrupt cessation. (See Section 4, Indications and Methods for Tapering Opioids)
13. Patients should be cautioned about the potential adverse effects of opioid medications, including impacts on alertness. Driving and operation of heavy equipment should be discouraged while on these medications. (See Appendix B, Sample of a Written Opioid Treatment Agreement)
14. At time of discharge, patients should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible Storage and Disposal of Opioid Medications)

See Section 9, Managing Peri-Operative Pain in Workers on Chronic Opioid Treatment Undergoing Elective Surgery, for management of patients who are being treated with opioids prior to surgery.

*Rationale:*

Sufficient pain control during the postoperative phase is needed to ensure rapid and adequate recovery of function.

## **2. OPIOIDS FOR SUBACUTE PAIN (1–3 MONTHS)**

If pain extends beyond the acute phase (beyond one month following onset), the use of non-pharmacological treatments such as cognitive-behavioral therapy, activity coaching, graded exercise, and other treatments such as acupuncture should be continued.

- If opioids are being considered beyond the acute phase, the following clinical practices should be followed:
  1. The following conditions are a relative contraindication to continuing opioids during

the subacute phase: Depression, anxiety, personality disorder, untreated sleep disorders, past substance abuse, drug seeking behavior, other psychotropic medications, PTSD, cognitive impairment, COPD, severe obesity, balance problems/fall risk, osteoporosis, and renal failure. If any of these conditions are present, written documentation must be provided to justify the use of opioids. Current substance use disorder is a contraindication to continued opioid treatment.

2. Medically indicated non-opioid treatments should be continued:
  - Pharmacologic therapy with non-opioid pain medications (e.g., acetaminophen, NSAIDs).
  - Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.
  - Complementary/alternative modalities, such as acupuncture.
3. Consult CURES again to ensure that the use of prescribed narcotics continues to be consistent with the history and prescription record.
4. Continue documenting clinically meaningful improvement in pain and function during the subacute phase. (See [Section 3.3.7](#), Monitoring Effectiveness of Chronic Opioid Treatment: Tracking Pain and Function and Determining Clinically Meaningful Improvement )
5. Screening for risk using validated tools is medically indicated, if this has not already been done in the acute pain phase. (See Section 3.3.5, Use of Tools to Monitor Patients on Chronic Opioid Treatment)
6. Administer a baseline urine drug test (UDT) in the office toward the beginning of the subacute period (4-6 weeks from onset of opioid treatment). (See Section 3.3.6, Use of Urine Drug Testing [UDT] for Initiation and Monitoring of chronic opioid treatment ) Aberrant results (e.g., those indicating diversion, use of illicit substances, or

medications which have not been prescribed) are a contraindication to continued opioid use. A history of opioid use disorder or substance use disorder is a relative contraindication to continued opioid use during the subacute phase. Prior to prescribing opioids beyond six weeks to patients with a history of substance use disorder, consultation with an addiction specialist should occur.

7. Remind patients at each visit that they should not take benzodiazepines or other sedative-hypnotics or drink alcohol while on opioids. Discontinue opioids or taper sedative-hypnotics and/or benzodiazepines if the patient is found to be taking them against provider's advice.
8. As during the acute treatment phase, opioids should be used at the lowest dose capable of producing analgesia and improving function.
  - In general, doses for opioid naïve patients should not exceed 80 mg/day MED. (See Section 4, Indications and Methods for Tapering Opioids)
  - Weaker opioids and the lowest effective dose should be used. Stronger opioids may be considered only if weaker ones are ineffective or not tolerated. The FDA categorizes drugs into five Schedules (from I to V). (US FDA CFR Title 21, Chapter 13) Schedule V drugs (weakest) have the lowest potential for abuse and Schedule I drugs (strongest) are considered to have the highest potential for abuse. (US FDA CFR Title 21, Chapter II, Part 1308)
9. Clinicians should monitor for indications for discontinuing opioids, including:
  - Resolution of pain or improvement to the point of not requiring opioids within the expected timeframe for the injury being treated.
  - Lack of improved function despite adherence to the treatment regimen.
  - Intolerance or severe adverse effects: it is likely that at least some side

effects will occur with opioid use. The nature and severity of side effects should be considered when deciding whether to discontinue the medication.

- Non-compliance, surreptitious medication use, aberrant drug screening results, diversion, consumption of medications or substances when advised to not take simultaneously.

10. Patients who have been treated for more than two weeks should have opioids discontinued via tapering, rather than abrupt cessation. (See Section 4, Indications and Methods for Tapering Opioids)

11. Patients should be cautioned about the potential adverse effects of opioid medications, including impacts on alertness. Driving and operation of heavy equipment should be discouraged while on these medications. (See Appendix B, Sample of a Written Opioid Treatment Agreement)

12. At each evaluation, patients should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible Storage and Disposal of Opioid Medications)

*Rationale:*

With rare exceptions, resolution of pain and resumption of regular function is anticipated after four to six weeks. The provider should carefully consider non-opioid alternative treatments and document the absence of factors that would increase the risk of harm prior to continuing opioid use.

### **3. Opioids for Chronic Pain and Chronic Opioid Treatment**

The term “chronic pain” is defined in this guideline as pain lasting three or more months from the initial onset of injury pain (i.e., over 12 weeks). Patients with chronic pain may be

candidates for treatment with opioids if pain management and functional improvement have not been achieved with other treatment modalities, including passive and active movement, cognitive behavioral therapy, and other practices such as acupuncture. Patients who require treatment with opioids to relieve pain or improve function for durations longer than three months are considered as being on chronic opioid treatment.

### ***Overview of Recommendations Regarding Chronic Opioid Treatment***

Steps that should be taken by prescribing physicians who are considering chronic opioid treatment are listed below and described in more detail in Section 3.3, Initiating and Monitoring Chronic Opioid Treatment.

- Prior to initiating opioids for chronic pain or chronic opioid treatment, the following steps should be taken and documentation provided in the medical record:
  1. Perform a comprehensive evaluation and assessment. (See Section 3.1, Comprehensive Evaluation and Assessment of Patient)
  2. Consider alternative treatments. (See Section 3.2, Consideration of Alternative Treatments for Chronic Pain and Chronic Opioid Treatment)
  3. Screen for risk of addiction or adverse events. (See Section 3.3.1, Screening for Risk of Addiction to Opioids or Adverse Events Prior to Initiation of Chronic Opioid Treatment)
    - Screen for drug misuse/abuse. (See Section 3.3.1.1, Screening for Drug Misuse/Abuse)
    - Screen for alcohol misuse/abuse. (See Section 3.3.1.2, Screening for Alcohol Misuse/Abuse)
    - Screen for additional psychosocial factors contributing to substance misuse/abuse. (See Section 3.3.1.3, Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse)

4. Complete patient treatment agreement/informed consent and discuss with patient. (See Section 3.3.2, Patient Treatment Agreement and Informed Consent)
  5. Initiate a trial period of opioid treatment. (See Section 3.3.3, Initiation of Chronic Opioid Treatment)
- Based on the above, if the decision is made to initiate chronic opioid therapy, the following medically indicated steps must be taken:
    1. Use CURES to ensure safe and effective opioid use. (See Section 3.3.4, Use of CURES to Ensure Safe and Effective Opioid Use)
    2. Use questionnaires and other validated screening tools to monitor chronic opioid therapy. (See Section 3.3.5, Use of Tools to Monitor Patients on Chronic Opioid Treatment)
    3. Use urine drug testing for initiation and monitoring of chronic opioid therapy. (See Section 3.3.6, Use of Urine Drug Testing [UDT])
    4. Monitor the effectiveness of chronic opioid therapy by tracking pain and function. (See Section 3.3.7, Monitoring Effectiveness of Chronic Opioid Treatment: Tracking Pain and Function and Determining Clinically Meaningful Improvement)
    5. Monitor and adjust dose of patients on chronic opioid therapy. (See Section 3.3.8, Opioid Titration and Dosing)
    6. Monitor and make dose adjustments during the maintenance period. (See Section 3.3.9, Maintenance of Chronic Opioid Treatment )
    7. Make regular efforts to taper opioids. (See Section 4, Indications and Methods for Tapering Opioids)

### ***3.1. Comprehensive Evaluation and Assessment of Patient***

Evaluation and assessment prior to initiating treatment with opioid medications beyond the subacute period (three or more months after initiation of opioid treatment) should include the following:

1. Identify the cause of the pain and develop an appropriate differential diagnosis.
2. Assess prior treatments for the current condition, documenting their effectiveness, adverse effects, and appropriateness.
3. Assess and document the severity of pain (using a numerical rating scale), pain interference (using pain inventory instruments), and function (using validated patient reported questionnaires), even if this has been done during the acute or subacute periods of treatment. This will establish a baseline and thus serve as a basis to track outcomes of chronic opioid treatment.
4. Assess psychological and social factors and co-morbid medical or mental health conditions that may compromise the safe use of opioids to treat chronic pain and document the following. (See subsections of Section 3.3.1, Screening for Risk of Addiction to Opioids or Adverse Events Prior to Initiation of Chronic Opioid Treatment)
5. Evaluate for the presence of co-morbid psychiatric conditions (e.g., depression, anxiety, PTSD) that may impact pain treatment in general and chronic opioid treatment specifically. (See Section 3.3.1.3, Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse) These factors include:
  - A history of substance abuse, misuse, or addiction (See Section 3.3.1.2, Screening for Alcohol Misuse/Abuse)
  - Use of current medications that might negatively interact with other medications used for pain treatment. Particular attention should be given to

identifying use of benzodiazepines or other sedative-hypnotics, which should not be prescribed simultaneously with opioids. (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics)

- The presence of any medical factors that could complicate treatment of pain in general or increase risks of adverse events with chronic opioid treatment, including any pertinent laboratory tests specific to the patient's circumstances. If not already identified in the acute phase, assess for the following conditions: Depression, anxiety, personality disorder, untreated sleep disorders (particularly sleep apnea), current or past substance abuse, drug seeking behavior, other psychotropic medications, PTSD, cognitive impairment, medication allergies, cardiac disease, COPD, chronic hepatitis, cirrhosis, cerebrovascular disease, severe obesity, balance problems/fall risk, osteoporosis, and renal failure. (Haack 2012)

These conditions are relative contraindications to chronic opioid therapy, and in their presence, written documentation should be provided to justify the use of these medications and show that other alternatives have been considered and are not feasible.

- Social factors that may impact pain management including: employment, job satisfaction, marital history, social network, and history of legal problems.

*Rationale:*

There is agreement across guidelines that the potentially serious adverse effects of chronic opioid treatment warrant comprehensive assessment to avoid potential complications.

***3.2. Consideration of Alternative Treatments for Chronic Pain and Chronic Opioid Treatment***

Non-opioid alternative therapies for pain treatment should be tried before resorting to chronic opioid therapy. In addition, these treatment modalities should be continued even if opioids are used for relieving chronic pain:

- Pharmacologic therapy with non-opioid pain medications (e.g., acetaminophen, NSAIDs)
  - Physical activity, including rest, passive and active range of motion, and physical therapy/occupational therapy with graded exercise matched to the injury
  - Psychological/behavioral therapy
  - Complementary/alternative modalities, such as acupuncture
  - Interventional treatments
- Refer to the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines of California's Division of Workers' Compensation (DWC) for specific recommendations for non-opioid treatment of chronic pain. (DWC 2009)

*Rationale:*

The guidelines reviewed offer consistent recommendations that alternative treatments for chronic pain are often medically indicated and offer benefits and promote recovery without many of the side effects of opioid treatment.

### ***3.3. Initiating and Monitoring Chronic Opioid Treatment***

#### **3.3.1 Screening for Risk of Addiction to Opioids or Adverse Events Prior to Chronic Opioid Treatment**

### **3.3.1.1 Screening for Drug Misuse/Abuse**

Screening for drug misuse or abuse should be performed in two situations:

1. Prior to initiating a trial of chronic opioid treatment, screening should be performed to predict the probability of a patient engaging in drug misuse/abuse when prescribed opioids for chronic pain. (See Appendix G, Summary of Screening and Monitoring Recommendations)
2. During the opioid trial or during chronic opioid treatment, screening should be performed as needed to identify current abuse/misuse of opioid medications. (See Appendix G, Summary of Screening and Monitoring Recommendations)

Validated screening tools for drug misuse, such as Opioids Risk Tool (ORT), Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R<sup>1</sup>), or others, should be used and the results documented. ORT, Patient Medication Questionnaire (PMQ), and SOAPP- R are questionnaires for predicting high-risk patients, whereas the Current Opioid Misuse Measure (COMM<sup>2</sup>) and the Prescription Opioid Misuse Index (POMI<sup>3</sup>) are questionnaires designed to identify current abuse/misuse of opioids. (See Appendix A1, Tools to Screen for and Monitor High-Risk Patients)

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<sup>1</sup> <http://www.painedu.org/soap.asp>

<sup>2</sup> <http://www.painedu.org/soap.asp>

<sup>3</sup> <http://www.oasas.ny.gov/AdMed/FYI/pomifyi.cfm>

- If the screening tools identify a predicted increased risk for substance misuse/abuse, chronic opioid treatment should only be initiated if other alternatives are not viable; in this case, documentation should be provided in the medical record that attempts are being made to address the identified risks.
- If the screening tools suggest current drug misuse or abuse, urine drug screening

may be considered. (See Section 3.3.6, Use of Urine Drug Testing [UDT] for Initiation and Monitoring of chronic opioid treatment)

- Routine genomic testing to predict adverse effects of opioids, including potential abuse or addiction, is not recommended.

*Rationale:*

A personal history of illicit drug and alcohol use are predictors of opioid misuse or abuse. The literature indicates that validated screening tools may be used to identify patients who may be currently misusing opioids as well as those at risk for future misuse; this will help to guide decision making for chronic pain treatment. Evidence that genetic testing reliably predicts the potential for abuse is currently lacking. (Racoosin 2013)

**3.3.1.2 Screening for Alcohol Misuse/Abuse**

- The CAGE-AID questionnaire should be completed and the results documented prior to initiating a trial of chronic opioid treatment. (See Appendix G: Summary of Screening and Monitoring Recommendations)
- If the screening tools identify a predicted increased risk for alcohol misuse/abuse, documentation should be provided to address the identified risks prior to continuing or initiating chronic opioid treatment.

*Rationale:*

Most current guidelines agree on this approach.

**3.3.1.3 Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse**

- Use a validated tool to screen for depressive symptoms (e.g., PHQ-9) to document results prior to initiating a trial of chronic opioid treatment. (See Appendix G, Summary of Screening and Monitoring Recommendations)

- The presence of other mental health conditions such as anxiety disorder, severe sleep disorder, PTSD or suicidal ideation should be assessed and documented.
- If the screening tools identify a mental health condition, these conditions should be documented and consultation with a licensed mental health professional obtained prior to initiating a trial of chronic opioid treatment.
- Chronic opioid treatment should not be initiated during acute psychiatric instability or if suicide risk is identified. Referral should be made to an appropriate mental health professional if these conditions are identified by the clinician.

*Rationale:*

Mental health disorders are a strong risk factor for both misuse/abuse and opioid overdose events. (Grattan 2012; Johnson 2013; Martins 2012; Outcalt 2013; Wassan 2007) Several guidelines provide strong recommendations for screening for these conditions. (ACOEM 2011, WA AMDG 2010, and US VA 2010)

### **3.3.2. Patient Treatment Agreement and Informed Consent**

A patient treatment agreement is a method for informing patients about potential risks and benefits of opioid use, relative responsibilities in the physician/patient relationship. In addition, an agreement allows the physician to obtain permission from the patient to conduct random urine drug tests. Both the patient and physician sign the agreement after reviewing its contents.

- Prior to initiating a trial of chronic opioid treatment, a written patient treatment agreement adherent to the principles described in the above section should be signed by the treating health care provider and patient. (See Appendix B for a sample and Appendix G, Summary of Screening and Monitoring Recommendations)

- The treatment agreement should address:
  - Consequences to the patient if evidence of diversion, misuse, or abuse comes to light
  - Details of the opioid trial (See Section, 3.3.3, Initiation of Chronic Opioid Treatment)
  - Alternative therapies available and potential adverse effects of opioid treatment
  - Activity limitations during opioid treatment (e.g., driving, operating machinery)
  - Responsible storage and disposal of opioid medications.
- The treatment agreement should be introduced when chronic opioid treatment begins.
  - The treatment agreement should be reviewed and updated with new signatures annually.
  - The treatment agreement should be updated if the patient does not adhere to the treatment plan.
- If misuse, abuse, or diversion is identified while the patient agreement is in force and the treating physician continues chronic opioid treatment, or if the original agreement terms are modified, documentation should be provided addressing the issue of concern and why and how the original agreement was modified.

*Rationale:*

The use of a treatment agreement is recommended to document patient understanding, involvement in their care, and agreement with expectations during opioid treatment.

### 3.3.3. Initiation of Chronic Opioid Treatment

- Initiation of opioids for the treatment of chronic pain should be considered a trial to assess efficacy (degree and duration of pain reduction, improvements in function, quality of life) and side effects. The trial of opioid treatment for a period up to several weeks should not be considered a commitment to long-term therapy.
- The following clinical practices are recommended for initiating chronic opioid therapy (FSMB 2013)
  1. The initiation of opioids should be described as a therapeutic trial for a limited period of time (typically no more than 90 days).
  2. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of efficacy (pain reduction, improvement in function and quality of life) and adverse effects.
  3. The lowest dose possible dose should be given initially and titrate to effect.
  4. Opioid therapy should begin with a short-acting opioid. Longer-acting opioids may be considered only if the shorter-acting medications are not effective.
- The provider should follow these clinical practices:
  1. Consult CURES both prior to the opioid trial. CURES may also be consulted during the trial period based on provider's assessment of need. (See Section 3.3.4 Use of CURES to Ensure Safe and Effective Opioid Use)
  2. Conduct urine drug screening prior to the trial. Urine drug screening may be repeated during the trial period, based on the provider's assessment of need. (See Section 3.3.6, Use of Urine Drug Testing [UDT] for Initiation and Monitoring of Chronic Opioid Treatment)
  3. Prior to the trial, use screening tools to identify patients at high risk of

aberrant behavior. Other screening tools to identify concurrent abuse may be used during the trial period, based on the provider's assessment of need. (See Section 3.3.1 Screening for Risk of Addiction to Opioids or Adverse Events Prior to and During Initiation of Chronic Opioid Treatment)

Appendix G contains a summary of screening and monitoring recommendations.

- Intravenous, intramuscular, submucosal, and transdermal (except buprenorphine) administration of opioids for chronic pain are discouraged if the patient is able to tolerate oral medication.

*Rationale:*

A trial period of opioid use prior to initiating chronic treatment is a precautionary recommendation to assess and document pain relief, functional improvement, titrate dose, and establish patient expectations to minimize potential adverse impacts. (FSMB 2013)

### **3.3.4. Use of CURES to Ensure Safe and Effective Opioid Use**

CURES is California's Prescription Drug Monitoring Program (PDMP). Providers should query the CURES database and document results in all of the following situations

- Prior to any first prescription for an opioid (i.e., in the acute pain phase, as well as before surgery).
- At the start of the subacute phase (four weeks following initial injury) and during the subacute period (4–12 weeks) if opioids are used.
- If chronic opioid treatment is continued, periodic checks should be performed based upon risk of diversion, misuse or abuse. The following schedule is recommended:
  1. Before the initiation or trial period for chronic opioid treatment

2. At least quarterly during titration to a “maintenance dose”
  3. At least annually during maintenance, and
  4. More often for patients at high risk for substance abuse.
- o If an unscheduled healthcare appointment results in an additional prescription for opioids (e.g. at an emergency room).

*Rationale:*

Evidence-based and expert, consensus-derived guidelines reviewed recommend evaluating current opioid use before a provider writes the first prescription. Studies suggest that approximately 5% of new claimants entering the workers' compensation system have received opioid prescriptions prior to injury. Of these, about 40% were already receiving chronic opioid treatment. (WA 2013) The goal of checking CURES after starting a trial of opioids is to verify that the patient has not received additional prescriptions since starting the trial. (Utah 2009; WA 2013) Accessing CURES periodically during chronic treatment, or if an unexpected visit or event occurs, aids in verifying appropriate use and identifying misuse. (Neven 2012; Juurlink 2013)

**3.3.5. Use of Tools to Monitor Patients on Chronic Opioid Treatment**

Tools such as the COMM and the POMI should be used in combination with clinical assessment to assess for aberrant behavior and to determine whether chronic opioid treatment should be discontinued. (See Section 4.1, Indications for Tapering Opioids) (Butler 2007; Butler 2011; Knisely 2008)

*Rationale:*

While there are no definitive studies to recommend any one tool over another, the use of validated screening instruments is an aid to clinical assessments in identifying aberrant behavior related to opioid treatment.

### **3.3.6. Use of Urine Drug Testing (UDT)**

Periodic drug testing is useful in assessing adherence to the treatment plan and in detecting the use of non-prescribed substances. While various biologic media may be used for drug testing, urine testing is preferred because it is convenient to collect and store, and testing is cost-effective and relatively easy to obtain.

#### *UDT Process:*

Standardized protocols should be developed in consultation with the testing laboratory and followed to ensure proper collection, handling, storage, and shipping of urine specimens. (Kahan 2011) Procedures should ensure compliance with local, state, and federal requirements pertaining to laboratory testing, such as the Clinical Laboratory Improvement Amendments (CLIA<sup>4</sup>). When UDT is conducted as part of pain treatment, forensic standards (such as those required by the Department of Transportation for employer drug testing programs) are generally not necessary, so it is not necessary to observe specimen collection and follow chain-of-custody protocols.<sup>5</sup> (US DoT; FSMB 2013)

#### *Type of UDT:*

- An initial UDT may be performed at a point of collection (in an office or in the field). The standard practice includes a measurement of temperature, specific gravity, and a panel of drugs. Point of collection (POC) screening with immunoassays should be considered an initial approach to test for multiple

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<sup>4</sup> "Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is any facility that does laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health."

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm>

(Accessed on February 12, 2014.)

"The Clinical Laboratory Improvement Amendments of 1988 (CLIA) law specified that laboratory requirements be based on the complexity of the test performed and established provisions for categorizing a test as waived. Tests may be waived from regulatory oversight if they meet certain requirements established by the statute.

The section of the statute specifying the criteria for categorizing a test as waived was excerpted without elaboration in the regulations at 42. CFR 493.15(b) and 493.15(c) contains a list of these waived tests."

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124202.htm>

(Accessed on February 12, 2014.)

<sup>5</sup> <http://www.dot.gov/odapc/mro>

drug classes and provide rapid results. However, results should be interpreted with caution because immunoassays (1) cannot detect alcohol and some prescribed opioids (e.g., Fentanyl and Oxycodone), (2) do not detect the presence of benzodiazepines with much accuracy, and (3) are subject to false positive and negative results.

- Testing performed in federally-certified laboratories that use a two-step testing process, enzyme-mediated immunoassay followed by gas chromatography mass spectrometry (GC/MS) or liquid chromatography mass spectrometry (LC/MS/MS), should be utilized if verification is required of positive results from POC screening or if a specific drug or metabolite needs to be identified. If POC testing has been performed, laboratory-based immunoassays do not need to be repeated.
- Both POC screening and lab-based immunoassay tests are subject to false negative and false positive results. Therefore, any positive result should be followed by confirmatory testing by a laboratory with GC/MS or LC/MS (described above).
- In addition to testing for the prescribed opiate medication, depending on the clinical circumstances, testing for additional drugs, including the following, may be considered using laboratory-based GC/MS or LC/MS/MS (WA AMDG 2010):

**Table 1. Drugs to Test Using UDT**

Prescribed and additional opiates	Cannabinoids
Alcohol	Cocaine
Amphetamines	Fentanyl
Barbiturates	Methadone
Benzodiazepines	Oxycodone

See Appendix C (Guidance on Conducting and Interpreting Urine Drug Testing) for additional information.

[Why include cannabinoids in CA where Medical Marijuana is allowed. Do we then consider it an illicit?](#)

*Frequency of UDT:*

- Urine drug screening should be performed at the following phases to document absence of opioids (non-compliance), presence of unprescribed drugs (prescription drug abuse), and/or presence of illicit drugs.
  - Prior to initiating treatment with opioids during the subacute phase (four weeks following injury). (See Appendix G, Chart Summary of

Screening and Monitoring Recommendations)

- Prior to initiating a trial of chronic opioid treatment. Urine drug screening may be repeated during the trial period, based on the provider's assessment of need.
  - During chronic opioid treatment, UDT should be conducted on a random basis and adjusted in frequency as relevant after assessment for risk of abuse, misuse or diversion.
  - UDT should be performed at least twice annually and up to four times a year on all patients on chronic opioid treatment. UDTs should be performed more frequently (i.e., four times a year) in patients on doses greater than 80 mg/day MED. In evidence based guideline this appears to be a consensus or non-evidence based recommendation. This seems excessive for low risk patients table below suggests once a year.
- The frequency of UDTs may be adjusted based upon risk assessment. Additional UDTs may be performed after documenting the following:
    - Provider concern: Misuse, abuse, or diversion
    - Basis for this concern: Why is there concern for misuse, abuse or diversion?
    - How to use the results of urine drug screening:
      - If the initial UDT detects opioids or illicit substances, the results should be documented and considered a relative reason to discontinue opioids.

- If UDT indicates illicit substance, but after weighing the potential adverse impacts and alternatives opioid treatment still appears the best option, the provider should provide appropriate written documentation explaining why detection of the unexpected substances does not prevent treatment with opioids, particularly chronic opioid therapy.
- If two-step UDT in a certified laboratory confirms that the patient is not taking the prescribed medications, suggesting possible medication diversion, the clinician should discuss the findings with the patient and discontinue treatment with opioids.
- It is important that all test results that suggest opioid misuse or abuse be discussed with the patient. These discussions should occur in a positive, supportive fashion, to encourage trust in the provider and healthy behaviors. Both the test results and discussion with the patient should be documented in the medical record. (FSMB 2013)

The recommended timing and frequency of UDT is summarized in the table below:

**Table 2. Timing and Frequency of UDT**

Rationale for UDT	Timing of UDT
<b>Based on duration of opioid treatment</b>	
At beginning of subacute phase of treatment	Four weeks after opioids are started to treat acute injury
	Three months after opioids are started to treat injury (Prior to initiating a trial; additional tests during the trial based on assessment of need)

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Chronic opioid treatment	On a random basis during chronic treatment; adjusted in frequency as relevant after assessment for risk of abuse, misuse or diversion (see below)
	2-4 times a year on all patients on chronic opioid treatment
	4 times a year on patients on > 80 mg/day MED
<b>Based on Risk of Misuse</b>	
Low	Once a year <u>(Is this inconsistent with 2/year above)</u>
Moderate	Up to twice a year
High or opioid dose > 80 mg/day MED	Four times a year

*Rationale:*

Every major guideline reviewed makes similar recommendations for the frequency and use of urine drug screening. There is fair evidence: (1) that UDTs provide diagnostic accuracy, (2) that UDTs identify patients who are non-compliant or abusing prescription drugs or illicit drugs, and (3) that UDTs may decrease prescription drug abuse or illicit drug use when patients are in chronic pain management therapy. (ASIPP 2012)

### **3.3.7. Monitoring Effectiveness of Chronic Opioid Treatment: Tracking Pain and Function and Determining Clinically Meaningful Improvement**

#### ***3.3.7.1 Tracking Pain and Function to Monitor Effectiveness of Chronic Opioid Treatment***

Monitoring the effectiveness of opioids and giving strong consideration to weighing the risks and benefits throughout the period of opioid use is crucial to maximizing potential benefit and avoiding serious short- or long-term adverse consequences.

Several methods are used for tracking pain and function. To provide consistency, pain and function should be tracked with validated instruments. Reliance on informal inquiry or observation, physical therapy notes, and similar non-standard and scientifically unvalidated methods are unreliable and lead to inconsistent tracking of effectiveness across practice types and systems. In order to track pain intensity, most guidelines rely on a 10-point, scale such as a numerical rating scale or visual analog scale. The most valid and consistent method to track function is to routinely measure physical function by documenting actual physical performance, including exertional capacity, degree of flexibility, and improved strength. An additional or alternate method is to track the types of physical function most meaningful to the patient, such as measures of the ability to stand, sit, lift, and carry.

The following outcomes should be documented when assessing the effectiveness of chronic opioid treatment:

1. Reduction in level of pain via a brief validated instrument (e.g. Numerical rating scale where 0 = no pain and 10 = worst pain imaginable). (See Appendix A2, Tools for Tracking Pain and Function)
2. Functional improvement attributable to the use of opioids via a validated instrument (e.g., the Graded Chronic Pain Scale, the Brief Pain Inventory,

Multidimensional Pain Inventory and the Pain Severity Scale of the SF-12<sup>6</sup>). Pain interference scales (Graded Chronic Pain Scale, Brief Pain Inventory) are brief and sensitive, but not fully reflective of physical function. In addition to tracking function, improved function should coincide with efforts at vocational rehabilitation and return to work. (Kerns 1985) (See Appendix A2, Tools for Tracking Pain and Function)

If there is a discrepancy between the reported improvement in pain, the reported level of function and the described work limitations; an explanation should be provided.

- Frequency with which providers should document patients' pain and function:
  - First three months of opioid therapy following injury: **every visit**
  - One year after initiation of chronic opioid treatment: **monthly**
  - For the duration of chronic opioid treatment: **quarterly**

*Rationale:*

Most major guidelines reviewed recommend tracking the effectiveness of opioid treatment to improve pain and function. Use of validated instruments is the most consistent, scientifically reliable way to do so. Chronic opioid treatment for work-related injuries, the subject of this Guideline, aims to restore function and not just alleviate pain. If pain is

considered the primary barrier to improved function, then chronic opioid treatment should lead to meaningful functional benefit in patients. In other words, a reduction in pain should correspond to increased function. In the absence of improved function, a decrease in pain intensity is not considered clinically meaningful improvement. (See Section 3.3.7.2,

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<sup>6</sup> <http://www.sf-36.org/tools/sf12.shtml>

### Determining Clinically Meaningful Improvement)

The use of a combined brief instrument to measure both pain and pain interference with function is attractive because of the reliability and validity of several instruments, as well as their public availability, and the fact that this type of instrument would be the least burdensome and costly to administer across most practices. Extensive research shows the reliability, validity and responsiveness of these instruments to change of pain severity. (Dworkin 2008; Ostelo 2008; Von Korff 2011) The Graded Chronic Pain Scale and the PEG<sup>7</sup> three-item scale both meet these criteria. (Krebs 2009) The West Haven-Yale Multidimensional Pain Inventory (WHYMPI) also performs well to assess clinical pain. (Kerns 1985)

The American Chronic Pain Association (ACPA) Quality of Life Ability Scale combines improved function across multiple categories such as work, home, and leisure activities, but this scale has not been validated. However, some physicians find this type of inclusion of specific descriptors useful. (ACPA 2012)

#### ***3.3.7.2 Clinically Meaningful Improvement in Pain and Function***

Clinically meaningful (at least 30%) improvement in pain and function or pain interference with function during the acute/subacute pain trial periods should be documented prior to initiating chronic opioid treatment. Continuing opioid treatment in the absence of this level of functional improvement is not medically necessary care. This recommendation does not apply to catastrophically injured workers. (See Section 10, Opioid Use in Catastrophic Injuries)

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<sup>7</sup> Selected items of the PEG assess average pain intensity (P), interference with enjoyment of life (E), and interference with general activity (G).

Workers already on chronic opioid treatment may not experience a significant improvement in pain and function from one visit to the next while they are on “maintenance doses” of opioids. In these workers, worsening of pain and/or function following attempts to wean to a lower dose, rather than improved function on a maintenance dose, may be a more appropriate indicator of the effectiveness of the weaning attempt.

*Rationale:*

The existing guidelines and other evidence reviewed suggest that during chronic opioid treatment, many patients may report modest improvements in pain, but no improvement in function. Functional improvement is a basic tenet guiding the provision of care for injured workers. Clinically meaningful improvement in pain and function is a goal of opioid treatment in the worker population.

### **3.3.8 Opioid Titration and Dosing**

Opioid titration refers to dose adjustments of opioid medications as required to adequately control pain and improve function. Opioid titration requires regular assessment of the patient's pain, and (when used for work-related injuries) functional improvement, as well as the amount of medication used in a defined previous time period.

Decisions to increase opioids should be made jointly by both the provider and the patient. It is the responsibility of the provider to inform the patient that current evidence shows a dose-related increase in adverse events.

The guidelines reviewed recommend increased clinical vigilance at daily doses ranging from 120–200 mg/day MED. (APS/AAPM 2009; US VA 2010; WA AMDG 2010) However, it should be noted that all doses of opioids carry risks and that many deaths associated with opioids have occurred at much lower doses. Note that methadone requires particular attention and care in titration and dosing. (See Section 8, Methadone)

- *Dosage increases*

Providers and patients should recognize that opioid treatment, regardless of dose, carries risks. For dosages above 80 mg/day MED, providers should be increasingly vigilant, as the known risk of adverse events increases while the evidence for increased benefit remains weak. In addition to the level of pain, functional improvement, and amount of medication used in a defined previous time period, providers should document:

- A patient treatment agreement acknowledging that the patient and provider recognize the risk of adverse events is significantly higher at these doses, while the benefit based on available data is unclear. (See Section 3.3.2, Patient Treatment Agreement and Informed Consent, and Appendix B, Sample of a Written Opioid Treatment Agreement)
  - The degree of documented meaningful improvement made by the patient and associated with clear-cut participation in formal return to work activities and/or evidence of independent functioning and self-management.
- *Frequency of visits during titration to a stable dose of opioids for chronic treatment:*

- During titration, regular face-to-face visits should occur every two to four weeks, with ongoing evaluation of progress against pain and toward functional goals as well as potential side effects and adverse events.
  - More frequent follow-up visits should occur if co-existing psychiatric problems, drug-behavior problems, or medical problems are suspected, or when titrating doses above 80 mg/day MED, as the risks of adverse effects increases with increasing dose.
- *Criteria for dosage increase:*

For each opioid dose increase in patients receiving chronic opioid treatment, all of the following must be documented:

- Patient treatment agreement with informed consent regarding risk/benefit of increasing doses
- Analgesia: Assess meaningful improvement in level of pain (current, recent, trends, etc.)
- Activity: Evaluate meaningful improvement in pain interference or function using validated instruments as well as quality of life
- Adverse events: Assess whether the medication is causing severe side effects. For instance, evidence of severe constipation during the current treatment episode is a clear contraindication for increasing the opioid dose. In the event of an overdose event, the clinician should consider discontinuing opioid medication.

- Aberrant behavior: Evaluate for possible drug abuse-related behavior. No evidence should exist for a current substance use disorder. If the patient has had a history of opioid use disorder, the concurrence of an addiction specialist is required to continue opioid treatment as well as for dose escalation.
- “Analgesia”, “Activity”, “Adverse events”, and “Aberrant behavior” assessments are also known as the “four As.” (Trescott 2007) The criteria prescribed here are a modification of the original criteria, specifically targeted to the California injured worker population.

At each evaluation, patients should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible Storage and Disposal of Opioid Medications)

Due to lack of sufficient evidence demonstrating its benefits, the routine prescription of naloxone to patients on chronic opioid treatment is not recommended.

*Rationale:*

A considerable body of medical evidence links increasing doses of chronic opioid treatment with increases in overdose-related morbidity and mortality and lack of efficacy of dose escalation. (Bohnert 2011; Dunn 2010; Gomes 2011; Naliboff 2011) The recommendations above, along with the other recommendations in this Guideline, are aimed at reducing adverse events in California’s injured workers.

The best data available to date, summarized above suggest that risk of morbidity and mortality rises substantially at and above 100 mg/day MED (see Appendix E). These same studies demonstrate that the risk also rises in the dose range 50–100 mg/day MED.

(Bohnert 2011; Dunn 2010; Gomes 2011) However, none of the studies breaks down the risk within the 50–100 dose range to determine a more nuanced dose level above which risk increases. Based on a review of the best and most recently available scientific evidence to date, 80 mg/day MED has been identified in this Guideline as the dose at which increased vigilance should be exercised.

Of note, other states such as Ohio<sup>8</sup> and Connecticut<sup>9</sup> are implementing guidelines with similar “thresholds.” (SCWCC 2014; SMBO 2013)

### **3.3.9. Maintenance of Chronic Opioid Treatment**

Once a stable dose of opioid has been established (maintenance period), patients should have regular face-to-face visits at least every three months with their provider, during which treatment goals, analgesia, activity (function), adverse effects, and aberrant behaviors are monitored.

1. Injured workers who receive chronic maintenance doses of opioids, should meet the

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<sup>8</sup> See Ohio's 2013 guideline, which recommends a threshold of 80mg MED and Connecticut's 2013 guidelines, which recommend a threshold of 90mg MED: <http://www.med.ohio.gov/pdf/NEWS/Prescribing%20Opioids%20Guidlines.pdf>, <http://wcc.state.ct.us/download/acrobat/protocols.pdf>.

<sup>9</sup> See Connecticut's 2013 guideline, which recommends a threshold of 90mg: <http://wcc.state.ct.us/download/acrobat/protocols.pdf>

following criteria:

- Patient does not meet conditions for tapering. (See Section 4.1, Indications for Tapering Opioids)
  - Additional testing, including quantitative blood levels of prescribed medications and other laboratory testing, as may be deemed necessary to monitor and treat patients receiving chronic opioid treatment is considered part of a medically necessary treatment and monitoring program.
2. At each visit during the maintenance phase of chronic opioid treatment, the “four A’s” should be documented (See Section 3.3.8 above, Opioid Titration and Dosing, for additional details). (Trescott 2007) If the patient does not meet any one of the following four criteria,<sup>10</sup> then tapering should be considered. (See Section 4, Indications and Methods for Tapering Opioids)
- Analgesia: meaningful improvement in level of pain
  - Activity: meaningful improvement in pain interference or function
  - Adverse events: whether the medication is causing severe side effects.
  - Aberrant behavior: No evidence should exist for a current substance use disorder. If the patient has had a history of opioid use disorder, the concurrence of an addiction specialist is required to continue opioid treatment as well as for dose escalation.
3. For injured workers whose dose is above 80 mg/day MED, and who have been on that dose or higher for at least 180 days (6 months), clinicians should conduct semiannual attempts to wean to lower than 80 mg/day MED; referral to a pain specialist may be considered. (See Section 4.2, Methods for Tapering Opioids).

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<sup>10</sup> For definitions of these four terms, see Section 3.3.8, Recommendations: Opioid Titration and Dosing.

4. At each evaluation, patients should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible Storage and Disposal of Opioid Medications)

*Rationale:*

The continued use of chronic opioid treatment in the injured worker should meet the statutory system goals of restoring the patient to full functional status, with the overall improvement of pain, function and return to work.

**3.3.10. Treating Break-Through Pain**

Patients who are under treatment with opioids for chronic pain and experience an increase in pain, otherwise known as breakthrough pain (BTP) should undergo a comprehensive assessment for the causative factors, including undertreatment of pain, opioid hyperalgesia, new pathology, drug diversion, dependency, addiction, abuse, and misuse.

Specific treatment should be based on the results of the assessment and should include, as appropriate to the individual case, education, cognitive behavioral therapy, exercise programs, and the addition of non-opioid medications such as nonsteroidal anti-inflammatory drugs (NSAIDS), and interventional techniques.

*Rationale:*

There is significant controversy regarding the nature of BTP in chronic noncancer pain and its optimal treatment. Systematic reviews recommend evaluation of the causes of episodic pain increase and thoughtful management utilizing the principles of chronic pain management. (Manchikanti 2011c)

## **4. INDICATIONS AND METHODS FOR TAPERING OPIOIDS**

### ***4.1 1 Indications for Tapering Opioids***

Tapering, also known as weaning, refers to reducing the prescribed dose of opioids to the lowest dose effective in controlling pain and improving function. It is recommended that opioids be tapered in most cases to zero in patients who meet any of the criteria listed below. In situations where there may be clinical indications for tapering to a lower dose (and not to zero), clinical justification should be documented. Patients who have been taking over 80 mg/day MED for over 6 months and who are making their semiannual weaning attempt need only wean to below 80 mg/day MED. (See Section 3.3.9 Maintenance of Chronic Opioid Treatment)

Criteria for tapering:

- Patient expresses a desire to discontinue therapy
  
- Resolution of pain condition
  
- No documented improvement in pain and function (or patient claims a lack of effectiveness) following last increase in dose
  
- Patient is non-adherent to the treatment plan (which may become evident through urine drug screening or through consulting CURES)
  
- Illegal or dangerous activity including: diversion, prescription forgery, suicide attempt, involvement in a motor vehicle accident and/or arrest related to opioids, aggressive or threatening behavior in the clinic. surreptitious medication use, including use of non-prescribed prescription drugs
  
- Consumption of medication or substances that they have been advised not to take concomitantly (sedating medication, alcohol, benzodiazepines)
  
- Severe adverse effects or overdose events.

Opioid-naïve, acute pain patients can generally discontinue opioid treatment without the need to taper (i.e., to gradually reduce doses). Acute pain patients should discontinue use of opioids within two weeks whenever possible.

Patients being tapered off opioids should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible Storage and Disposal of Opioid Medications)

*Rationale:*

The guidelines reviewed recommend tapering opioid doses when benefit is not demonstrated or there is likelihood of harm or misuse. Tapering, rather than abrupt cessation of medication, prevents withdrawal symptoms and provides the ability to monitor progress on changing treatment regimens in patients on high doses or who have been treated for extended periods.

#### ***4.2. Methods for Tapering Opioids***

A two-step algorithm method of tapering is recommended with a separate approach for patients meeting Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria for opioid use disorder:

- Step 1: Taper in outpatient setting using 10%–25% per week taper, with or without suboxone support. These cases may require pain medicine specialty and psychological support. Clonidine or other adjunctive agents may be used to provide further support.
- Step 2: Patients who fail step one are at higher risk and should be offered an inpatient detox. ( why necessitate inpatient detoxification? We are successfully managing these patients in outpatient facilities without inpatient stay, while inpatient stay may be necessary to require this and

combine only this with additional multidisciplinary treatment is limiting the treatment unnecessarily did you consider applying the ASAM criteria? We currently operate a ASAM II-D outpatient detox followed by a 6 week Intensive Outpatient Multidisciplinary program consistent with the ASAM guidelines. While pain patients taking opioids are not necessarily addicted the arguments for supportive treatment of them in a interdisciplinary fashion is reasonable and consistent with ODG. Access to such inpatient programs is very limited and cost associated with such inpatient treatment is unnecessarily high for all but the most complicated patients. accompanied by a multidisciplinary pain program lasting up to 4 weeks. This program may occur at the same time as the inpatient detox or it may occur in an outpatient setting right after the detox. Additionally, patients who have co-existing cardio-respiratory or other co-morbid conditions that may make outpatient tapering dangerous should be tapered in an inpatient setting.

- Patients who meet the DSM-V criteria for opioid use disorder should be treated by an addiction specialist, preferably concurrently with a pain medicine specialist. Treatment may include therapy in an inpatient multidisciplinary pain program (as described in Step 2 above) or a dedicated inpatient substance abuse center. Maintenance therapy may be needed for 6 months or longer depending on circumstances. In this population, tapering down to zero may thus require several tapering periods that occur over several months.
- In no case where tapering is indicated should a provider abandon a patient. Patient abandonment is defined by the American Medical Association as “termination of a professional relationship between physician and patient at an unreasonable time and without giving the patient the chance to find an equally qualified replacement.” (Alspaugh 1967)
- Patients being tapered off opioids should be advised regarding responsible storage and disposal of opioid medications. (See Section 11, Responsible

Storage and Disposal of Opioid Medications)

*Rationale:*

While the guidelines vary in their specific tapering regimens, they consistently recommend gradual, consistent tapers over a period of weeks to months and under careful supervision.

These recommendations appear inconsistent with the well established and referenced ASAM standards. They also pose a need for inpatient services to meet those with these disorders when access to such programs has not been established. I am concerned that these guidelines will be interpreted strictly to limit the access of chronic pain patients who are taking high dose opioids and are desiring opioid detoxification but are unable to taper medications as described in step one to an inpatient course. The access to these programs poses a threat to that treatment. As UR will simply use the criteria to limit other structured programs that are consistent with ASAM criteria and since they (UR) have no obligation to offer recommendations of suitable alternative treatment the result will be an administrative barrier to medically necessary treatment.

ODG has also offer recommendations on this topic. These are offered here in part:

*Weaning, opioids (specific guidelines)*

*Recommended for selected patients. See also Weaning, scheduled medications (general guidelines). For opioid weaning in an outpatient setting (without the aid of an addiction specialist) a slow taper is generally recommended. The longer the patient has taken opioids and the higher the dose, the more difficult they are to wean, especially in the setting of psychological or addiction risks noted on screening; or use of other centrally acting agents like SSRIs. The process is more complicated with medical comorbidity, older age, female gender, higher opioid doses, and the use of multiple agents. Opioids cannot be abruptly discontinued without probable risk of withdrawal symptoms. An evaluation for use of other substances is recommended for patients on high dose opioids who appear to have substance-use pathology. (Benzon, 2005)*

*Evidence of comorbid conditions: Treatment options for patients with complex conditions with multiple comorbidities (including psychological disorders) include weaning under supervision by*

a pain medicine specialist trained to handle these problems or by an addiction medicine/psychiatry specialist.

Suggested tapering protocols in an office setting without the aid of an addiction specialist: Opioid weaning should include the following: (a) Start with a complete evaluation of treatment, comorbidity, and psychological conditions; (b) Clear written instructions should be given to the patient and family; (c) If the patient cannot tolerate the taper, refer to an expert (pain specialist, addiction medicine specialist); (d) Taper by 20 to 50% per week of original dose for patients who are not addicted and are on relatively low doses (the patient needs 80% of the previous day's dose to prevent withdrawal); (e) A slower suggested taper is 10% every 2 to 4 weeks, slowing to a reduction of 5% once a dose of 1/3 of the initial dose is reached; (f) Greater success may occur when the patient is switched to longer-acting opioids and then tapered; (g) Office visits should occur on a weekly basis or more frequently as needed; (h) Assess for withdrawal using a scale such as the Subjective Opioid Withdrawal Scale (SOWS), Objective Opioid Withdrawal Scale (OOWS), or Clinical Opiate Withdrawal Scale (COWS); & (i) Recognize that this may take months.

Methadone weaning: Weaning after long-term use of methadone may be difficult. Use of adjunct drugs may be necessary. If the primary problem appears to be addiction, this is generally best monitored under the supervision of a specialist in this field. (TIP 45, 2006) Weaning can also be undertaken by pain medicine specialists with training in this area.

Medications used to manage withdrawal from opioids: Anti-withdrawal agents can be used for brief periods, and in tapering doses, to facilitate entry into drug-free or antagonist treatment.

(1) Methadone is the most common drug used for treating withdrawal, but use is restricted by federal regulations if it is used for addiction. Management of this drug is best left to pain medicine specialists due to the complexities involving equally effective dose conversions, long half life, medication interactions and relatively higher risk of overdose death.

(2) Buprenorphine (or buprenorphine/naloxone) is an alternative to methadone. This drug can be dispensed in a physician's office although a specific training program with certification is required for use. In the induction phase the goals are to extinguish withdrawal and provide narcotic blockade. Patients are generally instructed to abstain from short-acting opioids for 24 hours and from long-acting opioids for 48-72 hours prior to the first dose. Most protocols recommend a switch from long-acting to short-acting opioids before weaning. To minimize the chances of precipitated withdrawal, induction is recommended with buprenorphine monotherapy with an eventual switch to buprenorphine/naloxone. The patient must be in the early stages of withdrawal when they start their first dose. If precipitated withdrawal occurs during induction the dose of buprenorphine can be increased (up to 24 mg) until the symptoms

decrease. If withdrawal persists, the other option is to stop the induction and address symptoms with pharmacologic management. The patient is instructed to abstain from opioids until the follow-up the next day for reassessment of induction. After a patient is stabilized buprenorphine can then be tapered (with a suggested decrease of 2 mg every 5 days). (Kraus, 2011) (TIP 40, 2004) According to this RCT, a 4-week buprenorphine taper plus naltrexone maintenance treatment may boost abstinence rates, compared to shorter tapers. 50% of patients assigned to a 4-week taper were abstinent at the end of the 12-week period compared with 17% and 21% in the 2- and 1-week groups, respectively. Each group also received behavioral therapy. (Sigmon, 2013) For suggestions for maintenance therapy see Buprenorphine for opioid dependence.

(3) Clonidine can relieve many opioid withdrawal symptoms (an off-label treatment) as long as there are no contraindications to use. Dose is generally 0.1-0.2 t.i.d. to q.i.d as long as blood pressure is over 90 mm Hg systolic and there is no sedation or bradycardia. Clonidine is often maintained for 2-3 days after cessation of opioids and tapered over 5-10 days.

Adjunct medications for specific withdrawal symptoms include the following. Insomnia and restlessness: diphenhydramamine 50 to 100 mg; trazodone 75 to 200 mg; hydroxyzine 25 to 50 mg. Headaches, muscle pain and bone pain: acetaminophen, aspirin, or ibuprofen. Abdominal cramps: dicyclomine. Diarrhea: Peptobismol. Methocarbamol is also helpful for muscle pain. (TIP 45, 2006) (Tetrault, 2009)

Methadone weaning to buprenorphine or short-acting opioids prior to complete detoxification: The proposed benefits for a switch to buprenorphine from methadone are reduced risk of overdose, less frequent dosing, office-based treatment and less risk of cardiac adverse effects. The substitution can be difficult due to the lasting effects of methadone. Current clinical practice generally recommends reducing methadone to 30 mg/day for a recommended period of 36 to 72 hours (with some authors recommending a 7-day period). The transfer to buprenorphine should occur no earlier than 24 hours after the last methadone dose. In a series of small clinical studies the transfer is feasible over a range of low to moderate methadone doses (up to 60 to 70 mg) following abrupt discontinuation or taper with a 24-hour interval between medications (preferably assisted with ancillary treatment). Need for ancillary treatment and inpatient treatment increases with higher methadone doses. (Mannelli, 2012) (TIP 40, 2004) An alternative method involves the transfer of methadone to equianalgesic doses of a shorter acting opiate such as hydromorphone and then proceeding as in induction or withdrawal of short acting opiates (see above). Allow a week of transition between long acting and short acting drugs before induction.

Use of antagonist medications such as naltrexone: Antagonist meds such as naltrexone can be used post detoxification. The transfer is considered safe for patients who are methadone-free

for 10-14 days or 5-7 days after buprenorphine discontinuation. The switch from buprenorphine to naltrexone can occur in a shorter time when patients are treated as inpatients.

Buprenorphine weaning: Buprenorphine withdrawal for chronic use can also be difficult and is best accomplished not by weaning but by dosing up abruptly to high doses for 2-3 days (24-32 mg per day) and then abruptly discontinuing the buprenorphine and treating the withdrawal symptoms.

Opioid withdrawal signs and symptoms: These will depend on daily dose, duration of use, agent used, and interval between doses. A grading system is available in terms of signs and symptoms. Early withdrawal occurs within 8-24 hours. Grade 1 withdrawal is evidenced by lacrimation, rhinorrhea, diaphoresis, yawning, restlessness and insomnia. Grade 2 withdrawal is evidenced by dilated pupils, piloerection, muscle twitching, myalgia, arthralgia and abdominal pain. Fully developed withdrawal occurs within 1-3 days after last use. Grade 3 withdrawal is evidenced by tachycardia, hypertension, tachypnea, fever, anorexia, nausea, and extreme restlessness. Grade 4 withdrawal is evidenced by diarrhea, vomiting, dehydration, hyperglycemia, hypotension, and curled-up position.

Special concerns: (1) Evidence of cardiac illness due to adverse effects of withdrawal such as hypertension and tachycardia should be an indication for increased monitoring during weaning; (2) Anxiety disorder (especially those with panic) can worsen; (3) Pain may also worsen initially.

## **5. DOCUMENTATION OF MORPHINE EQUIVALENTS**

The total opioid dose as morphine equivalent dose (MED) in mg/day should be documented at every patient visit. Online dosing calculators may be used for this purpose. (See Appendix F3, Morphine Equivalent Dose (MED) Calculation for additional information)

An opioid dosing calculator can be helpful in tracking the total morphine equivalent dose,

along with pain and function, at patient visits. (ACOEM 2011, WA 2010) Online calculators permit calculation of prescribed opioids and should **only** be used to estimate the MED/day.

They should **not** be used to convert from one opioid to another, since the conversions are complex. (See Appendix F3, Morphine Equivalent Dose (MED) Calculation)

Dosing thresholds for select opioids are presented in Appendix F1 (Dosing Thresholds for Selected Opioids) to facilitate conversion or rotation. To assure patient safety, it is recommended that the dose be reduced by 25–50% after calculating the appropriate conversion dose. As an added precaution, consultation with a practitioner with relevant knowledge and experience (such as a pain specialist) may also be considered when converting from one opioid to another.

*Rationale:*

Several guidelines recommend using a dosing calculator to document dosage as mg/ day MED at each visit and verifying through the use of CURES. This allows the primary prescriber to know the exact dosing and ascertain compliance.

## **6. PAIN MEDICINE CONSULTATION**

The prescribing provider may find it useful to obtain consultation with a pain medicine specialist either prior to escalating the dose or at any time the provider deems it necessary during chronic opioid treatment, even when all criteria have been met. The purpose of such a consultation would be to assist with the complex issues related to the care of patients at all stages of pain.

Consultation of a pain medicine specialist may be considered medically necessary in the following situations, based on clinical assessment:

- At the acute or sub-acute phase, to help assess the risk-benefit ratio of using opioids to treat the pain of high-risk patients.

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- To aid with a complex pain condition when there is a need for help with a diagnosis or verification of a diagnosis.
- At the time of initiation or trial of chronic opioid treatment.
- To assist in the management of a patient with significant co-morbidities.
- To assist with the assessment of risk-benefit ratio of chronic opioid treatment when the criteria for dose escalation are met and the prescribing provider requires additional assistance.
- When the provider suspects development of significant tolerance to opioids, particularly at higher doses.
- To assist with the assessment and/or treatment of aberrant behavior or repeated questionable urine drug screening tests.
- To assist with maintenance therapy in patients meeting DSM-V criteria for opioid use disorder.
- To assist with tapering regimens.

### *Rationale:*

Primary care physicians report greater confidence in appropriately managing complex patients and those on chronic opioid treatment when they have access to specialists with pain management expertise. (Franklin 2013)

## **7. CONCURRENT USE OF BENZODIAZEPINES AND OTHER SEDATIVE HYPNOTICS DURING CHRONIC OPIOID TREATMENT**

- Prescribers should avoid introducing concomitant central nervous system (CNS) depressants to chronic opioid treatment regimens, including benzodiazepines and non- benzodiazepine sedatives, such as carisoprodol.
- Central muscle relaxants such as baclofen or tizanidine should be prescribed with extreme caution for patients receiving chronic opioid treatment or other opioid regimens, and monitoring of side effects should be performed upon introduction of a new drug to a regimen or during periods of dose adjustment/escalation.
- Throughout the time when they are on opioids (starting with their first prescription), patients should be counseled to avoid simultaneous use of opioids with non-opioid CNS depressants, including alcohol.
- If, after careful consideration, the clinical decision is made to prescribe other sedatives or muscle relaxants to patients on chronic opioid treatment, counseling should be provided to stagger dosing to avoid excess sedation and potentially disastrous complications.

### *Rationale:*

The available body of literature demonstrates that simultaneous use of opioids and sedating medications, particularly benzodiazepines, is associated with an increased risk of fatal overdose events.

## **8. METHADONE**

The use of methadone is indicated for the following types of patients (CPSBC 2010):

- Patients who have experienced inadequate pain control on previous opioid treatment regimens with dose-limiting side effects.
  - Patients experiencing confusion, hallucinations, or delirium on previous opioid (often indicating opioid toxicity).
  - Patients intolerant to opioids.
  - Patients at high risk for adverse effects to other opioids (e.g., have had previous anaphylaxis to morphine; COPD patients with history of CO<sub>2</sub> retention).
  - Patients with opioid addiction.
- Methadone is characterized by a narrow therapeutic window with complicated and variable pharmacokinetics and pharmacodynamics and should be initiated and titrated cautiously by providers who have substantial experience with its use and risks and are prepared to conduct the necessary careful monitoring. (APS/AAPM 2009; Utah 2009)
  - Methadone is a last-line drug that should be started at low doses and titrated slowly. The recommended starting dose is indicated in Appendix F1 (Dosing Thresholds for Selected Opioids) with dose increases occurring no more frequently than weekly. In older patients or those with renal or hepatic comorbidities, less frequent dosing and more cautious dose titration are recommended. (APS/AAPM 2009)
    - Extra caution is warranted in patients at risk for prolonged QTc interval, including those with structural cardiac disease, cardiac arrhythmias, or cardiac conduction abnormalities, and in patients taking another medication associated with QTc interval prolongation. (CPSBC 2010) Clinicians should consider obtaining an electrocardiogram (ECG) to evaluate the QTc interval in patients treated with methadone, especially at higher doses (80 mg/day MED or greater).

Appendix D points out black box warnings on methadone, as well as other opioid medications.

*Rationale:*

The available literature indicates that methadone is an option when pain relief has not been obtained or intolerable side effects limit the use of other opioids. Because significant toxicity may occur with inappropriate dosing decisions, methadone should be used with caution.

## **9. MANAGING PERIOPERATIVE PAIN IN WORKERS ON CHRONIC OPIOID TREATMENT UNDERGOING ELECTIVE SURGERY**

- **Before surgery (pre-operatively), the surgeon and attending physician should:**
  - Have a coordinated treatment plan for managing surgical pain, including identifying the post-operative opioid prescriber.
  - Obtain a pre-operative anesthesia consult one to two weeks prior to surgery.
    - Obtain consultation for special anesthesia care for workers on buprenorphine at least 2 weeks before surgery.
  - Access CURES and review the worker's controlled substance history to get accurate information on opioid dose and concurrent medication use; discuss any apparent discrepancies with the worker.
  - Prepare the worker for elective surgery by setting appropriate expectations for pain management. Workers need reassurance that their pain management needs will be met, and they need to know that their opioid use is expected to return to the pre-operative dose, or less, following surgery.

- Avoid escalating opioid dose before surgery.
- Advise patient not to take any benzodiazepines or sedative-hypnotics.
  - For opioid dose and pain management, as well as the advisability of preoperative urine drug screening, consider a consult with a pain medicine specialist before surgery for workers on high-dose opioids or who have comorbid mental health or substance use disorder

Patients using opioids with an MED of >80 will often have a very unpredictable response to post operative opioids. There needs to be a contingency to allow for preoperative detoxification or medication tapering in a structured outpatient setting to avoid the predictable marked escalation in post operative opioids to manage the acute pain concerns. Failure to provide a contingency for this will risk significant opioid escalation and delays in recovery and rehabilitation that can be managed much more efficiently pre operatively. Without this contingency identified in the guidelines UR will simply refuse to authorize this valuable preoperative preparation.

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Joyce Ho, MD  
Jay Westphal, MD

April 21, 2014

The proposed opioid guidelines certainly appear to be a step into the right direction, given the worsening opioid epidemic. I have the following concerns on the proposed guidelines, however:

1. My major concern is that the recommended tools such as Graded Chronic Pain Scale and PEG are subjective and are quite simplistic for accurately identify whether a patient indeed has functional benefits with opioid use. There are more objective tests such as 6-minute walk test that are validated by research and are objective. In addition, while any functional improvement is beneficial, given the significant risk of opioid use, should a patient in his normal working age be taking opioids if it does not result in return to work, specifically if the job is non-safety sensitive?
2. For acute use, the proposed guidelines recommend opioids to be not given while the patient is at work. It may seem to be at odds with the goal of returning the patient back to work in a timely fashion, especially for the non-safety-sensitive work.
3. Even for chronic use, 90 days seem to be an excessively long time for a trial of opioid. By

that time the patient would have been dependent and would almost always have increased discomfort if opioid is stopped at that point.

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Jeremy Merz, California Chamber of Commerce  
Jason Schmelzer, California Coalition on Workers' Compensation

April 21, 2014

The following 1st Forum comments on the draft Opioid Treatment Guideline Regulations are offered on behalf of the tens of thousands of insured and self-insured public and private California employers as well as companies that provide workers' compensation insurance coverage in the state.

Our coalition is pleased to support the general direction taken in the draft regulations as an excellent starting point, and we want to acknowledge the MEEAC for their tireless efforts on the "*Guideline for the Use of Opioids to Treat Work-Related Injuries.*"

In addition we commend MEEAC for their intended use of CURES, drug testing and the other referenced tools as a positive step in the use of opioids for the treatment of workers' compensation patients with the objective that make CURES will be more easily accessible, functional and educational for the prescribing community.

We offer the following suggestions for further consideration in finalizing the proposed regulations:

Part B of the DWC Guidelines, we recommend that the word "should" be replaced with "shall." We believe "should" does not send a strong enough message to prescribers to follow guidelines before prescribing opioids and waters down their intended efficacy. The Guidelines with the "should" versus "shall", as written, do not provide sufficient guidance to UR reviewers or IMR, such that they would be able to resolve disputes and in fact may lead to more disputes over their implementation.

We would suggest adding specific language on peer-to-peer review and outreach as a precursory recommendation prior to UR and/or IMR being triggered.

We would like MEEAC to consider Closed Formulary adoption. In doing so, we believe that it is important that MEEAC provide additional guidance (guidelines) relative to "Y" drugs or drugs that are on an approved list under a Closed Formulary, in order that their implementation into the treatment of the patient provide the most effective treatment.

We would suggest that the MEEAC expand its review of evidence-based guidelines to include the latest release of ACOEM (2014) and ODG (2014) before finalizing its proposed "*Guidelines for the Use of Opioids.*" We recognize the latest release of ACOEM came out subsequent to the proposed guidelines.

We would also suggest that the MEEAC consider adoption of a single guideline in lieu of state-specific written guidelines on opioid utilization. Our concern is that these Guidelines, once written, may soon be outdated. In addition, the Guidelines continue to be very lengthy making adoption challenging across a number of spectrums. Investment in education will be paramount to ensuring all parties in the system are following the Guidelines should the MEEAC continue to write them in lieu of adopting a single guideline standard.

The committee is to be commended for its thoughtful consideration with respect to the Guidelines on the very difficult subject matter of managing injured worker's pain. Our comments should not be perceived as overshadowing the work done thus far.

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David Price, Compliance Counsel  
PRIUM

April 21, 2014

General comments

1. PRIUM applauds the DWC for its effort to produce treatment guidelines reflecting the most recent medical evidence. PRIUM recommends that the proposed Guideline be updated on at least an annual basis in order to ensure that the Guideline continually reflects the most recent scientific evidence.
2. In order to ensure that the best and most recent available scientific evidence is considered in formulating the treatment Guideline, PRIUM recommends that the DWC apply the 2014 ACOEM Opioid Treatment Guidelines and the most recent changes to the Official Disability Guidelines in a future update to the DWC Guideline.
3. The proposed Guideline makes multiple references to a recommendation that healthcare providers initiate a "trial" period of opioid use prior to initiating chronic treatment. PRIUM recommends that the Guideline be modified to clearly delineate the duration of a "trial" period. Doing so will assist utilization review agents in determining when a prescription for opioid medication should be reviewed as a "trial" prescription and when a prescription should be reviewed simply as chronic treatment (in which case, the URA should determine whether a "trial" period has occurred, as per the Guideline.) Additionally, defining "trial" periods will prevent prescribing physicians from evading compliance with the Guideline by characterizing all chronic opioid treatment as "trial" prescriptions.
4. It appears that this Guideline was developed to augment the portions of the MTUS dealing with opioid treatment/pain management. Should utilization review agents cite this Guideline, rather than the MTUS, when reviewing the medical necessity of a prescription for opioid medications?

5. PRIUM was fortunate enough to be able consult with a few attorneys and clinical personnel in developing these comments; however, certain clinical personnel were unable to review the Guideline and respond within the timeframe allotted by the DWC. PRIUM requests that, in the future, additional time be allotted for public comment in order to ensure that the public has sufficient time to develop thorough comments that may be helpful to the DWC.

### Specific comments

1. In its present version, Part B, Section 3 (p.17) states that, “if the decision is made to initiate chronic opioid therapy, the following medically indicated steps *must* (emphasis added) be taken.” The listed steps include consultation of the CURES database as described in Section 3.3.4. In Section 3.3.4, (p. 26) the third bulleted paragraph states that, if chronic opioid treatment is continued, periodic checks of the CURES database *should* be performed and that “[t]he following schedule is *recommended* (emphasis added).”

In order to ensure consistency throughout the Guideline and to emphasize the necessity of consulting the CURES database prior to initiating chronic opioid treatment and at regular intervals throughout the course of the treatment, PRIUM recommends that the third bulleted paragraph in Part B, Section 3.3.4 be amended to read:

- “If chronic opioid treatment is continued, periodic checks must be performed based upon risk of diversion, misuse, or abuse. The following schedule is required.”

In the alternative, if it is the intent of the DWC that providers only be required to check the CURES database and document when results at the initial outset of chronic opioid treatment (and not annually or quarterly thereafter), PRIUM recommends that a new bulleted paragraph be added to Section 3.3.4 containing the following language:

- “Prior to initiating opioids for chronic pain or chronic opioid treatment, providers must query the CURES database and document the results in order to ensure safe and effective opioid use.”

2. Part B, Section 3 (p. 17) states that “if the decision is made to initiate chronic opioid therapy, the following medically indicated steps *must* (emphasis added) be taken.” The third step listed (p. 18) is urine drug testing for initiation and monitoring of chronic opioid therapy, pursuant to Section 3.3.6.

Section 3.3.6, under “*Frequency of UDT*” (p. 30) states that “[u]rine drug screening *should* (emphasis added) be performed at the following phases....”

In order to ensure consistency throughout the Guideline and to emphasize the necessity of performing urine drug screening prior to initiating chronic opioid treatment and to monitor the patient’s condition over the course of the treatment, PRIUM recommends

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that the first bulleted paragraph under “*Frequency of UDT*” be amended to read as follows:

- Urine drug screening must be performed at the following phases to document absence of opioids (non-compliance), presence of unprescribed drugs (prescription drug abuse), and/or presence of illicit drugs.”
3. In Part B, Section 7 (p. 46), the Guideline warns that prescribers should avoid introducing non-benzodiazepine sedatives, such as carisoprodol; however, the list of “Drugs to Test Using UDT” in Table 1 of Section 3.3.6. (p.30) does not contain carisoprodol. PRIUM recommends that carisoprodol be added to the list in Table 1.
  4. In addition to carisoprodol, PRIUM recommends that the following items be added to the list of “Drugs to Test Using UDT” in Table 1 of Section 3.3.6:
    - 6MAM (Heroin)
    - Meperidine
    - Methamphetamine D/L Isomer
    - MDMA
    - Phencyclidine (PCP)
    - Buprenorphine
    - Tramadol
    - Pregabalin
    - Gabapentin
    - Tapentadol
    - Tricyclics (TCAs)
    - Ritalinic Acid
    - EtG/EtS (alcohol biomarker)
    - Nicotine
  5. Part B, Section 3.3.7.1 (p. 33) states that “the following outcomes *should* (emphasis added) be documented when assessing the effectiveness of chronic opioid treatment.” In order to ensure safe and effective utilization of chronic opioid treatment, PRIUM recommends that the language above be amended to state:
    - “The effectiveness of chronic opioid treatment must be evaluated regularly over the course of the treatment. The following outcomes must be documented when assessing the effectiveness of chronic opioid treatment.”
  6. Part B, Section 3.3.8 states that, based on the “best and most recently available scientific evidence,” 80mg/day MED has been identified as the dose at which increased vigilance should be exercised. The rationale explains that this number was arrived at, in part, because no available studies break down the risk within the 50-100mg dose range to determine a more nuanced dose level above which risk increases. The 2014 ACOEM Opioids Treatment Guideline currently lists 50mg/day MED as the dose at which increased vigilance should be exercised. Does the DWC plan to revise the recommended

80mg/day MED threshold contained within the Guideline based on the recommendations contained within the current ACOEM Guideline?

7. Part B, Section 3.3.9, par. 3 (p. 40) states that clinicians *should* conduct semiannual attempts to wean opioid dosage to lower than 80mg/day MED where the patient has been at a dose above that threshold for at least 180 days. PRIUM recommends that the language be amended to state:
  - “Clinicians must make regular attempts to taper or discontinue opioids. For injured workers whose dose is above 80 mg/day MED, and who have been on that dose or higher for at least 180 days (6 months), clinicians must conduct semiannual attempts to wean to lower than 80 mg/day MED.”
8. Part B, Section 3 (p. 17) states that if the decision is made to initiate chronic opioid therapy, the provider *must* “use questionnaires and other validated screening tools” as per Section 3.3.5. Section 3.3.5 (p. 27) provides that such tools *should* be used to determine whether chronic opioid treatment should be discontinued. PRIUM recommends that the language at Part B, Section 3.3.5 (p.27) be amended to state the following:
  - “Tools such as the COMM and the POMI must be used in combination with clinical assessment to assess for aberrant behavior and to determine whether chronic opioid treatment should be discontinued.”
9. Part B, Appendix D contains several black box warnings for specific dangerous opioid medications. In light of the market release of Zohydro ER, a single-entity (without acetaminophen) extended-release opioid analgesic with no diversion-prevention technology, PRIUM recommends that the Zohydro ER black box warning be added to Appendix D.

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Robert Goldberg, MD, FACOEM  
Chief Medical Officer, Senior Vice President  
Healthsystems

April 21, 2014

Healthsystems strongly supports the use of evidence based medicine and appreciates the efforts of the Division of Workers' Compensation leadership, staff and advisory committees to develop the content of these opioid guidelines as a standalone section within the MTUS. Given the guideline documentation is extensive and the short timeframe for response, Healthsystems offers these preliminary comments, and may provide supplemental comments at a later date.

First, we applaud the DWC for updating the opioid management protocols and creating a standalone section for this issue. Opioid use and misuse impacts injured workers during their recovery period and if not properly managed, sometimes well beyond. There are far reaching

consequences to opioid misuse which can stem from a lack of clinical oversight. These behaviors can have dire consequences for not only the injured worker, but their family members and employers as well.

It is clear the proposal, "Guideline for the Use of Opioids to Treat Work-Related Injuries" involved significant research and discussions by stakeholders. We support the major components of the guidance for prescribers, including patient education, screening for high risk behaviors, PDMP checks and urine drug testing to ensure patient compliance. We also support the language on the use of Methadone, but would recommend that its use be even more strongly discouraged due to the cited risks of this medication and the limited expertise in its use that exists in the medical community that typically treats injured workers. The guidelines were based upon the available information as of December 2013, however since that time there have been two important updates to ACOEM and ODG which we urge the Division to also consider prior to adoption of the new section of the MTUS. We believe that the new ACOEM Opioids Guideline should become an important updated reference for the proposed Guideline and that its findings and recommendations should be strongly considered as the Guideline is finalized. As specific examples, ACOEM has recently reduced the recommended maximum daily morphine equivalent dosage (MED) to 50mg and ODG has just recently identified Zohydro, a new drug approved by the FDA in October 2013 as "not recommended for work-related injuries" in part because it lacks an anti-abuse formulation. These are significant changes which must be considered by the Division in the adoption of this new section of the MTUS.

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Walter W. Strauser, MD

April 20, 2014

- Part B 3.3.2. Patient treatment agreement and informed consent:
  - In the text, there are multiple references to completing a "patient treatment agreement/informed consent" prior to initiating opioid therapy for chronic pain, yet informed consent for treatment is different from an opioid therapy treatment agreement. Informed consent implies talking with the patient about treatment options and educating them about the risks and potential benefits of the various options, including opioid therapy, while a treatment agreement for opioid therapy specifically delineates the parameters of treatment, such as obtaining medicines from a single physician at a single pharmacy, etc. Informed consent should be differentiated from an opioid therapy treatment agreement. For example, the American Academy of Pain Medicine has produced separate sample documents, one entitled Guidelines for Treatment with Controlled Substance Medications and the other entitled Consent for Chronic Opioid Therapy.
- Part B 3.3.3. Initiation of chronic opioid treatment:
  - "Intravenous, intramuscular, submucosal, and transdermal (except buprenorphine) administration of opioids for chronic pain are discouraged if the patient is able to tolerate oral medication." There is no submucosal delivery system. There are sublingual delivery systems for buprenorphine (e.g., Suboxone), which is

commonly used off-label as long-term opioid therapy for chronic noncancer pain. There are oral transmucosal immediate release opioids (OTIR) (e.g., Actiq, Fentora), which are now strictly regulated by the FDA and limited to the treatment of cancer pain. For years, these ultra-short acting, OTIR opioids have been used off-label for treatment of chronic noncancer pain in injured workers, even though the 2009 MTUS Chronic Pain Medical Treatment Guideline said they were “not recommended for musculoskeletal pain.”

- Part B 3.3.6 urine drug testing (UDT):
  - The recommendations for UDT to be done twice annually in patients on chronic opioid treatment and four times annually in patients taking more than 80 mg of morphine equivalent daily are not supported by scientific evidence. In patients who are low risk, it is reasonable for UDT to be done annually but not necessarily more frequently unless there is a reason for more frequent testing. There is insufficient scientific evidence to justify more than annual random testing in low-risk patients. These tests have been over utilized in injured workers, and this only encourages more frequent testing. Since these tests are imperfect and subject to false positive results, more frequent testing will do more harm than good, especially in patients at low risk for drug abuse or diversion. It will also unnecessarily increase the costs of treating patients on long-term opioid therapy, since the threshold dose of 80 mg of morphine equivalent is quite low.
  - Urine drug testing does not specifically discuss patients who test positive for marijuana. This is a controversial issue, since medicinal marijuana is recognized at a state level though not recognized at a national level. By not specifically mentioning patients who test positive for cannabis, the implication is that this should be decided on a case-by-case basis, as is currently done in community practice. If the desire is to implicate cannabis as an “illicit substance,” it should be specifically cited as an illicit substance according to the guideline.
  - If a patient tests negative for a prescribed opioid, the recommendation is to discontinue treatment with opioids. This should not necessarily occur after a single negative test, because there can be reasons for negative tests. For example, a patient may not get their medications in a timely fashion due to delays through utilization review. If a patient is off opioid therapy for several days, he can test negative, but this does not imply abuse or diversion but rather the often encountered delays in authorization for these medicines.
- Part B 3.3.7. Monitoring effectiveness of chronic opioid treatment:
  - The frequency with which providers should document pain and function is unclear. The text indicates monthly monitoring one year after initiation of chronic opioid therapy and says quarterly monitoring “for the duration of chronic opioid treatment” but does not delineate at what point the clinician can reduce the frequency from monthly to quarterly, which I would say could begin at the one year mark. This would mean that monthly monitoring should occur from three months to 12 months after initiation of long-term opioid therapy and could be quarterly thereafter, assuming the patient was sufficiently low risk to warrant quarterly monitoring.
- Part B 3.3.9. Maintenance of chronic opioid treatment:

- One of the two criteria is the following: “Additional testing, including quantitative blood levels of prescribed medications and other laboratory testing, as may be deemed necessary to monitor and treat patients receiving chronic opioid treatment is considered part of a medically necessary treatment and monitoring program.” I have never seen a recommendation endorsed in the medical literature or in major pain meetings for quantitative blood levels of prescribed medications to monitor long-term opioid therapy. There is insufficient scientific evidence to support this criterion.
- Part B 4.1. Indications for tapering opioids:
  - Criterion 3 states “no documented improvement in pain and function (or patient claims a lack of effectiveness) following last increase in dose.” This should not necessarily imply a need to taper a patient off opioid therapy but suggests a reduction in dosage to the dosage that was in place prior to the “last increase in dose.” The patient may well have been getting some improvement in activity tolerance and reduction in pain to justify continuing opioid therapy even though the most recent dosage increment did not lead to further benefits. This should be clarified.
- Part B 6. Pain medicine consultation:
  - Pain specialists should be further characterized as individuals who have demonstrated additional training and expertise in the field of pain medicine as evidenced by board certification in pain medicine through the American Board of Medical Specialties or the American Board of Pain Medicine, as both these organizations are recognized in California as certifying specialists in pain medicine. Many pain medicine specialists are certified by both organizations, since certification through the American Board of Pain Medicine is not recognized nationally by all states.
- Part B 7. Concurrent use of benzodiazepines or other sedative hypnotics during chronic opioid treatment:
  - Benzodiazepines are described as contraindicated for concurrent treatment of injured workers on opioid analgesic therapy. This contrasts with the common concurrent prescription of opioids and benzodiazepines in the community. Some individuals with chronic pain who benefit from long-term opioid therapy also suffer from chronic anxiety disorders that warrant the use of benzodiazepine therapy, even though this obviously requires closer monitoring due to the potential for adverse drug-drug interactions. These patients can safely take the medications simultaneously but do require closer monitoring. Perhaps this should be described as a relative contraindication rather than an absolute contraindication to allow the treating clinician to offer justification for those patients who might need these treatments concurrently.
- Part B 8. Methadone:
  - The use of methadone is indicated for patients who are described in one of the bullet points as “intolerant to opioids,” which should be changed to “intolerant to other opioids,” since methadone is an opioid.
  - While methadone is an option for treating patients with opioid addiction, the guideline implies that clinicians treating injured workers can prescribe methadone to treat injured workers with opioid addiction, but patients with opioid addiction

who require methadone therapy must be treated in a federally-licensed methadone program. It is against the law for a physician to prescribe methadone to an opioid addict in his or her office, though buprenorphine (e.g. Suboxone) is an option for office-based treatment of opioid addiction and can also be used in the treatment of chronic pain, since buprenorphine is an opioid that is safer than methadone.

- Part B 10. Opioid use in catastrophic injuries:
  - The rationale includes this sentence: “This need should be balanced with practices aimed at minimizing adverse effects of unmitigated long-term opioid use.” There is no explanation for the use of the word unmitigated in this instance. The word is confusing and should be deleted.

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Phil Walls, RPh, Chief Clinical & Compliance Officer  
myMatrixx

April 19, 2014

myMatrixx applauds the California Division of Workers' Compensation for proposing an Opioid Guideline that is comprehensive and addresses acute, sub-acute and chronic pain.

We particularly applaud the three main goals:

- best practices
- preventing and reducing opioid-induced long-term disability, opioid misuse and abuse and related mortality
- promoting functional restoration

myMatrixx is especially supportive of the features of the proposed Guideline that will ensure patient safety, including:

- Consulting CURES
- Requiring urine drug testing, including 4 time/year for all patients taking more than 80 mg MED equivalents per day
- Weaning regimens

myMatrixx recommends that the Division consider including the following recommendation in both the Sub-Acute and Chronic section of the Guidelines:

- Screen for risk of addiction, adverse events using validated tools
  - Drug misuse/abuse (e.g., SOAPP-R, ORT)
  - Alcohol misuse/abuse (e.g., CAGE-AID, TICS)
  - Additional psychosocial factors contributing to substance misuse/abuse (e.g., PHQ-9)

myMatrixx also recommends that prior to publishing a proposed rule update to include findings and recommendations in the most recent ACOEM and ODG guidelines.

Steven D. Feinberg, M.D., MPH, American Board of Pain Medicine

April 14, 2014

This letter is in response to your request for comments for re: Guideline for the Use of Opioids to Treat Work-Related Injuries. I will review each part separately and this document is in response to Part A. I have put my comments in **YELLOW**.

#### **PART A: EXECUTIVE SUMMARY AND INTRODUCTION**

- If opioids are prescribed, the Controlled Substance Utilization Review and Evaluation System (CURES), California's Prescription Drug Monitoring Program should be accessed.
  - CURES remains difficult to use and while there is planned funding, as yet it is not easily accessible.
- If CURES indicates the simultaneous use of other narcotic medication, opioid use may be contraindicated.
  - This is a little ambiguous and should state that if the patient does not volunteer the information and is obtaining opioids from other providers, opioids are probably contraindicated. This is stated later on the page:
    - CURES is queried and the results documented; aberrant results are a contraindication to chronic opioid treatment.
- Central nervous system depressants, including anti-histamines, benzodiazepines, and alcohol, should not be used simultaneously with opioids and should be discontinued before prescribing opioid medication.
  - This statement is frankly a little naïve as most patients on opioids are on some type of psychotropic medication for depression, anxiety or sleep. This statement should be a warning about the concomitant use of these agents but not stated in absolute terms.
- Patients should be cautioned about the potential adverse effects of opioids, including impacts on alertness. Driving and operation of heavy equipment should be discouraged while on these medications.
  - This is not practical as driving on opioids is common (including among commercial drivers) and patients should be warned but not prohibited (actually discouraged is not a good choice of words) from driving. Rather, patients should not drive at all with side-effects that impair driving.
- At the time of initial prescription, and at every visit, patients should be advised regarding responsible storage and disposal of opioid medications.
  - Add: Opioids should never be obtained from others and should never be shared with others.
- A trial is conducted prior to committing to chronic opioid treatment.
  - We never commit to chronic opioid treatment. Rather, we prescribe opioids and continually trial reducing the dosage over time rather than assuming prolonged use.

- Results of periodic urine drug testing (at point of care initially and verified by a federally certified laboratory) performed on a random basis during chronic treatment, and if the provider is concerned about misuse, abuse, or diversion
  - May be this is nitpicky, but in office POC is close to worthless.
- Clinicians may consult with or refer to a pain specialist based on clinical need
  - Actually they “should” refer to a pain specialist when a variety of yellow and red flags are raised.
- Methadone may be indicated for specific types of patients and should be initiated, titrated, and monitored cautiously by providers who have substantial experience with its use and risks.
  - I recommend adding the word “only” i.e., ...cautiously only by providers...
- Monitor for indications for discontinuing opioids (any one of the following)
  - No pain reduction or functional improvement
  - Intolerance or moderate to severe adverse effects (suggest add the word moderate)
  - Non-compliance
- Advise patients on opioids
  - Not to use Marijuana or illicit substances
- Indications to discontinue opioid treatment or reduce dose
  - Add the word “moderate to”: Severe adverse effects or overdose events. i.e., moderate to severe effects....
  - Dose above 80 mg/day MED (semiannual attempts to reduce dose): suggest need to attempt to reduce dose even if below 80 mg/day.

#### ***A5.1 Guidelines Evaluated***

- **American College of Occupational and Environmental Medicine (ACOEM)**

*ACOEM's Guidelines for the Chronic Use of Opioids.* American College of Occupational and Environmental Medicine. 2011(ACOEM 2011)

DWC should reference the latest ACOEM Opioid Guideline:

<http://www.mdguidelines.com/acoem-practice-guidelines-3/opioids-2014>

#### **Work Loss Data Institute. Official Disability Guidelines (ODG)**

ODG Evidence-Based Medical Treatment and Return-to-Work Guidelines (Official Disability Guidelines). 2013 (18th) annual edition). (ODG 2013)

ODG 2014 is out and available

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Beth Darnall, PhD, Clinical Associate Professor  
Stanford University School of Medicine

April 14, 2014

I read with interest the draft *Guideline for the Use of Opioids to Treat Work-Related Injuries*. The committee is to be commended for their hard work, attention to detail, and for producing a very well-crafted and useful document.

Undoubtedly, patient harms in CA will be mitigated with its adoption, and I expect the benefit to extend to other states as CA becomes a national leader in opioid management.

I have specific comments below and preface their introduction by stating that I do not wish these comments to overshadow my overall highly favorable opinion of this effort and the resulting DWC Guidelines.

- (1) As with most guidelines, there is an overall emphasis on screening and monitoring for misuse of opioids. There is also a good (and appropriate) emphasis on monitoring patient function. Less emphasis is placed on monitoring the factors that may maintain the need for opioids. The Guidelines are in strong support of screening for psychological factors at point of script initiation— a very good thing. Depression and anxiety should be monitored closely over time as a person's psychological status is fluid, and some fluctuation may be attributable to the medications themselves. De novo or worsening anxiety or depression may perpetuate opioid prescription. A logical time to rescreen for anxiety / depression / distress is prior to dose escalation. Pain psychology should be consulted prior to dose increases so that patients can acquire knowledge and skills to self-management factors that influence pain and the need for opioids.
- (2) Breakthrough pain is briefly reviewed but my read of the document left me unclear as the CA DWC position on the matter. I recommend taking a clear position. The term "breakthrough pain" is predicated on the assumption that one should be pain free with opioids and we know this is unrealistic, unattainable, and promotes an opioid-focused mentality. If pain *is* increasing this may be an indication that opioids are not effective for the person or the specific pain condition and should be stopped, not increased.
- (3) The authors did a nice job with reviewing the risks associated with dose stratifications based on limited data. However, it cannot be overemphasized that 80mg is not necessarily a "safe dose" and that prescribers must be hypervigilant for individual factors and co-prescriptions that can prove fatal at the 80mg opioid dose or even less than that.
- (4) Will links be made available to documents that summarize opioid risks by subpopulation, particularly the iatrogenic risks that should be monitored for at each follow up visit? It seems important to provide that information in tandem with the Guidelines.

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Gracia Goade, Medical Director, GSG Associates

April 14, 2014

Part A: There is no mention that UDT should be qualitative only not quantitative, which are much more expensive; I know that later it goes into immunoassay and chromatography, point of service, etc. but this should be spelled out in everyplace where urine drug testing is mentioned

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since, otherwise, these quotes could be used as a justification for doing more advanced (and expensive) drug screening.

There is no mention of the use of Suboxone which, although more expensive, has a better safety record than Methadone.

All of the guidelines for use of opioid medications state they should only be considered if the patient has failed non-opioid treatments, including "activity coaching" and acupuncture; it is not clear what activity coaching is and acupuncture is not recommended in ODG for several body parts including the neck; it is not recommended for carpal tunnel syndrome and only for specific diagnoses for other body parts.

Part B Page 9, number 11 and all other places where these apply: driving and operation of heavy machinery "discouraged" while on opioid medication should be changed to "should not be done at all within four to six hours of taking opioid medication and is discouraged in anyone taking opioid medication at all." I don't think "discouraged" is strong enough in someone who has recently taken opioids Page 10: Post-op considerations should not include "failure with non-opioid medications" because postoperative pain requires immediate and consistent opioid pain relief for at least twenty-four hours. The Appendix Opioid agreement, page 72, should include some ranking of the potential side effects - e.g. nausea, constipation, very common heart failure, etc. very rare since it would seem that the intent of this agreement is to inform patients not to scare them.

In general, I am skeptical about the recommendation for increased usage of urine drug screens; in our experience, these are very expensive and usually provide little in the way of useful information; they almost never impact treatment recommendations. They should be reserved for high-risk patients only.

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Linda Taylor, Vice President, Managed Care Services  
Resolution Partners Micro & Macro, LLC

April 14, 2014

I was wondering if the guidelines were going to address the effects of hyperalgesia and what treatment protocols will assist a patient in being weaned from opioids with this complicating factor.

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Jennifer Christian, MD, President, Webility Corporation

April 13, 2014

I am writing to comment on the proposed new guideline for opioid use in work-related injuries. In addition to the alternative treatments in lieu of opioids now listed in the draft guideline, I strongly believe that patients should be

- educated about the nature of chronic pain (and the impact of expectations, thoughts, feelings and beliefs on pain intensity)
- told about/shown/taught a variety of simple self-management methods they can use “on the spot” to feel better.

One BIG advantage of this type of simple and very low cost “treatment” is that it builds patient skill and confidence that they can manage their own symptoms. In my company’s **[removed by DWC]** programs, we use

- a 5 minute You-Tube video **[Link removed by DWC]** and
- a one page sheet with self-soothing techniques for starters.

In the case of work-related chronic pain, a big driver of opioid overuse is ignorance, health illiteracy, and over-reliance on the healthcare provider ---- because the patients keep coming back because they feel bad and don’t know how to care for themselves, and thus keep demanding more from doctors who don’t have much else to offer them. I am disappointed that these evidence-based techniques have not been explored in more depth in any of the major opioid treatment guidelines and that these points are not made more forcefully in your guideline. I request that they be added.

The literature has shown that “external locus of control” predicts poor outcomes in chronic conditions, and that “strong internal locus of control” predicts better ones. The literature also shows that health illiteracy worsens outcomes. Informing and educating patients and teaching them self-management skills is also a core precept of the chronic disease model – as opposed to the acute care model. Informing them about the risks and benefits of medication is not enough – they must be taught how to care for themselves. Research has also shown that information is therapeutic. Patient EDUCATION and TRAINING in self-management prepares the patient to do their part in maximizing their own functional recovery.

Here is a real life example: One of our **[Removed by DWC]** clients Eddie made a big breakthrough after he saw the You-Tube video and tried using his sheet of self-soothing suggestions. He announced that he had learned he could choose where to put his attention – and that it didn’t need to be on his pain. He commented “everyone kept asking about my pain level, and so I kept focused on it –constantly asking myself ‘how much pain am I feeling now?’ I’ve realized I don’t have to do that, I can start focusing on other things instead.” Eddie was on 300 MED of opioids (and 11 other medications of various kinds) when we started. He never wanted to be on narcotics and wanted to get off because he was deathly afraid of becoming addicted. But he felt he had no choice. After that initial “a-ha!” as Eddie gradually the skills and confidence to manage his own symptoms other ways, we started supported him in designing and conducting a patient-initiated gradual opioid withdrawal program. After he was sufficiently confident and armed with a proposed tapering design, he took it to his family doctor who was receptive, and they got started. Interestingly, the pain physician he had been seeing was not sufficiently motivated or well organized to supervise a tapering program of this kind.

Michelle Thomas

April 11, 2014

Please consider requiring a narcotics contract be signed by the patient(to include at a minimum the requirement of receiving medication prescriptions from one physician and one pharmacy only, no use of street drugs, acknowledge consent to random urine screening and that if any of the above are disregarded the physician to stop prescribing)/

Please also consider requiring the physician to attempt generics use whenever available.