



California Workers' Compensation Institute

1111 Broadway Suite 2350, Oakland, CA 94607 • Tel: (510) 251-9470 • Fax: (510) 763-1592

April 21, 2014

VIA E-MAIL – DWCRules@hq.dir.ca.gov

Maureen Gray, Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
1515 Clay Street, 18th floor
Oakland, CA 94612

**Re: 1st Forum Comment on Draft Opioid Treatment Guideline Regulations
Section 9792.24.4**

Dear Ms. Gray:

These 1st Forum comments on a draft Opioid Treatment Guideline Regulation are presented on behalf of the California Workers' Compensation Institute (CWCI) members. Institute members include insurers writing 70% of California's workers' compensation premium, and self-insured employers with \$42B of annual payroll (24% of the state's total annual self-insured payroll).

Insurer members of the Institute include ACE, AIG, Alaska National Insurance Company, AmTrust North America, Chubb Group, CNA, CompWest Insurance Company, Crum & Forster, Employers, Everest National Insurance Company, Fireman's Fund Insurance Company, The Hartford, ICW Group, Liberty Mutual Insurance, Pacific Compensation Insurance Company, Preferred Employers Group, Springfield Insurance Company, State Compensation Insurance Fund, State Farm Insurance Companies, Travelers, XL America, Zenith Insurance Company, and Zurich North America.

Self-insured employer members are Adventist Health, Agilent Technologies, Chevron Corporation, City and County of San Francisco, City of Santa Ana, City of Torrance, Contra Costa County Schools Insurance Group, Costco Wholesale, County of San Bernardino Risk Management, County of Santa Clara Risk Management, Dignity Health, Foster Farms, Grimmway Enterprises Inc., Kaiser Foundation Health Plan, Inc., Marriott International, Inc., Pacific Gas & Electric Company, Safeway, Inc., Schools Insurance Authority, Sempra Energy, Shasta County Risk Management, Southern California Edison, Sutter Health, University of California, and The Walt Disney Company.

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 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.¹ 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.²

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 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

¹ 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.

² Thumula, V. Impact of Banning Physician Dispensing of Opioids in Florida. July 2013.

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.

Thank you for the opportunity to provide written testimony. Please contact me for further clarification or if I can be of any other assistance.

Sincerely,

Brenda Ramirez
Claims and Medical Director

BR/pm

cc: Christine Baker, DIR Director
Destie Overpeck, DWC Acting Administrative Director
Dr. Rupali Das, DWC Executive Medical Director
George Parisotto, DWC Acting Chief Counsel
CWCI Claims Committee
CWCI Medical Care Committee
CWCI Legal Committee
CWCI Regular Members
CWCI Associate Members