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September 1, 2015

VIA E-MAIL to dwcrules@dir.ca.gov

Maureen Gray, Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation, Legal Unit
Post Office Box 420603
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RE: Written Testimony – MTUS Guidelines on Chronic Pain Treatment and on Opioids Treatment – Sections 9792.24.2 and 9792.24.4

Dear Ms. Gray:

This written testimony on proposed regulations concerning Guidelines on Chronic Pain Treatment and on Opioids Treatment is presented on behalf of members of the California Workers' Compensation Institute (the Institute). Institute members include insurers writing 71% of California's workers' compensation premium, and self-insured employers with $46B of annual payroll (26% of the state's total annual self-insured payroll).

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

Self-insured employer members include Adventist Health, California State University Risk Management Authority, 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 Alameda, County of San Bernardino Risk Management, County of Santa Clara, Dignity Health, Foster Farms, Grimmway Enterprises Inc., Kaiser Permanente, Marriott International, Inc., Pacific Gas & Electric Company, Safeway, Inc., Schools Insurance Authority, Sempra Energy, Shasta County Risk Management, Shasta-Trinity Schools Insurance Group; Southern California Edison, Special District Risk Management Authority, Sutter Health, University of California, and The Walt Disney Company.

Introduction
Labor Code section 4600(a) requires employers to provide medical treatment that is reasonably required to cure or relieve injured employees from the effects of their injuries. Labor Code section 4600(b) provides that medical treatment that is reasonably required to cure or relieve injured employees from the effects of their injuries means treatment that is based on the guidelines in the Medical Treatment Utilization Schedule (MTUS). Labor Code section 4604.5 requires the recommended guidelines in the MTUS to reflect practices that are evidence and scientifically based, nationally recognized, and peer reviewed; and 5307.27 requires the MTUS to address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. To meet those standards and to be effective, the Medical Treatment Utilization Schedule must provide evidence-based treatment guidelines with clear recommendations (e.g., recommended, not recommended, no recommendation) developed according to a single set of the highest quality standards and criteria.

When promulgating the use of treatment guidelines one must keep in mind that the guidelines are not used exclusively by treating physicians. Rather, the Legislature requires that the guidelines be used by injured employees and their physicians, claims examiners, utilization review physicians, IMR, employers, applicants' attorneys, defense attorneys, judges at the WCAB and the reviewing courts. Therefore, the workers' compensation community must have treatment guidelines that are as straightforward and clear as modern medical science can make them.

Under Labor Code Section 4610, utilization review physicians must determine the appropriateness of requested treatment within very tight time frames. Treatment guidelines that provide clear direction, are well supported by scientific medical evidence, and are based on graded peer reviews are essential for the utilization review system to function as intended. Conversely, a treatment guideline that is indefinite and overly conditional is in conflict with the statutory requirements and fosters confusion and disputes.

Chronic Pain Medical Treatment Guidelines

§ 9792.24.2. Chronic Pain Medical Treatment Guidelines
Recommended revisions to the proposed regulations are indicated by highlighted underscore and ~~strikeout~~. Comments and discussion are indented and identified by *italicized text*.

Recommendation

(a) The Chronic Pain Medical Treatment Guidelines ~~(May, 2009)~~ [insert effective date of regulations], consisting of two parts, are adopted and incorporated by reference into the MTUS. Part 1 is entitled Introduction. Part 2 is entitled ~~Pain Interventions and Treatments.~~ the "~~Official Disability Guidelines~~ Chronic Pain Medical Treatment Guidelines ~~(ODG) Treatment in Workers' Compensation – Pain (Chronic)~~" consisting of an edited version from the Official Disability Guidelines published on April 6, 2015, which the Division of Workers' Compensation has adapted with permission from the publisher. ~~These guidelines replace Chapter 6 of the ACOEM Practice Guidelines, 2nd Edition (2004). Where the clinical topic sections of the MTUS in the series of sections commencing with 9792.23.1 et seq., make reference to Chapter 6 or when there is a reference to the "pain chapter," or "pain assessment," the chronic pain medical treatment guidelines will apply instead of Chapter 6~~. A copy of the ~~c~~Chronic ~~p~~Pain ~~m~~Medical ~~t~~Treatment ~~g~~Guidelines may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at .

Discussion

A proper title for Part 2 is "Chronic Pain Medical Treatment Guidelines" or "Chronic Pain Guidelines" as the Division is not adopting the ODG Guidelines, but rather a modified version of those Guidelines. Naming the guidelines "Official Disability Guidelines (ODG)" causes unnecessary confusion over whether references and citations to the guidelines refer to the modified version adopted in 9792.24.2 and specified in 9792.21.1(a)(1) or to the most current version of the Official Disability Guidelines as defined in 9792.20(i) and specified in 9792.21.1(a)(2)(A). The Institute has observed this to be a problem while reviewing UR and IMR reviewer determinations, as it is often unclear whether the citations are referring to the ODG version adopted into the MTUS or the current version of ODG's guidelines.

Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines

The Institute believes the proposed revised MTUS Chronic Pain Medical Treatment Guidelines have room for improvement. It is not always clear in the guidelines what, if anything, is actually recommended, and/or under what conditions a recommendation applies. Multiple studies pertaining to a treatment procedure/modality/good are typically described in the Guideline document, and frequently the descriptions include the study recommendations, which may be at odds with one another; however often there is nothing or little to indicate an MTUS Chronic Pain Medical Treatment Guidelines recommendation. Some guideline users take the position that if a study is described in the MTUS guidelines, its recommendations are MTUS recommendations. Other guideline users take the position that such recommendations are the study's and not MTUS recommendations. It is important that the MTUS guidelines are clear. If they are not, injured employees will not be protected from deleterious and unnecessary care and will not be assured of effective care. The Institute recommends the following modifications to clarify and strengthen the proposed Guidelines, and to ensure they conform to statutory and regulatory requirements.

Summary of General Recommendations

- Ensure each procedure, modality and good has a clear recommendation ("recommended" or "not recommended")

- Insert between the two columns of the Part 2 table a Recommendations column where each procedure, modality or topic is identified as "recommended" or "not recommended" and where frequency, duration, intensity and appropriateness (conditions) may be addressed

- Retitle the last column "Supporting Medical Evidence," and in that column provide a link to each supporting study and its strength of evidence determined per section 9792.25.1, and remove irrelevant citations from the column

- Improve the formatting of the Part 2 table by providing clearer subsection headings, spacing between subsections, and by removing duplicate subheadings

- Replace verbiage that conflicts with the definition of chronic pain in section 9792.20 with verbiage that conforms to that definition

- Delete from this MTUS chapter recommendations for treatment of non-chronic pain, including recommendations for acute pain, sub-acute pain and initial treatment

- Retitle part 2 of the MTUS Chronic Pain Medical Treatment Guidelines “Chronic Pain Medical Treatment Guidelines” to avoid confusion with ODG’s own guidelines

General recommendations

Recommendation
Ensure each procedure, modality and good has a clear recommendation (“recommended” or “not recommended”).

Discussion

Regulations that say a certain action “should” occur can be ignored with impunity, leaving physicians who request or provide inappropriate treatment free to continue doing so. In the context of utilization review such regulatory language is useless because it cannot be enforced. To prevent inappropriate treatment, and assure provision of effective treatment, the terms in the 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
Insert between the two columns of the Part 2 table a Recommendations column where each procedure, modality or topic is identified as “recommended” or “not recommended” and where frequency, duration, intensity and appropriateness (conditions) may be addressed.

Discussion

Adding a column that will clearly indicate the recommendation status will ensure that injured employees receive effective and timely medical care, and are protected from untimely, harmful and unnecessary care. It will also add certainty and reduce the confusion that generates so many disputes, delays and attendant administrative and financial burdens.

Recommendation
Retitle the last column “Supporting Medical Evidence,” and provide there a link to each supporting study and any description or other related information, add the strength of evidence for each supporting study as determined per section 9792.25.1, and remove irrelevant citations from the column.

Discussion

Separating supporting studies and information from the MTUS recommendation will improve the quality of medical care for injured employees and add clarity as described in the preceding recommendation.

Adding the strength of evidence rating will conform to the standards and methodology in section 9792.25.1 for evaluating the quality of the evidence supporting the recommendations. It is necessary to indicate the strength of evidence/consensus pursuant to section 9792.25.1 for each so that the strength of alternative evidence can be properly compared. This is necessary when a physician challenges the presumption of correctness pursuant to sections 9792.21(d)(2) and 9792.21.1(a)(2)(C), and when reviewing physicians must determine the level of the evidence cited by the physician pursuant to section 9792.25.1(a)(4) and compare it with the level of the evidence that underlies the MTUS recommendation.

If the quality and strength of evidence/consensus pursuant to section 9792.25.1 is not provided for each recommendation, both the UR and IMR physicians must identify and assess the underlying medical evidence pursuant to 9792.25.1(a)(4), creating an unnecessary additional burden and uncertainty.

Some citations that appear in the guidelines table are irrelevant and unnecessary. These should be removed, as they do not appear to relate to a recommendation and/or do not appear to assist a physician in determining the most appropriate course of treatment.

Recommendation
Improve the formatting of the Part 2 table with clearer subsection headings, spacing between subsections, and by removing duplicate subheadings.

Discussion
Much of the material runs together and could be made more user friendly with formatting changes such as additional spacing. Some sections that address specific procedures, modalities or goods include duplicate headings where only a single heading is necessary ("Dosing" headings are an example).

Recommendation
Replace verbiage that conflicts with the definition of chronic pain in section 9792.20 with verbiage that conforms to that definition

Discussion
According to section 9792.20, as used in Article 5.5.2 of the regulations, chronic pain means pain lasting three or more months from the initial onset of pain. If the language is not revised, there will be confusion and disputes over whether or not the pain is chronic and which guideline section is applicable.

Recommendation
Delete from this MTUS chapter recommendations for treatment of non-chronic pain, including recommendations for acute pain, sub-acute pain and initial treatment

Discussion
These chronic pain medical treatment guidelines do not apply when pain is not chronic, therefore these guidelines may not address non-chronic pain (pain of less than three month's duration, which would include acute pain, sub-acute pain and initial treatment. Acute pain, sub-acute pain and initial treatment are addressed in the other MTUS sections. If recommendations for non-chronic pain are not deleted, this will also result in confusion and disputes over whether or not the pain is chronic, and which guideline section is applicable.

Recommendation
Retitle part 2 of the MTUS Chronic Pain Medical Treatment Guidelines "Chronic Pain Medical Treatment Guidelines" to avoid confusion with ODG's own guidelines

Discussion

As also addressed in the Institute's section 9792.24.2 comments, the Division is not adopting the ODG Guidelines, but rather a modified version of those Guidelines. Naming the guidelines "Official Disability Guidelines (ODG)" causes unnecessary confusion over whether the references and citations refer to the modified version adopted in 9792.24.2 and specified in 9792.21.1(a)(1) or to the most current version of the Official Disability Guidelines as defined in 9792.20(i) and specified in 9792.21.1(a)(2)(A). The Institute has observed this to be a problem while reviewing UR and IMR reviewer determinations, where it is often unclear whether the ODG version adopted into the MTUS or the current version of ODG's guidelines is being cited,.

Specific Recommendations to Chronic Pain Medical Treatment Guidelines
Recommended revisions to Part 1, and sample revisions to the proposed guidelines in Part 2, are indicated by highlighted underscore and ~~strikeout~~ in the excerpts from the Chronic Pain Medical Treatment Guidelines document submitted with this testimony. Comments and discussion are indented and identified by *italicized text* and highlighted *italicized text*. *Samples of text recommended for transfer into a "Recommendation" column in the Part 2 table are indicated by colored* text *and highlighted colored* text.

Also note specific recommendations on pages numbered 48, 52 and 54 under the Chronic Pain/Functional Restoration Program heading that are recommended to clarify and strengthen criteria for outpatient and inpatient pain rehabilitation programs.

Opioids Treatment Guidelines

§ 9792.24.4. Opioids Treatment Guidelines

Recommendation
(b) The Opioids Treatment Guidelines describe the appropriate use of opioid medications during all treatment, including treatment as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain. These guidelines apply when alternative therapies do not provide adequate pain relief and the use of opioid medications is being considered as part of the treatment regimen.

Discussion

The modification recommended will clarify that the Opioid Treatment Guidelines are not limited to treatment provided as a part of a multidisciplinary treatment regimen, but are applicable in all treatment regimens, including when treatment is provided by a single physician in a single discipline.

Summary of Recommendations
The Institute recognizes that the Division has invested many hours and resources drafting its own separate opioids guideline. The guideline is good, but in many respects, the ACOEM V.3 Opioid Treatment Guideline (2014) is better than the proposed Opioids Treatment Guideline and the other guidelines reviewed. Therefore, the Institute urges the Administrative Director to consider adopting it. If the Administrative Director decides not to do so, the Institute recommends the following modifications to strengthen the proposed Guideline:

- 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 the results of the inquiry in the patient's records
- Specify "recommended" or "not recommended" and the strength of evidence/consensus for each recommendation.

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

Discussion

Labor Code section 4604.5 requires that the recommended guidelines in the MTUS reflect practices that are evidence and scientifically based, nationally recognized, and peer reviewed. The proposed MTUS Opioids Treatment Guideline, however, is based on recommendations found to be in common among other existing guidelines rather than being a guideline that is based directly on the best scientifically based, nationally recognized, and peer reviewed current medical evidence.

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

The ACOEM V.3 Opioid Treatment Guideline (2014) was released in February, 2014 and is the most current opioid treatment guideline available. 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 proposed guideline.

Recommendation
If the Administrative Director does not consider adopting the ACOEM V.3 Opioid Treatment Guideline (2014), in each instance where guideline recommendations are not in agreement, the Institute recommends that the Division review the medical evidence, and adopt in its guideline the recommendation that is based on the best available medical evidence. The following specific revisions are particularly recommended:

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 proposed 80 mg per day MED standard with the 50 mg per day MED standard.

Discussion
According to the available medical evidence, the death rate (hazard ratio) accelerates for morphine equivalent doses (MEDs) above 50 mg per day, as demonstrated in the three studies cited in Appendix E of Part 1 and Supplement 1 of Part 2, and clearly illustrated in Figure 2 of the section on Acute Pain (page 20) in the ACOEM V.3 Opioid Treatment Guideline (2014). Even though other guidelines, including the Medical Board of California's guideline, recommend higher daily MED limits, the medical evidence supports a 50 mg MED per day standard. Labor Code section 4604.5 requires the recommended guidelines in the MTUS to reflect practices that are evidence and scientifically based, nationally recognized, and peer reviewed, therefore the Institute believes the 50 mg MED per day standard is the correct standard for the MTUS.

A3.9 of Part 1, on page 17 states that where common recommendations across guidelines were lacking (the case here) recommendations in high-level studies were to be adopted, or else the recommendations of a major guideline were to be adopted, even if other guidelines did not replicate them, provided they aligned with the goals and objectives of the Opioids Treatment Guideline. The ACOEM recommendation for a 50 mg MED per day standard aligns more strongly with those goals and objectives than does an 80 mg MED per day standard, and particularly so with the first two:

- *To prevent and reduce opioid-related long-term disability, morbidity, mortality, and substance misuse and abuse*
- *To provide a set of best practices and universal precautions for safe and effective prescribing of opioids for acute, subacute, and chronic pain.*

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%. Merely discouraging injured employees from operating heavy equipment and driving while on these medications is inadequate and dangerous, not only for these injured employees, but for others around them as well.

Recommendation
Consider prohibiting the dispensing of opioids to injured employees from physician offices and clinics.

Discussion

In 2007, the DWC curtailed differential pricing for repackaged drugs 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. Physicians can reduce the epidemic of opioid overdoses and diversions by confirming through CURES that patients are not illegitimately 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. Suggesting they do so is helpful, but is not as effective as requiring them to do so.

Recommendation
Specify "recommended" or "not recommended" and the strength of evidence/consensus for each recommendation.

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[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. WCRI, July 2013.

Discussion

It is necessary to indicate the recommendation status as well as the quality and strength of evidence/consensus pursuant to section 9792.25.1 for each recommendation, so that the strength of alternative evidence can be properly compared. This is necessary when a physician challenges the presumption of correctness pursuant to sections 9792.21(d)(2) and 9792.21.1(a)(2)(C), and when reviewing physicians must determine the level of the evidence cited by the physician pursuant to section 9792.25.1(a)(4) and compare it to the level of evidence that underlies the MTUS recommendation.

If the recommendation status and the quality and strength of evidence/consensus pursuant to section 9792.25.1 is not provided for each recommendation, both the UR and IMR physicians must identify and assess the underlying medical evidence pursuant to 9792.25.1(a)(4), creating an unnecessary additional burden and uncertainty. Since the proposed Opioids Treatment Guidelines adopt recommendations that are found to be in common among other existing guidelines, reviewing physicians may have to identify the underlying medical evidence for the recommendation in each of these existing guidelines and assess the quality and strength of every one; a daunting, time consuming and perhaps impossible task that may well result in differing conclusions and therefore uncertainty.

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 considering these recommendations and comments. Please contact me if additional clarification would be helpful.

Sincerely,

Brenda Ramirez
Claims & Medical Director

BR/pm

cc: Christine Baker, DIR Director
Destie Overpeck, DWC Administrative Director
Dr. Rupali Das, DWC Executive Medical Director
John Cortes, DWC Attorney
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