

California Workers' Compensation Institute

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December 9, 2014

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 San Francisco, CA 94142

RE: 2nd 15-Day Comments – Medical Treatment Utilization Schedule (MTUS)

Dear Ms. Gray:

These comments on additional modifications to proposed revisions to the Medical Treatment Utilization Schedule (MTUS) regulations are 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, 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 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, Sutter Health, University of California, and The Walt Disney Company.

Recommended revisions to the modified proposed Medical Treatment Utilization (MTUS) regulations are indicated by <u>underscore</u> and <u>strikeout</u>. Comments and discussion by the Institute are indented and identified by <u>italicized text</u>.

Introduction

The Institute is very appreciative of the revisions and clarifications incorporated by the administrative director (AD) in the current proposed regulations. These changes are clearly aimed at creating a more efficient and effective process for identifying and providing proven, high-quality medical care to injured workers as promptly as possible. As noted, the medical treatment guidelines will be used not just by treating physicians, but by the entire workers compensation community to determine the best medical care available. The revisions to the proposed regulations are very helpful for all those individuals using the MTUS.

The Statutory Mandate

The statutory scheme adopted by the Legislature in 2004 made fundamental changes to the provision of medical care to injured employees. Amendments to the Labor Code in sections 4600, 4604.5 and 5307.27 defined the employer's liability to provide all medical care "reasonably required to cure or relieve the injured worker from the effects of his or her injury." Section 4600 now states:

(b) As used in this division and notwithstanding any other provision of law, medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury *means* treatment that is based upon the guidelines adopted by the administrative director pursuant to Section 5307.27. (Emphasis added)

Section 5307.27, defines medical care as follows:

On or before December 1, 2004, the administrative director shall adopt ... a medical treatment utilization schedule, that shall incorporate *the evidence-based, peer-reviewed, nationally recognized standards of care* recommended by the commission pursuant to Section 77.5, and that shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. (Emphasis added)

Section 4604.5 specifies:

The recommended guidelines set forth in the schedule adopted pursuant to subdivision (a) shall reflect practices that are **evidence and scientifically based, nationally recognized, and peer reviewed**. (Emphasis added)

The Supreme Court affirmed that determination in <u>SCIF v WCAB</u> (Sandhagen) (2008) 73 CCC 981, stating, in essence, that reasonable and necessary medical care under section 4600 is treatment provided in accordance with the medical treatment utilization schedule (MTUS). To the extent that the proposed Medical Utilization Treatment Schedule (MTUS) regulations include references to "best available research evidence with clinical expertise and patient values," they violate the statutory mandate established by the Legislature.

Value Assessment

The decision to approve a treatment or diagnostic test should not be based solely on whether there is evidence to support that request, as cost effectiveness is also an important component of the analysis. Incorporation of cost effectiveness has been the standard practice for groups such as the US Preventative Services Task Force. Cost-effectiveness analysis includes not only the expected benefits and harms, but also the costs of alternative strategies.

The American College of Cardiology and the American Heart Association announced in March 2014 that they will begin to include value assessments when developing guidelines. A study published in JAMA Internal Medicine (2013: 173(12):1091-1097) showed that when formulating

clinical guidance documents, 57% of physician societies explicitly integrated cost, 13% implicitly considered costs, and only 10% intentionally excluded costs.

Considering the cost of the therapy and approving a less expensive but equally effective treatment will help address and manage the rising costs of medical treatment. This has essentially been done with respect to brand versus generic drugs, and that concept should be expanded to all treatment requests. If a requesting provider believes a more expensive treatment will offer benefits not provided by a less expensive efficacious treatment, he or she can document why the more expensive treatment is needed at the time of request.

A treatment guideline that fails to include an assessment of cost vs benefit will unnecessarily increase expenses in the system.

Specific Recommendations

§ 9792.20(d) Medical Treatment Utilization Schedule -- Definitions § 9792.21(b) Medical Treatment Utilization

Recommendation

"Evidence-Based Medicine (EBM)" means a systematic approach to making clinical decisions which allows the integration of based on the best available research evidence with clinical expertise and patient values.

Discussion

The administrative director has not eliminated the use of clinical expertise and patient values, even though there is no definition of these factors in the proposed regulations and no possible useful definition in any scientific literature. These subjective assessments are diametrically opposed to the statutory standards and the specific declaration within the proposed regulations that the MTUS is based on the principals of evidence-based medicine. Evidence-based medicine does not merely allow the integration of the best available research evidence, it requires it.

The proposed regulations are replete with requirements to ascertain the strongest medical evidence that the proposed treatment is based on scientific medical evidence. Including the terms "clinical expertise and patient values" contradicts the language in section 9792.21(b) which states: "EBM is a method of improving the quality of care by encouraging practices that work, and discouraging those that are ineffective or harmful. EBM asserts that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for making clinical decisions." The AD has defined scientifically based and the strength of evidence in terms of a body of scientific medical literature used to support the recommended treatment. Clinical expertise and patient values are contrary to these statutory standards and cannot be imposed by regulation. Mendoza v WCAB (2010) En Banc Opinion 75 CCC 634.

Because the treatment schedule is used by injured workers, treating physicians, claims administrators, utilization review physicians, IMR, employers, applicants' attorneys, defense attorneys, judges, the WCAB and the reviewing courts, the treatment guidelines must be as straightforward as modern medical science can make them. 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 schedule that allows "clinical expertise and patient values" to influence the evaluation of treatment is in conflict with what the Legislature provided by statute. The Institute recommends eliminating these subjective, unscientific elements.

The Institute strongly supports the additional revisions and clarifications to § 9792.21.

§ 9792.20 Medical Treatment Utilization Schedule -- Definitions

Recommendation

(eb) "Chronic pain" means any pain lasting three or more months from the initial onset of pain of more than 3 month's duration from the initial onset that persists beyond the expected date of healing.

Discussion

During the course of the development of these regulations, the division and the community have debated the pros and cons of a definition based on a 3 month duration or pain beyond the expected period for healing. The definition of chronic pain must match the medical evidence. Most medical research (on which guidelines for chronic pain must be based), use a three month duration to define chronic pain. But some guidelines use the latter definition and both definitions have advantages and deficits.

The use of a specific period of time will eliminate potential litigation over what constitutes "the anticipated time of healing." Including the expected period for healing as a modifier of the 3 month standard will clarify that chronic pain extends beyond what the medical evidence suggests. Pain that exists beyond 3 months but within the expected period for healing would not be considered 'chronic pain' under this definition.

§ 9792.21.1 Medical Evidence Search Sequence

Recommendation

(b)(1)(A) may shall provide in the Request for Authorization (RFA) ...

Discussion

The Institute strongly supports subdivision (b)(1) as modified except that if the treating physician believes the medical condition or injury is not addressed by the MTUS, the Institute recommends requiring in (b)(1)(A) that the treating physician provide the citation to the other guideline or study containing the recommendation he or she believes establishes the reasonableness and necessity of the requested treatment.

Recommendation

(d)(1)(A) Indicate the <u>current version of the</u> MTUS is being cited and the effective year of the guideline;

Discussion

This clarification is necessary because it is not necessary to cite the effective year of a recommendation or set of recommendations as long as they are included in the currently adopted MTUS. The Institute believes the most current version of the MTUS should always apply when determining the most appropriate treatment.

Recommendation

(e) Eliminate this subdivision.

Discussion

Subdivision (e) is unnecessary. If the Division believes exception language should remain, the language must be modified to allow not only for approving medical treatment beyond what is covered in the MTUS, but also for not allowing medical treatment that is covered in the MTUS to account for medical circumstances warranting an exception.

The language contradicts language in other sections, is confusing, may be misunderstood and will likely result in unintended consequences. For example, disputes may arise over whether an insured employer may override the claims administrator or its utilization review decision. Removing the language will eliminate this problem and allow exceptions to continue unfettered where warranted by the medical circumstances.

§ 9792.23(b) Clinical Topics

The Institute strongly supports the proposed general approach taken in section 9792.23 to identify the most effective medical treatment. Specific recommendations are offered to improve its execution and results.

Recommendation

(b) For all conditions or injuries not addressed in the MTUS, the authorized treatment and diagnostic services in the initial management and subsequent treatment for presenting complaints shall be in accordance with other scientifically and evidence-based medical treatment guidelines that are nationally recognized generally by the national medical community pursuant to section 9792.21(d)(1-2).

Discussion

The recommended language change more closely conforms to the language and its meaning in Labor Code section 4604.5(d) which states:

"For all injuries not covered by the official utilization schedule adopted pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence-based medical treatment guidelines that are recognized generally by the national medical community and scientifically based."

As in the Labor Code section 4604.5(d) language, it will be clear under the recommended language that national standards prevail, and not local "community standards" that differ from generally accepted national standards or that are accepted only by a minority in the national medical community.

The recommended change to the section number corrects what appears to be an inadvertent typographical error, as it is section 9792.21(d)(2) that pertains to treatment quidelines other than the MTUS.

§ 9792.25.1 MTUS Methodology for Evaluating Medical Evidence

Recommendation

(a) When necessary to To evaluate the quality and strength of evidence used to support a contested_recommendation pursuant to section 9792.21.1, treating physicians,

Utilization Review and Independent Medical Review physicians shall apply the MTUS Methodology for Evaluating Medical Evidence.

Discussion

The recommended change clarifies that it is only necessary for physicians and reviewers to evaluate the quality and strength of evidence when section 9792.21.1 indicates that it is necessary to do so. This is a clarification that may eliminate unnecessary disputes over when medical reviewers must evaluate the quality and strength of evidence of recommendations.

§ 9792.25.1(b)

Recommendation

While the Institute strongly supports the proposed general approach to determining the quality and strength of evidence, the Institute suggests retaining the existing methodology for determining the strength of evidence. The ACOEM Treatment Guidelines underlie the bulk of the MTUS and ACOEM provides a strength-of-evidence rating for each of its individual recommendations. If ACOEM's strength-of-evidence standards are retained in the regulations, physicians and reviewers need only compare the strength of evidence supporting non-ACOEM recommendations. This will significantly reduce the number of disagreements and the time and resources needed to identify recommendations supported by the strongest evidence. If the Administrative Director decides not to retain the current methodology, the Institute recommends instead that the MTUS include the strength of evidence underlying each recommendation in the MTUS as evaluated under the new methodology.

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 Acting Administrative Director
Dr. Rupali Das, DWC Executive Medical Director
John Cortes, DWC Attorney
CWCI Claims Committee
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