



California Workers' Compensation Institute
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August 30, 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: 1st 15-Day Comments – Medical Treatment Utilization Schedule (MTUS)

Dear Ms. Gray:

These comments on 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 underline and ~~strikeout~~. Comments and discussion by the Institute are indented and identified by *italicized text*.

Introduction

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 SCIF v WCAB (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.

Hierarchy of Scientific Medical Evidence

We are concerned that the proposed revisions to the MTUS regulations do not establish, strengthen, and facilitate the standard of medical care established by the Legislature with the adoption of evidence-based medicine. "Hierarchy of evidence" should be strengthened in order to more clearly establish the relative weight to be given to peer-reviewed and nationally recognized scientific medical evidence, and the strength of evidence should be noted with each recommendation in the MTUS.

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.

Summary of Primary Recommendations

- Make a literature search optional for treating physicians and utilization reviewers
- Retain the current methodology for criteria and the hierarchy of evidence
- If AGREE II protocols are adopted, limit required use to the MEEAC and IMR
- Specify that when the MTUS presumption is successfully rebutted, medical care shall be in accordance with other evidence-based medical treatment guidelines that are nationally recognized and scientifically based as required under LC section 4604.5(d)
- Note the strength of evidence for each recommendation in the MTUS
- Incorporate principles of value assessment and comparative effectiveness into the MTUS

Specific Recommendations

§ 9792.20. Medical Treatment Utilization Schedule -- Definitions

Recommendation

(d) "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. Section 5703.27 requires the adoption of a treatment schedule that shall incorporate evidence-based, peer-reviewed, nationally recognized standards of care. 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(c) 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 not reflected in the statute and cannot be imposed by regulation. Mendoza v WCAB (2010) En Banc Opinion 75 CCC 634.

The MTUS has to be definitive in order to establish useful, clear, and scientific treatment guidelines as the statutes direct. The treatment schedule is not used exclusively by treating physicians. Rather, the Legislature requires that the treatment schedule be used by injured workers and physicians who treat them, claims administrators, utilization review physicians, IMR, employers, applicants’ attorneys, defense attorneys, judges and the WCAB and the reviewing courts.

Therefore, the workers compensation community must have a treatment schedule that is as straightforward as modern medical science can make it. Section 4610 charges utilization review physicians with the obligation to 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 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 Legislature not only defined the elements of the treatment schedule, it also provided that the guidelines set forth in the schedule “shall be presumptively correct on the issue of extent and scope of medical treatment” (section 4604.5). This statutory presumption provides additional legal authority and is intended to limit disputes over which course of care is medically appropriate. When disputes have to be resolved, the WCALJ should be able to rely on the clarity of the recommendations, the weight of the supporting medical evidence, and the strength of evidence within the MTUS. Similarly, when the WCAB is required to determine disputed medical care, the MTUS and the presumption will direct that decision to the extent the scientific evidence allows. “Clinical expertise and patient values” are not scientific medical evidence. The inclusion of “clinical expertise and patient values” will only create ambiguity and confusion, when the statutory standard is evidence-based, peer-reviewed, nationally recognized standards of care.

The Institute recommends eliminating the subjective, unscientific elements. Alternatively the Institute suggests using the definition of Evidence-Based Medicine (EBM) that the Institute of Medicine (IOM) adopted in 2009:

“EBM is the framework for methodologically analyzing best evidence so that the care provided to each patient delivers the most value. The benefits of EBM will be to reduce discrepancies in care of patients and improve value of the healthcare delivered. (IOM, Evidence-Based Medicine, 2009.)”

§ 9792.21. Medical Treatment Utilization Schedule; Medical Literature Search Sequence

Recommendation

(e) When the MTUS's presumption of correctness is ~~challenged successfully rebutted by a preponderance of the scientific medical evidence~~ pursuant to Labor Code section 4604.5 ~~or when there is a topical gap and a medical treatment or a diagnostic test is not addressed by the recommended guidelines set forth in the MTUS,~~ medical care shall be in accordance with ~~other scientifically- and evidence-based nationally recognized medical treatment guidelines the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed published studies that are nationally recognized by the medical community.~~

Discussion

4600(b) says "...notwithstanding any other 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) and Labor Code section 4604.5 says the guidelines "shall constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions."

The MTUS is presumptively correct unless the injury is not covered by the MTUS. The presumption of correctness of the MTUS stands until it is successfully rebutted, not just until it is challenged or when there is a "topical gap" and a medical treatment or a diagnostic test is not addressed by the recommended guidelines set forth in the MTUS. Labor Code 4604.5 states that the "presumption may be rebutted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of this or her injury," and as the presumption is "one affecting the burden of proof," the guidelines must be proved to be incorrect.

If the presumption is successfully rebutted by a preponderance of the scientific medical evidence, the MTUS does not apply. Labor Code section 4604.5(d) specifies that authorized medical care for injuries not covered by the MTUS must be in accordance with other evidence-based medical treatment guidelines that are nationally recognized and scientifically based.

Recommendation

(f) To find the best available medical evidence requires a search of the large body of medical literature. Conducting a comprehensive medical literature search is resource-intensive. Therefore, in the interest of efficiency and consistency, the medical literature search sequence set forth in subdivision 9792.21(g) shall be sufficient and applies to the following physicians:

(1) Treating physicians may apply the medical literature search sequence set forth in subdivision 9792.21(g) to find a recommendation that supports their Request for Authorization;

(2) Utilization Review physicians ~~shall~~ *may* apply the medical literature search sequence set forth in subdivision 9792.21(g) if the requesting treating physician cited a recommendation in the chart notes or Request for Authorization and the requested treatment or diagnostic service is being denied;

(3) Independent Medical Review physicians shall apply the medical literature search sequence set forth in subdivision 9792.21(g) to determine whether the presumption of correctness of the MTUS was successfully rebutted and if so to ensure that medical care is in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed studies that are nationally recognized by the medical community other scientifically- and evidence-based nationally recognized medical treatment guidelines.

Discussion

The Institute strongly recommends replacing “shall” with “may” in (2) so it is clear that a literature search is optional. There is no statutory basis or necessity for requiring the utilization reviewer to conduct a literature search, although he or she may choose to do so. It is inappropriate to require Utilization Review physicians to perform medical literature searches. Literature searches are time consuming and cannot reasonably be accomplished within the very tight UR timelines. To require UR physicians to perform literature searches whenever treating physicians cite recommendations that may be unsupported by the MTUS in chart notes or RFAs, is totally unreasonable. If this proposed requirement is retained, it will significantly increase the cost of utilization review, add fertile grounds for yet more disputes and more unnecessary expedited hearings, and result in ineffective or deleterious medical care and unnecessary treatment delays for injured employees. Intended or not, this will further undermine the legislative intent for effective, timely Utilization Review.

The Independent Medical Review physician must determine whether the presumption of correctness of the MTUS has been successfully rebutted. If the presumption is successfully rebutted by a preponderance of the scientific medical evidence, the MTUS does not apply. Labor Code section 4604.5(d) specifies that authorized medical care for injuries not covered by the MTUS must be in accordance with other evidence-based medical treatment guidelines that are nationally recognized and scientifically based.

See additional detail in comments on (e).

Recommendation

(g) Medical literature search sequence to find the best available medical evidence:

(1) Search the most current version of ACOEM or ODG to find a recommendation applicable to the injured worker’s specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. If the current version of ACOEM or ODG is more than five years old, or if no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then

(2) Search the most current version of other evidence-based medical treatment guidelines that are recognized by the national medical community and are scientifically based to find a recommendation applicable to the injured worker’s specific medical condition. ~~Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1.~~ Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: www.guideline.gov/.

If the current version of the medical treatment guideline is more than five years old, or if no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then

(3) Search for current studies, that are scientifically based, peer-reviewed, and published in journals that are nationally recognized by the medical community to ~~find~~ determine whether a preponderance of scientific medical evidence rebuts the MTUS's presumption of correctness ~~recommendation applicable to the injured worker's specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1.~~—A search for peer-reviewed published studies may be conducted by accessing the U.S. National Library of Medicine's database of biomedical citations and abstracts that is searchable at the following website: www.ncbi.nlm.nih.gov/pubmed. Other searchable databases may also be used.

Discussion

As discussed in (f) and (e), it is inappropriate to require medical reviewers to do a literature search. It is even less appropriate to require medical reviewers to identify the recommendations in guidelines, journals or studies that are supported by the highest level of evidence according to the strength of evidence methodology in 9792.25.1, which is per the AGREE II methodology. AGREE II is a tool designed primarily designed for use by guideline developers and requires extensive training and time to properly apply. It is impossible to correctly assess levels of evidence within the current UR timeframes and budgets. The Institute strongly recommends the deletions indicated, or alternatively this modification in (2):

The independent medical reviewer shall determine ~~Choose~~ the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1.

and this modification in (3):

The Independent Medical Reviewer shall ~~Choose the recommendation that is supported with the highest level of evidence according to~~ determine the strength of evidence according to the methodology set forth in section 9792.25.1.

The MTUS is presumptively correct unless the injury is not covered by the MTUS. The presumption of correctness of the MTUS stands until it is successfully rebutted, not just until it is challenged or when there is a "topical gap" and a medical treatment or a diagnostic test is not addressed by the recommended guidelines set forth in the MTUS. Labor Code 4604.5 states that the "presumption may be rebutted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of this or her injury."

Recommendation

(h) After applying the medical literature search sequence set forth in section 9792.21(g), ~~Utilization Review decisions and~~ Independent Medical Review decisions shall contain the citation of the medical treatment guideline recommendation, or peer-reviewed published study ~~yes with the recommendation supported~~ with the highest level of evidence. Treating physicians and utilization reviewers may cite the supporting medical treatment guideline or peer-reviewed published study ~~that contains the recommendation supported with the highest level of evidence in the chart notes or Request for Authorization, particularly if barriers to getting authorization are anticipated.~~

(1) The citation shall include, at a minimum, information that clearly identifies the source of the recommendation.

Discussion

As discussed in (f), (e) and (g), it is inappropriate to require medical utilization reviewers to do a literature search or to identify the recommendations in guidelines, journals or studies that are supported by the highest level of evidence according to the strength of evidence AGREE II methodology in 9792.25.1. AGREE II was not designed for utilization review as it requires extensive training and is time prohibitive to properly apply, especially within the brief UR timeframes.

If the requirement remains as currently proposed, it will become another fertile field for disputes and allegations of procedural defects fueling the jurisdictional battle between the WCAB and UR/IMR. Applicant's attorneys will argue over whether or not literature searches and strength of evidence analyses were required, and whether they were properly, completely, and timely performed. Under Dubon, any of these issues will shift the case from a prompt evaluation of the best medical care to litigation at the Board as to whether the UR decision contains "material procedural defects that undermine the integrity of the UR decision." This will simply become a new way to divert decisions by medical professionals, flood the Board with questionable disputes, and increase the cost of utilization reviews.

Chart notes are not required and are rarely submitted. The last two phrases in (h) are both unnecessary and confusing.

Recommendation

(i) Finally, if there is a discrepancy between the recommendations cited, the underlying medical evidence supporting the differing recommendations shall be evaluated according to the MTUS Hierarchy of Evidence for Different Clinical Questions set forth in section 9792.25.1 to determine which recommendation is supported with the highest level of evidence.

(1) Utilization Review physicians shall apply the MTUS Hierarchy of Evidence for Different Clinical Questions if the treating physician cited a recommendation in the chart notes or Request for Authorization and the requested treatment or diagnostic service is being denied. In these situations, Utilization Review decisions shall clearly document the levels of evidence as set forth in the MTUS Hierarchy of Evidence for Different Clinical Questions (e.g. 1a, 1b, 2, etc.) between the recommendation cited by the treating physician and the recommendation used to deny the treatment or diagnostic service request.

(2) Independent Medical Review physicians shall apply the MTUS Hierarchy of Evidence for Different Clinical Questions if to determine whether the presumption of correctness of the MTUS has been rebutted where there is a dispute over the ~~between the recommendations cited by the~~ treatment requested by the treating physician, ~~and the Utilization Review physician or if the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed studies that are nationally recognized by the medical community was not cited by either the treating physician or the Utilization Review physician and the IMR reviewer is able to cite a recommendation supported with stronger medical evidence.~~ In these situations, ~~the~~ The Independent Medical Review decisions shall clearly document the levels of

evidence as set forth in the MTUS Hierarchy of Evidence for Different Clinical Questions (e.g. 1a, 1b, 2, etc.) for all recommendations cited ~~including any recommendations cited by the Independent Medical Review physician.~~ The Independent Medical Review decision shall ~~contain the recommendation supported~~ be based on the MTUS if applicable; or on other scientifically- and evidence-based nationally recognized medical treatment guidelines for injuries not covered by the MTUS or if the MTUS presumption of correctness has been rebutted by a preponderance of the scientific medical evidence.~~with the best available medical evidence which determines medical care that is reasonably necessary to cure or relieve the injured worker from the effects of his or her injury.~~

Discussion

~~The Independent Medical Review process is a process for resolve medical necessity disputes over the denial or modification of treatment requested by the treating physician. There is no statutory authority for the Independent Medical Review Physician interjecting and ruling on his or her own treatment recommendation.~~

~~Labor Code section 4604.5(d) requires:~~

~~“ 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 by the national medical community and scientifically based.”~~

Recommendation

~~(j) Employers, at their discretion, may approve medical treatment beyond what is covered in the MTUS or supported by the best available medical evidence in order to account for unique medical circumstances warranting an exception. The treating physician shall provide clear documentation of the clinical rationale focusing on objective functional gains afforded by the requested treatment and impact upon prognosis.~~

Discussion

~~The claims administrator has the authority and responsibility for approving medical treatment. Insured employers do not have that authority.~~

~~Even if “employers” is replaced by “claims administrators,” the language may arguably conflict with Labor Code sections 4600 (a) and (b) that define treatment reasonably required to cure the injured worker from the effects of the injury as treatment based on the MTUS.~~

~~Since (j) is problematic and is not necessary, it is best deleted.~~

§ 9792.25. Strength of Evidence – Definitions

Recommendation

~~(a) For purposes of sections 9792.25-9792.26, the following definitions shall apply:~~

~~(1) “Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument” means a tool designed primarily to help guideline developers and users assess the methodological rigor and transparency in which a guideline is developed. The~~

Administrative Director adopts and incorporates by reference the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, May 2009 into the MTUS from the following website: www.agreetrust.org. A copy of the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, May 2009 version 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 <http://www.dwc.ca.gov>.

Discussion

The Institute continues to recommend retaining the current methodology for evaluating criteria and determining strength of evidence. Using AGREE II protocols will not limit MTUS recommendations to those supported by peer-reviewed, and nationally recognized scientific medical evidence as Sections 4604.5 and 5307.27 require. Extensive training is necessary for all those who will use the protocols. Applying the protocols is much more time consuming than the existing standards.

*As stated in (a), The AGREE II Instrument is “a tool designed primarily to help guideline developers and users **assess the methodological rigor and transparency in which a guideline is developed**” (emphasis added). While the appraisal guidelines may be appropriate to assist MEEAC with its duties, the instrument is not appropriate or intended for use by treating physicians or utilization reviewers.*

Recommendation

Delete (a)(2) through (a)(29).

Discussion

The Administrative Director intends to adopt the AGREE II protocols, and provides the AGREE II web site address. If the Administrative Director adopts the AGREE II methodology, including details such as definitions (2) through (29) in this section does not appear necessary since the AGREE II Instrument and AGREE II Training Tools and related resources are available on that web site. Including these details also adds complexity that is not necessary and which will lead to additional disputes and confusion.

Note:

AGREE II protocols are complex and time-consuming. Correctly applying the AGREE II tool will require thorough training. If the Administrative Director adopts the AGREE II tool, the Institute strongly recommends that the Administrative Director not require their use by treating physicians and utilization reviewers, and require that:

- 1) MEEAC members and IMR reviewers are thoroughly trained on applying the AGREE II tool before the effective date of these regulations.*
- 2) The MTUS include the strength of evidence for each recommendation.*

§ 9792.25.1 Strength of Evidence - Method for Evaluating the Quality of Evidence used to Support a Recommendation; MTUS Hierarchy of Evidence for Different Clinical Questions

Recommendation

Delete this proposed section.

Discussion

The Institute continues to recommend retaining the current methodology for evaluating criteria and determining strength of evidence. See comment on section 9792.25(a).

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. Das, DWC Executive Medical Director
John Cortes, DWC Attorney
CWCi Claims Committee
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