STATE OF CALIFORNIA DEPARTMENT OF INDUSTRIAL RELATIONS Division of Workers' Compensation

NOTICE OF MODIFICATION TO TEXT OF PROPOSED REGULATIONS

Workers' Compensation: Medical Treatment Utilization Schedule

<u>TITLE 8, CALIFORNIA CODE OF REGULATIONS,</u> SECTIONS 9792.20 – 9792.26

NOTICE IS HEREBY GIVEN, that the Acting Administrative Director of the Division of Workers' Compensation (hereinafter "Acting Administrative Director") pursuant to the authority vested in her by Labor Code Sections 59, 133, 4600, 4604.5, 5307.3 and 5307.27, proposes to adopt or modify the text of the following proposed regulations:

Amend Section 9792.20	Medical Treatment Utilization Schedule - Definitions
Amend Section 9792.21	Medical Treatment Utilization Schedule
Adopt Section 9792.21.1	Medical Evidence Search Sequence
Amend Section 9792.23	Clinical Topics
Amend Section 9792.24.1	Acupuncture Medical Treatment Guidelines
Amend Section 9792.24.3	Postsurgical Treatment Guidelines
Amend Section 9792.25	Quality and Strength of Evidence – Definitions
Adopt Section 9792.25.1	MTUS Methodology for Evaluating Medical Evidence
Amend Section 9792.26	Medical Evidence Evaluation Advisory Committee

PRESENTATION OF WRITTEN COMMENTS AND DEADLINE FOR SUBMISSION OF WRITTEN COMMENTS

Members of the public are invited to present written comments regarding these proposed modifications. Only comments directly concerning the proposed modifications to the text of the regulations will be considered and responded to in the Final Statement of Reasons.

Written comments should be addressed to:

Maureen Gray Regulations Coordinator Department of Industrial Relations P.O. Box 420603 San Francisco, CA 94612

The Division's contact person must receive all written comments concerning the proposed modifications to the regulations no later than 5:00 p.m. on December 9, 2014. Written comments may be submitted via facsimile transmission (FAX), addressed to the above-named contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail) using the following e-mail address: dwcrules@dir.ca.gov.

Due to the inherent risks of non-delivery by facsimile transmission, the Acting Administrative Director suggests, but does not require, that a copy of any comments transmitted by facsimile transmission also be submitted by regular mail.

Comments sent to other e-mail addresses or facsimile numbers will not be accepted. Comments sent by e-mail or facsimile are subject to the deadline set forth above for written comments.

AVAILABILITY OF TEXT OF REGULATIONS AND RULEMAKING FILE

Copies of the original text and modified text with modifications clearly indicated, and the entire rulemaking file, are currently available for inspection at the Department of Industrial Relations, Division of Workers' Compensation, 1515 Clay Street, 17th Floor, Oakland, California 94612, between 9:00 A.M. and 4:30 P.M., Monday through Friday. Please contact the Division's regulations coordinator, Ms. Maureen Gray, at (510) 286-7100 to arrange to inspect the rulemaking file.

FORMAT OF PROPOSED MODIFICATIONS

Proposed Text Noticed for 45-Day Comment Period:

The proposed text was indicated by underlining, thus: <u>added language</u>. Deletions are indicated by strikeout, thus: <u>deleted language</u>.

Proposed Text Noticed for 15-Day Comment Period on Modified Text:

The proposed text was indicated by italics and underlining, thus: <u>added language</u>. Deletions are indicated by italics and strikeout, thus: <u>deleted language</u>.

Proposed Text Noticed for 2nd 15-Day Comment Period on Modified Text:

The proposed text was indicated by bold and underlining, thus: **added language**. Deletions are indicated by bold and strikeout, thus: **deleted language**.

SUMMARY OF PROPOSED CHANGES

Proposed Amendments to Section 9792.21. – Medical Treatment Utilization Schedule

- The title of the section is amended to delete the phrase "Medical Literature Search Sequence" so that the section focuses on just the "Medical Treatment Utilization Schedule".
- Subdivision (b) is amended to delete the sentence "The MTUS provides a framework for the
 most effective treatment of work-related illness or injury to achieve functional improvement,
 return-to-work, and disability prevention" and is replaced with the clarification that the
 MTUS is based on the principals of Evidenced-Based Medicine (EBM) and that it requires

the evaluation of medical evidence by applying an explicit systematic methodology to determine the quality and strength of evidence used to support the recommendation for a medical condition or injury.

- Subdivision (c) is amended to delete most of the language that has been moved to subdivision (b) and is replaced with the clarification that the MTUS is presumptively correct on the issue of extent and scope of medical treatment and constitutes the standard for the provision of medical care in accordance with Labor Code section 4600. The MTUS shall be the primary source of guidance for treating physicians and physician reviewers for the evaluation and treatment of injured workers.
- Subdivision (d) is amended to delete "The MTUS is based on the principals of EBM. The recommended guidelines set forth in the MTUS are presumptively correct on the issue of extent and scope of medical treatment and diagnostic services for the duration of a medical condition and shall constitute the standard for the provision of medical care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions" because this language was moved to Subdivision (c). Subdivision (d) now makes clear that treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS and sets forth the two limited situations that may warrant treatment based on recommendations found outside of the MTUS.
- Subdivision (d)(1) is added to describe if a medical condition or injury is not addressed by the MTUS, then medical care shall be in accordance with other medical treatment guidelines or peer-reviewed studies found by applying the Medical Evidence Search Sequence set forth in section 9792.21.1.
- Subdivision (d)(2) is added to describe the MTUS' presumption of correctness may be rebutted by a preponderance of scientific medical evidence establishing that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of his or her injury. Makes clear that the treating physician who seeks treatment outside of the MTUS bears the burden of rebutting the MTUS' presumption of correctness by a preponderance of scientific medical evidence.
- Subdivisions (e), (f), (g), (h), (i), and (j) have been deleted and most of the language of these sections have been incorporated in the new section 9792.21.1.

Proposed Amendments to Section 9792.21.1. – Medical Evidence Search Sequence

• This section has been added which adopts most of the language from the former section 9792.21, subdivisions (e), (f), (g), (h), (i), and (j). Section 9792.21 was divided into two sections to distinguish the overview discussion of the MTUS from the process of finding medical evidence which is the topic of this new section. (Note: A flowchart has been added as an attachment to this "NOTICE OF MODIFICATION TO TEXT OF PROPOSED REGULATIONS" to provide a visual aide of the Medical Evidence Search Sequence described in this section.)

- Subdivision (a) requires treating physicians and medical reviewers to conduct the medical evidence search sequence for the evaluation and treatment of injured workers.
- Subdivision (a)(1) requires a search of the current MTUS to find a recommendation applicable to the injured worker's medical condition or injury.
- Subdivision (a)(2) sets forth the two limited situations when one can search for medical evidence outside of the MTUS. First, if a medical condition or injury is not addressed by the MTUS. Second, if the MTUS' presumption of correctness is being challenged. If these two limited situations exist then:
- Subdivision (a)(2)(A) (C) sets forth the search sequence for finding medical evidence outside of the MTUS if the two limited situations described in the previous subdivision exists. It begins with a search of the most current version of ACOEM or ODG, then to the most current version of other evidenced-based medical treatment guidelines, and then finally, to current studies that are scientifically-based, peer-reviewed, and published in journals that are nationally recognized by the medical community to find a recommendation applicable to the injured worker's medical condition or injury.
- Subdivision (b) sets forth the requirements for treating physicians, Utilization Review physicians and Independent Medical Review physicians after they have conducted the medical evidence search in the sequence specified above:
- Subdivision (b)(1)(A) suggests treating physician's may provide in the Request for Authorization (RFA) or in an attachment to the RFA a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury, if the medical condition or injury is not addressed by the MTUS.
- Subdivisions (b)(1)(A)1. (b)(1)(A)2. sets forth the requirement that the citation provided by the treating physician shall be the primary source relied upon which the treating physician believes contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury. If the treating physician provides more than one citation, then a narrative shall be included by the treating physician in the RFA or in an attachment to the RFA explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury but is not addressed by the primary source cited.
- Subdivision (b)(1)(B) requires treating physician's to provide in the Request for Authorization (RFA) or in an attachment to the RFA a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the treatment request that is applicable to the injured worker's medical condition or injury, if the medical condition or injury is addressed by the MTUS but the treating physician is attempting to rebut the MTUS' presumption of correctness.
- Subdivisions (b)(1)(B)1. and (b)(1)(B)2. repeats the same requirements provided for in subdivisions (b)(1)(A)1. and (b)(1)(A)2. respectively.

- Subdivision (b)(2)(A) sets forth the requirement that Utilization Review physicians shall provide in the Utilization Review decision, in addition to the requirements set forth in section 9792.9.1(e), a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury, if the RFA is being modified, delayed or denied.
- Subdivisions (b)(2)(A)1. (b)(2)(A)2. sets forth the requirement that the citation provided by the Utilization Review physician shall be the primary source relied upon which the he or she believes contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury. If the Utilization Review physician provides more than one citation, then a narrative shall be included by the reviewing physician in the Utilization Review decision explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury but is not addressed by the primary source cited.
- Subdivision (b)(3)(A) sets forth the requirement that Independent Medical Review physicians shall provide in the Independent Medical Review decision, in addition to the requirements set forth in section 9792.10.6(d), a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury.
- Subdivisions (b)(3)(A)1. (b)(3)(A)2. sets forth the requirement that the citation provided by the Independent Medical Review physician shall be the primary source relied upon which the he or she believes contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury. If the Independent Medical Review physician provides more than one citation, then a narrative shall be included by the reviewing physician in the Independent Medical Review decision explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury but is not addressed by the primary source cited.
- Subdivision (c) requires the MTUS Methodology for Evaluating Medical Evidence set forth
 in section 9792.25.1 be applied by the reviewing physician if different guidelines or studies
 containing recommendations that are at variance with one another were cited by the treating
 physician and/or the Utilization Review physician and/or the Independent Medical Review
 physician to determine which recommendation is supported by the best available evidence.
- Subdivision (d) provides the required citation format by the treating physician, Utilization Review physician and Independent Medical Review decision when providing the citation to the guideline containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury. Included are citation format requirements when citing the MTUS, other medical treatment guidelines, and a peer-reviewed study.

 Subdivision (e) is added to make clear employers and their representatives, 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 medical circumstances warranting an exception.

Proposed Amendments to Section 9792.23 – Clinical Topics

• Subdivision (b) is amended to provide the correct citation from Section 9792.25(b) to 9792.21(d)(1) due to the changes made as a result of this rulemaking.

Proposed Amendments to Section 9792.24.1 – Acupuncture Medical Treatment Guidelines

• Subdivision (d) is amended to provide the correct citation from Section 9792.20(f) to 9792.20(e) due to the changes made as a result of this rulemaking.

Proposed Amendments to Section 9792.24.3 – Postsurgical Treatment Guidelines

• Subdivision (d)(1) is amended to provide the correct citation from Section 9792.25(b) to 9792.21(d)(1) due to the changes made as a result of this rulemaking.

Proposed Amendments to Section 9792.25 – Quality and Strength of Evidence - Definitions

• The section heading is amended to add the phrase "Quality and" before the phrase "Strength of Evidence – Definitions" to clarify the terms being defined relate to the evaluation of medical evidence which involves a process to determine the quality and strength of evidence.

Proposed Amendments to Section 9792.25.1 – MTUS Methodology for Evaluating Medical Evidence

- The section heading is amended to delete the phrases "Strength of Evidence", "the Quality of" and "used to Support a Recommendation; MTUS Hierarch of Evidence for Different Clinical Questions" and replaced with a simple and succinct heading "MTUS Methodology for Evaluating Medical Evidence."
- Subdivision (a) is amended to delete the language "To evaluate the quality of evidence used to support a recommendation found in a medical treatment guideline or in a study published in the medical or scientific literature, the MTUS Hierarchy of Evidence for Different Clinical Questions as set forth in section 9792.25.1(b) shall be applied as follows:" and replaced with "To evaluate the quality and strength of evidence used to support a recommendation, Utilization Review and Independent Medical Review physicians shall apply the MTUS Methodology for Evaluating Medical Evidence. This methodology provides a process to evaluate studies, not guidelines. Therefore, the reviewing physician shall evaluate the underlying study or studies used to support a recommendation found in a guideline. Medical care shall be in accordance with the recommendation supported by the best available evidence. The MTUS Methodology for Evaluating Medical Evidence shall be applied as follows:" to provide better guidance and clarification of what is being evaluated and who should be doing the evaluation.

- Subdivision (a)(1) is amended to delete the language used and move most of it to Subdivision (a)(2) and replace it with "The reviewing physician shall determine if different guidelines or studies were cited to guide the injured worker's medical care by the treating physician, the Utilization Review physician and/or the Independent Medical Review physician that contain recommendations that are at variance with one another" a description of the first step when applying the MTUS Methodology for Evaluating Medical Evidence.
- Subdivision (a)(2) is amended to adopt most of the language that was previously in Subdivision (a)(1) to provide a description of the second step when applying the MTUS Methodology for Evaluating Medical Evidence. Reviewing physicians shall evaluate the quality of evidence by determining if the studies used to support the recommendations are applicable to the injured worker and his or her medical condition or injury if different guidelines or studies were cited to guide the injured worker's medical care containing recommendations that are at variance with one another. Applicability refers to the extent to which the individual patients, subjects, settings, interventions, and outcome measures of studies used to support a recommendation are similar to the worker and his or her medical condition or injury. A recommendation supported by inapplicable studies should not be used and reviewing physicians shall provide an explanation of their rationale in the Utilization Review or Independent Medical Review decision if they conclude a recommendation is supported by studies inapplicable to the worker and his or her medical condition or injury.
- Subdivision (a)(2)(A) is added to make clear that "The evaluation of medical evidence can end after this step if a citation to a guideline or a study contains a recommendation supported by inapplicable studies and the other citation contains a recommendation that is supported by studies applicable to the injured worker's medical condition or injury."
- Subdivision (a)(3) is amended to adopt most of the language that was previously in Subdivision (a)(2) to provide a description of the third step when applying the MTUS Methodology for Evaluating Medical Evidence. Reviewing physicians shall continue to evaluate the quality of evidence if the guidelines or studies cited contain recommendations supported by studies applicable to the worker and his or her medical condition or injury by determining what factors, if any, bias may have had in the studies used to support the Reviewing physicians shall evaluate the quality of evidence by recommendations. determining what factors, if any bias may have had in the studies used to support the recommendations. Factors to consider include, but are not limited to, vested interests such as financial interests, academic interests, industry influence, and the methodological safeguards to protect against biases related to the generation of the randomization sequence, concealment of allocation, blinding, selective outcome reporting, early stopping, intention to treat, and confounding bias. A recommendation supported by studies determined to be of poor quality due to the presence of bias should not be used and reviewing physicians shall provide an explanation of their rationale in the Utilization Review or Independent Medical Review decision if they conclude a recommendation is supported by studies determined to be of poor quality due to the presence of bias.
- Subdivision (a)(3)(A) is added to make clear that "The evaluation of medical evidence can end after this step if a citation to a guideline or a study contains a recommendation supported by studies determined to be of poor quality due to the presence of bias and the other citation

contains a recommendation that is supported by studies determined to be of good quality due to the absence of bias."

- Subdivision (a)(4) is amended to move this language to Subdivision (a)(4)(B) and replaced with "If the guidelines or studies cited contain recommendations supported by studies applicable to the worker and his or her medical condition or injury and if the recommendations are supported by studies that are determined to be of good quality due to the absence of bias, then the reviewing physician shall determine the strength of evidence used to support the differing recommendations by applying the Hierarchy of Evidence for Different Clinical Questions set forth in 9792.25.1(b). To apply the Hierarchy of Evidence for Different Clinical Questions, the following steps shall be taken:"
- Subdivision (a)(4)(A) is amended to describe the first step in applying the Hierarchy of Evidence for Different Clinical Questions. The phrase "one of the" is adding and the word "follows" has been replaced with the phrase "following categories" for clarity. The entirety of Subdivision (a)(4)(A) has been re-lettered from previous Subdivision (a)(3) for clarity.
- Subdivision (a)(4)(B) has been re-lettered from previous Subdivision (a)(4) for clarity.
- Subdivision (a)(4)(C) has been re-lettered from previous Subdivision (a)(5).
- Subdivision (a)(4)(C)1. has been re-lettered from previous Subdivision (a)(5)(A) and is amended to add the phrase "in the Utilization Review or Independent Medical Review decisions" for clarity.
- Subdivision (a)(4)(C)2. has been re-lettered from previous Subdivision (a)(5)(B).

Proposed Amendments to Section 9792.26 – Medical Evidence Evaluation Advisory Committee

• Subdivision (g) is amended to delete "strength of evidence m" and replaced with "MTUS Methodology for Evaluating Medical Evidence" for clarity and consistency with the changes made.