

**STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF WORKERS' COMPENSATION**

ADDENDUM TO FINAL STATEMENT OF REASONS

Subject Matter of Regulations: Workers' Compensation–Medical Treatment Utilization Schedule

**TITLE 8, CALIFORNIA CODE OF REGULATIONS,
SECTIONS 9792.20 – 9792.26**

REQUEST AND GOOD CAUSE FOR EFFECTIVE DATE UPON FILING WITH THE SECRETARY OF STATE

After submission of the proposed regulations for review by the Office of Administrative Law, the Division provides the following additional reasons why there is good cause for the effective date of these regulations to be upon filing with the Secretary of State.

The proposed regulations will affect a staggering number of medical treatment requests, utilization review decisions and independent medical review decisions. There are approximately 550,000 to 650,000 new workers' compensation claims every year requiring medical treatment. Data reported to the Division's Workers' Compensation Information System for 2013 indicated there were 26.2 million treatment request bills. Representatives of claims administrators and Utilization Review organizations estimate 25% of requests for treatment required a physician's review through UR. With these figures, approximately 17,945 treatment requests are sent to utilization review physicians each day.

With regards to Independent Medical Review, in 2014 there were 377,000 treatment requests reviewed through IMR. There were 145,000 IMR final determinations which included 2.6 treatment disputes per IMR application. With these figures, approximately 1,032 treatment requests are reviewed through IMR each day, resulting in 397 IMR final determinations issued by independent medical review physicians each day.

As already stated, our current regulations contain a process to evaluate medical evidence if there is a dispute between which recommendation should guide the injured workers' medical condition or injury. However, it is limited in scope because it only provides a method to evaluate studies supported by randomized controlled trials. There are few if any randomized controlled trials to support most of the interventions commonly used to manage occupational injuries. Nevertheless, utilization review and independent medical review physicians currently review and approve many treatment requests that are not supported by randomized controlled trials despite the current lack of regulatory guidance. Arguably, one can point to Labor Code section 4610.5(c)(2) for guidance to rank evidence that is not supported by randomized controlled trials. However, the language used in Labor Code section 4610.5(c)(2) is too broad and lacks specificity to give treating physicians, reviewing physicians and other members of the regulated public meaningful

guidance. For example, the statutory phrase contained in Labor Code section 4610.5(c)(2)(B) provides the following as an evidentiary standard, “scientifically-based, peer-reviewed, and published in journals that are nationally recognized by the medical community” but unfortunately, it is a very broad description of many levels of medical evidence. The gold standard for medical evidence are studies that used high-quality randomized controlled trials, but the various types of observational studies are also considered medical evidence, albeit ranked lower in the medical evidence spectrum. In either case, any of these studies could be considered “scientifically-based, peer-reviewed, and published in journals that are nationally recognized by the medical community.” To illustrate the problem with our current regulations, if there is a dispute about which recommendation should guide an injured workers’ medical condition or injury but both recommendations are supported by observational trials, there is no regulatory or statutory guidance to determine which recommendation should prevail. Despite the lack of guidance, we know utilization review and independent medical review physicians are currently making these determinations.

The proposed regulations remedy this deficiency by providing a more comprehensive methodology to evaluate medical evidence to guide the evaluation of competing recommendations. Granted, over the years, utilization review decisions and independent medical review decisions have been made without the benefit of this added clarity. Nevertheless, recommendations supported by medical evidence that runs the gamut of the medical evidence spectrum can now be properly evaluated once these regulations become effective. The clarity provided by the proposed regulations will allow treating physicians, reviewing physicians and claims administrators to make better informed decisions and will reduce disputes over medical treatment. Treating physicians will have a better idea of what treatment will likely be approved or denied which will allow injured workers’ to receive appropriate medical care more quickly. Reviewing physicians will use the same standard to review treatment requests whether or not the recommendation is supported by a randomized controlled trial, an observational study or even a published expert opinion. Finally, claims administrators can give more accurate estimates of the costs of their claims. The urgency and good cause for these regulations to become effective sooner rather than later is made apparent by the staggering numbers of utilization review decisions and independent medical review decisions that are in dire need of regulatory guidance. Again, these regulations would affect 17,945 utilization decisions, and 397 independent medical review final determinations, each day. If the regulations become effective July 1st rather than April 20, 2015, seventy-one days will pass where members of the public will not have the benefit of the clarity and guidance provided by these proposed regulations. As a result, the anticipated system-wide savings and improved health-outcomes for California’s injured workers is good cause for these regulations to become effective upon filing with the Secretary of State.

JUSTIFICATION FOR INCORPORATION BY REFERENCE

The Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, published in May 2009 has been incorporated by reference into the regulations. Incorporation by reference is necessary because this document incorporated by reference is voluminous and it would be cumbersome and otherwise impractical to publish the entire publication in the California Code of Regulations (1 CCR § 20(c)(1), (c)(2)). Moreover, this document incorporated by reference is

copyrighted intellectual property of an international collaboration and may not be published in the California Code of Regulations. The regulations specify how this document incorporated by reference may be obtained.

RESPONSE TO OAL'S CONCERNS REGARDING THE COMMENT CHART

After submission of these proposed regulations for review, the Division made changes in the respective comment charts in response to questions raised by the Office of Administrative Law. Changes in the respective comment charts are indicated as follows:

The additional text was indicated by underlining, thus: added language. Deletions are indicated by strikeout, thus: ~~deleted language~~.

The list below provides a brief summary of the changes made and the page number(s) where the changes can be found in the respective comment charts.

45 Day Comment Period Chart:

1. Robert McLaughlin's oral comments made during the Public Hearing and Diane Worley's written comments pertaining to section 9792.21(e). The Division inadvertently failed to respond to these comments. The comments, response and action have been added on page 8 of the 45 Day Comment Period Chart.
2. Brenda Ramirez's written comments pertaining to section 9792.25(a)(1). Additional text was added responding to commenter's recommendation to specify that the published September 2013 AGREE II version be frozen on pages 65-66 of the 45 Day Comment Period Chart.

First 15 Day Comment Period:

1. Diane Worley's written comments pertaining to section 9792.21(j). A typographical error was corrected and the citation was changed from 9792.21(e) to 9792.21.1(e) on page 84 of the First 15 Day Comment Period Chart.
2. Dean Gean, Bernyce Peplowski, Robert Blink, Steven Feinberg and Steven Levitt's written comments pertaining to section 9792.21(j). It appears the commenters were looking at a 45 day comment period version of the proposed regulations rather than the 15 day text, when they refer to section 9792.21(j). Section 9792.21(j) from the text of the 45 Day Comment Period version of the proposed regulations was amended into subsection (h) in the text of the 15 Day Comment Period proposed regulations with slight changes. Therefore, taken in that context, it appears these comments pertain to section 9792.21(h) of the first 15-day text rather than section 9792.21(j) as referenced by commenters. The Division's initial response to these comments was not responsive because it failed to notice commenters' mistaken reference. A response has been added pertaining to commenters' recommended changes as it relates to section 9792.21(h) on pages 87-88 of the First 15 Day Comment Period Chart.

Second 15 Day Comment Period:

1. Brenda Ramirez’s written comments pertaining to section 9792.21.1(b)(1)(A). Commenter recommends the word “may” be amended to the word “shall.” Additional text was added to specifically respond to commenter’s suggestions on page 79 of the Second 15-Day Comment Period Chart.
2. Brenda Ramirez’s written comments pertaining to section 9792.25.1(a). Commenter recommends language to amend this section. Additional text was added to the response to more specifically address commenter’s suggested language on pages 83-84 of the Second 15-Day Comment Period Chart.
3. Diane Worley’s written comments pertaining to section 9792.21.1(a). Commenter suggests there is no statutory authority to require treating physicians apply “a mandatory medical evidence search sequence (a hierarchy)”. Additional text was added to the response to clarify section 9792.21.1(a) establishes the sequence in which one shall conduct a medical evidence search, it does not establish a medical evidence hierarchy as commenter suggests. Additional text was added to the response to better address commenter’s concerns on pages 26-28 of the Second 15 Day Comment Period Chart.
4. Lori Kammerer’s written comments pertaining to sections 9792.21.1(b)(1)(A) and 9792.21.1(b)(1)(B). Commenter suggests the deletion of both sections as written and suggests language that sets forth the requirements treating physicians must include in their Request for Authorization. Commenter deletes all the requirements for Utilization Review and Independent Medical Review physicians. Additional text was added to the response to explain the reasons for rejecting commenter’s suggestions that were not accepted on pages 65-66 of the Second 15 Day Comment Period Chart.
5. Lori Kammerer’s written comments pertaining to sections 9792.21.1(b)(2), 9792.21.1(b)(3), 9792.21.1(c), 9792.21.1(d), and 9792.21.1(e). The division responded to commenter’s concerns regarding sections 9792.21.1(b)(2), 9792.21.1(b)(3), 9792.21.1(c), and 9792.21.1(d) but inadvertently failed to address commenter’s suggested deletion of section 9792.21(e). Additional text was added to the response to explain the reasons for rejecting commenter’s suggested deletion of section 9792.21(e) on page 69 of the Second 15 Day Comment Period Chart.

Third 15-Day Comment Period:

1. Brenda Ramirez’s written comments pertaining to sections 9792.21.1(b)(1). The division inadvertently failed to respond to specific recommended language changes suggested by commenter. Additional text was added to respond to the specific suggested language revisions made by commenter on pages 12-14 of the Third 15 Day Comment Period Chart.

CHANGES IN REGULATORY TEXT

After submission of these proposed regulations for review by the Office of Administrative Law, the Division made a number of changes to the proposed regulations as suggested by that Office. Those changes include: (1) correction to typographical errors; (2) correction to punctuation and grammar; (3) insertion of underlined Labor Code citations to section 4610.5 in the References; (3) correction to a subsection heading that was unnecessarily repeated; (4) correction to a cross-reference located within the regulations; and (5) correction of underline to include the parenthesis as well as the text. These changes will not affect the meaning, interpretation or implementation of the regulations as the meanings of the regulations are apparent from the text of the regulations.

The changes are as follows:

1. Section 9792.21:
 - a. Page 3, (b). A comma “,” between the words “work” and “and” is deleted.
 - Correction made to punctuation.
 - b. Page 4, Authority & Reference. Reference to 4610.5 is inserted with underline.
 - Reference inserted.
2. Section 9792.21.1:
 - a. Page 8, Authority & Reference. Reference to 4610.5 is inserted with underline.
 - Reference inserted.
3. Section 9792.24.3:
 - a. Page 9, (d)(1). “(d)” is stricken from “(d)(1)” because it unnecessarily repeats the subdivision letter.
 - Correction made to subsection heading.
 - b. Page 9, (d)(1). “5(b)” is deleted and replaced with “(e)”.
 - Correction made to cross-reference within the regulations.
 - c. Page 9, (d)(1). “(d)(1)” is deleted because it unnecessarily repeats the subdivision letter and number.
 - Correction made to subsection heading.
4. Section 9792.25:
 - a. Page 14, (a)(2). The word “their” is stricken and replaced with the underlined word “its” is added.
 - Correction made to grammar.
 - b. Page 14, (a)(2). The underlined word “and” is added.
 - Correction made to indicate new text.
 - c. Page 14, (a)(2). The underlined word “variables” is added.
 - Correction made to indicate text inadvertently omitted.
 - d. Page 14, (a)(2). An underlined semi-colon “;” between the words “influence” and “confounding” is added.
 - Correction made to punctuation.

- e. Page 14, (a)(2). The word “selection” is stricken because it was inadvertently typed twice.
 - Correction made to a typographical error.
 - f. Page 15, (a)(15). Underlined commas “,” between the words “thinking” and “that” and between the words “recommended” and “and” are added.
 - Corrections made to punctuation.
 - g. Page 17, (a)(29). The word “increase” is replaced with the word “increased”.
 - Correction made to grammar.
5. Section 9792.25.1:
- a. Page 20, (b). MTUS Hierarchy of Evidence for Different Clinical Questions table, third box from 1b, the letter “s” is deleted from the word “trials” to make it singular instead of plural.
 - Correction made to grammar.
 - b. Page 21, (b), Authority & Reference. Reference to 4610.5 is inserted with underline. “4610.5”
 - Reference inserted.
6. Section 9792.26:
- a. Page 21, (a). The underline is extended to include parenthesis in the word “(MEEAC)”.
 - Correction to extend underline to include parenthesis as added text.