

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
General Comment/ Suspend rulemaking	Commenter wishes to reiterate his recommendation that the adoption [of this treatment schedule] be suspended until the Governor appoints a permanent medical director.	Barry Eisenberg Executive Director American College of Occupational and Environmental Medicine (ACOEM) March 10, 2009 Written Comment	Disagree. The comment does not address the substance of the subject of the 3 rd 15-day notice. Commenter raised the same arguments during the 1 st 15-day comment period, and the comments were appropriately addressed in the 1 st 15-day comment period chart.	None.
General Comment/ Documents relied upon in the rulemaking	Commenter notes that many of ODG's responses reference supporting information without citation, such as state studies demonstrating cost savings associated with adoption of ODG's guidelines. Commenter believes that it would be appropriate for the Division to request that such supporting documents be submitted by ODG and that the Division provide these for public comment in an additional 15 day comment period.	Barry Eisenberg Executive Director American College of Occupational and Environmental Medicine (ACOEM) March 10, 2009 Written Comment	Disagree. The documents referenced by commenter were submitted by ODG to the DWC, and were considered by DWC in responding to comments submitted by the regulated public during the 45-day notice period. The documents were noticed and added to the rulemaking file as documents relied upon in the 1 st 15-day notice as: "Work Loss Data Institute, Official Disability Guidelines Licensed by Top WC Payors," and "Work Loss Data Institute, Official Disability Guideline's Jurisdictional Adoptions of Treatment Guidelines in North America with Contact Information, March 1, 2008." The public was informed in the 1 st 15-day notice that the entire rulemaking file was available for public inspection during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays, at the offices of the Division of Workers' Compensation, located at 1515 Clay Street, 17th Floor, Oakland,	None.

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			California. DWC did not receive a request from the commenter regarding these documents although they were available to the public for inspection.	
General Comment/ CWCI's Economic Impact Statement	Commenter believes that the rejection of CWCI's economic impact comment by "statistics" of other states experiences - this is a further example of the misuse of inappropriate marketing language to a specific question about the economic impact of the proposed chronic pain guidelines. Commenter states that it would be appropriate for the Division to ask ODG to provide the state studies that support its claims and add these studies to the public record.	Barry Eisenberg Executive Director American College of Occupational and Environmental Medicine (ACOEM) March 10, 2009 Written Comment	Disagree. DWC did not rely on ODG's referenced documents to write the Economic Impact Statement. Regardless, the documents referenced in the comment are part of the rulemaking file. (See response submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General Comment/ Documents relied upon in the rulemaking, above.)	None.
General Comment/ Cost Reduction Claims	<p>Commenters reference page 7 of the table titled: "ODG Response to the California MTUS 15-day Comments dated 1-5-09," in response to a CWCI comment on the economic impact of the proposed changes. Commenters state that response contains more marketing language from WLDI:</p> <p>"ODG has been proven to reduce workers' compensation costs. In Ohio use of ODG Treatment reduced medical costs by 64 percent, cut lost days by 69 percent, and minimized treatment delays. http://www.disabilitydurations.com/ In Florida workers' comp rates went down by 58.3% after adoption of evidence-based guidelines, primarily ODG. In Hawaii WC rates went down 61% after an agreement to use ODG was signed by the Governor. In North Dakota WC premiums, already the lowest in the nation, dropped another 40% after adoption of</p>	Brenda Ramirez Claims & Medical Director Michael McClain General Counsel & Vice President California Workers' Compensation Institute (CWCI) March 10, 2009 Written Comment	Disagree. DWC did not rely on ODG's referenced documents to write the Economic Impact Statement. Regardless, the documents referenced in comment are part of the rulemaking file. (See response submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General Comment/ Documents relied upon in the rulemaking, above.)	None.

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	<p>ODG. In West Virginia a rate reduction of 27.5% followed ODG. And in Texas, inappropriate medical procedures declined by 72% after adoption of ODG, saving \$220 million per year, and the preliminary rate decreased by 25%. http://www.odg-twc.com/states.htm”</p> <p>Commenters state that the links in the WLDI do not appear to support the numbers asserted about cost reductions in other states and no other evidence for them is provided. Commenters state that WLDI comment does not address CWCI’s concerns about the economic impact of the proposed changes in California.</p>			
General Comment/ Delegation of rulemaking power	<p>Commenter applauds the Division for this step towards transparency, but believes these documents are an unsatisfactory attempt to document a multi-faceted regulatory process with an internal quality control tracking document. Commenter questions how much authority the Division ceded to a third party commercial entity that has a financial interest in the outcome of the rulemaking. Commenter opines that the appearance is that ODG has the authority to “accept” or “reject” public comments on the proposed rulemaking, leaving the question of whether the Division has outsourced its responsibilities.</p> <p>Commenter opines that by sorting out the responses to specific questions several observations are worth noting, first and foremost being the frequency of “rejected” to a comment (outside of Topical Compounds). Commenter states the perception is that the Division has delegated the responsibility to ODG to decide which comments merit further research by the Division and which comments can be “rejected.”? Commenter opines that there seems a trend towards rejection of methodology and evidence issues, perhaps appropriately, but that it would seem incumbent on</p>	Barry Eisenberg Executive Director American College of Occupational and Environmental Medicine (ACOEM) March 10, 2009 Written Comment	<p>Disagree. Commenter raised the same arguments during the 1st 15-day comment period, and the comments were appropriately addressed in the 1st 15-day comment period chart. For the benefit of the regulated public the response as contained in the 1st 15-day comment chart is set forth below.</p> <p>“Disagree with the comment that DWC has delegated rulemaking authority to ODG. In the present rulemaking, DWC proposed to adapt the October 31, 2007 ODG chapter on pain version as the basis for the DWC chronic pain medical treatment guidelines in its Notice of Proposed Rulemaking issued June 2008. In the Notice of proposed Rulemaking, DWC noticed in Appendix A that DWC proposed to adapt the October 31,</p>	None.

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	<p>the Division to provide an independent response to each comment. Based on the data provided, commenter notes that 342 out of 500 (68.4%) of the comments were rejected by ODG or designated as “na.” Outside of Compounded Topicals and excluding 17 “na” Author Recs, only 43 of 409 comments (10.5%) were “Accepted.” Commenter believes that this process is incomplete and that the Division has not responded to the vast majority of the comments.</p> <p>[Note: Commenter submitted a table of comments accepted and rejected by ODG. This table is part of the rulemaking file and available upon request.]</p>		<p>2007 ODG chapter on pain version as the basis for the DWC chronic pain medical treatment guidelines. DWC further noticed that the ODG chapter on pain was being modified to meet the requirements of the MTUS. The explanation of these modifications is set forth in Appendix A, which was served to the public as a supplement to the Initial Statement of Reasons. (See Appendix A—Chronic Pain Medical Treatment Guidelines supplements the necessity statement and justification for Section 9792.24.2. Chronic Pain Medical Treatment Guidelines (DWC 2008) set forth in the Initial Statement of Reasons.) Based on public comments received during the 45-day notice, DWC proposed to adapt an updated version of the ODG chapter on pain, dated October 23, 2008. DWC again reviewed the October 23, 2008 ODG chapter on pain version, and modified the version to meet the requirements of the MTUS. The modifications were explained in Appendix A1, which was served to the public as a supplement to the Notice of Modification to Text of Proposed Rulemaking (1st 15-day notice; See Notice of Modification to Text of Proposed Rulemaking, Appendix A1—Chronic Pain Medical Treatment Guidelines, November 2008). During the 45-</p>	

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			day comment period and during the 1 st 15-day comment period, DWC received comments from the public. ODG, who continuously updates its guidelines, evaluated the submitted comments to determine whether the issues raised were already addressed in its most recent updates or whether further evaluation of the evidence-base was necessary. DWC considered ODG's responses and made its own determination on whether or not to accept ODG's changes in its guidelines. Thus, commenter is incorrect in asserting that DWC delegated its rulemaking power to ODG. DWC made individual and independent decisions on all comments received from the regulated public in connection with the rulemaking.	
General Comment/ Delegation of rulemaking power	Commenter is troubled by the appearance that the Acting Administrative Director is delegating to a private entity her responsibility to respond to comments from the public regarding a proposed rule. Commenter does not recall that such an appearance of delegation occurred when the ACOEM guidelines were first adopted, nor when other additions were made to MTUS.	Keith Bateman Vice President Workers' Compensation Property Casualty Insurers Association of America	Disagree. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General Comment/Delegation of rulemaking power.	None.
General Comment/ Delegation of rulemaking power	Commenter notes with dismay that the DWC has apparently delegated to the Work Loss Disability Institute (WLDI) responsibility for responding to comments on the use of the ODG and proposed changes. Commenter opines that the WLDI appears to have limited interest in further public comments; on review of the 49 pages of comments submitted by a	David C. Deitz, MD, PhD, Vice President National Medical Director, Commercial Professional Services Liberty Mutual Group	Disagree. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General	None.

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	variety of organizations and physicians during the last 15-day comment period (see “ODG Response to the California MTUS 15-day Comments dated 1-5-09”) ODG accepted not one comment on a topic other than “Compounded Topicals.” Commenter hopes that the DWC will comment separately on some of these suggestions.	February 20, 2009 Written Comment	Comment/Delegation of rulemaking power.	
General Comment/ Delegation of rulemaking power	<p>Commenter notes that responses to comments on the proposed regulation thus far appear in tables labeled ODG Response. Commenter opines that it appears from the document entitled “ODG Response to the California MTUS 15-day Comments dated 1-5-09” that the DWC relies on ODG to accept or reject comments and revise the proposed guidelines. Commenter states that the ODG responses to the last set of comments disputed the need for any substantive methodological changes in the proposed regulations. However, commenter states that the WLDI is not a clinical expert or expert panel, nor is it unbiased as it is a commercial vendor of guidelines.</p> <p>Commenter states that there is minimal evidence of response on the basis of critical analysis. Commenter states that there has been no response to the comments from the DWC staff or the MEEAC, which would be the appropriate groups to consider further evidence and scientific critiques. Commenter opines that as a commercial content vendor, ODG has a vested interest in defending its work.</p> <p>Commenter opines that the WLDI’s responses to critiques of the ODG methodology display a lack of understanding of evidence-based medicine as practiced at leading institutions and medical societies in the developed world. Commenter cites an example on page on 2 of the last response, which states that ACOEM’s Strength of Evidence criteria are a subset of ODG’s ratings 1a to 2b. It further states that ODG</p>	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General Comment/Delegation of rulemaking power.	None.

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	<p>“goes beyond this (up to 10c).” In fact, commenter opines that the ODG “rating system” simply classifies documents by type of document or study according to (often inaccurate) PubMed labels. Commenter states that it is a labeling system. Commenter states there is no critical analysis or assessment of methodological quality in this scheme. Categories 3 to 10 include case studies, other guidelines, books, industry materials and so on that no one else classifies as well designed, reproducible evidence.</p> <p>Commenter points out that ODG’s responses state that there are not a lot of high quality studies in a number of areas. WLDI states that this is justification for including low quality materials not used elsewhere due to lack of reliability. Commenter opines that the fact that primary source research is sparse in this area is no excuse to use unreliable or secondary material and attempt to pass it off as “evidence based.” The parachute study story is sometimes used, as it is here (page 43), to justify continuing use of ineffective or dangerous procedures, generally in non-life threatening situations, rather than to perform needed research. Commenter opines that this is sophistry rather than science and that it in no way benefits California workers. Commenter states that this approach has been uniformly rejected by California Medical Schools in their evidence-based continuing and primary education offerings.</p>			
General Comment/ Strength of Evidence Methodology	<p>Commenter references ODG’s response as follows: “Rejected Strength of Evidence/Methodology – “The ACOEM Strength of Evidence Criteria is a subset of ODG’s, covering 1a to 2b, whereas ODG also goes beyond this (up to 10c) where necessary.....”</p> <p>Commenter states that there is little in this comment that indicates any knowledge of evidence-based guideline development, certainly not with respect to</p>	Barry Eisenberg Executive Director American College of Occupational and Environmental Medicine (ACOEM) March 10, 2009 Written Comment	Disagree. Commenter questions whether the chronic pain medical treatment guidelines, as adapted from the ODG guidelines, meet the rating methodology as set forth in Section 9792.25(c) of the MTUS. The comment does not address the substance of the subject of the 3 rd 15-day notice. Similar comments	None.

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	<p>the question asked here and in other comments – How does the ODG process meet the criteria of an ACOEM evidence based methodology prescribed by the Medical Treatment Utilization Schedule? Commenter opines that a response that is based on a “tongue in cheek” article comparing parachutes to clinical evidence from the popular press belies the importance of this issue. Commenter states that the Division should not acknowledge such a flippant response to this question and again raises the issue whether ODG is speaking for the Division.</p> <p>Commenter opines that the methodology question has not been answered. Commenter contends that a critique of ACOEM’s methodology does not answer the question as to how ODG’s methodology satisfies California requirements. Commenter states that ACOEM’s methodology does rely on RCTs when they exist and are appropriate to the clinical question. This is done to ensure that a guideline is evidence-based and simply not a compendium of research studies.</p>		<p>were raised during the 45-day comment period, and the comments were appropriately addressed in the 45-day comment period chart. (See, response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers’ Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), 45-day comment chart.)</p>	
<p>General Comment/ Strength of Evidence Methodology</p>	<p>Commenter is concerned that the DWC has failed to adequately demonstrate its compliance with its own hierarchy of evidence rule. Commenter opines that this is a comment to which only the DWC should be responding because it's the DWC's rule, not that of the Work Loss Data Institute. Commenter recognizes that in the future the DWC will likely incorporate other entities' treatment guidelines into its MTUS because it lacks the resources to develop its own guidelines. However, commenter states that it will always remain the DWC's responsibility to provide the rationale for its action in compliance with the workers compensation act and Government Code requirements. Commenter states that given the importance assigned to MTUS by the legislature, it is</p>	<p>Keith Bateman Vice President Workers’ Compensation Property Casualty Insurers Association of America</p>	<p>Disagree. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General Comment/Strength of Evidence Methodology.</p>	<p>None.</p>

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	important that the public believe that MTUS represents what is recognized as the best scientifically and evidence-based, peer-reviewed medical treatment guidelines available.			
General Comment/AGREE Instrument	Commenter states that the use of the AGREE instrument in ODG's responses is completely misapplied. Specifically to be of any interpretive use it needs to be implemented independently. Commenter opines that for ODG to claim that they are AGREE compliant by self declaration belongs in their marketing materials not the Division's regulatory documentation. Commenter believes that ODG's inability to recognize the (mis)use of the instrument by a medical society (ASSIP) whose primary mission is to preserve and expand reimbursement is a perfect example of a guideline process that is driven by expediency and not intellectual honesty.	Barry Eisenberg Executive Director American College of Occupational and Environmental Medicine (ACOEM) March 10, 2009 Written Comment	Disagree. Commenter argues that ODG should not state that its guideline complies with the requirements of the AGREE Instrument. The comment does not address the substance of the subject of the 3 rd 15-day notice. Similar comments were raised during the 45-day comment period, and the comments were appropriately addressed in the 45-day comment period chart. Specifically, during the 45-day comment period the issue was raised as to whether ODG's guidelines complied with recognized standards for evidence-based medicine, including those developed by the AGREE Instrument. In the Initial Statement of Reasons (ISOR), at p. 40, DWC indicated that the 2005 RAND Report identified the Work Loss Data Institute's Official Disability Guidelines (ODG) as meeting the requirements of the statute. (See, 2005 RAND Report, Table 4., p. 21; Table 4.2, p. 27.) See, also Lab. Code, §§ 5307.27, 4604.5(b.) Specifically, the 2005 RAND report found that the ODG guidelines complied with the AGREE Instrument (2005 RAND Report, at pp. xix, 32). The DWC	None.

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			determined that the ODG guidelines met the requirements of the statute based on the findings of the 2005 RAND Report as stated in the ISOR, at p. 40. RAND used the AGREE Instrument to evaluate the ODG guidelines. (See response to Steven C. Schumann, M.D., Legislative Chair, Western Occupational & Environmental Medicine Association, A Component Society of ACOEM, dated August 12, 2008, on Section 9792.20(e), Evidence-based concept, 45-day comment chart.)	
General/Nationally Recognized Guideline	The response to Dr. Lessenger’s question as to the use of a Nationally recognized guideline – ODG states that their guidelines have been “adopted by 23 states and provinces.” Commenter states that statutory and/or regulatory citations should be provided to support this claim.	Barry Eisenberg Executive Director American College of Occupational and Environmental Medicine (ACOEM) March 10, 2009 Written Comment	Disagree. Commenter argues that “statutory and/or regulatory citations should be provided to support [the] claim” that the ODG guidelines are “nationally recognized.” The issue of whether the ODG guidelines meet the requirements of the statute was raised during the 45-day comment period, and the comments were appropriately addressed in the 45-day comment period chart. (See also response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General Comment/AGREE Instrument. See also response to same commenter on the subject of General Comment/ Documents relied upon	None.

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General Comment/ Conflict of Interest	The response to Dr. Lessenger’s statements regarding potential conflicts of interest of ODG contributors – “Complete CV available on request.” Commenter asks if the Division made this request to insure that there are no conflicts of interest. For more complete transparency commenter opines that these documents should be made available to DWC for inclusion in the public record.	Barry Eisenberg Executive Director American College of Occupational and Environmental Medicine (ACOEM) March 10, 2009 Written Comment	in the rulemaking, above.) Disagree. Commenter argues that DWC should review ODG’s conflict of interest declarations. Similar comments were raised during the 45-day comment period, and the comments were appropriately addressed in the 45-day comment period chart. (See response to comment submitted by Jeffrey S. Harris, M.D., August 11, 2008, on Section 9792.20(h), Medical Treatment Guidelines development/Methodology, regarding conflict of interests, 45-day comment chart.)	None.
General Comment/ Conflict of Interest	<p>Commenters point out that the Division does not state in the Newline or the Notice of Addition the reasons it has added these documents to the rulemaking file.</p> <p>Commenters further state that no reason is given, either, for sending comments submitted to the DWC within and outside the public commentary periods to ODG, and no explanation is provided for ODG submitting to the DWC tables containing its responses to comments directed to the DWC, so it is difficult to respond to the documents. Commenters ask if the DWC requested ODG to respond to the public comments. Commenters ask if the DWC is intending to rely on the ODG comments for the DWC response to public comments that must be submitted to the Office of Administrative Law. Commenters state that in the regulatory process, the public was invited to submit comments to the DWC for the DWC to consider on proposed regulatory changes to the MTUS regulations. Commenters state that those comments were not intended to go to ODG for ODG’s consideration in modifying its proprietary guidelines.</p>	Brenda Ramirez Claims & Medical Director Michael McClain General Counsel & Vice President California Workers’ Compensation Institute (CWCI) March 10, 2009 Written Comment	<p>Disagree. The Notice of Addition of Documents to Rulemaking file issued February 2009 indicates that the documents were added to the rulemaking file because they were used to support the rulemaking file.</p> <p>Disagree with comment objecting to DWC communicating public comments to ODG. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General Comment/Delegation of rulemaking power, above.</p> <p>Disagree with comments objecting to content of ODG’s January 16, 2009 letter. The letter was used as</p>	None.

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	<p>Commenters state that the letter to Carrie Nevans from Phil Denniston on WLDI letterhead includes a number of links to which the regulated public does not have access without a password.</p> <p>Commenters state that Mr. Denniston has directly contacted the Institute and others who provided written comments to the DWC to express his disappointment with their comments.</p> <p>Commenters opine that because ODG has a direct financial interest in the outcome of the proposed changes to the MTUS regulations and potential for conflict of interest, the objectivity of ODG's responses to the public comments is questionable and its responses therefore have little or no value in the rulemaking context. Commenters believe that the authority and responsibility to respond objectively to public comments rests with the DWC. Commenters find it difficult to understand why ODG's responses to public comments have been added to the rulemaking file.</p> <p>Commenters state that the responses in the ODG tables, including those to CWCI comments, are generally dismissive, non-responsive and/or inappropriate. Commenters opine that it appears that any criticism of ODG-based guidelines is rejected out of hand with no serious rationale. Commenters ask is the regulated community to assume that the DWC ratifies and adopts the responses by WLDI to support its regulations? Is WLDI speaking for the Division?</p>		<p>a supporting document to the rulemaking file regarding ODG's process for updates of the ODG guidelines following communication of the public comments. Regarding the comments that the letter contains a number of links which are not accessible to the public, the documents that were relevant to this rulemaking which were relied upon were made part of the rulemaking file, and appropriately noticed to the public. For example, the document entitled "Work Loss Data Institute, Official Disability Guidelines' Explanation of Medical Literature Ratings" was noticed and added to the rulemaking file in the 1st 15-day notice. Further, the document referenced in the letter regarding ODG's process for updating the guidelines is referenced in the document entitled "Work Loss Data Institute, Official Disability Guidelines, Treatment in Workers' Comp, Methodology Description using the AGREE Instrument (Appendix B)." This document was also noticed and added to the rulemaking file in the 1st 15-day notice. ODG in its correspondence also refers generally to its change log which captures its updates. DWC noticed and added to the rulemaking file the pertinent copies of the change log it used it its</p>	

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			<p>rulemaking as noticed in the 2nd 15-day comment notice. These documents are listed as: (1) ODG Updates Change Log, November, 2008; and (2) ODG Updates Change Log, December, 2008.</p> <p>Commenters allege that Mr. Denniston has directly contacted the Institute and others who provided written comments to the DWC to express his disappointment with their comments. DWC has no knowledge of this information. The development of the proposed regulations is solely based on the rulemaking file which is available to the public for review.</p>	
General Comment/Links in tables are inaccessible	Commenters state that the WLDI responses to CWCI comments on pages 9 and 10 of the table titled "ODG Response to the California MTUS 15-day Comments dated 1-5-09" are not directly responsive and contain links to sites that cannot be accessed without passwords.	Brenda Ramirez Claims & Medical Director Michael McClain General Counsel & Vice President California Workers' Compensation Institute (CWCI) March 10, 2009 Written Comment	Disagree. See response to comment submitted by Brenda Ramirez, Claims & Medical Director and Michael McClain, General Counsel & Vice President, California Workers' Compensation Institute (CWCI), dated March 10, 2009, on the subject of General Comment-Conflict of Interest, above. Specifically, see response regarding documents relied upon and noticed to the public in the various notices. Moreover, see response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated March 10, 2009, on the subject of General	None.

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			Comment/Delegation of rulemaking power, above. Specifically, see response regarding the extent to which ODG responses to the comments were taken into consideration by DWC in the rulemaking process.	
General Comment/ Proprietary References	<p>Commenters reference, on page 8 of the table titled “ODG Response to the California MTUS 15-day Comments dated 1-5-09,” in response to a CWCI comment, WLDI comments:</p> <p>“ODG surpasses all other guidelines in specificity. With the ODG Treatment UR Adviser, ODG identifies every possible CPT Procedure Code (necessary for reimbursement) for every ICD9 Diagnosis Code used in workers’ comp, along with appropriateness and number and duration of visits. Plus, within the ODG Procedure Summaries, unless a treatment is not recommended or repeat procedures are not an issue (as in one-time surgeries), ODG also provides this information, even giving dosage frequency, intensity and durations for pharmaceutical therapies, which no other guideline does...”</p> <p>Commenters opine that this response and others like it appear to be marketing for proprietary ODG products. Commenters state that neither the “ODG Treatment UR Advisor”, “CPT procedure codes,” “ICD-9 codes,” nor “ODG procedure summaries” are part of the proposed regulations. Commenters opine that statements in the tables such as this may suggest that the regulated public needs to purchase proprietary ODG products if the proposed regulations are adopted.</p>	Brenda Ramirez Claims & Medical Director Michael McClain General Counsel & Vice President California Workers’ Compensation Institute (CWCI) March 10, 2009 Written Comment	Disagree. DWC did not adopt ODG’s other “ODG products,” namely “ODG Treatment UR Advisor,” “CPT procedure codes,” “ICD-9 codes,” nor “ODG procedure summaries.” The chronic pain medical treatment guidelines were adapted to be a stand-alone guideline within the framework of the MTUS. The guidelines are available to the public at no cost, and will be placed on the DWC website for use by the regulated public. “ODG’s products,” as listed by commenters are not necessary to the use of the DWC chronic pain medical treatment guidelines. This response by ODG reflects DWC’s independence in the rulemaking process. Because the chronic pain medical treatment guidelines were developed to stand-alone independent from “other ODG’s products,” comments regarding ODG’s programs were not taken into consideration in developing the proposed regulations.	None.
General Comment/ Inappropriate references to	Commenters state that in the table headed “ODG Updates and Comments as a result of the California MTUS Comments dated 08-12-08,” on page 12,	Brenda Ramirez Claims & Medical Director	Disagree. See response to comment submitted by Brenda Ramirez, Claims & Medical	None.

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proprietary products	WLDI responds to a CWCI comment recommending the use of CPT codes in the Postsurgical Treatment Guideline by suggesting that users go to the ODG ICD9/CPT Code Crosswalk UR Advisor. Commenter states that the ODG ICD9/CPT Code Crosswalk UR Advisor is not included in the proposed regulations and believes that it is inappropriate for a vendor to promote another of its commercial products here.	Michael McClain General Counsel & Vice President California Workers' Compensation Institute (CWCI) March 10, 2009 Written Comment	Director and Michael McClain, General Counsel & Vice President, California Workers' Compensation Institute (CWCI), dated March 10, 2009, on the subject of General Comment/ Proprietary References, above.	
General Comment/ Chronic Pain Definition	<p>Commenters state that in response to a comment by PCIA expressing concern over the proposed definition of "chronic pain" because of the lack of any universally accepted tables of anticipated time of healing, WLDI says:</p> <p>"Relates to DWC's intro, not ODG (definition of chronic). Commenter says, 'ACIC is unaware of any universally accepted tables of anticipated time of healing.' Beyond normal healing period can be quantified via RTW guidelines (like ODG)."</p> <p>Commenters state that in response to a comment by CWCI expressing concern over the proposed definition of "chronic pain", WLDI says that the definition of chronic pain "needs to be used in conjunction with ODG disability duration guidelines to determine normal healing time in days, based on the specific injury or illness."</p> <p>Commenters wonder if it is the position of the DWC that the time-periods listed in proprietary ODG RTW Guidelines or ODG disability guidelines can be used as the anticipated period of healing? Commenters state that the ODG RTW Guidelines are not included in the proposed regulations.</p>	<p>Brenda Ramirez Claims & Medical Director</p> <p>Michael McClain General Counsel & Vice President</p> <p>California Workers' Compensation Institute (CWCI) March 10, 2009 Written Comment</p>	Disagree. "ODG RTW Guidelines or ODG disability guidelines" were not adopted into the MTUS. See response to comment submitted by Brenda Ramirez, Claims & Medical Director and Michael McClain, General Counsel & Vice President, California Workers' Compensation Institute (CWCI), dated March 10, 2009, on the subject of General Comment/ Proprietary References, above.	None.
General Comment/ Chronic Pain Definition	Commenter opines that there are two major problems with the proposed regulation. One is that the methods by which the recommendations were produced does not comport with the DWC's own regulations. The	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. Commenter questions whether the chronic pain medical treatment guidelines, as adapted from the ODG guidelines, meet the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>other is that by defining “chronic pain” in a vague and arbitrary way and then pre-empting current portions of the MTUS at that point, the regulation effectively returns to the pre-reform situation of primacy of the treating physician’s subjective opinion. Commenter believes that the situation has been correlated with previous steep increases in costs, quantity of care, and unwanted disability without benefit to injured workers.</p>		<p>rating methodology as set forth in Section 9792.25(c) of the MTUS. The comment does not address the substance of the subject of the 3rd 15-day notice. Similar comments were raised during the 45-day comment period, and the comments were appropriately addressed in the 45-day comment period chart. (See, response to comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers’ Compensation Institute, August 12, 2008, on the issue of proposed section 9792.25(c)(1), 45-day comment chart.)</p> <p>Commenter also objects to the definition of the term “chronic pain” as “arbitrary.” Disagree. The comment does not address the substance of the subject of the 3rd 15-day notice. Similar comments were raised during the 45-day comment period, and the comments were appropriately addressed in the 45-day comment period chart. (See response to comments submitted by Brenda Ramirez, Claims and Medical Director, California Workers’ Compensation Institute, dated August 12, 2008, on Section 9792.20(c), Chronic Pain Definition, 45-day comments chart) Moreover, comments stating that the regulations “effectively</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			return to the pre-reform situation” without substantiation are not supported.	
General Comment/ Chronic Pain Definition	Commenter opines that the regulation as proposed invalidates the various body part guidelines currently in use as a treating physician declares that pain has continued beyond the expected period. Commenter believes that the criterion is subjective; the proposed guideline contains no benchmarks for cessation of pain for any diagnoses. Commenter opines that by invalidating the current body part guidelines at that point leaves clinicians, reviewers and patients with no guidance at all for diagnosis and treatment of many cases outside of the medications and interventions in the proposed regulation. Commenter states that the proposed regulation leaves out many tests and procedures commonly and repetitively used for chronic pain patients. Commenter states that there is evidence of effectiveness of procedures, imaging, and other areas not covered by ODG. Commenter states that this material appears currently in the guidelines and in the proposed elbow guideline. Commenter opines that by blocking the use of this data it creates a vacuum that invites conflict and poor treatment, since the majority of costs and disability in California are incurred for such “chronic cases” and represents a return to random medicine with demonstrably inferior results.	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. See response to comment submitted by commenter Jeffrey S. Harris, MD, MPH, MBA, March 7, 2009, on the subject of General Comment/Chronic Pain Definition, and specifically the subject relating to the definition of the term “chronic pain.”	None.
General Comment/ Methodology	Commenter states that the most recent reform of the workers compensation laws in California mandated the use of [high grade] scientific evidence to guide medical care. The intent was to ensure the best quality treatment for California workers. That in turn would produce better outcomes more efficiently. To that end, after a comparative evaluation by experts at the RAND Corporation, the DWC adopted the guidelines published by the American College of Occupational and Environmental Medicine (ACOEM). ACOEM is	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. Commenter again questions whether the chronic pain medical treatment guidelines, as adapted from the ODG guidelines, meet the rating methodology as set forth in Section 9792.25(c) of the MTUS. The comment does not address the substance of the subject of the 3 rd 15-day notice. Commenter raised the same	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>the non-profit, member-supported professional society dedicated to protecting and enhancing worker health.</p> <p>Commenter points out that the DWC also adopted into regulation a specific process, or methodology, for guideline development based on an extensive search and synthesis of the international literature on evidence-based guideline development. This methodology maximizes the likelihood that the resulting recommendations are based on the most reliable, least biased scientific studies. The recommendations would therefore support the most effective and efficient methods of testing and treatment for workers with occupationally related health complaints.</p> <p>Commenter believes that regulations adopted as part of the Medical Treatment Utilization Schedule (MTUS) must follow the methodology as adopted. Importantly, for quality assurance and control, performance of each step of the methodology in a complete and unbiased manner must be clearly evident for each clinical question and each recommendation. The recommendations should clearly address specific diagnoses and indications. To validate the quality of the systematic reviews, reviewers must be able to see each literature search, study analysis of potential bias, study rating, and rating of the body of evidence. For guidelines, which expert panels formulate using high quality, complete systematic reviews, ratings of the strength of evidence and recommendations with accompanying rationales must be easy to see. If this information is not clearly visible and complete, it is not possible to determine the likelihood that guideline recommendations would provide benefits for injured workers that significantly exceed potential harms. Harms in this context clearly include lack of functional improvement and failure to</p>		<p>comments during the 45-day notice and the comments were appropriately addressed in the 45-day comment period chart. (See, response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on the issue of proposed section 9792.20(h), Medical Treatment Guidelines development/Methodology, 45-day comment chart.)</p> <p>With respect to the comment that “it appears that the DWC, through its Medical Director, outsourced most evidence gathering and analysis, as well as [preliminary] recommendation formulation, to the Work Loss Data Institute (WLDI), using its Official Disability Guidelines (ODG) product,” Disagree. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational and Environmental Medicine (ACOEM), dated, March 10, 2009, on the subject of General Comment/ Delegation of rulemaking power, above.</p> <p>Commenter incorrectly assumes that it is the role of MEEAC to apply the DWC methodology to all adopted guidelines. Disagree. This is not correct. MEEAC applies the DWC methodology when DWC via MEEAC supplements the</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>return the worker to work.</p> <p>Commenter states that the conclusions of each step should follow logically from the data or rating in the prior step. The ratings must be based on explicit analysis that has passed professional quality review at one or more levels. If the source material cannot be verified to follow these steps and evidence high quality output as a result, the recommendations that follow are considered to be of uncertain validity. The entire exercise becomes speculative. It is unlikely to be beneficial to patients. The above are widely used criteria for the use of external systematic reviews and guidelines.</p> <p><u>Does the Proposed Regulation Follow the Required Methodology?</u></p> <p>Commenter states that the proposed regulation consists of some systematic reviews, some recommendations and a good deal of descriptive material that is not considered part of the evidence-based process. Commenter opines that it appears that the DWC, through its Medical Director, outsourced most evidence gathering and analysis, as well as [preliminary] recommendation formulation, to the Work Loss Data Institute (WLDI), using its Official Disability Guidelines (ODG) product. Commenter states that there are two separate areas to be considered here – the adequacy and transparency of the systematic reviews (evidence search, analysis, grading, and synthesis) and the “guideline” itself, or the collection of recommendations that address specific answerable clinical questions for the working population. Trained expert panels use evidence syntheses to formulate recommendations and assign strengths of recommendations, which are in turn based on the strength of the evidence for each</p>		<p>guidelines. For example, the MEEAC conducted the evidence-based review in the ODG guidelines, which were labeled “under study” and made recommendations based on the evidence. This comment was also raised and addressed during the 45-day comment period. (See, comment submitted by Brenda Ramirez, Claims and Medical Director, California Workers’ Compensation Institute, dated August 12, 2008, Section 9792.25(c)(1), Grading Methodology, 45-day comment chart.)</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommendation.</p> <p>Commenter opines that it appears that the DWC intended to use its Medical Evidence Evaluation and Assessment Committee (MEEAC) and the Medical Director for the decision-making for recommendations, based on high quality evidence syntheses. Commenter states that a careful reading of the latest iteration of the proposed chronic pain regulation does not reveal the mandated output for most of the important steps in the systematic review process. Commenter states that is also does not reveal proper panel rating of recommendations. Commenter has submitted an explanation of the steps in prior comments, and they are listed in the methodology regulation. Commenter states that the MEEAC was trained in the methodology at the beginning of the process of developing this proposed regulation, presumably to be able to assess the quality and strength of the evidence and to propose recommendations based on high grade evidence.</p>			
General Comment/ Formulation of Answerable Clinical Questions	<p>Commenter states that specific problem formulations as generally used are not present in the document, despite ODG assertions to the contrary. Commenter points out that there is a list of general questions on ODG's web site. Commenter opines that this is not the same thing as specific answerable clinical questions for various disease entities. Commenter believes that if there are no clinical questions posed, then it is not clear which evidence should be evaluated, and for what indications.</p>	<p>Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substance of the subject of the 3rd 15-day notice.</p>	<p>None.</p>
General Comment/ Comprehensive Literature Search	<p>Commenter states that ODG asserts that specific search criteria were used, but they are not present in the proposed regulations. Commenter states that the search terms and results are not shown, nor is any evidence of subsequent hand searches. Commenter states that the number of references is a fraction of the number cited by the recent American Pain</p>	<p>Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substance of the subject of the 3rd 15-day notice. Commenter raised the same comments during the 45-day notice and the comments were appropriately addressed in the 45-</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Society/ACP guideline, the recent ACOEM pain management guideline, and other professional documents.		day comment period chart. (See, response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.20(h), Medical Treatment Guidelines Development/Literature Search, 45-day comment chart.)	
General Comment/ Screening for Inclusion and Exclusion	Commenter states that there are inclusion and exclusion criteria on the WLDI website but not in the document. Commenter opines that they are rather general; examples include publication in English and with 10 or more subjects [a very low and statistically unstable number (N)]. Commenter believes that there are much more sophisticated screening criteria available. Commenter opines that by using such tools to eliminate lower quality studies makes the subsequent evaluation process more efficient.	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The comment does not address the substance of the subject of the 3 rd 15-day notice. Commenter raised the same comments during the 45-day notice and the comments were appropriately addressed in the 45-day comment period chart. (See, response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.20(h), Medical Treatment Guidelines Development/ Inclusion Criteria, 45-day comment chart.)	None.
General Comment/ Critical Analysis and Rating of Included Studies	<p>Commenter states that study designs are rarely described in any detail. Commenter opines that many of the descriptions may be Pub Med abstracts, which are not designed to identify sources of bias. Commenter states that there is little if any critical analysis of each study, no evidence grades assigned and no evidence tables presented.</p> <p>Commenter states that as a first step, ODG still uses a list of study designs rather than uniform analysis and grading of each high-grade study. Commenter opines that the ODG “rating system” simply classifies documents by type of document or study according to (often inaccurate) PubMed labels. It is merely a labeling system. Commenter states that there is no critical analysis or assessment of methodological</p>	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The comment does not address the substance of the subject of the 3 rd 15-day notice. Commenter raised the same comments during the 45-day notice and the comments were appropriately addressed in the 45-day comment period chart. (See, response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.25(c)(1)/ Critical Appraisal of Quality of Individual Studies, and Section 9792.20(h), Medical Treatment Guidelines Development/ Literature Search	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>quality in this scheme. Categories 3 to 10 include case studies, other guidelines, books, industry materials and so on that no one else classifies as well designed, reproducible evidence.</p> <p>WLDI states that it does have quality ratings (page 28 of their response) but they are subjective rather than objective. More to the point, commenter states that they are not visibly applied to any extent in the proposed regulations. Commenter opines that if they were, the results would be summarized, or preferably detailed in evidence tables. Commenter believes that there is a difference between publishing a Cochrane description on a web page and performing visible, complete and accurate analysis of studies.</p>		45-day comment chart.)	
General Comment/ Synthesis and Rating of the Body of Evidence	<p>Commenter states that there are no evidence syntheses presented for each body of evidence by diagnosis in the proposed regulation and that there is no meta-analysis of the collective study data, which would help characterize the direction and strength of the evidence.</p> <p>ODG states on page 28 of its response that there are syntheses of high quality studies and lists a URL. Commenter points out that the link is password-protected, so that the information is not available to the public or available for quality review.</p>	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The comment does not address the substance of the subject of the 3 rd 15-day notice. Commenter raised the same comments during the 45-day notice and the comments were appropriately addressed in the 45-day comment period chart. (See, response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section9792.25(c)(1)/ Critical Appraisal of Quality of Individual Studies.)	None.
General Comment/ Formulating and Rating Recommendations	<p>Commenter states that it is not clear whether the MEEAC, as the expert panel, formulated the recommendations or whether someone (not identified) at WLDI did. Commenter points out that recommendations in the revised draft are still labeled as “recommended” or “not recommended,” despite a requirement in the DWC regulations to include an alphabetical strength of evidence rating</p>	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The comment does not address the substance of the subject of the 3 rd 15-day notice. Commenter raised the same comments during the 45-day notice and the comments were appropriately addressed in the 45-day comment period chart. (See,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	(Recommended, A B or C level evidence, Insufficient evidence, and Not Recommended with C, B or A level evidence). Sometimes the condition for which the intervention is recommended is stated; often it is not.		response to comment submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on Section 9792.20(h) Medical Treatment Guidelines Development/Recommendations, 45-day comment chart.)	
General Comment/ External Review	Commenter states that there is no evidence of structured external expert reviews. Commenter states that professional content and methods experts, often through appropriate specialty societies and universities, generally do these reviews. In large medical organizations, this can be a specialized internal function. Commenter opines that this is not the same as a public comment period and that the vendor cannot perform it.	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The chronic pain medical treatment guidelines and postsurgical treatment guidelines are adapted from the ODG guidelines. The ODG guidelines have been externally reviewed by experts prior to publication. Appendix B, ODG Treatment in Workers' Comp, Methodology Description using the AGREE Instrument, which has been noticed as a document relied upon by DWC during the 1 st 15-day notice, states, at Item No. 13: “The guideline has been externally reviewed by experts prior to its publication,” as follows: “Prior to publication, select organizations and individuals making up a cross-section of medical specialties and typical end-users externally reviewed ODG Treatment in Workers Comp. See Exhibit E, ODG Methodology Outline. Complimentary review access is also made available to all major medical specialty groups as well as other stakeholders. Among those groups providing feedback	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>are American Academy of Disability Evaluating Physicians, American Academy of Neurology, American Association of Occupational Health Nurses, American Academy of Orthopaedic Surgeons, American Academy of Pain Medicine, American Academy of Physical Medicine and Rehabilitation, American Association of Neurological Surgeons, American Board of Independent Medical Examiners, American Chiropractic Association, American College of Radiology, American Federation of Labor and Congress of Industrial Organizations, American Pain Society, American Physical Therapy Association, American Society of Anesthesiologists, American Society of Interventional Pain Physicians, California Guidelines Evaluation Committee, California Society of Industrial Medicine and Surgery, Canadian Chiropractic Association, Congress of Neurological Surgeons, Council of Acupuncture and Oriental Medicine Associations, Council on Chiropractic Guidelines and Practice Parameters, Department of Defense, Insurance Council of Texas, Kaiser Permanente, North American Neuromodulation Society, North American Spine Society, Reflex Sympathetic Dystrophy Syndrome Association,</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Texas Medical Association, & Texas Orthopedic Association.” Thus, commenter is incorrect in stating that the ODG guidelines are not externally reviewed.	
General Comment/ Guideline Development	<p>Commenter opines that a robust and reproducible guideline development process is not trivial and requires trained staff and panelists, proper analysis and rating and structured quality review.</p> <p>Commenter states that in most guideline and systematic review development efforts, a “Guideline Development Team,” composed of clinical leaders and subject matter experts, examines the evidence summaries, evidence tables, analytic comments and ratings and determines the validity of the comments. Commenter believes that the MEEAC was intended to fill this role.</p> <p>Commenter stresses that the DWC should be very clear that ODG is a vendor providing source material to the staff, Medical Director and Medical Evidence Evaluation Advisory Committee (MEEAC). Commenter opines that the MEEAC then was intended to provide clinical input and a series of ranked clinical recommendations by disease entity consistent with the MTUS methodology to the Medical Director. Commenter states that panels such as this generally include methodologists to provide scientific oversight to the analysis and recommendations formulated by the expert panel (the MEEAC).</p> <p>Commenter states that there is no evidence that that was the process used here. Even if there were, commenter opines that it would be difficult if not impossible for a Guideline Development Team (in this case the MEEAC) to do these tasks given the absence</p>	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. See response to comment submitted by Jeffrey S. Harris, MD, MPH, MBA, dated March 7, 2009, on the subject of General Comment/Methodology, above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	of visible evidence tables, evidence summaries that include grades for each key study as specified by DWC regulations, evidence syntheses, ratings of each body of evidence, or strength of evidence ratings attached to recommendations.			
General Comment/ Adoption of External Guidelines Requires a Formal Quality Review	<p>Commenter states that the ODG guidelines are external to the DWC. In such cases, commenter points out that most medical organizations that entertain the use of guidelines developed elsewhere perform formal quality assessments of the methodology, its application, and the consistency of recommendations with the level and strength of evidence. Commenter states that medical groups such as Kaiser Permanente, the Mayo Clinic, Intermountain Healthcare, and some Federal health systems have specific internal and external QA and QC steps.</p> <p>Commenter states that the AGREE criteria are widely used but have not been revised for some time. Commenter states that there have been significant refinements in the area covered in “rigor of development.” Commenter opines that the AGREE criteria are not germane in this case since the DWC has adopted a specific, more quantitative methodology as a regulatory requirement.</p> <p>At a minimum, commenter expected the MEEAC methodologist, methodologists on the DWC staff, or well qualified external methodologists with the appropriate clinical background to have reviewed the design and application of the proposed external guideline against the MTUS methodology. Commenter states that no such review has been performed or posted for public view his knowledge. Commenter is unaware that either the DWC or the MEEAC have methodologists or a quality control program. Commenter states that the WLDI has not disclosed the presence or qualifications of</p>	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The ODG guidelines, as adapted by the DWC, into the chronic pain medical treatment guidelines and the postsurgical treatment guidelines are guidelines subject to external review as set forth in the response to General Comment/External Review, above. The MEEAC reviews these guidelines to insure that they comply with the requirements of the statute (Section 9792.26(c)(1), and the regulations (which incorporate the guidelines) are noticed to public comments, which insures compliance with the requirements of the statute. DWC is not required by statute to follow procedures follow by other institutions.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>methodologists.</p> <p>Commenter believes a review to safeguard California workers, the quality of care, and the legislative intent of the use of evidence-based medicine, requires assessors with expertise in evidence-based and occupational medicine and without conflicts. Commenter states that such expertise should be available at the University of California or similar institutions.</p>			
Format and Content	<p>Commenter states that the proposed chronic pain regulation continues to resemble a non-critical review article, textbook or dictionary rather than the required stepwise set of information presented in the development of an evidence-based guideline and specifically required by DWC regulation. (Commenter references his prior comments of December 15, 2008 and the EBM publications referenced therein).</p> <p>Commenter states that conspicuously missing from the document are sections on diagnostic criteria, work relatedness, work modification, and many commonly used diagnostic tests and procedures for chronic pain patients. Commenter opines that it is not possible to appropriately use guidelines for occupational medicine or other areas of medicine without following the well accepted clinical decision making process from presenting complaint through diagnosis to treatment plan. In occupational medicine, that process includes a return to work plan as a key part of patient management.</p>	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The comment does not address the substance of the subject of the 3 rd 15-day notice. Commenter raised similar comments during the 45-day notice and the comments were appropriately addressed in the 45-day comment period chart.	None.
General Comment/ Marketing & Sales Comment in the ODG Comments	Commenter states that there are a number of comments in the ODG responses that address competitive sales issues rather than scientific analysis of specific content in the proposed regulations. Commenter believes that the purpose of comment and review is to improve the scientific accuracy of the	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. Commenter appears to state that statements contained in the various “ODG Updates and Comments” documents which were noticed in the “notice of addition of documents to the	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>draft guidelines. Commenter opines that these comments have a different focus. Some examples:</p> <p>ODG several times cites a “peer-reviewed” study that rated ACOEM guidelines below 30% on AGREE criteria. Since previous editions of the ACOEM guidelines are not part of the current proposal, commenter believes that the comments are irrelevant as well as inaccurate.</p> <p>Commenter states that there are two such reviews. The first was a review done several years ago by a group of chiropractors. It was published in The Spine Journal, a chiropractic journal. Commenter states that the review was done on the second edition of the guidelines, which has undergone major revisions. Commenter states that the review is not current. Further, it did not focus on rigor of development, but on issues such as stakeholder input. Commenter opines that the ratings themselves were poorly done.</p> <p>Commenter states that the interventional pain physicians, who have particular financial interests in interventional therapy, did the second review, again on the original second edition. Commenter states that no one contacted ACOEM for comments and further details, as is typically done. Commenter opines that the way the ratings were applied was not impressive. Commenter states that interestingly, when Dr. James Lessinger, a California occupational physician, redid their review, the score was 100%.</p> <p>Commenter provides another example of material irrelevant to the present proposal: On page 7 of the responses, ODG asserts that the use of the ODG guidelines reduced costs by 64% in Ohio. Commenter states that aside from the fact that the statement is not germane to the accuracy and reliability of the</p>		<p>rulemaking file” reference competitive sales issues. Commenter appears to argue that this information which is not pertinent to evidence-based review influence DWC’s decisions. As previously indicated, DWC considered ODG’s responses and made its own determination on whether or not to accept ODG’s comments. The various comments charts reflect DWC’s own analyses and responses to the comments submitted. For example, DWC considered and rejected ODG’s analysis on the <i>Manchikanti</i> studies.</p> <p>With regard to commenter’s reference to ODG’s comment regarding costs, DWC disagrees. DWC did not rely on ODG’s referenced documents to write the economic impact statement. DWC relied on its own economic impact information as reflected in the Economic and Fiscal Impact Statement (Form 399).</p> <p>With regard to the comments relating to ODG’s other features, disagree. DWC did not adopt these features and did not rely on them to write its regulations.</p> <p>Commenter objects to the use of the “visits” in the ODG and DWC guidelines. Disagree. The use of</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>proposed guidelines, he finds it hard to believe, as one of the lead authors of a recent Ohio DWC-commissioned study that demonstrated continued cost escalation in excess of that in some other states. Commenter states that no peer reviewed or graded reference is presented to support this assertion. Commenter states that the comment does not address the provision of better quality care.</p> <p>Commenter opines that the statement that “ODG surpasses all other guidelines in specificity” makes no sense in the evidence-based model. Commenter states that including all CPT codes is a billing issue, not a scientific one. Commenter opines that the issue is linking appropriate care to synonymous diagnostic groups, not which CPT code was used.</p> <p>Commenter states that both the ODG chronic pain guideline and the post-operative care guideline include suggested numbers of visits. Commenter states that suggested numbers of visits generally refer to physical therapy and chiropractic services. Commenter states that no specific appropriateness criteria are included. It is unclear to commenter how the numbers were derived and he states that no evidence is presented to support them, as the DWC noted in its ancillary analysis. Commenter opines that it appears to be someone’s (uncredited) opinion. ODG states that in the absence of evidence, “retrospective normative data” is used. Commenter states that term generally means claims data, which reflects current, rather than best, practices. It is not considered high-grade evidence. Commenter states that this “evidence” or its source is nowhere to be found in the ODG guideline.</p> <p>Commenter states that the dosage, frequency and duration for medications appear to be taken from</p>		<p>the term “visits” is a term directly related to the statute, wherein the number of physical medicine visits are limited to 24. (Lab. Code, § 4604.5(d)(1). The postsurgical treatment guidelines are an exception to the 24-visit limitation cap.</p> <p>Disagree with commenter in that manufacturers’ published data is regulated by the FDA, and therefore is evidence-based.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>manufacturer's data rather than well-designed, independent comparative effectiveness studies. Ceiling doses and frequencies are rarely given. Most references are to one (unrated) pharmacology book.</p>			
<p>General Comment/ Opioids Recommendations</p>	<p>Commenter states that there are a number of substantive errors in the guideline proposal as well. As an example, the document states that short acting opioids are "recommended" for "chronic pain" (no clinical diagnostic criteria given – just a vague time frame). In fact, commenter states that most of these medications have mood elevating side effects and are therefore not recommended for chronic pain in most evidence-based guidelines. Commenter states that they are often used intentionally or unintentionally to treat co-existing mood disorders and they are not appropriate drugs for that purpose. (Commenter states that the Oxycontin manufacturer sponsored studies of its use as an antidepressant in the 1990s to obtain FDA approval as an anti-depressant. Commenter opines that it is fortunate that it was not officially approved for such use.) Commenter believes that this statement poses many problems and should be changed.</p> <p>Commenter states that there are other statements emphasizing the use of long acting medications, creating conflict among recommendations. There is also a statement that opioid agonist/antagonists avoid toxicity. Commenter states this is inaccurate. Commenter states that Suboxone is highly restricted to specially trained practitioners precisely because it is dangerous and hard to use.</p>	<p>Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substance of the subject of the 3rd 15-day notice. Commenter raised similar issues during the 45-day notice period, and his comments were properly addressed in the 45-day comment chart. (See, comments submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on various subjects related to Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Opioids, 45-day comment chart.)</p>	<p>None.</p>
<p>General Comment/ Inclusion of Non-Occupational Conditions</p>	<p>Commenter states that there are recommendations and discussion still address fibromyalgia, myofascial pain syndrome, pelvic pain, herpes zoster, diabetic neuropathy, and other diagnoses for which there is no evidence of occupational causation. Osteoarthritis, phantom limb pain, and cancer, which commenter</p>	<p>Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substance of the subject of the 3rd 15-day notice. Commenter raised similar issues during the 45-day notice period, and his comments were properly</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 3 rd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	states are generally not occupational, are also mentioned. Commenter believes these conditions to be irrelevant to an occupational medicine guideline. ODG asserts that many jurisdictions accept these diagnosed as work related. Commenter opines that if this is true, it ignores the total lack of evidence for causal connection. Commenter opines that such mentions have in the past been used to (somewhat misleadingly) claim that such entities are work-related and that this is not a beneficial situation. Commenter believes that such material should be removed. Commenter opines that it appears that this material may also have been drafted for the general population rather than the working population.		addressed in the 45-day comment chart. (See, comments submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on various subjects related to Section 9792.24.2, General/Work Relatedness, 45-day comment chart.)	
General Comment/ Transparency	Commenter states that ODG asserts its process is transparent but he believes that it is clearly not. Commenter states that the WLDI has yet to publish the list of its guideline developers and methodologists with their qualifications and conflict of interest statements. (Commenter states that their advisory panel is a users group rather than an expert panel, according to some of its members). Commenter states that it has not published its sponsorship and sources of income, which might include device manufacturers or pharmaceutical companies. Commenter states that it has not published a list of outside reviewers, their affiliations or their comments in an open site or as an attachment to the proposed regulation. Commenter also state that the MEEAC has not published its affiliations nor has it published detailed minutes of its deliberations for public view.	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The comment does not address the substance of the subject of the 3 rd 15-day notice. Commenter raised similar issues during the 45-day notice period, and his comments were properly addressed in the 45-day comment chart. (See, comments submitted by Jeffrey S. Harris, M.D., dated August 11, 2008, on various subjects related to Section 9792.20(h), Medical Treatment Guidelines development/ Methodology, 45-day comment chart.)	None.
General Comment/Incorrect Assertion of Payment and Conflict of Interest	Commenter strenuously objects to WLDI's inaccurate statements and mischaracterization of others and himself in response to his previous comments. Commenter states that the WLDI cites him as the "author of every edition of the competing product" (page 30). Commenter states that, in fact, he was the unpaid editor, not the author, of the First Edition of	Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment	Disagree. The comment does not address the substance of the subject of the 3 rd 15-day notice. As previously stated, DWC considered ODG's responses and made its own determination on whether or not to accept ODG's comments.	None.

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	<p>the ACOEM Guidelines, which is out of print. Commenter states that Lee S. Glass was the unpaid editor of the Second Edition, and that Kurt Hegmann is the editor of the revised Second Edition. Commenter states that ODG has asserted elsewhere here and elsewhere that editors and panel members are paid by ACOEM. Commenter states that in fact, only Dr. Hegmann was paid, at a rate far below his normal compensation, to manage the research teams in Salt Lake City and Chicago. Neither of the former editors and none of the expert panel members, methodologists or reviewers were paid for his or her participation in the ACOEM guideline development process. Published conflict statements in the revised ACOEM guidelines do not reveal potential commercial conflicts for panel members. Commenter states that ACOEM, as noted, is a professional medical society that produces guidelines to improve its' members' quality of care, not a commercial guideline company.</p>		<p>The various comments charts reflect DWC's own analyses and responses to the comments submitted.</p>	
<p>General Comment - Recommendation</p>	<p>Commenter states that the revised proposed chronic pain and post-operative regulations are still not evidence-based as required by DWC regulation. Since they are not, commenter opines that recommendations are likely to produce random outcomes, potentially putting California injured workers in harm's way, raising costs with little benefit, and further negatively impacting the California economy and competitiveness. Commenter opines that the proposed regulation represents a return to pre-reform outcomes and costs.</p> <p>Commenter respectfully and strongly suggests that the DWC suspend its proposal of the chronic pain guideline and the post-operative guideline as they stand until independent and well qualified EBM and occupational medicine experts and methodologists, perhaps from the University of California, can fully and formally evaluate the document and the</p>	<p>Jeffrey S. Harris, MD, MPH, MBA March 7, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substance of the subject of the 3rd 15-day notice.</p>	<p>None.</p>

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	<p>development process, as well as potential alternatives. Commenter opines that regulation, science, legislative intent, and worker health improvement require critical and objective quantitative quality appraisal. Commenter believes the proposed guideline is found lacking and that DWC should evaluate alternatives or start the process of internal guideline development, which was its original intent.</p>			