

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
General Comment	<p>Commenter would like to applaud the DWC for finally getting around to trying to help the under-served work comp PATIENTS whose needs and concerns should come before work comp insurance company PROFITS.</p> <p>Commenter opines that this represents a very small step in moving forward against the crime being perpetrated against him and others like him, the work comp patients, by the insurance companies. Commenter would like to see the Schwarzenegger administration prosecuted for collusion with the work comp industry.</p>	<p>Michael Garcia December 4, 2015 Written Comment</p>	<p>Agree.</p> <p>Disagree: Goes beyond the scope of this rulemaking because no changes were suggested specific to these proposed regulations.</p>	<p>None.</p> <p>None.</p>
General Comment	<p>Commenter opines that the Division will not act on his comments but will submit them anyway.</p> <p>Commenter opines that the MTUS is one of the best "Pain Management Guidelines" ever written. Commenter states that it is science and that it is evidence based medicine. Commenter states that 20 some pain specialists gather every 5 years to update the MTUS. Commenter opines that the problem isn't with the MTUS.</p>	<p>Robert R. Kutzner, MD Pain &amp; Addiction Medicine, MD Health Clinics.com December 7, 2015 Written Comment</p>	<p>Disagree: The DWC must respond to any and all comments made during rulemaking.</p> <p>Disagree in part: The DWC through IMR enforces the MTUS.</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter states that the problem is that the State Div. of WC does not enforce the MTUS</p> <p>Commenter opines that this causes immense problems and stinks of cronyism and insider profiting. Commenter states that physicians who follow the MTUS have their requests for approval AUTOMATICALLY DENIED by some clerk. On appeal, it goes to Utilization Review with doctors who are adversarial, support the insurance company, and don't know the MTUS themselves. Commenter opines that employers and Tax Payers pay the price. Patients endure needless suffering, an abomination. Commenter states that this situation leaves the physician with hands tied except to give narcotics for the needless suffering which ultimately promotes Addiction, Physical Dependence, and Overdose. Commenter wonders how brain dead the system can be.</p> <p>Commenter states that he has dealt with WC since 1986 and he opines</p>		<p>Disagree: The DWC disagrees with commenter's description of how the MTUS is enforced. Goes beyond the scope of this rulemaking because no changes were suggested specific to these proposed regulations were made.</p> <p>Disagree: Goes beyond the scope of this rulemaking because no changes were</p>	<p>None.</p> <p>None.</p>

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	<p>that never has it been managed so poorly, so inefficiently, and so fiscally irresponsible.</p> <p>Commenter states that the DWC is responsible because DWC does not enforce the MTUS.</p> <p>Commenter opines that the system is really a joke and exists only to be a public rip off of employers and taxpayers money.</p> <p>Commenter requests that the DWC stop making incessantly more guidelines and requests that the DWC please start enforcing them.</p> <p>Commenter opines that at least the Division should make insurance companies acknowledge the MTUS. Commenter states that the DWC does not even do this.</p>		<p>suggested specific to these proposed regulations were made.</p> <p>Disagree: See above.</p> <p>Disagree: See above.</p> <p>Disagree: The DWC has not updated the MTUS since 2009. Also, see above regarding enforcement.</p> <p>Disagree: Utilization Review decisions must follow the request UR and MTUS statutory and regulatory mandates.</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>
Chronic Pain Medical Treatment Guidelines	Commenter requests that the Division update the Chronic Pain Medical Treatment Guideline citations with twenty first century peer reviewed and	Solomon (Sandy) Perlo, MD DLFAPA Adjunct Professor, Division of		

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	<p>published definitions of chronic pain and submits two publications.<sup>1</sup></p> <p>Commenter references the following statements:</p> <p>1. <i>"This definition describes pain as a subjective experience; therefore, unlike hypertension or diabetes, there is no objective measurement for pain intensity."...</i></p> <p>2. <i>"Because pain is a subjective experience, it cannot be readily validated or objectively measured (AMA, 2001)Therefore, unlike many other chronic diseases, which may have objective measurements that can be used to assess the extent of the problem and treatment outcomes, chronic pain has no objective measurement. Measuring a patient's pain requires correlating objective data with the patient's subjective reporting to arrive at a comprehensive outcome representing the state of pain</i></p>	<p>Occupational and Environmental Medicine David Geffen School of Medicine, UCLA December 12, 2015 Written Comment</p>	<p>Disagree: The DWC will not revise its definition of Chronic Pain because it is the current nationally recognized standard. Although the Davydov and Perlo article on use of "a scientifically validated cardiovascular metric" (serial blood pressure and orthostatic blood pressure readings with psychological testing), provides encouraging progress in further understanding the physical, emotional and cognitive dimensions of chronic pain; however, it is a single study with 50 subjects and has not been replicated nor considered to be the nationally recognized standard.</p>	<p>None.</p>

<sup>1</sup> Bushnell et al., "Cognitive and emotional control of pain and its disruption in chronic pain;" [NATURE REVIEWS: NEUROSCIENCE: July 2013 (14): 503-511] and Elman, Zubieta, and Borsook "The Missing "P" in Psychiatric Training: Why is it Important to Teach Pain to Psychiatrists? [Arch Gen Psychiatry. 2011 January ; 68(1): 12-20]

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	<p>Commenter opines that these statements are factually incorrect. Commenter states that the peer reviewed 2015 publication by Davydov and Perlo introduces for the first time into California's consensus based workers' comp system an evidence-based objective metric of chronic pain that "most accurately" rates chronic pain whole person impairment (CP/WPI) in 3 separate dimensions at a 95% threshold of reliability and confidence: Pain sensation; pain severity and pain magnification. These 3 dimensions of CP/WPI do not overlap. They are independently supported in the literature: Figure 1 from Bushnell et al., <b>“Cognitive and emotional control of pain and its disruption in chronic pain;”</b> [NATURE REVIEWS: NEUROSCIENCE: July 2013 (14): 503-511]. Commenter states that this independently validates a three-dimensional structure of chronic pain that is identical with ours.</p>		<p>Disagree: The DWC disagrees that the statements above are “factually incorrect.” Commenter states that “the peer reviewed 2015 publication by Davydov and Perlo <b>introduces for the first time</b>” {emphasis added} an objective metric of chronic pain. We will allow greater review and scrutiny by the national medical community before a dramatic change such as the one proposed by commenter is incorporated into the MTUS. Also, see above.</p>	<p>None.</p>

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	<p>Figure 1 states that “pain can have a negative effect on emotions and on cognitive function. Conversely, a negative emotional state can lead to increased pain, whereas a positive state can reduce pain. Similarly, cognitive states such as attention and memory can either increase or decrease pain. Of course, emotions and cognition can also reciprocally interact. The minus sign refers to a negative effect and the plus sign refers to a positive effect.”</p> <p>Commenter states that "Chronic Pain" by definition is a 21st century psychiatric disorder. The 2011 publication by <b>Elman, Zubieta, and Borsook</b> “<b>The Missing “P” in Psychiatric Training: Why is it Important to Teach Pain to Psychiatrists?</b> [Arch Gen Psychiatry. 2011 January; 68(1): 12–20] validates chronic pain as a 21st century psychiatric disorder because it is a condition that involves clinical brain neuroscience using a multi-systems model. The study's abstract is</p>		<p>Disagree: The biopsychosocial approach taken by the proposed MTUS also considers the effects of the mind and psychology on the body and the experience of pain.</p> <p>Disagree: The article by Elman, et al., although informative, focuses on pain training for psychiatric residents treating psychiatric patients.</p>	<p>None.</p> <p>None.</p>

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	<p>reproduced below:</p> <p><b>ABSTRACT:</b>  <b>Context</b>—Pain problems are exceedingly prevalent among psychiatric patients. Moreover, clinical impressions and neurobiological research suggest that physical and psychological aspects of pain are closely related entities. Nonetheless, remarkably few pain-related themes are presently included in psychiatric residency training.</p> <p><b>Objective</b>—Our objective is twofold: (1) to provide clinical and scientific rationale for psychiatric training enrichment with basic tenets of pain medicine and (2) to raise the awareness and sensitivity of clinicians, scientists and educators alike to the important yet unmet clinical and public health need.</p> <p><b>Results</b>—Three lines of translational research evidence, extracted from the comprehensive literature review, are presented in support of the objective.</p>			

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	<p>First, the neuroanatomical and functional overlap between pain and emotion/reward/motivation brain circuits suggests integration and mutual modulation of these systems. Second, psychiatric disorders are commonly associated with alterations in pain processing, whereas chronic pain may impair emotional and neurocognitive functioning. Third, pain may serve as a functional probe for unraveling pathophysiological mechanisms inherent in psychiatric morbidity given its stressful nature for the organism.</p> <p><b>Conclusions</b>—Pain training in psychiatry will not only contribute to deeper and more sophisticated insights into pain syndromes but also into psychiatric morbidity at large regardless of patients’ pain status. Furthermore, it will ease artificial boundaries separating psychiatric and medical formulations of brain disorders, thus fostering cross-fertilizing interactions between specialists in various disciplines entrusted with the care of pain patients.</p>		<p>Disagree: The DWC will not revise its definition of Chronic Pain because it is the current nationally recognized standard. Although the Davydov and Perlo article on use of “a scientifically validated cardiovascular metric” (serial blood pressure and orthostatic blood pressure readings with psychological testing), provides encouraging progress in further understanding the physical, emotional and</p>	<p>None.</p>

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	<p>Commenter states that this publication illustrates "chronic pain and the brain" as a psychiatric disorder with 3 figures attached to the publication "Chronic pain and the brain" is a metaphor introduced by Borsook et al [2012]for the damage that chronic pain does not just to the brain but to other body parts as well.</p>		<p>cognitive dimensions of chronic pain; however, it is a single study with 50 subjects which has not been replicated nor considered to be the nationally recognized standard. We will allow greater review and scrutiny by the national medical community before a dramatic change such as the one proposed by commenter is incorporated into the MTUS. Also, see above.</p>	
General Comment	<p>Commenter states that he support the modifications made by the Division following the first comment period, but opines that several key comments were overlooked.</p> <p>Commenter states that the choice to use the Official Disability Guidelines as the basis for the Chronic Pain Treatment Guidelines is a positive step. Commenter represents a utilization review organization and has concerns about the fact that the Division has chosen to adopt a specific edition of the ODG, rather than allowing the Chronic Pain</p>	<p>Ben Roberts Executive Vice President PRIUM December 18, 2015 Written Comment</p>	<p>Disagree: In order to properly incorporate the ODG guidelines by reference into our regulations, subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the document by title and date of publication or issuance." Therefore, incorporating the "most current version" without stating the date of publication or issuance is not allowed. Also, allowing the MTUS to be automatically updated</p>	None.

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	<p>Treatment Guidelines to reflect the most current version of ODG.</p> <p>Commenter opines that guidelines are most effective if they are current and regularly updated to reflect current medical evidence, and opines that the language, as proposed, will minimize the effectiveness of the Guidelines.</p> <p>Commenter proposed that the reference to a specific version of the Official Disability Guidelines be removed and replaced with language indicating that the current or most recent version of the Official Disability Guidelines should be referenced.</p> <p>Commenter opines that by referencing the most recent version of the Official Disability Guidelines, the Division would allow new and contemporaneous evidence based medicine to be introduced into the California workers' compensation system. Commenter opines that this is of particular importance as the Division contemplates the implementation of a Prescription Drug</p>		<p>whenever ODG updates their guidelines is an unlawful delegation of the DWC's regulatory authority and will not be permitted by the Office of Administrative Law.</p> <p>Disagree: See above. In addition, any amendments to any guideline incorporated by reference into the MTUS must go through the formal rulemaking process cannot merely reference the most recent version of the ODG guidelines.</p> <p>Disagree: See above. Also, this rulemaking pertains to the Chronic Pain Medical Treatment Guidelines and the Opioids Treatment Guidelines not the upcoming drug formulary regulations. Comment goes beyond the scope of this rulemaking.</p>	<p>None.</p> <p>None.</p>

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	<p>Formulary. As new medications and dosages are frequently approved by the FDA, and reactions to those changes needs to occur quickly in order to ensure that the Formulary and the Guidelines properly address them. Commenter notes that under the current proposed regulations, it appears that the formal rulemaking process would need to occur in order to make the changes needed to be current.</p>			
General Comment	<p>Commenter supports the general direction taken in the draft regulations and would like to acknowledge the MEEAC for their tireless efforts.</p> <p>Commenter supports adopting the Official Disability Guidelines (ODG) without substituting unique California guidelines for opiates. Commenter is disappointed that the latest proposed regulations did not contain the recommendation to automatically update the MTUS when the ODG is updated. Commenter opines that allowing automatic updates ensures patients receive medical care that relies on the most current evidenced-based medicine. The pace of change</p>	<p>Jeremy Merz California Chamber of Commerce</p> <p>Jason Schmelzer California Coalition on Workers' Compensation</p> <p>Faith Conley California State Association of Counties December 18, 2015 Written comment</p>	<p>Agree.</p> <p>Disagree: In order to properly incorporate the ODG guidelines by reference into our regulations, subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the document by title and date of publication or issuance." Therefore, incorporating the "most current version" without stating the date of publication</p>	<p>None.</p> <p>None.</p>

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	<p>regarding medical information requires regular updates to any guidelines or formulary. Commenter states that this has been unequivocally documented by numerous healthcare studies.</p> <p>Commenter requests that the Department of Industrial Relations (DIR) to pause the rulemaking process on the Guidelines. Commenter notes that subsequent to the initial comment period, AB 1124 (Perea) was signed into law. This legislation directs DIR to create a prescription drug formulary. Commenter opines that the success of both the formulary and the Guidelines is predicated on consistency in concepts and language between the two sets of regulations. Commenter opines that DIR should promulgate formulary regulations prior to completing the rulemaking process for the Guidelines so both sets of regulations can be examined and issues can be addressed without having to go through another regulatory process.</p>		<p>or issuance is not allowed. Also, allowing the MTUS to be automatically updated whenever ODG updates their guidelines is an unlawful delegation of the DWC’s regulatory authority and will not be permitted by the Office of Administrative Law.</p> <p>Disagree: The DWC will not “pause the rulemaking process” for the Chronic Pain Medical Treatment Guidelines and the Opioids Treatment Guidelines. As the DWC proceeds with the upcoming Formulary regulations pursuant to AB 1124, it will most definitely keep consistency in concepts and language in mind. Also, this rulemaking pertains to the Chronic Pain Medical Treatment Guidelines and the Opioids Treatment Guidelines not the upcoming drug formulary regulations. Comment goes beyond the scope of this rulemaking.</p>	None.

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Chronic Pain Medical Treatment Guidelines – Post Operative Pain	<p>Commenter would like to confirm the Division’s support for the recommendation of acupuncture as a first line of treatment for work-related injuries as an alternative to opioids for mild and moderate-acute, subacute and chronic pain.</p> <p>Commenter notes that there is no mention of acupuncture for post-operative pain after discharge. Commenter states that acupuncture for post-operative pain is considered an effective protocol and there are numerous studies that be accessed that attest to the efficacy of acupuncture in this situation. Commenter has previously referenced specific studies in his comments dated Sept 2, 2015. Commenter notes that several large health insurance companies, including Aetna and Cigna, have posted clinical policy bulletins which include acupuncture as a covered benefit meeting medical necessity guidelines for post-operative pain. Commenter</p>	Michael L. Fox, PhD, Lac, President California Acupuncture Association December 18, 2015 Written Comment	<p>Agree: The proposed Chronic Pain Medical Treatment Guidelines incorporate both pharmacologic and non-pharmacologic treatment including acupuncture provided it is reasonable and necessary. See MTUS Acupuncture guideline.</p> <p>Disagree: Acupuncture is already approved for use within the MTUS. Content for acupuncture is found in the current Acupuncture Guidelines. In addition, Acupuncture is addressed in Section 3.2 ”Consideration of Alternative Treatments for Chronic Pain and Chronic Opioid Treatment” where it states: “Non-opioid alternative therapies for pain treatment should be tried whenever possible before resorting to chronic opioid therapy (references cited) and, “in addition these treatment</p>	<p>None.</p> <p>None.</p>

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	requests that the Division consider adding acupuncture as an option for post-operative pain		modalities should be continued even if opioids are used for relieving chronic pain: Complementary/alternative modalities, such as acupuncture, massage, and yoga. (references cited)”	
Opioid Medical Treatment Guideline	Commenter recommends that the language be stronger regarding the Opioid Treatment Guidelines. In order to make the language stronger, commenter recommends using the word “shall” instead of “should” or “recommend”.	Karen L. Sims Assistant Claims Operations Manager Claims Medical and Regulatory Division State Fund December 18, 2015 Written Comment	Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.	None.
9792.23(b)(1)	Commenter recommends the following revised language:  In providing treatment using other guidelines pursuant to subdivision (b) above and in the absence of any cure	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI)	Disagree: Commenter’s suggested language to incorporate the phrase “to treatment for chronic pain” will not be incorporated because it is unnecessary.	None.

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	<p>for the patient who continues to have pain lasting three or more months from the initial onset of pain, the chronic pain medical treatment guidelines in section 9792.24.2 shall apply to treatment for chronic pain and supersede any applicable chronic pain guideline in accordance with section 9792.23(b).</p> <p>Commenter supports the modification the Administrative Director has made here and elsewhere in these regulations, including in the Guidelines, which replaces “that persists beyond the anticipated time of healing” with “lasting three or more months from the initial onset of pain.” Commenter opines that without this modification, the language will be inconsistent with the definition of chronic pain in Section 9792.20(b), and will result in confusion and disputes.</p> <p>Commenter states that the addition of “to treatment for chronic pain” is necessary to clarify that the Chronic Pain Medical Treatment Guidelines are meant to address the treatment for</p>	<p>December 18, 2015 Written Comment</p>	<p>Section 9792.24.2 clearly defines that the Chronic Pain Medical Treatment Guidelines apply when the patient has chronic pain as defined in section 9792.20.</p>	

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9792.24.2(b) – (d)	<p>chronic pain.</p> <p>Commenter recommends the following revised language:</p> <p>(b) The Chronic Pain Medical Treatment Guidelines apply <u>to treatment for chronic pain</u> when the patient has chronic pain <u>as defined in section 9792.20</u>.</p> <p>(c) When a patient has chronic pain and <u>the treatment for</u> the <u>injury or</u> condition is covered in the Clinical Topics sections of the MTUS but is not addressed in the Chronic Pain Medical Treatment Guidelines, the Clinical Topics section applies <u>to that treatment</u>.</p> <p>(d) When a patient has chronic pain and the <u>treatment injury or condition</u> is addressed in both the Chronic Pain Medical Treatment Guidelines and <u>the specific guideline found</u> in the Clinical Topics section of the MTUS or <u>if the treatment injury or condition</u> is only addressed in the Chronic Pain Medical Treatment Guidelines, then the Chronic Pain Medical Treatment Guidelines shall apply <u>to treatment for</u></p>	Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) December 18, 2015 Written Comment	Disagree: Commenter's recommended language will not be incorporated because it mixes concepts up and is confusing. For example, commenter suggests 9792.24(b) be amended to state "(b) The Chronic Pain Medical Treatment Guidelines apply <u>to treatment for chronic pain</u> when the patient has chronic pain as defined in section 9792.20" but then goes on to state that "whether or not the injury or condition is covered in a set of guidelines is the controlling factor, and not merely whether a treatment is covered within the set of guidelines" the language currently proposed for section 9792.24.2(b) is correct and is consistent with commenter's statement above. As proposed, section 9792.24.2(b) states, "The Chronic Pain Medical Treatment Guidelines apply	None.

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	<p><u>chronic pain.</u></p> <p>Commenter opines that whether or not the injury or condition is covered in a set of guidelines is the controlling factor, and not merely whether a treatment is covered within the set of guidelines. A treatment may appear in a guideline, but there may be no recommendation regarding that treatment for the given injury or condition. This recommended language is also consistent with the terms used in Labor Code section 4604.5(d) ...” For all injuries not covered by the official utilization schedule...”</p> <p>Commenter states that the addition of “to treatment for chronic pain” is necessary to clarify that the Chronic Pain Medical Treatment Guidelines are used to address treatment for chronic pain.</p>		<p>when the patient has chronic pain as defined in section 9792.20.” Commenter subsequently suggests deleting the word “treatment” in (c) and (d) and replacing it with the phrase “injury or condition.” Again, this is the exact opposite of what we are trying to convey. The word “treatment” will remain in proposed sections (c) and (d). Finally, commenter suggests deleting the phrase “the specific guideline found” and leaving the phrase “Clinical Topics section of the MTUS.” This suggestion will not be incorporated because the phrase provides important clarification as to which Clinical Topics section guideline of the MTUS we are referring to.</p>	
Chronic Pain Medical Treatment Guideline	In written testimony submitted on September 1, 2015, commenter recommended modifications to improve the MTUS Chronic Pain Medical Treatment Guidelines. CWCI	Brenda Ramirez Claims & Medical Director California Workers’ Compensation	Agree.	None.

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	<p>appreciates the modifications that were made to conform to the definition of chronic pain in Section 9792.20.</p> <p>Commenter opines that it is not always clear in the Guidelines what (if anything) is being recommended, and/or under what conditions a recommendation applies. Commenter notes that multiple medical studies pertaining to a treatment for an injury or condition are described, but states that study recommendations are sometimes at odds with one another; and often there is nothing or little to indicate an MTUS Chronic Pain Medical Treatment Guidelines recommendation. Commenter opines that this generates unnecessary confusion and dispute. It is important that the MTUS guidelines are as clear as possible because if they are not, injured employees will not be protected from harmful and unnecessary care and will not be assured of effective care. Commenter requests that the Administrative Director reconsider her other recommendations (summarized</p>	<p>Institute (CWCI) December 18, 2015 Written Comment</p>	<p>Disagree: The words “recommended” or “not recommended” are generally included at the beginning of each Procedure/topic, and very often further criteria are included. All recommendations must be supported by scientific medical evidence. The recommendations are as clear as the supporting evidence allows. There are a few sections that do not contain recommendations. These sections will contain helpful descriptions or definitions or refer readers to another section of the guideline that will contain related recommendations. It is not required that all sections contain recommendations. The intent of an evidence-based guideline is to assist the physician by making evidence-</p>	<p>None.</p>

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	<p>below) that will clarify which is the most effective and safe treatment for injured employees.</p> <p><b>Summary of General Recommendations</b></p> <ul style="list-style-type: none"> <li>Remove terms such as “should” and instead ensure each procedure, modality and good it addresses has a clear recommendation (e.g., “recommended” or “not recommended”)</li> <li>Insert between the two columns of the Part 2 table a Recommendations column where each procedure, modality or topic is identified</li> </ul>		<p>based recommendations, not to provide a step by step directive for how to practice medicine. Specific individual patient factors should always be considered and evaluated.</p> <p>Disagree: See above. Also, the MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.</p> <p>Disagree: Adding two additional columns is unnecessary because the second column usually begins with the procedure summary</p>	<p>None.</p> <p>None.</p>

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	<p>as “recommended” or “not recommended” and where conditions, frequency, duration, intensity and appropriateness may be addressed</p> <ul style="list-style-type: none"> <li>• Retitle the last column “Supporting Medical Evidence,” and in that column provide a link to each supporting study and its strength of evidence determined per section 9792.25.1, and remove irrelevant citations from the column</li> </ul>		<p>recommendation before it delves into the additional details of the treatment procedures. Commenter’s suggestion will lead to unnecessary repetition of information.</p> <p>Disagree: Commenter also suggests that the DWC should replace all of ODG’s ratings with a rating according to the methodology set forth in section 9792.25.1. This request entails over 800 pages of revisions to ODG’s guideline that the DWC is incorporating by reference. The DWC has chosen to incorporate an existing, well-respected guideline because we have limited resources and are not primarily in the guideline making business. Requiring UR and IMR physicians to assess the underlying medical evidence pursuant to section 9792.25.1 is merely requiring them to do what they’re supposed to be doing when</p>	None.

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	<ul style="list-style-type: none"> <li>• Improve the formatting of the Part 2 table by providing clearer subsection headings, spacing between subsections, and by removing duplicate subheadings.</li> <li>• Delete from this MTUS chapter recommendations for treatment of non-chronic pain, including recommendations for acute pain, sub-acute pain and initial treatment.</li> <li>• Retitle part 2 of the MTUS Chronic Pain Medical Treatment Guidelines “Chronic Pain Medical Treatment Guidelines” to avoid confusion with ODG’s</li> </ul>		<p>there are competing recommendations.</p> <p>Disagree: “Part 2: Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” is ODG’s Procedure Summaries. Any changes to this section must come from and be approved by ODG/WLDI.</p> <p>Disagree: Material that describes and differentiates treatment for acute and subacute pain in the context of chronic pain is intended to clarify which treatment is appropriate for chronic pain. Recommendations for treatment in this proposed guideline are for Chronic Pain.</p> <p>Disagree: Part 2: is correctly entitled the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” because it is an edited version of the</p>	<p>None.</p> <p>None.</p> <p>None.</p>

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	own guidelines		Official Disability Guidelines published on April 6, 2015.	
9792.24.4(b)	<p>Commenter recommends the following revised language:</p> <p>The Opioids Treatment Guidelines describe the appropriate use of opioid medications <b>during treatment, including</b> treatment as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain. These guidelines apply when <b>alternative therapies do not provide adequate pain relief and</b> the use of opioid medications is being considered as part of the treatment regimen.</p> <p>Commenter opines that some will argue that this wording restricts the application of Opioids Treatment Guidelines to only “treatment that is part of an overall multidisciplinary treatment regime.” Commenter does not believe that this is the Administrative Director’s intention. Commenter states that the modification recommended will</p>	<p>Brenda Ramirez Claims &amp; Medical Director California Workers’ Compensation Institute (CWCI) December 18, 2015 Written Comment</p>	<p>Disagree: Commenter’s suggested language will not be incorporated because the current iteration with the phrase “as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain” already includes treatment provided by a single physician in a single discipline.</p>	None.

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	<p>clarify that the Opioid Treatment Guidelines are applicable to all treatment regimens, including when treatment is provided by a single physician in a single discipline.</p> <p>Commenter states that since opioids are necessary only when “alternative therapies do not provide adequate pain relief,” she recommends retaining the phrase which will serve to remind physicians to use alternative therapies for pain relief instead of opioids whenever possible.</p>		<p>Disagree: Commenter’s suggested language to reinstate the phrase “alternative therapies do not provide adequate pain relief and...” will not be incorporated because the proposed Opioids Treatment Guidelines allow the option to go straight to opioids without first having to demonstrate that the alternative therapies do not provide adequate pain relief.</p>	<p>None.</p>
<p>Opioid Medical Treatment Guideline</p>	<p>Commenter acknowledges that the Division has invested many hours and resources drafting its Opioids Treatment Guideline but notes that the Administrative Director made only a few modifications, all of which were minor corrections. The commenter’s previous recommended improvements have not been assimilated. Commenter recommends that the Administrative Director reconsider the following two recommendations that would result in the most improvements:</p> <ul style="list-style-type: none"> <li>• Remove terms such as</li> </ul>	<p>Brenda Ramirez Claims &amp; Medical Director California Workers’ Compensation Institute (CWCI) December 18, 2015 Written Comment</p>	<p>Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.</p>	<p>None.</p>

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	<p>“should” and instead ensure that each service or good that the Guidelines addresses has a clear recommendation (e.g., “recommended” or “not recommended”)</p> <ul style="list-style-type: none"> <li>Consider prohibiting opioid dispensing from physician offices and clinics.<sup>2</sup></li> </ul>		<p><u>Disagree: The DWC does not have authority to prohibit physician prescribing in the office setting. It is beyond the scope of the MTUS to limit physician prescription authority, which is governed by the Medical and Pharmacy Boards of California.</u></p>	<p><u>None.</u></p>
<p>Chronic Pain Medical Treatment Guidelines – Home Health Care</p>	<p>Commenter states that the proposed definition of and criteria for home health care services is an improvement on the existing MTUS standard, which has resulted in harsh results for a number of seriously injured folks who needed some in-home help.</p> <p>Commenter still has major concerns.</p> <p>Commenter opines that the proposed regulations will likely leave a number of workers unable to access in-home</p>	<p>Julius Young December 19, 2015 Written Comment</p>	<p>Agree.</p> <p>Disagree: The definition of homebound, modified from CMS, was intended to describe</p>	<p>None.</p> <p>None.</p>

<sup>2</sup> Thumula, V. Impact of Banning Physician Dispensing of Opioids in Florida. WCRI, July 2013.

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	<p>services even though they are needed. This may include</p> <ul style="list-style-type: none"> <li>a) workers who are not totally homebound but have intermittent episodes of pain or psychological disability that makes it hard for them to leave the home</li> <li>b) workers who are not homebound (for instance they might occasionally drive a car) but cannot handle the essential activities of daily living inside their place of residence. There are workers who need help with personal care and domestic care who are not homebound but require those types of services. The fact that they can get outside their home some does not speak to their needs inside the home, which is what home services are all about.</li> </ul> <p>Commenter requests evidence that the DWC has studied the needs of these workers.</p> <p>Commenter opines that these guidelines as written would appear to offer no support for any in-home help to such folks, and he is not aware of any efforts by the DWC or DWC to</p>		<p>the injured worker that might require home health care services. This definition is intended to provide guidance and is not meant to constrain access to home health care when medically necessary. The ability to drive, for example is not a necessarily a preclusion from the need for home health care services. An injured worker may be wheelchair bound or use other assistive devices and still be able to drive a modified vehicle, and still require home care services for assistance with activities of daily living.</p> <p>Disagree: The proposed Home Health Care Services section cites the studies used to support the recommendations. In addition, this comment goes beyond the scope of this rulemaking because no changes were suggested specific to these proposed</p>	None.

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	<p>look at studies or conduct hearings on the needs of such individuals.</p> <p>Commenter opines that the reference to 30, 60, 90 and 120 days will set up situations where there will be lots of frictional costs as chronically severely ill workers are constantly forced to seek re authorization for services that may be needed for years. Commenter opines that it is likely to result in UR/IMR disputes and it is not clear how the WCAB’s Patterson case will affect this.</p> <p>Commenter states that CMS references pertain to payment criteria under Medicare and not to medical studies on reasonableness or necessity of care to cure or RELIEVE. CMS does not pay for certain things, but referencing CMS is not a reference to studies on the necessity for care.</p>		<p>regulations.</p> <p>Disagree: Commenter mischaracterizes this recommendation by stating “chronically severely ill workers are constantly forced to seek re authorization for services....” The language strongly suggests period re-assessments by using the word “should” instead of “shall” and clearly states, “at interval matched to the individual patient conditions and needs.” Finally, the 30, 60, 90 or 120 are clearly provided as an “example” for the interval reassessments.</p> <p>Commenter is correct that policy expression documents such as those published by Medicare/CMS should not be used to support a recommendation in the MTUS. Here, the (CMS, 2014) citation is not used to support a recommendation pertaining to medical necessity, rather, the</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter recommends that the division look at the criteria and procedures used under the IHSS program. Commenter opines that since IHSS services and access are more comprehensive, some workers will want to access that, and he predicts that this will be a continuing political football that will plague the DWC.</p>		<p>CMS citation describes the characteristics of someone who may need home health care services. This citation was left in the proposed guideline because it offers an important operational description, not a recommendation pertaining to medical necessity. This operational description is nationally recognized by the medical community and is even incorporated in the Ellenbecker 2008 study. Finally, CMS was also cited in the previous MTUS Chronic Pain Guidelines and was approved by the Office of Administrative Law in 2009.</p> <p>Disagree: IHSS does not apply to the MTUS because IHSS is overly restrictive. IHSS requires MediCal eligibility, in addition, the California Welfare and Institutions Code Section 14132.95 states personal care services may be: “Provided to a beneficiary who has a chronic, disabling</p>	<p>None.</p>

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			<p>condition that causes functional impairment that is expected to last at least 12 consecutive months or that is expected to result in death within 12 months and who is unable to remain safely at home without the services described in this section.” In addition, section (d) (2) states: Ancillary services including meal preparation and cleanup, routine laundry, shopping for food and other necessities, and domestic services may also be provided as long as these ancillary services are subordinate to personal care services. Ancillary services may not be provided separately from the basic personal care services.” These restrictions are not compatible with the requirements of Labor Code 4600(h). Furthermore, the administrative requirements of IHSS, including the assessment and management of cases by county social workers in each California county is</p>	

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			impractical and would burden those county social service departments.	
9792.23(b)(1)	Commenter appreciates the proposed amendment defining chronic pain as that “lasting three or more months form the initial onset of pain” as this definition provides clarity and removes ambiguity of the phrase “that persists beyond the anticipated time of healing.”	Diane Worley California Applicants’ Attorneys Association (CAAA) December 19, 2015 Written Comment	Agree.	None.
9792.24.4(b)	Commenter appreciates the amendment deleting the phrase “alternative therapies do not provide adequate pain relief” because she believed that it’s inclusion could be interpreted by reviewers to mean that opioids cannot be prescribed until a clinical history established inadequate pain relief after a trail of all the alternative therapies listed in the proposed Opioid Medical Treatment Guidelines. Commenter states that this amendment simply clarifies the Opioids Medical Treatment Guidelines simply apply when use of opioid medication is being considered as part of the treatment regimen.	Diane Worley California Applicants’ Attorneys Association (CAAA) December 19, 2015 Written Comment	Agree.	None.
Chronic Pain	Commenter is concerned about the	Diane Worley	Disagree: The definition of	None.

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<p>Medical Treatment Guidelines – Home Health Care</p>	<p>proposed revisions to the Chronic Pain Treatment Guidelines is regarding Home Health Care Services on pages 88 and 89 and the changes related to the definition of “homebound” as a threshold eligibility requirement to obtain services:</p> <p>“Homebound is defined as “confined to the home”. To be homebound means: The individual has trouble leaving the home without help (e.g., using a cane, wheelchair, walker, or crutches; special transportation; or help from another person) because of the occupational illness or injury</p> <p>OR</p> <p>Leaving the home isn't recommended because of the occupational illness or injury AND the individual is normally unable to leave home and leaving home is a major effort (CMS, 2014).”</p> <p>Commenter opines that the reference to CMS, 2014 in the guideline for home health services needs to be clearly limited. Commenter notes that the revised definition of “homebound”</p>	<p>California Applicants’ Attorneys Association (CAAA) December 19, 2015 Written Comment</p>	<p>homebound, modified from CMS, was intended to describe the injured worker that might require home health care services. This definition is intended to provide guidance and is not meant to constrain access to home health care when medically necessary. The ability to drive, for example is not a necessarily a preclusion from the need for home health care services. An injured worker may be wheelchair bound or use other assistive devices and still be able to drive a modified vehicle, and still require home care services for assistance with activities of daily living.</p> <p>Disagree: that the reference to CMS, 2014 creates ambiguity. The operational definition of homebound is widely excludes additional CMS limitations,</p>	<p>None.</p>

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	<p>comes from this Medicare reference, but states that Medicare also doesn't allow for payment for some types of intermittent skilled care, 24-hour-a-day care at home, personal care services, or meals delivered to your home. Commenter opines that including a general reference to CMS 2014 may create enough ambiguity to a UR or IMR reviewer that medically necessary home health care services which would otherwise be authorized are denied. Commenter recommends that the reference to CMS 2014 be deleted from page 89 of the Chronic Pain guidelines.</p> <p>Commenter opines that this restrictive definition of "homebound" will narrow the obligation to provide attendant care to many injured workers. Commenter asks what about the stroke victim who can "easily" leave the house but has cognitive and mental deficiencies which prevent them from taking care of their hygiene, medical needs, and daily chores? Or the paranoid, agoraphobic worker with PTSD who gets out of the house upon his psychiatrist's</p>		<p>and clearly describes how home health care services could apply to a wide range of clinical conditions with varying levels of disability. The definition broadly establishes that there must be a clinical reason for provision of services in the home. Subsequent language in this section of the proposed guideline clearly states that non-clinical services are covered and provides the framework for establishing medical necessity.</p> <p>Disagree: that any of the situations listed by the commentator would be excluded by the proposed definition of "homebound". Rather, the medical condition, objective deficits in function, specific activity precluded by such deficits, and expected services required, including scope and extent of services, as documented by the physician, would be the basis for</p>	None.

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	<p>recommendations but has intermittent episodes where they do not leave the house, fail to take medications and don't eat properly? Or the severe migraine sufferer who can function normally when they do not have headaches, but when the headaches come on they become light sensitive for several days or weeks in a row and cannot get out in daylight or drive at night?</p> <p>Commenter is concerned that limiting eligibility for home health care services with an unduly restrictive MTUS and definition of "homebound" will inevitably result in the denial of home health care services to the most vulnerable injured worker population. Commenter opines that limiting the eligibility requirement for home health care services in a treatment guideline without an evidentiary or scientific basis to support the limitation is setting an arbitrary review process in conflict with the established principles of Evidence Based Medicine.</p>		<p>establishing medical necessity.</p> <p>Disagree: See above. Also, this section requires the case by case assessment of the individual and does not restrict any particular medical condition. The definition of homebound, modified from CMS, describes the injured worker that might require home health care services. This definition is intended to provide guidance and is not meant to constrain access to home health care when medically necessary. The ability to drive, for example is not a necessarily a preclusion from the need for home health</p>	<p>None.</p>

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	<p>Commenter notes that Labor Code Section 5307.27 requires that the MTUS be evidence based, peer reviewed and based on nationally recognized standards of care. Commenter opines that the current proposed reference in the MTUS to “homebound” does not meet any of these required standards. CMS 2014 sets forth payment eligibility criteria for the federal government run Medicare health insurance program. These are not evidence based treatment guidelines.</p> <p>Commenter recommends that this added language defining “homebound” be deleted from the chronic pain treatment guidelines, as well as the overall eligibility requirement that a worker be</p>		<p>care services. An injured worker may be wheelchair bound or use other assistive devices and still be able to drive a modified vehicle, and still require home care services for assistance with activities of daily living.</p> <p>Disagree: The section on Home Health Care Services complies with Labor Code section 5307.27 because it “reflects practices that are evidence and scientifically based...” Ellenbecker (2008) contains the evidence base for 7 domains of home health care, thus establishing an analytical framework that is evidence-based. Commenter is correct that policy expression documents such as those published by Medicare/CMS should not be used to support a recommendation in the MTUS. Here, the (CMS, 2014) citation is not used to support a recommendation pertaining to medical necessity, rather, the</p>	None.

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	<p>“homebound” to obtain services, as it is derived from CMS 2014.</p> <p>Commenter recommends that the MTUS for home health care services not be any more restrictive in defining the scope of personal care services to be authorized than that which would be authorized by the IHSS.</p> <p>Commenter states that there has been a requirement in the IHSS program since 2004 for consumers to submit certification from a physician or other</p>		<p>CMS citation describes the characteristics of someone who may need home health care services. This citation was left in the proposed guideline because it offers an important operational description, not a recommendation pertaining to medical necessity. This operational description is nationally recognized by the medical community and is even incorporated in the Ellenbecker 2008 study. Finally, CMS was also cited in the previous MTUS Chronic Pain Guidelines and was approved by the Office of Administrative Law in 2009.</p> <p>Disagree: IHSS does not apply to the MTUS because IHSS is overly restrictive. IHSS requires MediCal eligibility, in addition, the California Welfare and Institutions Code Section 14132.95 states personal care services may be: “Provided to a beneficiary who has a chronic, disabling</p>	None.

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	<p>appropriate licensed medical professional to document the need for protective supervision (WIC 12301.21). Commenter states that in 2011, Governor Schwarzenegger proposed and the legislature agreed to add a requirement for all applicants for IHSS to obtain certification from a licensed health care professional “declaring that the applicant or recipient is unable to perform some activities of daily living independently, and that without services to assist him or her with activities of daily living, the applicant or recipient is at risk of placement in out-of-home care.” County social workers are authorized to use their discretion to authorize IHSS if they disagree with the information in the medical certification.</p> <p>Commenter has enclosed an IHSS eligibility form used for this medical certification. Commenter notes that simply stated on the form “IHSS is a program intended to enable aged, blind, and disabled individuals who are most at risk of being placed in out-of-home care to remain safely in their</p>		<p>condition that causes functional impairment that is expected to last at least 12 consecutive months or that is expected to result in death within 12 months and who is unable to remain safely at home without the services described in this section.” In addition, section (d) (2) states: Ancillary services including meal preparation and cleanup, routine laundry, shopping for food and other necessities, and domestic services may also be provided as long as these ancillary services are subordinate to personal care services. Ancillary services may not be provided separately from the basic personal care services.” These restrictions are not compatible with the requirements of Labor Code 4600(h). Furthermore, the administrative requirements of IHSS, including the assessment and management of cases by county social workers in each California county is</p>	

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	<p>own home by providing domestic/related and personal care services. IHSS services include: housekeeping, meal preparation, meal clean-up, routine laundry, shopping for food or other necessities, assistance with respiration, bowel and bladder care, feeding, bed baths, dressing, menstrual care, assistance with ambulation, transfers, bathing and grooming, rubbing skin and repositioning, care/assistance with prosthesis, accompaniment to medical appointments/alternative resources, yard hazard abatement, heavy cleaning, protective supervision (observing the behavior of a non-self-directing, confused, mentally impaired or mentally ill individual and intervening as appropriate to safeguard recipient against injury, hazard or accident), and paramedical services (activities requiring a judgment based on training given by a licensed health care professional, such as administering medication, puncturing the skin, etc., which an individual would normally perform for him/herself if he/she did not have functional limitations, and which, due</p>		<p>impractical and would burden those county social service departments.</p>	

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	<p>to his/her physical or mental condition, are necessary to maintain his/her health). The IHSS program provides hands-on and/or verbal assistance (reminding or prompting) for the services listed above.”</p> <p>Commenter opines that the IHSS doctor certification form could be modified for use in the workers’ compensation system as a simple method to certify and authorize personal care services.</p> <p>Commenter states that the goal of revising the chronic pain guidelines should be to expand and possibly introduce other Evidence Based Medicine treatment modalities to provide as many treatment options for injured workers and their treating physicians as possible. Commenter opines that restricting eligibility requirements for home health care services needed by the most seriously injured workers may prove not only catastrophic to the worker, but to their family, their employer, and other social welfare programs which must pick up the tab.</p>		<p>Disagree: The goal of revising the chronic pain guidelines and the MTUS in general, is to provide an analytical framework for the evaluation and treatment of injured workers. The recommended guidelines in the MTUS are carefully selected because they provide guidance for the most effective treatment for work related injuries or conditions. The recommendations in the proposed guideline allows room for the provision of home health care services that is tailored to the injured worker’s specific clinical needs provided that it is medically</p>	<p>None.</p>

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			necessary. In order to be compatible with case law interpretation of Labor Code section 4600, non-clinical services that is medically necessary and reasonable may be provided even when there are no skilled home health care services being provided.	
General comment	<p>Commenter notes that the current MTUS was adopted in July 2009. Commenter states that since that time there have been four new studies published about H-Wave®, all quality peer reviewed studies and all with positive results. Commenter states that these four studies are in addition to an already large body of positive, quality studies supporting H-Wave®.</p> <p>Commenter states that not a single study has ever concluded that H-Wave® is either ineffective or carries the risk of any side effects. Commenter opines that there is no scientific medical basis since July 2009 for adopting a new entry for H-Wave® that is more stringent and limited than the one from July 2009. Commenter opines that the only need</p>	<p>Nicholas P. Roxborough, Esq. Roxborough, Pomerance, Nye &amp; Adreani, LLP Electronic Waveform Lab December 19, 2015 Written Comment</p>	<p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines “H-wave stimulation (HWT)” section.</p>	<p>None.</p>

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	<p>for a new entry would be to reflect the additional positive studies that have been published in the interim.</p> <p>Commenter cites the following example:</p> <p>PubMed ID ("PMID") 9353612 is a prospective, blinded, controlled study showing chronic pain relief on diabetic peripheral neuropathy - one of the most challenging conditions to treat. PMID 9702441 is another prospective, blinded, controlled study demonstrating H-Wave outperformed a pharmaceutical in the treatment of chronic peripheral neuropathy pain. PMID 9638542 is a published retrospective long term follow up study showing that the benefits of H-Wave® remain high even after years of use treating chronic pain. PMID 20181141 showed promising results in the field of tissue healing with the use of H-Wave.</p> <p>Commenter states that two of the newest studies of H-Wave® (PMID: 22381420 &amp; 19204915), which are both prospective, blinded, controlled</p>		<p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines "H-wave stimulation (HWT)" section.</p> <p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the</p>	<p>None.</p> <p>None.</p>

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	<p>studies performed by Dr. Tom Smith of the Orthopedic Research Department of Wake Forest University, showed conclusive evidence of H-Wave's ability to affect nitric oxide, increase blood flow, and create angiogenesis, which are the foundations of recovery and healing. Copies of these studies can be provided upon request.</p> <p>With the long-standing medical based evidence supporting H-Wave®, and the now four new positive studies published since the MTUS was adopted in July 2009, commenter opines that the proposed MTUS should treat H-Wave more favorably. Commenter states that the exact opposite has resulted. The proposed entry contains a less favorable opinion of H-Wave® with more stringent prescription requirements than the current MTUS.</p> <p>Commenter notes that the April 2015 entry states: "There is insufficient evidence to recommend the use of H-wave stimulation (HWT) for the treatment of chronic pain as no high</p>		<p>proposed Chronic Pain Medical Treatment Guidelines “H-wave stimulation (HWT)” section.</p> <p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines “H-wave stimulation (HWT)” section.</p> <p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain</p>	<p>None.</p> <p>None.</p>

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	<p>quality studies on this topic were identified." (Emphasis added.) Commenter opines that this statement is inaccurate. There are numerous impactful studies, only a few of which are mentioned above, demonstrating that H-Wave® treatment is effective in treating chronic pain. Commenter notes that this statement is at odds with previous ODG H-Wave® entries, which recommend use of the H-Wave® for "chronic soft tissue inflammation." Commenter states that the research cited in the entry discloses that WLDI relied on nothing and cites to no intervening medical evidence to support its sudden new position on H-Wave® treatment. Commenter opines that for these reasons the MTUS should not adopt the ODG's current H-Wave entry.</p> <p>Commenter opines that the entry violates the precepts of evidence based medicine in other ways. It cites 12 different studies, of which 9 are highly approving of H-Wave treatment and 3 (McDowell 1995, McDowell 1999, &amp; McDowell2 1999) which are represented as neutral or negative.</p>		<p>Medical Treatment Guidelines "H-wave stimulation (HWT)" section.</p> <p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines "H-wave stimulation (HWT)" section.</p>	<p>None.</p>

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	<p>Commenter states that these three studies were conducted outside of the United States using an unrelated device that is only sold overseas, calling itself "h-wave." Commenter states that this device is not the H-Wave® device manufactured here in California by EWL or prescribed to patients in California.</p> <p>Commenter notes that unlike the real H-Wave®, the overseas device is not cleared by the FDA and cannot even be sold, prescribed, or marketed in the US. When doctors in California (or anywhere in the US) prescribe H-Wave for a patient, the patient receives H-Wave®, and not the device studied by McDowell, et al. Commenter states that the references to the McDowell studies are erroneous, highly irrelevant, and misleading to the public. Commenter states that these studies are not grounds for developing any opinion-medical or otherwise about H-Wave®. Commenter opines that this would be like Consumer Reports publishing a review of Rolex watches based on</p>		<p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines “H-wave stimulation (HWT)” section.</p> <p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines “H-wave stimulation (HWT)” section.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>counterfeits they bought on the street comer. Commenter opines that the McDowell studies are equally irrelevant to an evaluation of H-Wave®, have no business appearing in California's MTUS entry for H-Wave®, and must be removed forthwith. Commenter states that their removal should result in an even more favorable recommendation, as the only studies of H-Wave® in existence are positive and favorable.</p> <p>Commenter opines that the proposed H-Wave® entry lacks any justification for imposing all new stringent prescription requirements that appear designed to make doctors less likely to prescribe H-Wave® for their patients. Commenter states that the new requirements are pedantic, directing doctors to follow an exact regimen of treatment and documentation before and during H-Wave use, including the reasons the physician believes that H-Wave 'may lead to functional improvement', trying a TENS unit for a month, physical therapy or home exercise, medications that 'have not resulted in functional improvement',</p>		<p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines “H-wave stimulation (HWT)” section.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>and the patient's participation in an 'evidence based functional restoration program.' Commenter states that these are not required by the FDA, any licensing reviews, or medical research concerning indications for the use of H-Wave®.</p> <p>Commenter notes that the entry even instructs physicians to monitor their patients on the use of H-Wave, which is opines is an absurd and burdensome "requirement" given that monitoring is already part of treating an injured worker who is suffering from chronic pain. Commenter states that doctors who prescribe H-Wave receive no compensation for doing so.</p> <p>Commenter opines that requiring doctors to monitor this treatment which has no side effect seems designed to discourage doctors from ever prescribing H-Wave.</p> <p>Commenter states that there have been no intervening negative studies since the MTUS was adopted in 2009 which could possibly support the new requirements. Commenter opines that these numerous duties and excessive documentation requirements, <b>with no</b></p>		<p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines "H-wave stimulation (HWT)" section.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><b>medical support</b>, truly serve no rational purpose other than to discourage potential prescribers or create pitfalls in the treatment process, creating easy excuses to deny H-Wave® treatment in utilization review.</p> <p>Commenter states that these new requirements appear to be ostensibly based on the observation that none of H-Wave's® 15 quality studies are "high quality". Commenter references the MTUS entry for the <b>Interferential device</b>, the most similar device to H-Wave® appearing in the Chronic Pain Guidelines. Commenter opines that the language is surprising. The MTUS boasts a total lack of, not just "high" quality studies but, any "quality" studies altogether. Yet the entry remains positive and approving of Interferential treatment. Commenter states that unlike his client's product, it does not require prescribers to jump through hoops to get the device approved.</p> <p>Commenter opines that a review of the facts reveals a proposed H-Wave®</p>		<p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines "H-wave stimulation (HWT)" section.</p> <p>Disagree: Comments go beyond the scope of this</p>	<p>None.</p> <p>None.</p>

<b>MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES</b>	<b>RULEMAKING COMMENTS 15 DAY COMMENT PERIOD</b>	<b>NAME OF PERSON/ AFFILIATION</b>	<b>RESPONSE</b>	<b>ACTION</b>
	<p>entry which appears bent on criticizing H-Wave®. Commenter states that independent evidence uncovered through the state's Public Records Act and through discovery in a lawsuit brought by EWL against State Fund, reveals that certain individuals have been waging a personal campaign against EWL since 2004.</p> <p>Commenter alleges a conspiracy between members of DIR, State Compensation Insurance Fund, the MEEAC committee and ODG to restrict H-Wave Treatment to injured workers.</p>		<p>comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines “H-wave stimulation (HWT)” section.</p> <p>Disagree: Comments go beyond the scope of this comment period because no changes were made to the proposed Chronic Pain Medical Treatment Guidelines “H-wave stimulation (HWT)” section.</p>	None.