

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>9792.20 (c) – Definition of Chronic Pain and</p> <p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines</p> <p>Part 1. Introduction</p>	<p>Commenter objects to the definition of the term “chronic pain” and modification to the Introduction of the Chronic Pain Medical Treatment Guidelines, at page 1, paragraph no. 1, wherein the sentence is modified to state: <u>“If the patients continues to have pain that persists beyond the anticipated time of healing.”</u> Commenter opines that the removal of the word “tissue”, the use of the term “anticipated” (very vague and ambiguous) will cause “unbelievable problems.”</p>	<p>Frank Hall, MSN, RN, CMM Supervisor U.R. & Nurse Case Management December 18, 2008 Written Comment</p>	<p>Disagree. The 1st 15-Day Notice of Modification of Text of Proposed Rulemaking, dated November 2008, set forth the reason for deleting the word “tissue” from the definition of “chronic pain.” The Notice states, at page 9, that “[s]ubdivision 9792.20(c) is corrected for clerical error to delete the word “tissue” from the definition of “chronic pain.” The definition is corrected to reflect the definition as quoted from the textbook of Bonica’s Management of Pain, wherein the term is defined, in pertinent part, as “pain that extends beyond the expected period of healing.” (Turk, D. and Okifuji A. Pain Terms and Taxonomies in Bonica’s Management of Pain, 3rd edition. Philadelphia, PA, Lippincott Williams and Wilkins:17.)” Commenter states that the removal of the word “tissue” from the definition of the term “chronic pain,” as well as, the use of the word “anticipated” in the definition “will cause unbelievable problems.” Disagree. The definition is applied in the treatment algorithms found in the Clinical Topics section of the MTUS. In following the clinical algorithms, a determination can be made that a case has reached a chronic stage (i.e., pain persists beyond the anticipated time for</p>	<p>None.</p>

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			healing). The diagnosis of chronic pain is a clinical determination that takes into consideration patient specific factors. Chronicity is not defined solely by the passage of time. Rather it is a clinical diagnosis for a condition that it is unlikely to get better for which there is no remedy. Commenter in fact appears to be objecting to the definition of the term “chronic pain.” In as much as commenter objects to the definition of the term “chronic pain,” his comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Comments relating to the definition of the term “chronic pain” were appropriately addressed during the 45-day comment period.	
9792.20(c) Chronic Pain Definition	<p>Commenter recommends that the definition of “chronic pain” be revised consistent with the alternate language below:</p> <p>(c) “Chronic pain” means any pain that persists beyond the anticipated time of healing <u>of more than 3 months duration.</u></p> <p>(c) “Chronic pain” means any pain <u>of more than 3 months duration</u> that persists beyond the anticipated time of healing.</p> <p>Commenter states that the chronic pain section of the MTUS is founded on medical evidence that is based primarily on the most commonly accepted meaning of chronic pain, which is pain that endures more than 3 months. Commenter argues that to meet the evidence-</p>	<p>Brenda Ramirez Claims and Medical Director</p> <p>Michael McClain General Counsel and Vice President</p> <p>California Workers’ Compensation Institute (CWCI) December 18, 2008 Written Comment</p>	<p>Disagree. Commenter objects to the definition of the term “chronic pain.” The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Comments relating to the definition of the term “chronic pain” were appropriately addressed during the 45-day comment period. Moreover, disagree for reasons set forth in the response to comment submitted by Frank Hall, MSN, RN, CMM, Supervisor U.R. & Nurse Case Management, dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain</p>	None.

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	<p>based statutory requirement, the regulation therefore must use this definition since it is the one most commonly used in connection with the medical evidence.</p> <p>Commenter argues that defining chronic pain as “any pain that persists beyond the anticipated time if tissue healing” also raises a number of other issues. Who or what will define “anticipated time of tissue healing?” Is there a standard reference for the anticipated time based on an average of many events or on a standard deviation from the average? Or is it based on the physician’s experience? Commenter indicates that if a physician anticipates tissue healing within 7 days for a cut or sprain, and an injured employee still reports pain on the 8th day, under this definition the employee is suffering chronic pain. The definition may be over-inclusive and potentially result in unnecessary referrals to chronic pain programs and specialists. Commenter argues that on the other hand, those who suffer pain from chronic conditions for which tissue healing is either not expected or expected in the distant future, would not be characterized as having chronic pain under this definition, and may not receive appropriate referrals.</p>		Medical Treatment Guidelines, Part 1. Introduction, above.	
9792.20(c) Chronic Pain Definition	<p>Commenter opines that the proposed guidelines contain a fatally flawed definition of chronic pain. Commenter states that he raised the issue in his August 12, 2008 letter, but it has yet to be addressed. Commenter requests that serious consideration should be given to the recommendation previously made by CWCI that the definition of chronic pain include duration of at least three months. Commenter opines that the failure to incorporate that recommendation contributes to the chronic pain guidelines confusing acute and chronic pain treatments. Moreover, who is to determine that pain “beyond the anticipated time of healing” exists and whether it is to be treated as</p>	Keith T. Bateman Property Casualty Insurers of America December 18, 2008 Written Comments	Disagree. Commenter objects to the definition of the term “chronic pain.” The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Comments relating to the definition of the term “chronic pain” were appropriately addressed during the 45-day comment period. Moreover, disagree for reasons set forth in the response to comment submitted by Frank Hall, MSN,	None.

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	chronic pain. How is it to be “anticipated”? Qualified practitioners may differ on what they anticipate. Commenter is unaware of any universally accepted tables of anticipated time of healing. Commenter is concerned that this will be used to create a “back door” <u>Minnear</u> .		RN, CMM, Supervisor U.R. & Nurse Case Management, dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 1. Introduction, above. Further, disagree with commenter that the definition of “chronic pain” return to the “treating physician’s presumption” with respect to chronic pain because the MTUS remains presumptively correct, and it relies on the treating physician’s following the guidelines as reviewed by the utilization review process.	
9792.20(c) Chronic Pain Definition	Commenter opines that the definition of “chronic pain” is guaranteed to create disputes and increased litigation. Commenter argues that the “anticipated time of healing” can certainly be interpreted in various ways by various examiners. Commenter believes that it must be tied to a specific guideline or individual, such as the Primary Treating Physician, in order to achieve clarity. Commenter states that without sufficient specificity it will simply be another issue for dispute, and will result in wasted time, money and energy.	Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments	Disagree. Commenter objects to the definition of the term “chronic pain.” The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Comments relating to the definition of the term “chronic pain” were appropriately addressed during the 45-day comment period. Moreover, disagree for reasons set forth in the response to comment submitted by Frank Hall, MSN, RN, CMM, Supervisor U.R. & Nurse Case Management, dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 1. Introduction, above.	None.
9792.20(e) Evidence-based	Commenter opines that the definition of “Evidence-based” is archaic and should be redefined with the modern understanding of how it modifies “medicine”	Barry Eisenberg Executive Director American College of	Disagree. The comment does not address the proposed modifications to the text of the regulations	None.

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	and “guidelines” in a much more rigorous process that is in the current definitions than is implied here. Evidence Based as envisioned by the legislature specifically includes evaluation of “a graded body of evidence.” The definition as written ignores this intent, especially when one considers that vast and ever increasing amount of citations, any of which could be labeled “evidence based” with the same implied strength as a graded body of evidence.	Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment	subject to the 1 st 15-Day Notice of Modification of Text of Proposed Rulemaking, dated November 2008.	
9792.20(f) Functional Improvement Definition	Commenter recommends the word “quantifiable” be reinstated to the definition of “functional improvement.” Commenter states that it is important that functional improvement be objective. Commenter indicates that the ability to extend certain treatments is predicated on functional improvement. Commenter opines that if functional improvement can be subjective, treatment may be extended with only a pro-forma “continuing to improve” statement that will be difficult, if not impossible to disprove.	Brenda Ramirez Claims and Medical Director Michael McClain General Counsel and Vice President California Workers’ Compensation Institute (CWCI) December 18, 2008 Written Comment	Disagree. Subdivision 9792.20(f) was modified to delete the word “quantifiable” and reinstate the original phrase “clinically significant” as contained in the original definition of the term “functional improvement.” The modification resulted from many comments submitted by the public, stating that functional improvement may not actually be quantifiable, and that the term “clinically significant” may be more appropriate and easier to be communicated by the treating physician in the reports. Moreover, disagree with the comment “that if functional improvement can be subjective, treatment may be extended with only a pro-forma ‘continuing to improve’ statement.” The proposed regulations define “Functional improvement” to mean (1) either a clinically significant improvement in activities of daily living or (2) a reduction in work restrictions, and (3) a reduction in the dependency on continued medical treatment.	None.

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			The commenter is incorrect in stating that “that [it] will be difficult, if not impossible to disprove” functional improvement because the requirement of meeting the three components of the definition of “functional improvement” cannot be met when a physician reports “continues to improve.” The application of this definition, requires a demonstration that effective treatment is being provided, and that this treatment is improving functional outcomes. The application of the definition will facilitate the provision of high quality treatment, and will limit poor, ineffective treatment, thus minimizing inappropriate care and limiting overutilization.	
9792.20(f) Functional Improvement	Commenter opines that the removal of “quantifiable” from the definition of “Functional Improvement” will result in a significant degradation to the quality of services provided to injured workers in California. “Clinical significance” is open to widely varying degrees of interpretation and will likely result in a continuation of conflict between providers and experts with no mandate for actionable metrics. This definition change alone will result in an increased likelihood of inappropriate care and over utilization.	Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment	Disagree. See response to comment submitted by Brenda Ramirez, Claims and Medical Director and Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.20(f), Functional Improvement Definition, above.	None.
9792.20(f) Functional Improvement Definition	Commenter asks how is “clinically significant” to be determined and what does it mean in terms of functionality? If some subjective pain index shows a drop in the level of pain, but there is no improvement in the ability to work or perform the tasks of daily living, is the change in the level of pain “clinically significant”?	Keith T. Bateman Property Casualty Insurers of America December 18, 2008 Written Comments	Disagree. See response to comment submitted by Brenda Ramirez, Claims and Medical Director and Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI),	None.

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			dated December 18, 2008, on Section 9792.20(f), Functional Improvement Definition, above. Moreover, the definition of “functional improvement” as set forth in the proposed regulations is not met when a drop in the level of subjective pain index is shown but there is no clinically significant improvement in work restrictions or activities of daily living.	
9792.20(f) Functional Improvement Definition	<p>Commenter opines that while this is an improvement over its predecessor, in his reading, there remains no accommodation within this definition for the very real and very frequent outcome of many successful therapy regimes – function maintenance. Commenter states that recognition that “functional improvement” may not be quantifiable is an important step, but alleges that the current language continues to fall short of including those individuals for who without their treatment, degeneration of function occurs and for whom an inability to return to work or a lack of “improvement of work restrictions” are permanent realities. Commenter’s previous written comments contained examples of diagnosis degenerate without treatment; whereas with treatment, maintenance of function is the best that can be expected.</p> <p>Commenter respectfully requests that the Division include this vital level of success within the definition of “functional improvement.”</p>	Stephen J. Cattolica AdvoCal December 18, 2008 Written Comments	Disagree. See response to comment submitted by Brenda Ramirez, Claims and Medical Director and Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.20(f), Functional Improvement Definition, above. Moreover, to maintain function at certain level requires demonstration that the function is improved up to that level while on treatment, and absent that treatment, there is deterioration from the achieved level of performance. The term “functional maintenance” does not require a definition as the maintenance concept is derived from applying the definition of functional improvement.	None.
9792.20(f) Functional Improvement	Commenter states that removing the word “quantifiable” from the definition of Functional Improvement presents a serious problem. Without	Steven Suchil, Assistant Vice President	Disagree. See response to comment submitted by Brenda Ramirez, Claims and Medical	

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Definition	measurable goals commenter opines that the state will return to the days and cost of unlimited physical medicine. Commenter strongly recommends that “quantifiable” be returned to the definition with or without the added words “clinically significant”, which could mean anything and will definitely be interpreted by each practitioner.	American Insurance Association December 18, 2008 Written Comments	Director and Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.20(f), Functional Improvement Definition, above. Moreover, disagree with comment that “the state will return to the days and cost of unlimited physical medicine” because there is a statutory 24-visit limitation for these services. (Lab. Code, § 4604.5(d)(1).)	
9792.20(f) Functional Improvement Definition	<p>Commenter states that the removal of the word “quantifiable” from the definition of the term “functional improvement,” together with the definition of the term “chronic pain” will cause unbelievable problems as follows:</p> <ul style="list-style-type: none"> • Commenter states that by eliminating one of the few requirements for objective verification of symptoms, you change the entire landscape of treatment to be totally dependent on a patients subjective reporting. Commenter opines that the opportunities for ABUSE are enormous. • Commenter notes that the discussion should be in <i>keeping</i> these terms in place. Commenter believes that by their own admission, those offering testimony in opposition to these clinical anchors such as functional improvement, etc., state the <i>exceptions</i> to the guidelines are the ones for whom these system safeguards should be eliminated. <p>Commenter believes that this is backwards logic. Commenter states that these “exceptions” and anecdotes are the very ones for which Utilization and peer review should apply. Otherwise, the evidenced-</p>	Frank Hall, MSN, RN, CMM Supervisor U.R. & Nurse Case Management December 18, 2008 Written Comment	Disagree. See response to comment submitted by Brenda Ramirez, Claims and Medical Director and Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.20(f), Functional Improvement Definition, above.	None.

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	<p>based guidelines should apply to the majority of injured workers.</p> <p>Commenter indicates that to build a system foundation on exceptions and then expect the majority to work backward from there shifts far too many burdens on the normal practice of administering benefits. Commenter opines that this would be like making the rule that <i>everyone</i> is automatically entitled to a full cardiac work up on the outside chance that a few people may have an exceptional cardiac anomaly.</p>			
9792.23 and 9792.24.2	<p>Commenter strongly urges the Medical Director to reconsider making the proposed Chronic Pain recommendations the de facto rule for chronic pain associated with injuries of any body part. Careful review of the available evidence shows that more specific recommendations are available, which would be better applied to injured workers, than the more generalized recommendations contained in the proposed recommendations. The purpose of a well conducted, systematic evidence review is to identify the specific situations where the best treatment option is recommended for an injured worker. Having chronic pain recommendations that apply in situations where there's not more specific recommendations available may be warranted, but having chronic pain recommendations that supersede well-researched, scientific and truly evidence-based recommendations only increases the probability of inappropriate care and unnecessary expense.</p>	<p>Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment</p>	<p>Disagree. Commenter objects to the chronic pain medical treatment guidelines as adapted from the Work Loss Data Institute, Official Disability Guidelines, Treatment in Workers' Comp-Chapter on Pain (Chronic), version dated October 23, 2008, on the basis that the guidelines are not evidence-based. In as much as commenter objects to the chronic pain medical treatment guidelines because they are adapted from ODG's guidelines, his comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Comments relating to the issue of whether the ODG guidelines are evidence-based were appropriately addressed during the 45-day comment period. Commenter, however, raises the issue that the Administrative Director "reconsider making the proposed Chronic Pain recommendations the de facto rule for chronic pain</p>	None.

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			<p>associated with injuries of any body part.” Commenter in fact is requesting that the Clinical Topics sections of the MTUS which adopt the ACOEM body chapters be used to address chronic pain because there are “more specific recommendations are available” in the chapters, and they are “well-researched, scientific and truly evidence-based recommendations.” DWC disagrees with commenter’s statement. The DWC chronic pain guidelines were developed because the Administrative Director determined that the MTUS, which adopted the ACOEM clinical topics, required further supplementation regarding chronic pain recommendations. The justification for the supplementation and proposed adoption of the DWC chronic pain guidelines was set forth in the ISOR, at pp. 39-40, as follows:</p> <p>“The ACOEM’s Practice Guidelines’ Chapter 6—Pain, Suffering, and the Restoration of Function (Chapter 6) relating to chronic pain, was originally adopted as part of the MTUS when the ACOEM Practice Guidelines, 2nd Edition, was adopted into the MTUS by regulations, effective June 15, 2007. In the proposed regulations, the DWC is replacing Chapter 6 with the Chronic Pain</p>	

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			<p>Medical Treatment Guidelines (DWC 2008). Chapter 6 is being replaced because upon re-examination it has been determined that the chapter does not provide enough specificity for chronic pain and does not serve as an appropriate introduction to the specific chronic pain treatments which are being adapted from the Work Loss Data Institute, Official Disability Guidelines, Treatment in Workers' Comp-Chapter on Pain (Chronic), version dated October 31, 2007.</p> <p>“The determination that Chapter 6 does not provide for specific treatment guidelines for chronic pain is based on a re-evaluation of the 2005 RAND Report prepared under the direction of the CHSWC. In its 2005 Report, RAND discussed the areas where the ACOEM Practice Guidelines, 2nd Edition, required further supplementation. At page 56, the report states, in pertinent part, that:</p> <p>“ ‘Concern was ... expressed [by the multidisciplinary clinical panel] that [the ACOEM] guidelines are directed to the primary-care physician caring for a worker at the acute state of an injury, and they do not adequately address chronic conditions, particularly pain management.’</p>	

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			<p>(2005 RAND Report, at p. 56.)</p> <p>“In its 2005 Report, RAND further found that ‘[s]takeholders interviews suggest that payors in the California workers’ compensation system are applying ACOEM guidelines ... for topics the guidelines do not address or address only minimally.’ (2005 RAND Report, at p. 85.) This reflects the need to supplement the ACOEM Practice Guidelines by some mechanism.</p> <p>“RAND further stated in its report that if the state wished to develop a patchwork of existing guidelines addressing work related injuries, its research suggested that chronic pain, among others, is a priority topic. RAND recommended that ‘[w]hen guidelines within a patchwork have overlapping content, the state may want to identify and resolve conflicting recommendations.’ (2005 RAND Report, at p. 86.)</p> <p>“Pursuant to RAND’s findings and recommendations, the MEEAC was created to provide advice concerning the review of new evidence and other guidelines that could be used as the basis for supplementing the ACOEM Practice Guidelines in the identified high priority areas.</p>	

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			<p>Chronic pain was identified as a high priority area. In light of these findings, the Administrative Director proposes to add the Chronic Pain Medical Treatment Guidelines to the MTUS.”</p> <p>Moreover, disagree with the comment that “having chronic pain recommendations that supersede well-researched, scientific and truly evidence-based recommendations only increase the probability of inappropriate care and unnecessary expense.” The chronic pain medical treatment guidelines apply after the body part specific clinical topics sections fail to remedy the medical condition. After application of the specific body part treatment guidelines, and when the patient is determined to have chronic pain as defined in the regulations, the chronic pain medical treatment guidelines are applicable. Further, it is necessary for the chronic pain medical treatment guidelines to supersede the body part sections as they are no longer applicable upon reaching the diagnosis of chronic pain and a remedy is not found in the clinical topic sections.</p>	
9792.23.1(b) Neck and Upper Back Complaints/ Acupuncture	Commenter states that since the ACOEM guidelines are evidence based and the acupuncture guidelines are not, the ACOEM guidelines should prevail over the acupuncture guidelines wherever there is a conflict. Commenter indicates that the statutory requirement is	Brenda Ramirez Claims and Medical Director Michael McClain	Disagree. Commenter objects to the Acupuncture Medical Treatment Guidelines on the basis that the guidelines are not evidence-based. Commenter	None.

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	<p>for evidence-based guidelines and therefore evidence-based guidelines must prevail here and elsewhere in the MTUS. Commenter recommends the following revised language:</p> <p>(b) In the course of treatment for neck and upper back complaints where acupuncture or acupuncture with electrical stimulation is being considered, the acupuncture medical treatment guidelines in section 9792.24.1 shall apply <u>except for recommendations and supersede the text</u> in the ACOEM chapter referenced in subdivision (a) above <u>that relate relating</u> to acupuncture or acupuncture with electrical stimulation.</p>	<p>General Counsel and Vice President</p> <p>California Workers' Compensation Institute (CWCI) December 18, 2008 Written Comment</p>	<p>argues that because the Acupuncture Medical Treatment are not evidence-based, "the ACOEM guidelines should prevail over the acupuncture guidelines wherever there is a conflict." In as much as commenter objects to the Chronic Pain Medical Treatment Guidelines her comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. The Acupuncture Medical Treatment Guidelines regulations were approved by OAL, and became effective on June 15, 2007. As indicated in the Notice of 1st 15-day Changes to Proposed Rulemaking, dated November 2008, the reorganization of the MTUS, by separating the chapters into different sections and adopting them separately, affected the Acupuncture Medical Treatment Guidelines. Comments were submitted by the regulated public that language needed to be inserted in the clinical topics sections of the regulations to clarify that the Acupuncture Medical Treatment Guidelines apply and supersede the text in the ACOEM chapters where acupuncture is addressed. The phrase "and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to acupuncture" was inserted in subdivision (b) in § 9792.23.1</p>	

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			Neck and Upper Back Complaints for clarification purposes. This language is consistent with language contained in 8 CCR 9792.21(a)(2). The modification was a non-substantive modification for clarification purposes, and was not intended to open the Acupuncture Medical Treatment guidelines for substantive comments.	
9792.23.1(d) Neck and Upper Back Complaints	<p>Commenter states that “definitive treatment” is a new term that has no definition. Commenter states that it should be defined to avoid confusion or dispute here and elsewhere in these regulations. Commenter adds that wherever the phrase “the chronic pain medical treatment guidelines in section 9792.24.2 shall apply”, both here and elsewhere in these regulations, the phrase “with respect to pain” should be added to clarify that the recommendations in the MTUS clinical topics continue to apply to treatment for the underlying condition or injury, and chronic pain guidelines apply only to treatment for pain.</p> <p>Commenter recommends that the division define “definitive treatment,” and the following modification to subdivision (d).</p> <p>(d) If surgery is performed in the course of treatment for neck and upper back complaints, the postsurgical treatment guidelines in section 9792.24.3 for postsurgical physical medicine shall apply together with any other applicable treatment guidelines found in the MTUS, or in accordance with section 9792.23(b). In the absence of any definitive treatment for the patient who continues to have pain that persists beyond the anticipated time of healing, the chronic pain medical treatment guidelines in section</p>	<p>Brenda Ramirez Claims and Medical Director</p> <p>Michael McClain General Counsel and Vice President</p> <p>California Workers’ Compensation Institute (CWCI) December 18, 2008 Written Comment</p>	<p>Agree in part. Commenter requests that the phrase “definitive treatment” be defined in the regulations to avoid confusion. Agree that the use of the phrase “definitive treatment” may cause confusion. Because the term “medical treatment” is already defined in the regulations in subdivision 9792.20(g) as “care which is reasonably required to cure or relieve the employee from the effects of the industrial injury consistent with the requirements of sections 9792.20-9792.26,” DWC believes that it is pertinent not to add another definition to the regulations related to medical treatment. DWC believes that it is more appropriate to extract from the definition of the term “medical treatment” the word which best described the phrase “definitive treatment” in the context of subdivision 9792.23.1(d), which is making a reference to the identification of a chronic</p>	<p>Section 9792.23.1(d), Neck and Upper Back Complaints is modified as follows:</p> <p><u>“(d) If surgery is performed in the course of treatment for neck and upper back complaints, the postsurgical treatment guidelines in section 9792.24.3 for postsurgical physical medicine shall apply together with any other applicable treatment guidelines found in the MTUS or in accordance with section 9792.23(b). In the absence of any surgical options for the complaint and definitive treatment cure for the patient has chronic pain who continues to have pain that persists beyond the anticipated time of healing, the chronic pain medical treatment guidelines in section 9792.24.2 shall</u></p>

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	9792.24.2 shall apply <u>with respect to pain</u> .		condition. It is determined that the word “cure” is the appropriate word to substitute the phrase “definitive treatment” because when there is an “absence of any <i>cure</i> for the patient” and the patient “continues to have pain that persists beyond the anticipated healing,” that patient has a chronic condition and the chronic pain medical treatment guidelines apply. Moreover, the definition of “medical treatment” encompasses the concept of “cure” when it states “care which is reasonably required to cure or relieve.” (See also, Lab. Code, 4600(a).) Thus, subdivision 9792.23.1(d), as modified provides, “If surgery is performed in the course of treatment for neck and upper back complaints, the postsurgical treatment guidelines in section 9792.24.3 for postsurgical physical medicine shall apply together with any other applicable treatment guidelines found in the MTUS. In the absence of any cure for the patient who continues to have pain that persists beyond the anticipated time of healing, the chronic pain medical treatment guidelines in section 9792.24.2 shall apply.” Disagree with commenter’s suggestion to add the phrase “with respect to pain” to clarify that the recommendations in the MTUS clinical topics continue to apply to	<u>apply.</u> ”

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			treatment for the underlying condition or injury, and chronic pain guidelines apply only to treatment for pain. DWC believes that regulations as drafted are clear with regard to the application of the clinical topics and the chronic pain guidelines, and the phrase “with respect to pain” is superfluous.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines (Authority)	<p>Commenter opines that if the AD intends to adopt the ODG-based chronic pain guideline, the October 2008 version must be re-noticed for an administrative hearing in accordance with Government Code section 11346.8.</p> <p>The change offered by the Administrative Director in this instance is a completely different treatment guideline than the one subject to the original administrative hearing. The individual changes are too numerous to list and the new guideline is approximately 50 pages longer. The difference that matters is, of course, qualitative. The recent revisions to the schedule are significant and substantial, and therefore these provisions must be subject to a further administrative hearing.</p> <p>While the Notice of Modification states that adopting these changes allows the “MTUS [to] reflect the most recent advances in the science of medicine,” that reasoning does not ensure due process in the adoption of the regulations.</p> <p>As the Notice of Modification notes, Government Code section 11346.8(c) prohibits any agency from adopting, amending, or repealing a regulation which has been changed from that which was originally made available to the public pursuant to Section</p>	<p>Brenda Ramirez Claims and Medical Director</p> <p>Michael McClain General Counsel and Vice President</p> <p>California Workers’ Compensation Institute (CWCI) December 18, 2008 Written Comment</p>	<p>Disagree. Commenter objects to the proposed chronic pain medical treatment guidelines as adapted from the ODG October 23, 2008 version. Commenter opines that the “version must be re-noticed for an administrative hearing in accordance with Government Code section 11346.8.” Disagree with the comment. In the November 2008 Notice of Modification to Text of Proposed Rulemaking, Appendix A1, the Administrative Director gave notice of the proposed chronic pain medical treatment guidelines as adapted from the ODG October 23, 2008 version. Appendix A1, which issued with the Notice, specifically states at pp. 2-3, in relevant part:</p> <p>“The second paragraph, fifth sentence, of the Introduction, at page 1, is modified to delete the date “October 31, 2007” and to substitute it with the date “October 23, 2008.” This date reflects the new date of the new ODG version</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>11346.5, unless the change is “(1) non-substantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action....” The AD asserts that the provision of the 15-day comment period is sufficient to meet the demands of section 13346.8, arguing that the regulated community has received adequate notice and that the new guideline “is sufficiently related to the original text.”</p> <p>Pursuant to that rationale, the Administrative Director could discard the ODG based pain guidelines and issue the ACOEM guidelines or any other pain management treatment guidelines deemed adequate by the AD because they are all “sufficiently related to the original text,” i.e. they are all pain management guidelines.</p> <p>Commenter’s recommendation is made to ensure that the MTUS reflects the most recent advances in the science of medicine for the protection of injured workers. Commenter urges the AD to carefully consider the merits of the options available, the policies adopted by the Legislature regarding the use of evidence based medicine, and the need for clarity and specificity in treatment guidelines that will be used by treating physicians, medical networks, attorneys, utilization reviewers, WCALJs, and the appeals board.</p>		<p>of the chronic pain chapter which is being adapted in the DWC Chronic Pain Medical Treatment Guidelines. This new version is being adapted because many comments were submitted by the public requesting that the most recent version of ODG be adapted in order to allow the “MTUS [to] reflect the most recent advances in the science of medicine.” (See, California Medical Association’s comment, August 11, 2008.) In this regard, DWC notes that Government Code section 11346.5(a)(3) requires the Notice of Proposed Rulemaking set forth an informative digest, containing in relevant part, a concise and clear summary of existing laws and regulations, if any, related directly to the proposed action and of the effect of the proposed action and a policy statement overview explaining the broad objectives of the regulation and, if appropriate, the specific objectives. Government Code Section 11346.8(c) prohibits any agency from adopting, amending, or repealing a regulation which has been changed from that which was originally made available to the public pursuant to Section 11346.5, unless the change is “(1) non-substantial or solely grammatical in nature, or (2) sufficiently related to the original</p>	

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			<p>text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action....”</p> <p>“The Notice of Proposed Rulemaking issued in June 2008 put the public on adequate notice that the subject of Chronic Pain Medical Treatment Guidelines as adapted from Work Loss Data Institute’s Official Disability Guideline was addressed as part of the formal rulemaking. Specifically, the Notice states at page 11, in relevant part, as follows:</p> <p>“ ‘15. Section 9792.24.2—Chronic Pain Medical Treatment Guidelines (DWC 2008)</p> <p>“ ‘Section 9792.24.2(a) provides that the Chronic Pain Medical Treatment Guidelines (DWC 2008), consisting of two parts, are adopted and incorporated by reference into the MTUS. It indicates that Part 1 is entitled Introduction, and Part 2 is entitled Pain Interventions and Treatments. This section further provides that the guidelines replace Chapter 6 of the ACOEM Practice Guidelines, 2nd Edition (2004).” Moreover, Part I, of the Chronic Pain Medical Treatment Guidelines, entitled: Introduction, indicates that the</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>guidelines is being adapted from the ODG guidelines as follows:</p> <p>“ ‘The chronic pain medical treatment guidelines consist of two parts. Part 1 is the introduction. Part 2 consists of pain interventions and treatments. With a few exceptions, Parts 2 is primarily an adaptation of evidence-based treatment guidelines, from the Work Loss Data Institute’s Official Disability Guidelines (ODG) Treatment in Workers’ Comp – Chapter on Pain (Chronic). The version adapted is dated October 31, 2007, and it is being adapted with permission from the ODG publisher. Any section not adapted directly from ODG is labeled [DWC].’</p> <p>“DWC is precluded from automatically adopting future versions of documents incorporated by reference into a regulation in the absence of formal rulemaking. However, DWC is able to adopt the most recent version of the ODG guidelines at this time because: (1) this rulemaking is still in progress and is not yet completed; (2) the regulated community has received adequate notice and has, in fact, requested the most recent version; (3) the update of the guidelines “is sufficiently related to the original</p>	

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			<p>text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action.” The ODG guidelines version being adapted is dated October 23, 2008, as requested by the public. Thus, as modified, the sentence states, ‘The version adapted is dated October 23, 2008, and it is being adapted with permission from the ODG publisher.’ ”</p> <p>For the reasons set forth in Appendix A1, which issued with the Notice, as quoted above, DWC believes that it complied with the requirements of the Administrative Procedure Act, and a second hearing is not necessary. The update of the guidelines “is sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action.”</p>	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines (Authority)	Commenter states that it should be noted that the proposed regulations encompass hundreds of pages and many complex changes from the last proposed version. Commenter opines that a 15 day comment period is grossly inadequate to perform a complete analysis in order to assure that the public and the participants in the workers’ compensation system are provided with the best possible guidance for management of chronic pain and post-operative care. Both are significant health problems and deserve careful and complete attention to improve outcomes, which currently include higher than optimal disability	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. See response to comment submitted by Brenda Ramirez, Claims and Medical Director and Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines (Authority), above.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	and excess resource use.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines (Authority)	Commenter believes that by adopting a new version of the Work Loss Data Institute’s chronic pain medical treatment guidelines the entire DWC Chronic Pain Treatment Guidelines should be open to comment. Commenter further believes, as discussed in more detail in the comments submitted by CWCI, that this revision to the earlier DWC proposal must be re-noticed for an administrative hearing in accordance with Government Code section 11346.8. The assertion that the provision of the 15-day comment period is an adequate substitute for an administrative hearing and somehow meets the statutory obligations of the Administrative Director is erroneous.	Keith T. Bateman Property Casualty Insurers of America December 18, 2008 Written Comments	Disagree. See response to comment submitted by Brenda Ramirez, Claims and Medical Director and Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines (Authority), above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines (Cost Impact)	<p>Commenter states that in the Notice of Modification, the Administrative Director, essentially found, in accordance with the requirements of Government Code section 11349.5, that the application of the chronic pain management and postsurgical treatment guidelines will not have an adverse economic impact on employers. The AD noted that “the State may incur increased medical costs for a subset of its claims” as a result of this regulation but that the fiscal impact, if any, is “difficult if not impossible to estimate.” While conceding that the selection of pain management and postsurgical treatment guidelines will increase the cost of medical care, the AD counters that the regulations provide greater specificity and clarity to the MTUS, which is expected to bring about a reduction in treatment and utilization review costs for some claims.</p> <p>Commenter disagrees and believes that if adopted the ODG-based chronic pain and postsurgical treatment guidelines will reduce the quality of medical care for injured employees and increase the cost by undermining the statutory cornerstone of the standard of medical care in workers’ compensation – the</p>	<p>Brenda Ramirez Claims and Medical Director</p> <p>Michael McClain General Counsel and Vice President</p> <p>California Workers’ Compensation Institute (CWCI) December 18, 2008 Written Comment</p>	Disagree. With respect to the issues of (1) rating methodology, (2) evidence-based recommendations, and (3) recommendation that the ACOEM chronic pain chapter update be adopted, the comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and her comments were appropriately addressed in the 45-day comment period chart. 3. Moreover, disagree with the comment disputing the Administrative Director’s statement that the guideline would lead to greater specificity and clarity in the MTUS, which would in turn be expected to reduce costs due to treatment, utilization review, and	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>reliance on evidence-based medicine. Commenter argues that it is the failure of the proposed regulations “to provide greater specificity and clarity” that is the distinguishing feature between the ODG chronic pain management guidelines and the ACOEM guidelines.</p> <p>Commenter argues that the ODG guidelines use ungraded medical evidence, often fail to provide specific recommendations for treatment, include vague, ambiguous language to qualify their conclusions, and fail to follow the Strength of Evidence and Rating methodology previously adopted for the treatment schedule. Yet, by including them in the treatment schedule, they will be afforded the legal presumption of correctness contained in Labor Code section 4604.5.</p> <p>Commenter states that in SB 899, the Legislature made the social policy decision that treatment necessary to cure and relieve the effects of the industrial injury would be defined by evidence supporting its effectiveness. The Legislature adopted the ACOEM guidelines pending the creation of the medical treatment utilization schedule by the Administrative Director. To enhance the utility of the MTUS based on the ACOEM structure and philosophy, the Legislature added a legal presumption for all medical care sanctioned by the MTUS. The Supreme Court has recently affirmed that determination stating, in essence, that reasonable and necessary medical care under section 4600 is any treatment provided in accordance with the medical treatment utilization schedule. <u>State Compensation Insurance Fund v WCAB (Sandhagen) (2008) 73 CCC 981.</u></p> <p>Commenter states that the Legislature adopted evidence-based medicine as the standard of care in</p>		<p>disputes. The current MTUS is now comprised of the ACOEM Practice Guidelines, 2nd Edition, and the acupuncture medical treatment guidelines. The ACOEM Practice Guidelines, 2nd Edition, contains a chapter entitled “Pain, Suffering, and the Restoration of Function” [chapter 6] which provides about three pages describing a general approach to treating and managing chronic pain. As such, it is greatly lacking in specificity and clarity. The proposed chronic pain medical treatment guidelines, which are adapted from the October 23, 2008 ODG chronic pain chapter, will replace this chapter. The proposed chronic pain medical treatment guidelines consist of an alphabetized comprehensive list of all possible known interventions and treatments for chronic pain, each of which provides a concise synopsis of effectiveness, defined clearly as “Recommended,” or “Not Recommended.” The structure and content of the proposed chronic pain medical treatment guidelines inherently provide greater specificity and clarity compared to what is currently in use in the MTUS for the treatment of chronic pain. The chronic pain guidelines apply “in the absence of any cure for the patient who continues to have pain</p>	

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	<p>California and applied the presumption in order to deliver the highest quality medical care to injured workers, limit disputes over what treatment is appropriate, and ensure that the proper treatment will be promptly determined and paid. Evidence-based medicine creates a clear, bright line for physicians, workers, judges, and claims administrators.</p> <p>Commenter opines that if the ODG-based guidelines are adopted as written, the quality of medical care for some injured employees will likely be impaired and the cost of medical care for the State and all California employers will escalate at a time when premium is falling and the cost of medical care is increasing.</p> <p>Commenter states that needless ambiguity in the treatment schedule serves no one. Guidelines with ungraded evidence, contradictory or incomplete recommendations, and recommendations that are internally inconsistent, do not facilitate the legislative goal of identifying the best medical care for injured workers. Where guidelines are not clear, reviewers may be powerless to prevent injured workers from receiving inappropriate or unnecessary care and medical costs will rise as a consequence.</p> <p>Commenter opines that while the financial impact of full implementation of the ODG-based guidelines is impossible to gauge, they will clearly create incentives for some physicians to shift from the conservative evidence- based ACOEM guidelines to the more consensus driven ODG guidelines. Commenter argues that the threshold for use of the ODG-based guidelines is set by a vague definition of chronic pain, creating an opportunity to “medicalize” and over treat otherwise routine occupational conditions.</p>		<p>that persists beyond the anticipated time of healing.” The proposed chronic pain medical treatment guidelines further state that “it is a clinical decision to recognize chronicity or persistence of pain when 1) the condition is not improving over time, 2) fails to improve with treatments directed to the specific injured body part (see Clinical Topics section of the MTUS), 3) or in the absence of a specifically correctable anatomic lesion (see Clinical Topics section of the MTUS). (Chronic Pain Medical Treatment Guidelines, at p. 4.) The current MTUS states that the most clinically useful definition of chronic pain might be “chronic pain persists beyond the usual course of healing of an acute disease or beyond a reasonable time for an injury to heal” (ACOEM Practice Guidelines, 2nd Edition, Chapter 6, p. 108). The proposed definition of chronic pain and the conditions under which a clinician recognizes chronicity offer more guidance and specificity than the current MTUS. The structure and content of the proposed chronic pain medical treatment guidelines inherently provide greater specificity and clarity compared to what is currently in use in the MTUS for the treatment of chronic pain. It is expected that this improved</p>	

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	<p>The Administrative Director’s statement that the fiscal impact is “difficult if not impossible to estimate” militates against any change from the structure and philosophy of the ACOEM guidelines. The ACOEM pain management guidelines have been issued more recently and comply with the strength of evidence rating adopted for the treatment schedule. Unless the AD can provide evidence supporting the assertion of no adverse economic impact on California employers, the proposed regulations fail to meet the obligations imposed by Government Code section 11349.5.</p> <p>Commenter states that the economic impact studies model the likely impact of proposed regulatory change. Commenter indicates that an economic impact analysis allows stakeholders the opportunity to plan for administrative and operational changes shaped by legislative and regulatory reform. Commenter states that changes to the MTUS will affect underwriting, reserving, safety and health programs, medical management systems, vendor relationships, medical network panels, return-to-work programs and more. Commenter indicates that after extensive consultation with the Division, we found that such an economic impact analysis for the proposed chronic pain guidelines is not possible due to the DWC’s subjective definition of chronic pain, the conflict in evidence grading systems and lack of explicit recommendations. Commenter indicates that without an objective financial impact analysis, the Division is taking a significant and unnecessary risk that can compromise the fundamental intent of the prior reforms to raise quality of care and lower the cost of health care delivery. The subjective nature of the chronic pain definition is expected to increase the number of patients diagnosed with chronic pain and opens the door to an exit from meaningful guidelines</p>		<p>specificity and clarity, which are grounded in definitive evidence-based treatment recommendations, will thereby increase the quality of care and reduce costs due to utilization review, disputes, and indemnity.</p>	

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	because the ambiguous language in the guidelines will make it difficult or impossible to deny unnecessary or inappropriate care. Both these factors will contribute to a significant increase in medical costs.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	<p>Commenter recommends that the Administrative Director delete the revised ODG-based chronic pain guidelines and instead adopt into the Medical Treatment Utilization Guidelines the update to Chapter 6 on chronic pain that was revised and adopted by ACOEM in 2008. Commenter offers the following discussion in support of her recommendation.</p> <p>Commenter states that Labor Code section 5307.27 requires the Administrative Director to adopt a medical treatment utilization schedule (MTUS) that is “scientific and evidence-based, peer reviewed, and nationally recognized.” (See, also Lab. Code § 4604.5(b)). Commenter indicates that the MTUS must address, at a minimum, the quality of medical evidence as well as the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases (Section 5307.27). Commenter argues that unlike the proposed ODG-based chronic pain guidelines, the guidelines in the updated chapter 6 of the ACOEM Practice Guidelines meet the statutory requirements and provide clear, definite recommendations that are supported by high-grade medical evidence graded in accordance with the Strength of Evidence Range contained in the regulations. Commenter further argues that clear, evidence-based recommendations ensure that California injured employees receive the most effective treatment and protect injured workers against ineffective and harmful treatment, as the enabling legislation intends. Commenter adds that because the ODG-based guidelines are not as clear</p>	<p>Brenda Ramirez Claims and Medical Director</p> <p>Michael McClain General Counsel and Vice President</p> <p>California Workers’ Compensation Institute (CWCI) December 18, 2008 Written Comment</p>	<p>Disagree. Commenter requests that the ACOEM update to Chapter 6 on chronic pain be adopted instead of the DWC chronic pain medical treatment guidelines as adapted from the October 23, 2008 version of the ODG guidelines. Commenter in essence argues that the ODG guidelines are not evidence-based, and therefore the DWC chronic pain medical treatment guidelines do not meet the requirements of the statute. DWC disagrees. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Comments relating to whether or not the DWC chronic pain medical treatment guidelines meet the requirements of the statute, whether the ODG guidelines are evidence-based, and the recommended adoption of the ACOEM update to Chapter 6 on chronic pain instead of the DWC chronic pain medical treatment guidelines as adapted from the ODG chronic pain chapter, were all appropriately addressed during the 45-day comment period.</p>	None.

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	<p>and do not meet the same high standards of scientific evidence as the ACOEM guidelines, adopting ACOEM’s updated guidelines on chronic pain is a better alternative.</p> <p>Commenter notices that in the Notice of Modification the Division suggests that ODG guidelines are evidence based because RAND considered them so. However, RAND study panelists did not review the evidence-base as the authors stated that they were “unable to provide panelists with literature reviews for the therapies under consideration...an especially important limitation for the evaluations of the physical modalities because panelists understood this literature differently, and some panelists were not at all familiar with the relevant literature on chiropractic manipulation of the carpal tunnel”. . Also, the updated ODG guidelines are a different version than those reviewed by RAND panelists. Commenter concludes that it is wrong for the DWC to declare the proposed version of the chronic pain guidelines as evidence-based based solely on the statement by RAND.</p> <p>Commenter states that the DWC decided a more comprehensive chapter on chronic pain was necessary for the MTUS and initially proposed replacing ACOEM’s chapter on chronic pain with one based on ODG’s guidelines. Commenter indicates that since that time, both ACOEM and ODG have released extensively updated chronic pain guidelines. Commenter states that when ACOEM guidelines are compared with ODG’s using Appraisal of Guidelines for Research and Evaluation (AGREE) instrument, ACOEM’s guidelines score higher than ODG’s. ACOEM’s guidelines also score higher than ODG’s under the guideline criteria of the Institute of Medicine (IOM), American Medical Association (AMA), and Shaneyfelt and Associates.</p>			

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	<p>Note: Footnotes containing complete references for the aforementioned documents can be reviewed in the original comment in the complete rulemaking file.</p> <p>Commenter indicates that for example, in a comparison of the ACOEM and ODG guidelines, ACOEM guidelines were successful and ODG guidelines were deficient in meeting the following guideline criteria:</p> <p>AGREE instrument</p> <ul style="list-style-type: none"> • Systematic methods were used to search for evidence. • The criteria for selecting the evidence are clearly described. • The methods used for formulating the recommendations are clearly described. • There is an explicit link between the recommendations and the supporting evidence. • The recommendations are specific and unambiguous. • The different options for management of the condition are clearly presented. • Key recommendations are easily identifiable. • The guideline presents key review criteria for monitoring purposes. • Guideline development members have reported conflicts of interest. <p>Institute of Medicine</p> <ul style="list-style-type: none"> • Practice guidelines should identify the specifically known or generally expected exceptions to their recommendations. • Practice guidelines should use unambiguous language, define terms precisely, and use 			

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	<p>logical, easy-to-follow modes of presentation.</p> <ul style="list-style-type: none"> The procedures followed in developing guidelines, the participants involved, the evidence used, the assumptions and rationales accepted, and the analytic methods employed should be meticulously documented and described. <p>AMA</p> <ul style="list-style-type: none"> Practice guidelines should be as comprehensive and specific as possible. <p>Shaneyfelt and Associates</p> <ul style="list-style-type: none"> The method of identifying scientific evidence is specified. The method of data extraction is specified. The methods for grading or classifying the scientific evidence are specified. The formal methods of combining evidence or expert opinion are used and described. The role of value judgments used by the guideline developers in making recommendations is discussed. Recommendations are specific and apply to the stated goals of the guideline. The recommendations are graded according to the strength of the evidence. 			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	<p>Commenter recommends that the DWC restore Chronic Pain Guidelines into the topic sections, replacing ACOEM's Chapter 6 in the current guidelines with ACOEM's updated chronic pain guidelines.</p> <p>Commenter requests that if the DWC decides not to</p>	<p>Brenda Ramirez Claims and Medical Director</p> <p>Michael McClain General Counsel and Vice President</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and her</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>adopt the updated ACOEM’s updated chronic pain guidelines and decides to instead adopt updated ODG guidelines, commenter recommends revising the proposed guidelines to address only chronic pain; specifying the frequency, duration, intensity, and appropriateness for each treatment; clearly stating in the guidelines the recommendation status (at a minimum “Recommended,” “No recommendation,” or “Not Recommended”) together with the strength of evidence as determined by the methodology in Section 9792.25 for each service, and including in the regulations by reference, the appendix of evidence-based reviews with studies rated according to the methodology in Section 9792.25.</p> <p>In support of her request, commenter states that the proposed ODG-based chronic pain guidelines fall short of complying with statutory requirements, are not limited to chronic pain, and do not include a recommendation status and strength of evidence rating for each procedure.</p> <p>Commenter states that some of the proposed guidelines do not appear to be based on the evidence and/or no evidence is referenced. MTUS study ratings and MTUS levels of evidence underlying the recommendation are not determined and/or not provided. Commenter states that often it is difficult to tell whether or not a specific medical procedure or drug is being recommended or not recommended, and if recommended, under what circumstances, how frequently, how intensely and for how long. Without this information, the guidelines will not be successful in ensuring the most effective treatment for injured employees.</p> <p>Commenter argues that despite the title “Chronic Pain Medical Treatment Guidelines,” more than chronic</p>	<p>California Workers’ Compensation Institute (CWCI) December 18, 2008 Written Comment</p>	<p>comments were appropriately addressed in the 45-day comment period chart.</p>	

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	<p>pain is addressed in the proposed guidelines. Although some direct references to acute pain have been removed, it is still not always clear whether recommendations in the proposed guidelines are for the treatment of chronic pain or for acute or subacute pain or for the treatment of a particular condition. Commenter indicates that when the guidelines address services for conditions other than chronic pain that are covered by other sections of the MTUS, contradictions, confusion and disputes over competing presumptions will arise. Commenter opines that this uncertainty and conflict can be avoided by remaining with ACOEM practice guidelines which offer consistency across chapters including the updated chronic pain guidelines.</p> <p>Commenter states that the evidence relied upon in the updated ODG guidelines has not been evaluated according to the rating methodology in section 9792.25. Commenter believes that it is important to list the ratings for the study so that they can be used by treating physicians, reviewers, adjudicators, and judges to determine whether the presumption of correctness for a treatment addressed in the Chronic Pain section of the MTUS is overcome by superior evidence. Commenter believes that that listing will reduce the number of disputes and the resources needed to resolve such issues.</p> <p>Commenter indicates that the hierarchy of medical evidence – the grading system that stratifies conservative, high quality research from the lower quality, less reliable case studies and anecdotes – is the backbone of the State’s MTUS. Commenter adds that the hierarchy of medical evidence used in the proposed pain management guidelines, based largely on ODG, uses a more liberal hierarchy of medical evidence than the ACOEM standard of evidence.</p>			

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	<p>Commenter opines that if adopted, the MTUS will be forced to combine dissimilar methods of grading medical evidence, a situation that can only lead to an increase in variation of medical treatment and a reduction in overall quality of care. Commenter states that a study of a prior proposal to create a “patchwork” of disparate hierarchies and guidelines demonstrated the sub-optimal, unintended consequences of clinical and administrative “mixed signals.”</p>			
<p>9792.24.2 General Comment Chronic Pain Guidelines (Rating Methodology)</p>	<p>Commenter acknowledges that the proposed MTUS Chronic Pain Guidelines includes many specific changes suggested by ACOEM and others. However the chronic pain proposal, as adapted from Work Loss Data Institute’s Official Disability Guidelines Treatment in Worker’s Comp – Chapter on Pain (Chronic), Oct 23, 2008, continues to have significant problems. Commenter alleges that there are errors of fact and science that are a result of the use of a methodology that is neither evidence-based nor transparent. The proposal introduces intentional and unintentional consequences and if enacted, could result in over utilization and reintroduce significant costs to California workers’ compensation system, contrary to the expressed intent of the Legislature.</p> <p>Commenter recommends that DWC suspend adoption of the proposed chronic pain guidelines until a new medical director is appointed by the Governor. A new medical director is needed to provide the oversight necessary to correct errors of fact and science, understand the process of evidence based guideline development, and specifically evaluate the degree to which implementation of these guidelines would unexpectedly increase costs to the California workers’ compensation system and reduce the quality of care delivered to injured workers.</p>	<p>Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment</p>	<p>Agree in part. Agree with commenter regarding the studies Manchikanti, 2008, and Manchikanti2, 2008 as contained in the individual treatment guideline topic on “Acetaminophen (APAP),” at pp. 11-12. The text of the guideline provides commentary which is off-topic and not pertinent to ODG’s recommendations in the specific treatment guideline on Acetaminophen. Thus, the individual treatment guideline topic on “Acetaminophen (APAP)” is modified to strike the last two sentences of the guideline, wherein ODG discusses two Manchikanti et al. articles.</p> <p>Disagree with the remaining comments as the comments do not address the substantive changes made to the proposed regulations during the 1st 15-day notice. The same arguments regarding the ODG’s rating methodology (alleged errors of fact and science)</p>	<p>Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, <i>Acetaminophen</i>, has been amended as follows:</p> <p>“Acetaminophen (APAP)</p> <p>See Medications for Acute Pain Recommended as an initial choice for treatment of chronic pain & acute exacerbations of chronic pain. A Cochrane review of the literature on drug relief for low back pain (LBP) suggests that the popular nonsteroidal anti-inflammatory drugs (NSAIDs) are no more effective than acetaminophen, but NSAIDs had more adverse effects than acetaminophen. The results of this study support recommending NSAIDs as a</p>

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	<p><u>Errors of Fact</u> In the comments we submitted in August to the Commission, we noted several examples where the proposed guideline referenced out-of-date diagnostic tests, provided faulty citations, referenced evidence of questionable value, etc. Several of these have been fixed, but other errors remain. Commenter urges the Division, itself, to review the proposal in detail to correct all errors rather than delegating this task to ODG.</p> <p><u>Errors of Science</u> In several instances, the proposed treatment recommendations state there is insufficient evidence or a lack of evidence, when in fact high-quality evidence in the nature of randomized control trials (RCTs) does exist and has been identified by ACOEM. Again, we urge the Division, itself, to review the proposal in detail to correct all errors rather than delegating this task to ODG.</p> <p><u>Methodology</u> The Acetaminophen recommendation is illustrative of a more profound problem with the use of ODG as a guideline source, that is, a reliance on other systematic reviews and meta-analyses with no transparent process that includes original research and independent evaluation. The proposed guidelines are not evaluated according to the rating criteria and strength of evidence standards in section 9792.25(c)(B) as required in section 9792.26(c) of these regulations. Section 9792.26(c)(3) requires the members of the medical evidence evaluation advisory committee to "Apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where...a guideline is developed by the Administrative Director. ..."</p>		<p>were raised during the 45-day comment period, and these comments were appropriately addressed in the 45-day comment period chart. Moreover, disagree with the suggestion to "suspend adoption of the proposed chronic pain guidelines until a new medical director is appointed by the Governor[.]" because "[a] new medical director is needed to provide the oversight necessary to correct errors of fact and science, understand the process of evidence based-guideline development, and specifically evaluate ... implementation of these guidelines." The chronic pain medical treatment regulations are under the direct oversight of an associate medical director, who works under the direct supervision of the Administrative Director. The Administrative Director, with rulemaking power as delegated by statute, is the one who makes all the decisions regarding the adoption of the MTUS.</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</p>	<p><u>treatment option after acetaminophen. (Roelofs-Cochrane, 2008) See NSAIDs. Long-term administration of moderate to high doses of acetaminophen should not be considered safer than NSAIDs from the perspective of the risk for developing hypertension or kidney failure. In addition this drug is one of the most common causes of severe drug-induced liver injury. Risk factors include supratherapeutic doses (> 4g a day), and use in patients with a history chronic alcohol ingestion. With new information questioning the use of NSAIDs, acetaminophen should be recommended on a case-by-case basis. The side effect profile of NSAIDs may have been minimized in systematic reviews due to the short duration of trials. On the other hand, it now appears that acetaminophen may produce hypertension, a risk similar to that found for NSAIDs.</u></p> <p><u>Osteoarthritis (hip, knee, and hand): Recommended as an initial treatment for</u></p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>While the Cochrane study is “on topic,” it does not specifically address working populations and should be reinforced by an original evidence evaluation. The Manchikanti articles are not well conducted – focusing on interventional recommendations aspects of ACOEM’s Guidelines – nor are they appropriate for this document. For ODG to conclude that these articles constitute high quality, scientific and evidence-based research brings into question their independence and/or suitability to produce guidelines suitable for California’s injured workers.</p> <p>Unfortunately, this example is illustrative of a guidelines process that selectively uses examples from the literature to confirm pre-conceived recommendations. It can be called “evidence based,” but it should not be confused with original, transparent processes that truly evaluate high-quality science in the systematic way that California’s legislature envisioned. DWC’s assumption that ODG represents a guideline that is “scientifically and evidence-based” and that it does not have the responsibility “to identify areas that are not scientifically and evidence based” is not in the best interests of California’s injured workers and should be re-evaluated. The obvious lack of an active, rigorous evidence evaluation process presents a significant risk of recommendations that are over simplistic and result in increased morbidity, mortality and cost.</p> <p>It should be re-emphasized that the methodology, as adopted by the Division in the MTUS, relies on randomized controlled trials for the determination of a graded body of evidence that results in a clear recommendation statement. The reason for using RCT’s is that they represent a true scientific evaluation of a clinical question without the often confusing preponderance of anecdotal information</p>		<p>June 2008. In the Notice of proposed Rulemaking, DWC noticed in Appendix A that DWC proposed to adapt the October 31, 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 the 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</p>	<p><u><i>mild to moderate pain, in particular, for those with gastrointestinal, cardiovascular and renovascular risk factors. (Laine, 2008) If pain is inadequately treated or there is evidence of inflammation, alternate pharmacologic treatment should be considered. In patients with moderate to severe disease, initial treatment with an NSAID may be warranted. The decision to use either class of drugs should be made on a case-by-case basis, incorporating factors including side effect profile and patient preferences. Current guidelines note that evidence is limited to make an initial recommendation with acetaminophen, and that NSAIDs may be more efficacious for treatment. In terms of treatment of the hand it should be noted that there are no placebo trials of efficacy and recommendations have been extrapolated from other joints. (Zhang, 2007) The selection of acetaminophen as a first-line treatment appears to be made primarily based on side effect profile in</i></u></p>

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	<p>masquerading as clinical science. In the absence of a body of quality of evidence, ACOEM’s Guideline recommendations are designated as “insufficient evidence” with an associated, positive, negative or no-recommendation conclusion that is the unanimous (or, very rarely, consensus) decision of a known panel of multi-disciplinary specialists without financial interests in the outcome. This process, mandated by legislation, results in recommendations that are easily used in clinical practice and utilization review. DWC has not provided a reason why it would propose to discontinue relying on guidelines developed with such a robust process.</p>		<p>to Text of Proposed Rulemaking, Appendix A1—Chronic Pain Medical Treatment Guidelines, November 2008). During the 45-day comment period and during the 1st 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.</p> <p>Moreover, DWC notes that ODG via its internal updating process, completed on November 4, 2008, has expanded its evidence base in the individual treatment guideline topic on “Acetaminophen (APAP)”. The revised guideline does not change the basic recommendation for acetaminophen but it contains a more complete evidence-base</p>	<p><u><i>osteoarthritis guidelines. (Zhang, 2008) The most recent Cochrane review on this subject suggests that non-steroidal anti-inflammatory drugs (NSAIDs) are more efficacious for osteoarthritis than acetaminophen in terms of pain reduction, global assessments and improvement of functional status. No significant difference was found between overall safety, although patients taking NSAIDs were more likely to experience an adverse GI event. It is important to note that the median trial duration was only 6 weeks. (Towheed, 2008) See NSAIDs; NSAIDs, GI symptoms & cardiovascular risk; & NSAIDs, hypertension and renal function.</i></u></p> <p><u><i>Low back pain (acute and chronic): Both acetaminophen and NSAIDs have been recommended as first-line therapy for low back pain. There is insufficient evidence to recommend one medication over the other. Selection should be made on a case-</i></u></p>

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			<p>review. (See, ODG Updates Change Log, November, 2008, added to the Rulemaking file.) The revised individual treatment guideline topic on “acetaminophen” recommends both acetaminophen and NSAIDs, depending on the patient’s risk factors, and the guideline has very specific patient selection recommendations under "NSAIDs, GI symptoms & cardiovascular risk" and "NSAIDs, hypertension and renal function." It is noted that for some patients acetaminophen should be the first choice, due to the proven adverse effects of NSAIDs. DWC agrees with ODG’s revisions to the individual treatment guideline topic on “Acetaminophen (APAP).” Because DWC is deleting the Manchikanti, 2008, and Manchikanti2, 2008 discussion and references in the individual treatment guideline topic on “Acetaminophen (APAP),” the entire updated guideline is re-adapted into the current version of these regulations (See, ODG Acetaminophen Guideline Update, January 21, 2009, added to the rulemaking file).</p>	<p><u>by-case basis based on weighing efficacy vs. side effect profile. In the past many low back pain guidelines recommended acetaminophen as a first-line treatment but recent systematic reviews either failed to find evidence to support the view that acetaminophen was effective for the treatment of non-specific low back pain (Davies, 2008) or found that there was only “fair” quality evidence to support use vs. “good” quality evidence for NSAIDs. (Chou, 2007) Problems with research in this area include a lack of large high quality trials, inadequate reporting of methods and results, and choice of treatment contrasts. Further research on this topic has been suggested. It appears that part of the reason that acetaminophen was recommended as a first-line treatment over NSAIDs in most guidelines, in part, was that acetaminophen appeared to have less adverse effects. (Roelofs-Cochrane, 2008) See adverse effects below.</u></p>

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				<p><u>Adverse effects:</u> <u>Hepatotoxicity:</u> <u>Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. (Hunt, 2007) A warning is given on all acetaminophen products that patients that consume > 3 alcoholic drinks a day should discuss use with their physician, although a systematic review of acetaminophen use in alcoholic subjects concluded that there was little credible evidence to implicate therapeutic doses as a cause of fulminant hepatotoxicity in alcoholics. (Dart, 2007) Recent RCTs found that short-term treatment (3-5 days) of acetaminophen in newly abstinent alcoholic patients did not cause hepatic injury. (Kuffner, 2007) (Bartels, 2008) Acetaminophen, when used at recommended maximum doses, may induce ALT elevations >3x ULN in up to nearly 40% of subjects. Renal toxicity: Renal insufficiency occurs in 1 to 2% of patients with overdose. (Mazer, 2008) Hypertension and</u></p>

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				<p><u>cardiovascular risk: Cohort analysis reveals that acetaminophen use is associated with hypertension but evidence from randomized controlled trials is limited. This risk is similar to that found for NSAIDs. (Forman, 2007) (Montgomery, 2008) An increased cardiovascular risk was found in the Nurse's Health Study. (Chan, 2006) (Laine, 2007) (Laine, 2008)</u></p> <p><u>Dose: The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day.</u></p> <p><u>(Laine, 2007) These ODG recommendations are contrary to the recently released update to the ACOEM Practice Guidelines, which say NSAIDs are recommended for treatment over acetaminophen, and they conclude that acetaminophen is modestly less efficacious. (ACOEM, 2008) But an independent review of these guidelines utilizing the Appraisal of Guidelines for Research and</u></p>

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				<i>Evaluation (AGREE) instrument concluded that they scored below 30% with a recommendation from AGREE, "not recommended or suitable for use in practice." (Manchikanti, 2008) (Manchikanti2, 2008)</i>
9792.24.2 General Comment Chronic Pain Guidelines – Rating Methodology	<p>Commenter states that by failing to use a rigorous methodology and properly framed recommendations, the proposed chronic pain guideline fosters misunderstanding of the form and purpose of evidence-based medicine (EBM). In doing so, it opens the door for a return to lower quality, less effective care for California’s workers. As California is a pace-setter for the rest of the nation, wider effects are possible as well.</p> <p>Commenter notes that the medical advisory panel for New York workers’ compensation medical care has specifically ruled out the use of proprietary guidelines such as the one used as the basis for the chronic pain and post operative therapy guidelines, on the grounds that the methodology does not meet scientific standards.</p> <p>Commenter alleges that the methodology used to develop the ODG portions of the proposed guidelines do not follow methods required by state regulation or generally accepted by evidence-based medicine experts. One of the major problems with ignoring required and recognized methods is that it confuses the public, physicians, payers, regulators and administrative law judges about the content, process and outcomes of evidence-based medicine. Commenter believes that it also reduces the reliability of the recommendations.</p>	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational & Environmental Medicine (ACOEM), dated December 18, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines (Rating Methodology), above.	None.

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	<p>Commenter notes that there are well accepted steps for the conduct of systematic reviews of the scientific literature and methods for development of evidence-based guidelines that were not used in the development of the proposed chronic pain guideline. These methods are reflected in publications from the World Health Organization, the Cochrane Collaboration, the National Institute of Medicine, the Oxford Centre for Evidence-Based Medicine, the Agency for Healthcare Quality and Research, The Permanente Federation, the Veterans Administration, the Mayo Clinic and professional societies for Otolaryngology, Emergency Medicine, Occupational and Environmental Medicine, Internal Medicine, and others. Commenter opines that as a result, patients, providers and payers are not assured of the transparency, reproducibility, or reliability of the process or the advice provided.</p> <p>Commenter states that there were at least three opportunities to use the proper methods to develop the proposed guidelines. ODG could have followed internationally accepted methods. The DWC staff did so in developing added materials. The MEAAC was specifically trained in the methods outlined below during its first meeting.</p> <p>Most of the steps are listed below, followed by observations about the proposed regulations:</p> <ul style="list-style-type: none"> • Formulation of answerable clinical questions <ul style="list-style-type: none"> ○ The proposed guideline does not demonstrate specific clinical questions, including the population to be addressed, the intervention, comparison groups or specific outcomes (the PICO formulation, used by Cochrane, the WHO, Kaiser and others). Interventions are considered, but without the rest of the 			

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	<p>elements, it is not clear that the research addresses the working population, and comparisons and outcomes are random.</p> <ul style="list-style-type: none"> • Specification of search terms and strategies <ul style="list-style-type: none"> ○ The small portions of the proposed guideline research done by the DWC staff included these specifications, but the remainder of the document does not. As a result, the majority of literature on the topic was not reviewed, possibly due to faulty search specifications. There are over 1400 quality references available on various aspects of chronic pain, but only a fraction of these are cited. • Specification of inclusion and exclusion criteria <ul style="list-style-type: none"> ○ The inclusion criteria used for the proposed guideline allow consideration of lower quality study designs, review articles, state guidelines of any quality and methodology, conference proceedings (which have no quality controls in most cases), manufacturers’ promotional and other materials, and other material that is not acceptable in any other EBM context. • Screening/first level review of included studies <ul style="list-style-type: none"> ○ There is no evidence in the proposed guideline that any studies were rejected from consideration. Abstracts from MEDLINE are simply reprinted in the evidence section, and are briefly quoted in the body of recommendations. As such, there appears not to have been screening to assure that studies were in fact the type labeled in MEDLINE, or for other gross errors. A number of researchers have noted that labeling errors in 			

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	<p>MEDLINE abstracts are not uncommon.</p> <ul style="list-style-type: none"> • Critical appraisal of included studies <ul style="list-style-type: none"> ○ There is minimal evidence that studies were appraised for quality of design or execution. This is an absolutely critical step in EBM. There are notations of levels a, b and c, and a description of these levels in the ODG on-line methodology, apparently abstracted from an older version of the Cochrane handbook. However, there no evidence tables or critical analysis paragraphs available, leaving the reader without the necessary data to understand the strengths and weaknesses of the studies used. ○ What appraisal there is does not use the methodology required in Table A of 9792.22 (c) (1). That table uses an 11 point scale with specific criteria. There is no evidence that such a specific scheme, derived from work done by the Cochrane back group, was used. There is no way to crosswalk this method to the a-c system described in the ODG website. • Synthesis of high quality studies <ul style="list-style-type: none"> ○ The paragraphs describing the studies cited are brief and do not contain a synthesis of the studies listed. The synthesis is also a critical step, bringing together the various studies cited considering their quality, differences in design, and weight of conclusions. ○ There are no comparisons of statistical effects or forest plots to aid the reader in understanding the strength or consistency of the evidence. • Grading the body of evidence <ul style="list-style-type: none"> ○ Generally accepted methods, and more specifically, the MTUS in Table B of 			

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	<p>9792.22 (c) (2) specify criteria for the strength of evidence to aid the public in understanding the likelihood of benefits exceeding harms and the degree of certainty that the test or treatment in question will be effective. These ratings do not appear in the vast majority of the ODG portions of the proposed regulations, leaving the reader to speculate about the strength of the collective evidence. It therefore cannot support informed clinical decision making. The words “strong” and “moderate” are occasionally used, but are not supported by any analysis to indicate the source of the rating.</p> <ul style="list-style-type: none"> • Drafting recommendations <ul style="list-style-type: none"> ○ In almost all other non-proprietary guideline development efforts, recommendations are individually drafted based on the strength of the evidence, and then reviewed, revised and discussed by an expert panel. The discussions are summarized if needed in the guideline document, particularly when there was disagreement or when consensus recommendations were developed. This process is not evident in the proposed guideline as published. ○ Assigning a Strength of Recommendation is a widely accepted step following recommendation drafting and discussion. The panel typically assigns the rating, with review by a methodologist. There are no Strength of Recommendation ratings in the proposed guideline, depriving the reader of key overview information on probable effectiveness and risk versus benefit for each recommendation. 			

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	<ul style="list-style-type: none"> • External review <ul style="list-style-type: none"> ○ The AGREE criteria and generally accepted practice is to secure considered review from a broad group of experts not associated with the guideline development process and free of conflicts of interest. This is different than public comment. There is no evidence of this step in the proposed guideline. • Revision <ul style="list-style-type: none"> ○ The revision step, which is often iterative, is based on specific comments received. Since the DWC did not respond specifically to comments submitted, it is not clear how the revision process proceeded. 			
9792.24.2 General Comment Chronic Pain Guidelines (Rating Methodology)	<p>Commenter opines that there are serious scientific, clinical and legal flaws in the chronic pain medical treatment guidelines proposed by the California Division of Workers Compensation for inclusion in the Medical Treatment Utilization Schedule (MTUS), Title 8, California Code of Regulations, Sections 9792.20 – 9792.23. Until these problems are corrected, or a different proposal substituted, commenter believes that the proposed guideline should not be adopted.</p> <p>Commenter alleges that that this guideline conflicts with other guidelines in the MTUS, that it does not follow accepted principles of evidence based medicine or the methodology in Article 5.5.2, Subchapter 1 of Section 9792.20. Further commenter points out that it has been changed after the initial comment period to ignore the emphasis on functional improvement in Section 9792.20. Commenter believes that adoption of the proposed guideline will result in increased friction in the workers’ compensation and will not improve the health of workers with work-related health complaints.</p>	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational & Environmental Medicine (ACOEM), dated December 18, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines (Rating Methodology), above. Commenter further states that he did not “see or receive a specific response to ... [his 45-day] comments as required by state procedure.” DWC disagrees . DWC is not required to personally respond to commenter. DWC is required to consider his comments and respond to them in the summary of comments which is part of the final statement of reasons and included in the rulemaking file. (See, Government Code section 11346.9(a)(3).)	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter alleges that his original 45 day comments were ignored in the revision published for this (15 day) comment period. Commenter did not see or receive a specific response to those comments as required by state procedure.</p>			
<p>9792.24.2 General Comment Chronic Pain Guidelines – Marketing Language</p>	<p>Commenter states that there is a propensity in the ODG-based recommendations to include prose that is clearly marketing based and that is not reflective of a scientific and evidence-based process. Such language includes several negative recommendations to drugs produced by Cephalon, and the edits to Actiq (p. 11) describing it as “potent lollipop” instead of “addictive” is one example. There are so many references to Cephalon as a major producer of opioid pharmaceuticals that one might conclude that its repeated mention is a result of product placement more than a review of scientific evidence.</p> <p>Similarly, the language describing recent studies for H-wave stimulation (p. 123) describes a “low quality meta analysis” that is based on retrospective, non-controlled data from a manufacturer’s customer service questionnaire and that “More definitive studies may be on the way.” This is not graded evidence suitable for clinical guidance. It is more an “advertisement” for H-Wave technologies.</p> <p>Similarly, the additional language describing a subgroup analysis that “approached statistical significance” in long term spinal cord stimulator use in CRPS patients (p. 109) would not even be allowed in FDA-approved marketing language. Certainly it should not be included in guideline language. In reality, there is little quality evidence to support long term SCS use and commenter believes its use for injured workers should appropriately be focused on exceptional clinical situation.</p>	<p>Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment</p>	<p>Disagree with the comment that the DWC chronic pain medical treatment guidelines, as adapted from the October 23, 2008 ODG-version, contains recommendations that include language “that is clearly marketing based and that is not reflective of a scientific and evidence-based process.” Commenter argues that the modifications to the individual treatment guideline on “Actiq” contains “marketing” language because the guideline describes the as “potent lollipop” instead of “addictive,” and that references to “Cephalon” results in “product placement more than a review of scientific evidence. Disagree with the comment. The recommendation for the individual treatment guideline for “Actiq” is “not recommended.” It would appear that “marketing” language and “product placement” are hardly the intention of the guideline when the drug itself is not recommended.</p> <p>Commenter also criticizes the individual treatment guideline on “H-wave stimulation (HWT)” as “describe[d] [in] a ‘low quality</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>meta analysis’ that is based on retrospective, non-controlled data from a manufacturer’s customer service questionnaire.” Commenter opines that this “is more an ‘advertisement’ for H-Wave technologies.” Disagree with the comment. ODG clearly describes the study's quality rating in the guideline, and the recommendation is “not recommended as an isolated intervention.” Thus again, it would appear that “marketing” language is hardly the intention of the guideline when the device itself is not recommended as an isolated intervention.</p> <p>Commenter also argues in connection with the individual treatment guideline on “spinal cord stimulators (SCS)” that “a subgroup analysis that ‘approached statistical significance’ in long term spinal cord stimulator use in CRPS patients would not even be allowed in FDA-approved marketing language.” Disagree. The product is FDA approved for pain.</p>	
9792.24.2 Chronic Pain Guidelines	Commenter states that in reviewing the MTUS on treatment modalities and things such as topical, oral, and opioid-based medications, treatments, etc., it appears that DWC is attempting to “re-create” it’s own cut and paste version of ODG and/or ACOEM. Commenter believes this is much too complex of a process to take on and then subject to the political	Frank Hall, MSN, RN, CMM Supervisor U.R. & Nurse Case Management December 18, 2008 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raises the same arguments which were raised during the 45-day comment period,	None.

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	process, which has no place in constructing medicinally-based treatment protocols. Commenter states that the end result, is that you attempt to accommodate far too many groups and the end product does not “protect the public,” as is DWCs original and first priority.		and these comments were appropriately addressed in the 45-day comment period chart. Commenter does not appear to understand the rulemaking process. The necessity for the chronic pain medical treatment guidelines is pursuant to Labor Code section 5307.27, and the need to “accommodate far too many groups” is part of the rulemaking process.	
9792.24.2 Comparison to ACOEM Chapter	Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2 nd Edition, (ACOEM Practice Guidelines). Under the heading <u>Type of Guideline</u> and subheading <u>Peer-reviewed</u> , commenter states that the Original DWC Chronic Pain Medical Treatment Guidelines is probably peer-reviewed. Commenter states that he is unsure because neither DWC nor ODG has published a methodology in a peer-reviewed journal. Commenter states that the ACOEM Chronic Pain Update (August 2008) and the November, 8, 2008 DWC Revision is peer reviewed.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Comparison to ACOEM Chapter/ Consensus Issue	Under the heading <u>Type of Guideline</u> and subheading <u>Evidence-based</u> , commenter states that he is unsure whether Part I of the DWC Chronic Pain Medical Treatment Guidelines is evidence-based because he is unsure as to whether a complete search of the literature was done. Commenter opines that Part 2 of the DWC Chronic Pain Medical Treatment Guidelines is not evidence-based because the guideline began with an evidence-based guideline and evolved into a consensus-based guideline. Commenter also adds that a complete search of the literature was not done. Commenter states that the ACOEM Chronic Pain	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Update is evidenced based.</p> <p>Regarding DWC's November 8, 2008 revision, commenter states that Part 1 is not evidence based and that Part 2 is not evidence based and has a high reliance on consensus guidelines and conference data.</p> <p>Commenter states that ACOEMS final version (August 2008) is evidence based.</p>			
<p>9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter</p>	<p>Under the heading <u>Type of Guideline</u> and subheading <u>Nationally-recognized</u>, commenter opines that the DWC Chronic Pain Medical Treatment Guidelines is not nationally-recognized. Commenter states that guidelines will not be recognized or used outside California. Commenter adds that guidelines will not be used as a text or reference because it is superficial and lacks scientific credibility. Commenter opines that the guidelines will only be used as evidence before the Workers' Compensation Appeals Board. Commenter opines that the guidelines are not even comprehensive or clear enough to be used in utilization review. He believes the guidelines are too superficial to be a reference text. Commenter states that the ACOEM Chronic Pain Update is nationally-recognized and internationally recognized. Commenter adds that the ACOEM Chronic Pain Update will be used as a text and reference throughout the English-speaking world.</p> <p>Commenter states that the DWC November 8, 2008 revision is not nationally-recognized or used outside California. Commenter opines that work will not be used as a text or reference because it lacks scientific credibility and that the work's only use will be as evidence before the Workers' Compensation Appeals Board. Commenter concludes that it is too superficial to be a reference text.</p>	<p>James E. Lessenger, MD December 07, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Under the heading <u>Type of Guideline</u> and subheading <u>Consensus input</u>, commenter opines that the consensus input in the DWC Chronic Pain Medical Treatment Guidelines is high. Commenter notes that the guidelines use consensus conference literature and non-peer reviewed articles. Commenter states that the ACOEM Chronic Pain Update contains low consensus input.</p> <p>Commenter states that the DWC November 8, 2008 revision's consensus input is very high. The guidelines repeatedly reference consensus guidelines, articles, and reports from consensus conferences. Commenter states that the ACOEM Chronic Pain Update contains low consensus input.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Under the heading <u>Type of Guideline</u> and subheading <u>Political input into the composition of the committee and contents of Guidelines</u>, commenter indicates that the DWC Chronic Pain Medical Treatment Guidelines and the DWC November 8, 2008 revision has high political input into the composition of the committee and contents of Guidelines as opposed to the ACOEM Chronic Pain Update which is none.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Under the heading <u>Methodology</u> and subheading <u>Published Methodology</u>, commenter indicates that the originally proposed DWC Chronic Pain Medical Treatment Guidelines are not published as opposed to the ACOEM Chronic Pain Update which is published. Commenter states that methodology used by ACOEM is published in each update and in a separate publication in a peer-reviewed journal.</p> <p>Commenter states that DWC's November 8, 2008 revision is not published. Commenter states that there are some references which are graded, but there is no documentation of what system or criteria is used for</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the grading.			
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Methodology for grading data objectively</u> , commenter opines that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 update does not have a methodology for grading data objectively as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Consulting professional methodologist</u> , commenter opines that the DWC did not consult a professional methodologist in developing its Chronic Pain Medical Treatment Guidelines or its November 8, 2008 revision as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Statement of conflicts of interests of the committee</u> , commenter states that the Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain a statement of conflicts of interests of the committee as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Peer-reviewers listed</u> , commenter states that the Chronic Pain Medical Treatment Guidelines and its November 8, 2008 revision does not contain a list of its peer-reviewers as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Committee members listed</u> , commenter states that the Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain a list of its committee members as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Peer-review societies listed</u> , commenter states that the Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain a list of the peer-review societies as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Sources of the original manuscript</u> , commenter states that Part I of the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision is an original document. Commenter further states that Part 2 of the DWC Chronic Pain Medical Treatment Guidelines and November 8, 2008 revision is a combination of ODG Guidelines and the Colorado Guidelines. Commenter further states that these sources for the original DWC Chronic Pain Medical Treatment Guidelines “are cited but without attribution that it was copied.” Commenter adds that the ACOEM Chronic Pain Update is completely original.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Pain specialist on committee</u> , commenter states that it is unknown whether DWC has a pain specialist on the committee which participated in the formulation of the Chronic Pain Medical Treatment Guidelines or the November 8, 2008 revision. Commenter adds that ACOEM has a pain specialist on its committee.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Updates</u> , commenter states that he is unsure how the DWC Chronic Pain Medical Treatment Guidelines or the November 8, 2008 revision will be updated. Commenter surmises that given the cumbersome regulatory process of the DWC, updates and corrections of dosing and other errors will undoubtedly be few and far between. Commenter adds that the ACOEM Chronic Pain Update is updated every three years with more frequent updates in the monthly Insights as needed.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Clearly defined recommendation categories</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision do not contain clearly defined recommendation categories as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Recommendation categories</u> , commenter states that it is unknown whether the DWC Chronic Pain Medical Treatment Guidelines or the November 8, 2008 revision contains recommendation categories. Commenter states that the DWC Chronic Pain	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Medical Treatment Guidelines contain no clear standardized categories. Commenter adds the ACOEM Chronic Pain Update contains nine (9) standardized and defined categories.		comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Clearly defined data grading</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision do not contain clearly data grading as opposed to the ACOEM Chronic Pain Update.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Clarity recommendations</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines are not clear in their recommendations as opposed to the ACOEM Chronic Pain Update which is extremely clear. Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines are much improved, but a few recommendations are still buried in the manuscript and are unclear.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the very same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>Methodology</u> and subheading <u>Data sources</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines cites consensus conferences and non-peer reviewed publications (ex. Pg 36) as the data source. Commenter also adds that the DWC Chronic Pain Medical Treatment Guidelines uses state regulation as a reference for acupuncture and not scientific literature, quotes manufacturer promotional sales literature, and uses websites as sources. Commenter adds that the ACOEM Chronic Pain Update uses peer-reviewed journal articles,	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>guidelines, high quality review articles, and randomized controlled studies as its data source.</p> <p>Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines cites consensus conferences, articles, and guidelines; and non-peer reviewed publications. Commenter further states that it uses state regulations as a reference for acupuncture and not scientific literature. Commenter also notes that it quotes manufacturer promotional sales literature and uses website and other regulations as sources.</p>			
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Length (pages)</u> , commenter states that the originally proposed DWC Chronic Pain Medical Treatment Guidelines is 83 pages, the November 8, 2008 revision is 132 pages and the ACOEM Chronic Pain Update is 432 pages.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Available</u> , commenter states that it is unknown when the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision will be available. He opines that the regulatory process is ponderous and complicated. Commenter adds that the ACOEM Chronic Pain Update was available in August 2008.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>References (number)</u> , commenter states that Part 1 of the DWC Chronic Pain Medical Treatment Guidelines contains 13 references. Commenter also states that Part 2 uses, but does not list the references. Commenter opines that this point is a “fatal flaw.” He	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the very same arguments during the 45-day	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>further opines that the lack of a reference list is unacceptable. Commenter adds that the ACOEM Chronic Pain Update contains 1557 references and that this number includes 546 randomized controlled trials (RCTS).</p> <p>Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines, Part 1 contains 13 references and Part 2 contains about 350 references; however it is difficult to count because there is some duplication and some of the references given in the text are not in the reference section.</p>		comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Parts of sections</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision contains 2 sections as opposed to the ACOEM Chronic Pain Update which has 22 sections, plus 5 algorithms, references, and 5 appendices.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the very same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Summary of table recommendations for diagnostic testing</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain a summary of table of recommendations for diagnostic testing. Commenter adds that the ACOEM Chronic Pain Update has a summary of table of recommendations for diagnostic testing.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the very same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Summary table of recommendations for management of chronic pain</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain a	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the very same	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	summary table of recommendations for management of chronic pain. Commenter adds that the ACOEM Chronic Pain Update has a three summary table of recommendations for CRPS, Neuropathic Pain and for management of chronic persistent pain, which is broken into 3 parts: recommended, no recommendation, and not recommended.		arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>“Red Flag” list and definitions</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain a “Red Flag” list and definitions while the ACOEM Chronic Pain Update does.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the very same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Non-Red Flag list and definitions</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain a non-red flag list and definitions while the ACOEM Chronic Pain Update does.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Number of treatment algorithms</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain treatment algorithms while the ACOEM Chronic Pain Update contains 5.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Appendices</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not contain appendices while the ACOEM Chronic Pain Update contains five (5) opioids, fibromyalgia, pain history questions, psychological testing, and a review of low quality studies and guidelines.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Discussion of the initial assessment</u> , commenter states that the discussion of the initial assessment in the DWC Chronic Pain Medical Treatment Guidelines is superficial while in the ACOEM Chronic Pain Update it is comprehensive. Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines contains no discussion of the initial assessment.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Discussion of causation analysis</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision contain no discussion of causation analysis while the ACOEM Chronic Pain Update does.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Discussion of the initial history and physical examination</u> , commenter states that the discussion of the initial history and physical examination in the DWC Chronic Pain Medical Treatment Guidelines is superficial (half a page) while the discussion in the ACOEM Chronic Pain Update is detailed and	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>extensive (8 pages).</p> <p>Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines contains no discussion of the initial history and physical examination.</p>		<p>comments were appropriately addressed in the 45-day comment period chart.</p>	
<p>9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter</p>	<p>Under the heading <u>General Content</u> and subheading <u>Index</u>, commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision do not contain an index while the ACOEM Chronic Pain Update does.</p>	<p>James E. Lessenger, MD December 07, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>
<p>9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter</p>	<p>Under the heading <u>General Content</u> and subheading <u>Definitions (number)</u>, commenter states that Part 1 of the DWC Chronic Pain Medical Treatment Guidelines contains 4 definitions and Part 2 contains 1 definition. Commenter adds that the ACOEM Chronic Pain Update contains 31 definitions in a separate section.</p> <p>Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines, Part 1, contains 4 definitions and Part 2 contains 4 definitions.</p>	<p>James E. Lessenger, MD December 07, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>
<p>9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter</p>	<p>Under the heading <u>General Content</u> and subheading <u>Number of diagnostic studies reviewed</u>, commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains 3 diagnostic studies reviews while the ACOEM Chronic Pain Update contains 14.</p> <p>Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines contains 7 diagnostic studies reviews.</p>	<p>James E. Lessenger, MD December 07, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Number of interventions reviewed</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains 53 interventions reviews while the ACOEM Chronic Pain Update contains 69 categories with up to 7 evaluations in each category. Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines contains 40 interventions reviews.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Number of medication classes reviewed</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision contains 23 medication classes reviews while the ACOEM Chronic Pain Update contains 24.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Recommendations clearly set apart</u> , commenter states that the recommendations in the DWC Chronic Pain Medical Treatment Guidelines are not clearly set apart. He indicates that they are embedded into the discussion and difficult to pick out. Commenter adds that the recommendations in the ACOEM Chronic Pain Update are clearly set apart and highlighted. Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines are much improved. For the most part recommendation in contained in the first sentence; however, at least one is buried in the text.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain	Under the heading <u>General Content</u> and subheading <u>Basic principles discussed</u> , commenter states that in all three guidelines the basic principles are discussed.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chapter			Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Under the heading <u>General Content</u> and subheading <u>Discussions of the literature upon which the recommendations were made</u>, commenter states that the discussions of the literature upon which the recommendations were made in the DWC Chronic Pain Medical Treatment Guidelines are minimal. He indicates that they are substantial and thorough in the ACOEM Chronic Pain Update.</p> <p>Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines are more moderate. Some references are discussed and graded, but the grading system is not given and there is no methodology statement provided.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Review of pain pathophysiology</u> , commenter states that all three guidelines contain a review of pain pathophysiology.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Discussion of risk factors for chronic pain</u> , commenter states all three guidelines contain a discussion of risk factors for chronic pain.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Under the heading <u>General Content</u> and subheading <u>Review of treatment models</u>, Commenter states that the DWC Chronic Pain Medical Treatment Guidelines review 5 treatment models. He indicates that the ACOEM Chronic Pain Update reviews one treatment model: biopsychosocial model. He further indicates that this model is generally accepted at the only workable model in treatment.</p> <p>Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines review 4 treatment models.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Under the heading <u>General Content</u> and subheading <u>Summary of recommendations and evidence</u> , commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision do not contain a summary of recommendations and evidence while the ACOEM Chronic Pain Update does.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Under the heading <u>General Content</u> and subheading <u>Portability</u>, commenter states that the DWC Chronic Pain Medical Treatment Guidelines can be folded and put into a coat pocket like a racing program. Commenter adds that the ACOEM Chronic Pain Update is in book form, but the web form will be available for “cut and paste.” Commenter adds that a collection of the summary tables would make a useful booklet.</p> <p>Commenter states that the November 8, 2008 update</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	of the DWC Chronic Pain Medical Treatment Guidelines opines that when the cross-outs are removed from the draft that there will be about 100 pages.			
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Under the heading <u>General Content</u> and subheading <u>Dosing information</u>, commenter states that the DWC Chronic Pain Medical Treatment Guidelines contains dosing information. He opines that it is inappropriate for the DWC to impinge on the power and authority of the Federal Government and the FDA to set dosage guidelines. He believes that there is a great tendency for error in this area and the method of correction of errors in this system is cumbersome. He believes this is dangerous. He indicates that there is no efficient and rapid method of making changes to update new information or to correct errors. Commenter adds that the ACOEM Chronic Pain Update has dosing information for opioids. He adds that for other treatments, the frequency, duration, interactions, side effects, rational for recommendation and indications for discontinuation are given for each recommended medication.</p> <p>Commenter states that the November 8, 2008 update of the DWC Chronic Pain Medical Treatment Guidelines still contains dosing information but less than in the previous draft and there is more emphasis on the manufacturer's labeling.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	Commenter submitted a chart comparing the original draft of the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2 nd Edition, (ACOEM Practice Guidelines). Under the <u>General Content</u> heading, commenter offers the following comments:	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><u>Off label dosing information</u></p> <p>Commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision contain off-label dosing information. Commenter opines that it is inappropriate for the DWC to impinge on the power and authority of the Federal Government and the FDA to authorize “off label” prescribing guidelines in State regulation. Commenter states that DWC offers citations but no reference lists as to their rationale for this. He believes this is dangerous. Commenter adds that the ACOEM Chronic Pain Update offers no off-label dosing information.</p>			
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the <u>General Content</u> heading, commenter offers the following comments:</p> <p><u>Off-label drug use indicated as such</u></p> <p>Commenter states that the original draft of DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision discusses off-label drug use indicated as such but in an inconsistent manner. He further adds that DWC Chronic Pain Medical Treatment Guidelines contains no disclaimer regarding off-label drug use. Commenter adds that the ACOEM Chronic Pain Update discusses off-label drug use indicated as such and indicates that all chapters include analyses of numerous interventions, whether or not FDA-approved. For non-FDA-approved interventions, recommendations are based on the available evidence; however, this is not an endorsement of their use. In addition, many of the</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	medications recommended are utilized off label.			
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the <u>General Content</u> heading, commenter offers the following comments:</p> <p><u>Costs</u></p> <p>Commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revisions is presumably free online through the DWC website. Commenter adds that a printed copy of the ACOEM Chronic Pain Update is \$59.95, and Online access to all the ACOEM Guidelines is \$199 a year.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the heading <u>Summary</u> commenter opines that the original draft of the DWC Chronic Pain Medical Treatment Guidelines does not reflect well upon his profession (medical). Commenter opines that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines is much improved but still lacking in detail and documentation and remains a consensus guideline based upon consensus statements, guidelines and articles. Commenter believes that the ACOEM Chronic Pain Update is comprehensive and authoritative. Further, commenter opines that it is new, freshly evaluated data.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Direct Comparison	Under the heading <u>Advantages</u> commenter opines that the original draft of the DWC Chronic Pain Medical	James E. Lessenger, MD	Disagree. The comment does not address the substantive changes	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
to ACOEM Chronic Pain Chapter	<p>Treatment Guidelines is short portable and free. Commenter opines that the advantage of the November 8, 2008 revision is that it is free. Commenter points out the that the ACOEM Chronic Pain Update is:</p> <ul style="list-style-type: none"> ➤ Comprehensive and authoritative ➤ Can be downloaded to a palm pilot ➤ Has a directory for easy access ➤ Has algorithms, lists and charts ➤ Uses only high quality or moderate quality randomized control trials ➤ Contains system review articles, review articles and other high quality articles ➤ When using low grade RCTs, they are labeled as such 	December 07, 2008 Written Comments	made to the proposed regulations during the 1 st 15-day notice. Commenter raised the substantially the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2 Direct Comparison to ACOEM Chronic Pain Chapter	<p>Under the heading <u>Disadvantages</u> commenter opines that the original draft of the DWC Chronic Pain Medical Treatment Guidelines is superficial and contains no charts or lists for a quick reference. Commenter opines that it is not comprehensive, lacks authoritative vigor, lacks scientific creditability and uses consensus conference data and non-peer reviewed articles.</p> <p>Commenter opines that the disadvantages of the November 8, 2008 revision is that it is superficial (although it is improved with more detail), especially concerning opioids and CRPS. Commenter further states that there are no charts or lists for a quick reference. Commenter opines that it is not comprehensive, lacks authoritative vigor, lacks scientific creditability and uses consensus conference data and non-peer reviewed articles.</p> <p>Commenter opines that the only disadvantage to the ACOEM Chronic Pain Update is that it is too bulky to easily carry and that is cost money for the user.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the substantially the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>9792.24.2 General Comment Chronic Pain Guidelines – Definitional Issues and Conflicts with other Guidelines in the MTUS</p>	<p>Commenter opines that revised proposed guideline for chronic pain defines chronic pain as pain which persists beyond the expected time of healing. No such expected times, based on epidemiologic studies, are included in the proposed guideline, leaving this time period to subjective judgment. The proposal states that when chronic pain is diagnosed, the recommendations in other sections of the MTUS, the majority of which apply to specific body parts, no longer apply. Commenter believes that there are several problems with this:</p> <p>Commenter states that the proposed guideline does not contain evidence or recommendations for diagnostic tests such as nerve conduction tests or imaging, or procedures such as back or carpal tunnel surgery. Commenter indicates that many if not the majority of procedures for complaints that include pain are requested or occur after the acute period of the complaint. Commenter opines that as a result, the proposed guideline bars the use of the considered recommendations about these topics in other sections of the MTUS. Commenter concludes that this leaves reviewers, physicians, judges and others without guidance for appropriate use of these tests and treatments. Commenter notes that in the aggregate, such modalities are expensive and some have significant risk. He opines that abrogating the evidence-based recommendations in this way exposes injured workers to significant potential harms.</p> <p>Commenter adds that the criteria for recommendations for testing and procedures are not time based for the most part. Commenter indicates that such modalities must meet clinical examination and historical criteria regardless of the time frame. Commenter notes that in the absence of such criteria, there are many “fishing expeditions” resulting in false</p>	<p>Jeffrey S. Harris, MD December 15, 2008 Written Comments</p>	<p>Disagree with the comment regarding the definition of the term “chronic pain.” The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Issues regarding the definition of the term “chronic pain” and diagnostic tests were raised during the 45-day comment period, and the comments in that regard were appropriately addressed in the 45-day comment period chart.</p> <p>Moreover, disagree with the comment that the proposed guidelines “does not contain evidence or recommendations for diagnostic tests.” The MTUS is designed to provide that when a topic is not addressed in the chronic pain medical treatment guidelines, but it is addressed in the clinical topics sections, the treatment guidelines in the clinical topics sections apply even when the injured worker has been diagnosed with chronic pain. Accordingly, guidelines for the diagnostic tests such as nerve conduction tests or imaging, or procedures such as back or carpal tunnel surgery will be found in the applicable clinical topics sections.</p> <p>Commenter adds that the criteria for recommendations for testing and procedures are not time based</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>positive tests and unnecessary and potentially harmful procedures. Commenter argues that workers are put at risk.</p> <p>Commenter argues that the barring of use of such evidence as presumptively correct may result in conflicts and friction, as the evidence is still extant, and may be used by regulation when the presumptively correct guideline is silent on a particular area.</p>		<p>for the most part. The reason for that criteria not being time based is because the diagnostic and procedures tests are not included in the chronic pain medical treatment guidelines since they are contained in the applicable clinical topics sections.</p> <p>Commenter believes that the fact that the diagnostic and procedures tests are not contained in the chronic pain medical treatment guidelines as presumptively correct may result in conflicts and friction, as the evidence is still extant. Disagree. The MTUS was designed precisely to avoid friction and conflicts. the MTUS is not silent as to the evidence or recommendations for diagnostic and procedures tests. The evidence and recommendations on these tests are contained in the clinical topics sections and, if not covered by the chronic pain medical treatment guidelines, the clinical topics sections apply. DWC does not find it appropriate to re-write material which is already contained in the clinical topics section and transposing it to the chronic pain medical treatment guidelines.</p>	
9792.24.2 General Comment Chronic Pain Guidelines –	Commenter opines that the revisions to the original proposed guideline removed reference to improved functional outcomes as a point of emphasis and a criterion for continuing therapy, e.g. using objective	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Issues	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Outcomes	<p>clinical effectiveness as a criterion. Commenter states that most publications and experts in workers' compensation and pain management emphasize functional recovery. Commenter opines that lack of attention to function ignores a key outcome and ignores the intent of workers' compensation medical care, which is restoration of the worker's functional abilities. Commenter argues that because research is sparse in many areas of pain management, use of objective functional improvement is critical to managing therapy. Commenter opines that continuing ineffective treatment makes no sense, raises the risk of untoward effects without benefit, and is an unnecessary economic burden.</p> <p>Commenter states that the Medical Board of California guideline on the use of opioids includes functional improvement as an outcome to be monitored. Note also, however, that the MBC guideline was originally drafted for cancer patients, in whom pain management may be a greater focus. Commenter indicates that very few if any experts advocate focusing on pain levels alone in managing musculoskeletal complaints.</p>		<p>relating to the definition of "functional improvement," and its application in the chronic pain medical treatment guidelines were raised during the 45-day comment period, and the comments in that regard were appropriately addressed in the 45-day comment period chart.</p> <p>Moreover, DWC notes that in the acute stage, complete functional recovery is expected for the majority of injuries; however, for those injured workers who go on to become diagnosed with chronic pain, functional recovery will plateau. Return to pre-injury status is unlikely and rare. Therefore the focus on the treatment of chronic pain shifts to maintain function at the best level of functional improvement achieved. Functional outcomes are still monitored, but the goal is to maintain the functional improvement gained by treating chronic pain. The chronic pain medical treatment guidelines is also consistent with state guidelines and statutes that govern pain management. There is no conflict between the MTUS and these statutes because there is no internal conflict in the application of the statutes and the regulations.</p>	
9792.24.2 Chronic Pain Guidelines -	Commenter opines that the second half of the proposed guideline looks like a dictionary in alphabetical order. As such, many similar	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Format	<p>recommendations in a group are scattered throughout the document rather than being grouped for a better clinical picture. Commenter states that in addition, there is a great deal of material that is descriptive and not on point for a specific clinical problem formulation. Commenter alleges that much of this material is not found in evidence-based guidelines as it is more of a textbook type of approach. Commenter states that it should be removed. Commenter points out that this type of material may comprise a significant portion of the guidelines.</p> <p>Commenter points out that there are also many statements about current practice patterns or “widely used” therapies. Commenter alleges that there are not evidence based and may mislead the reader or be quoted out of context. Commenter believes that they should be removed.</p>		during the 1 st 15-day notice. Issues relating to the format and evidence-base of the chronic pain medical treatment guidelines were appropriately addressed in the 45-day comment period chart.	
9792.24.2 General Comment Chronic Pain Guidelines – Use of Material not Generally Considered Evidence	<p>Commenter points out that the ODG material uses books, review articles, meeting proceedings, state guidelines, other guidelines, manufacturers’ materials and other material as “evidence”. Commenter states that one of these is regarded as evidence by other guideline developers. They for the most part do not follow EBM methods. Potential bias is clearly an issue.</p> <p>Commenter also points out that the ODG material repeatedly cites guidelines from the States of Washington and Colorado. While these are well constructed, and with due respect to the developers, they are not primary source material. They are the product of a consensus process in some areas, and have been through a discussion process in other areas of the country with different practice patterns and issues. To commenter’s knowledge, while these are arguably public documents, permission for their use was not obtained from the developers. EBM requires</p>	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Issues relating to the evidence-base of the chronic pain medical treatment guidelines were appropriately addressed in the 45-day comment period chart. Moreover, it is noted that ODG’s has its own methodology and style and they classify and refer to different forms of evidence. ODG makes clear that when there are no high quality, studies, they reference what is available, including available state guidelines. (See, ODG’s <i>Explanation of Medical Literature Ratings</i>).	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the consideration of primary sources, e.g. studies, not conclusory material.			
9792.24.2 General Comment Chronic Pain Guidelines - Transparency	Commenter notes that the National Institute of Medicine, Cochrane, and the AGREE Collaboration, among others, regard transparency as a key attribute of excellent guidelines. Commenter states that the proposed regulation does not list the members of the MEEAC, DWC staff, the ODG staff or consultants, or reviewers who were involved in guideline development. It does not list their employment, grants, funding, or other potential conflicts of interest, as other high quality guidelines do. Commenter states that there is no way to understand possible conflicts (or lack thereof). Readers are left to guess the affiliations and biases of these personnel.	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Issues relating to the transparency with regard to the development of the chronic pain medical treatment guidelines were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 General Comment Chronic Pain Guidelines – Diagnostic Criteria	<p>Commenter states that the ODG material does not define or give criteria for specific pain diagnoses other than CRPS. As there are often misdiagnoses in occupational medicine, commenter believes that this is important information. Commenter also states that there are no definitions or criteria for chronic persistent pain, radicular pain, chronic pain syndrome, or other important entities.</p> <p>Commenter believes that therapy should be evaluated for specific diagnoses rather than generic “chronic pain.” Studies are generally done with subject entry criteria based on the diagnostic criteria. Commenter opines that many of the recommendations do not specify which diagnosis the treatments are specified for. Commenter states that such recommendations are not operationizable and should be corrected or removed. Commenter states that time did not allow creating a specific list, but the problem is endemic in the document.</p>	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments with respect to diagnostic criteria during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 General Comment Chronic Pain	Commenter states that the recommendations and discussion address fibromyalgia, myofascial pain syndrome, phantom limb pain, and other diagnoses for	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines – Non-Occupational Diagnoses	which there is no evidence of occupational causation. Osteoarthritis and cancer, which are generally not occupational, are also mentioned. Commenter believes that these are irrelevant to an occupational medicine guideline. Commenter opines that such mentions have in the past have been used to (somewhat misleadingly) claim that such entities are work-related. This is not a beneficial situation. Commenter believes that such material should be removed. Commenter opines that this material may have been drafted for a different population than the working population (see the Problem Formulation issue above).		during the 1 st 15-day notice. Issues relating to non-occupational diagnoses (e.g., work-relatedness) were raised the 45-day comment period, and these issues were appropriately addressed in the 45-day comment period chart. Moreover, the chronic pain medical treatment guidelines is not intended to address the issue of causation. That is an issue to be determined by the workers' compensation administrative law judge.	
9792.24.2 General Comment Chronic Pain Guidelines – Drug Recommendations	<p>Commenter states that many of the discussions of specific medications appear to be abstractions of pharmacy or pharmacology books rather than the results of analyses of critically appraised studies. Commenter states that this is not appropriate. In addition, commenter states that there are no recommendations for one drug within a class over another, looking at the risk: benefit profile. Finally, commenter states that many of these topics have no recommendations attached to them. Commenter believes that the section contains good material in addition to the cited material, but the above should be revised.</p> <p>Commenter states that there are still no indications, duration, frequency, or contraindications for some treatments listed.</p>	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raises the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2 General Comment Chronic Pain Guidelines – Physical Therapy Studies	Commenter notes that there is no mention of the PEDRO database of physical therapy studies and as physical therapy is a significant part of these proposals, this omission is a serious oversight.	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			comments were appropriately addressed in the 45-day comment period chart. (See Section 9792.20(h), Medical Treatment Guidelines Development/Literature Search.)	
9792.24.2 General Comment Chronic Pain Guidelines – Overall Summary	<p>Commenter opines that the proposed regulation does not use generally accepted methods of evidence-based medicine. Commenter believes that the developers clearly do not understand the principles or practice of evidence-based medicine. It uses materials not accepted anywhere else as “evidence”. Commenter states that it does not comply with adopted DWC methodology, is poorly written, redundant, and internally conflicting at times. Commenter opines that by using a vague definition of chronic pain, it creates conflict with other sections of the MTUS derived from ACOEM chapters and negates evidence-based recommendations for imaging and surgery. Commenter alleges that document has a significant potential to harm injured workers, reduce productivity, and drive up costs for employers without benefit, possibly risking jobs in the process. Commenter states that it is an embarrassment to the Division of Workers Compensation and should be discarded in favor of a clearer, better constructed guideline.</p> <p>Commenter believes that the division should check each recommendation for process, content and format.</p>	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 General Comment Chronic Pain Guidelines	Commenter recommends that before the Administrative Director proceeds with the adoption of these modifications to the Medical Treatment Utilization Schedule, commenter requests that the Administrative Director re-refer the proposed Chronic Pain Treatment Guidelines back to the Medical Evidence Evaluation Committee with instructions that	Keith T. Bateman Property Casualty Insurers of America December 18, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>it provide a written assessment as to whether the proposed guidelines or potential alternatives, such as those of ACOEM, meet the statutory requirements of Labor Code Section 5307.27 and clearly utilize the strength of evidence standards of sec 9762.25 (c)(B).</p> <p>Commenter acknowledges that this is an extraordinary recommendation, but believes that it is justified by the following:</p> <ul style="list-style-type: none"> • Appropriate treatment of chronic pain is an area in which there are significant differences of opinion within the provider community. Therefore, before guidelines are adopted which are given the presumption of correctness, it is imperative that the chronic pain guidelines meet statutory requirements and have an extremely strong scientific and evidence basis, so as to maximize their legitimacy and to minimize the potential for dispute. • When the Administrative Director initially proposed the addition of a chronic pain guideline, there were a limited number of chronic pain guidelines available that had been developed by a multidisciplinary body. With the addition of the ACOEM chronic pain chapter, there is a significant competitor of the ODG chronic pain guidelines. It is commenter's recommendation that the two be compared in terms of meeting the statutory criteria set forth in the Labor Code and in their compliance with utilization of the strength of evidence standards of section 9762.25 which is the foundational basis of scientifically and evidence-based Medical Treatment Utilization Standards. • As commenter previously pointed out in his August 12, 2008 comment letter, the proposed chronic pain guidelines rather than providing useful and evidence-based guidelines are more like a smorgasbord of treatments from which a provider may select without 		<p>comments were appropriately addressed in the 45-day comment period chart.</p>	

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	<p>clear guidance of when and under what circumstances a specific treatment is recommended. As a consequence, they provide little guidance to either a provider or a utilization reviewer. This is likely to lead to differing interpretations that will generate more litigation, rather than help to reduce it. This needs to be corrected before the guidelines are finalized.</p>			
<p>9792.24.2 General Comment Chronic Pain Guidelines</p>	<p>Commenter states that with the passage of SB228 in early 2003, the Legislature sought to control the skyrocketing cost of providing medical treatment for injured workers through the adoption of comprehensive fee schedules tied to Medicare and, for pharmaceuticals, to Medi-Cal's reimbursement formula. The Legislature also clearly expressed its intent to limit inappropriate medical treatment and over-utilization of medical services through a mandate to adopt medical treatment utilization guidelines that are evidence and scientifically based, nationally recognized and peer reviewed.</p> <p>Commenter does not believe that the proposed regulations meet the statutory criteria. While the ACOEM guidelines met these requirements, the subsequent addition of the Acupuncture Guideline did not, and it is not clear that the proposed Official Disability Guidelines (ODG) Chronic Pain and Post-Surgical Guideline's comply with the criteria.</p> <p>The ODG website states:</p> <p>"Using a comprehensive annual update process based on scientific medical literature review, survey data analysis, and expert panel validation, the Official Disability Guidelines product line has demonstrated a unique ability to adapt to market forces while maintaining an unparalleled stronghold in evidence-based methodology."</p>	<p>Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

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	<p>Commenter states that it is questionable whether maintaining self-reported evidence-based methodology meets the statutory requirement of evidence and scientifically based, nationally recognized and peer reviewed. Further, while ODG was one of the guidelines being reviewed by RAND, it was not determined to be the best source of evidence based medicine at that time and it has had significant revisions since that analysis.</p> <p>To ensure actual compliance with statutory criteria, commenter suggests that the ODG and ACOEM Chronic Pain guidelines be critically reviewed for their respective statutory compliance. It is commenter's belief that the Medical Evidence Evaluation Advisory Committee (MEEAC) made their preference known by choosing the ODG guideline for the proposed Chronic Pain guideline, but no mention is made regarding the basis for this decision.</p> <p>Commenter alleges that in the case of the proposed Postsurgical guideline, it is clearly stated there are no studies to support the allocation of services.</p> <p>Commenter's greatest concern is that the various Chronic Pain treatments are not identified with the level of evidence and the Postsurgical guideline speaks in terms of number of visits, but is silent as to the treatment to be provided. Commenter speculates that without specificity, disputes will be rampant, unnecessary treatment to some is assured, and medical costs will rise.</p> <p>Commenter believes that the continued addition of guidelines that do not clearly state the level of evidence is eroding the goals of improved patient care and reduced expenses related to unnecessary</p>			

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	<p>treatments and litigation. Commenter is already observing the cost for medical care starting to rise. Commenter states that in the absence of fee schedule increases this indicates increased utilization.</p> <p>Beginning with Sec. 9792.23.1(b), the various Clinical Topics all state that the Acupuncture Guideline is to supersede the ACOEM guideline with respect to Acupuncture. This must be done to prevent “dueling guidelines”, but commenter believes that this exemplifies how sub-standard evidence is overtaking higher quality evidence in the MTUS. Commenter states that while Acupuncture accounts for a tiny fraction of Workers’ Compensation medical dollars, blurring evidence and clinically based Chronic Pain and Physical Medicine treatment will have an enormous impact.</p>			
9792.24.2 General Comment Chronic Pain Guidelines	<p>Commenter notes that while the latest version of the chronic pain guidelines have eliminated some of the references to acute pain; he believes that it remains a problem. As commenter pointed out previously, the discussions of treatments are not always internally consistent, conflict with other guidelines, and are not transparent regarding the evaluation of the strength of the evidence so it appears that similar strengths sometimes justify a positive recommendation and other times produce a “not recommended.”</p> <p>Commenter is concerned that if these proposed revisions are adopted, they will be the beginning of the end to utilization control reforms of SB 899. Commenter urges the Administrative Director to adopt his recommendation and reopen the process of adopting a chronic pain guideline.</p> <p>Commenter endorses the concerns expressed by CWCI, and also urges the Administrative Director to carefully consider the important points raised by</p>	Keith T. Bateman Property Casualty Insurers of America December 18, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	ACOEM in its comments.			
9792.24.2 General/Wait to Review ACOEM Chronic Chapter	Commenter is concerned about the premature adoption of any treatment guideline for chronic pain. In light of the complicated treatment issues, commenter recommends that the DWC and the community have an opportunity to review the new ACOEM chronic pain guidelines and compare it to others prior to promulgation of any chronic pain treatment guidelines.	Marie W. Wardell Claims Operations Manager – State Compensation Insurance Fund December 18, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 General Positive	<p>Commenter applauds the strong and balanced MEEAC process, the Administrative Director as well as Dr. Searcy (and their entire staff) for their openness and fair and balanced approach. As commenter has stated publicly, in his work with states throughout the country he regularly refer agency staff to the division, and holds them out as an example of an incredibly well-informed, thoughtful staff with a great expert physician panel model in place. Simply put, commenter opines that Californians are indeed very lucky to have such strong, fair and balanced leadership at DWC.</p> <p>Commenter has reviewed the Chronic Pain proposed regulations and overall believes that they directionally are fair and balanced. Commenter opines that incorporating language from the latest version of the Work Loss Data Institute’s Official Disability Guidelines on chronic pain was certainly a complement to the fair and balanced nature of the division’s proposed regulations. Commenter sincerely appreciates that it provides appropriate coverage for various implantable devices used to treat chronic pain when other treatments have failed. Commenter is also pleased to see that for these implantable therapies as well as for other pain treatments, the primary focus of reaching a goal of functional improvement has been</p>	N. William Fehrenbach Reimbursement Director Medtronic December 18, 2008	Agree.	None.

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	eliminated in this draft and is instead coupled with pain relief and/or reduction in oral medication use. This change is further supported by California Health and Safety Code section 124960 ensuring that patients, with no requirement of functional improvement: <i>“should have access to proper treatment of his or her pain.”</i>			
9792.24.2 General Comment Chronic Pain Guidelines	Commenter appreciates the Division’s ongoing efforts to improve the implementation of guidelines-based treatment, which commenter believes has improved the timeliness and quality of care provided to California’s injured workers. As a representative of the regional component society for ACOEM, commenter also appreciates the diligence, expertise, and integrity that members of his society put toward the development and updating of the ACOEM Practice Guidelines, and commenter supports ACOEM’s comments on these proposed regulations.	Steven C. Schumann, MD, Legislative Chair Western Occupational & Environmental Medical Association (WOEMA) December 18, 2008 Written Comment	Agree in part. Agree with the comment that the DWC strives to “improve the implementation of guidelines-based treatment,” which commenter believes “has improved the timeliness and quality of care provided to California’s injured workers.”	None.
9792.24.2 General Comment Chronic Pain Guidelines	Commenter opines that while reviewing the information and the recommendations listed in the Proposed Chronic Pain Medical Treatment Guidelines, they may be well intended; it appears that the primary motivating focus is on is heavily slanted towards pharmaco-economics and not balanced, with the beneficial, ACOEM’s “Stay at Work /Return to Work” philosophy. Although this document does provide some useful information, it is incomplete and contradictory.	Tom Van Auken Deutsche Medical Services December 9, 2008 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raises similar arguments which were raised during the 45-day comment period. These comments were appropriately addressed in the 45-day comment period chart. Moreover, see response to comment submitted by Jeffrey S. Harris, MD, dated December 15, 2008, on the issue of Section 9792.24.2, General Comment, Chronic Pain Guidelines – Outcomes, above.	None.
9792.24.2 General Comment	Commenter questions the basis, other than “many comments submitted by the public” that the OGD	Frank Hall, MSN, RN, CMM	Disagree. The comment does not address the substantive changes	

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Chronic Pain Guidelines	<p>guidelines are to be supplanted by ACOEM? Commenter states that it appears that the change is being made on a political basis under the guise of "...the most recent advances in the science of medicine," rather than an evidence-based, treatment orientation. Commenter bases his reasoning on the following:</p> <ul style="list-style-type: none"> • He was unsuccessful in finding where DWC has done any objective research in comparing the actual make up of the research basis of the ACOEM and ODG references, other than possible comments from unlicensed financial stakeholders who do not possess the requisite skills and training to make judgments as to the quality of medical research. Commenter hopes that the collection of input upon which the division will eventually base its decision will include the most comprehensive medical assessment possible. • Does DWC have a process whereby they compare the composition of study rigor along with number of and dates of all ACOEM and ODGs studies, rather than just relying on a date by which these two authority organizations got their final products to the publishers? The two dates I noticed in comparing the difference of ACOEM and ODG publication times were only a matter of months at best which does not appear to be a basis for supplanting one over the other. Commenter believes it is the actual study dates from ACOEM and ODG the division must analyze. • OF NOTE: The ACOEM <i>Chronic Pain</i> chapter formally updates Chapter 6, and will soon be updated with the final, typeset version. It is dated 08/14/2008. More than 200 recommendations for chronic pain are outlined in the new evidence-based guidelines, which were developed by a multi-disciplinary panel of national experts and were reviewed by representatives of leading medical and health organizations. The recommendations focus on diagnostic and other 	Supervisor U.R. & Nurse Case Management December 18, 2008 Written Comment	made to the proposed regulations during the 1 st 15-day notice. Commenter raises similar arguments which were raised during the 45-day comment period. These comments were appropriately addressed in the 45-day comment period chart. Moreover, disagree with the comment objecting to DWC taking into consideration public comments to arrive at its chronic pain medical treatment guidelines. DWC is required pursuant to the Administrative Procedure Act to consider the public's input received during the hearing and during the noticed opportunity to comment before adopting the proposed regulations. (Gov. Code, §§11346.8(a), 11346.9(a)(3).)	

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	<p>testing and treatments for several chronic pain conditions, including: complex regional pain syndrome (CRPS), neuropathic pain, trigger points/myofascial pain, chronic persistent pain, and chronic low back pain. In addition, an extensive volume of literature was utilized to develop the recommendations, which features more than 1,500 references, including 546 randomized controlled trials.</p> <ul style="list-style-type: none"> • Per some commenter’s utilization peer review physicians (Dr. Alan Randle is our medical director,) they believe ACOEM to have a much more rigorous research basis than ODG. • Although commenter is not clear as to the genesis of considering the switchover from ACOEM to ODG, his analysis of the makeup of the “public comments” from an August 11th hearing in Los Angeles and an August 12th hearing in Oakland of this year shows the following: <p>Of the 22 individuals who offered testimony at these hearings,</p> <ul style="list-style-type: none"> a.) 7 were representatives or employees from vendor companies who sell products to the worker’s compensation system. b.) 7 were providers or employees of professional societies among whose function is to lobby on behalf of their organizations to governmental agencies. c.) 3 providers (includes physician and non-physician) d.) 2 representatives from ACOEM e.) 1 pharmacist f.) 1 applicant attorney g.) 1 injured worker h.) 1 injured worker’s wife <p>1.) Nineteen out of twenty-two testimonies, or eighty-six percent (86%), stand to make <i>direct financial gain</i></p>			

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	<p>by the changes being proposed.</p> <p>2.) Commenter noted there were <i>no</i> comments from defense attorneys, utilization review physicians or nurses, adjusters, nor peer review organizations. If the above noted sample is representative of “public comment” research, it would be highly skewed and unbalanced. This would apply to any comments you may have received via e mail, letters or other sources if their makeup is more of the same.</p> <p>3.) Only one (1) physician without a stated representative connection to a lobbying organization made comments. His testimony did not really offer any objective or factual basis in research, but were merely subjective comments with no concrete substantiation.</p> <p>4.) Also recall that professional societies such as the California Society of Interventional Pain Physicians are lobbying organizations and offer only <i>consensus-based</i> opinions, <i>not</i> evidence based research, and should <i>not</i> be considered when constructing evidence-based practice guidelines.</p> <p>5.) Also, why would the California Medical Association’s (CMA) comment, August 11, 2008, be cited in DWC’s proposal? Although it is comprised of physicians, as quoted on line, CMA is a lobbying institution and advocacy organization active in the legal, legislative, reimbursement and regulatory areas on behalf of California physicians and their patients.</p> <p>6.) Of note, Susan Borg, an applicant attorney offered testimony at the August 12th 2008 hearing in Oakland. I was appalled at the amount of errors, misconceptions, self-contradictions, sensationalized, inflammatory language, specious arguments, and lack</p>			

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	<p>of factual basis that her testimony contained.</p> <p>NOTE: Commenter remarks on the hearing testimony in detail, a copy of which is available for inspection in the complete rulemaking file.</p>			
9792.24.2 General Comment Chronic Pain Guidelines	<p>Commenter would like to express his appreciation to Carrie Nevans, to Anne Searcy, MD and to all who have worked diligently to develop these guidelines. Commenter states that in general they represent a major step forward in assuring access to cost effective pain care to injured workers. Commenter states that the current proposed document in many instances represents an improvement over the previous one of last August. However, commenter believes that some of the changes that were made introduce several points of confusion and error that would best be rectified at this time.</p>	<p>Philipp M. Lippe, M.D. Medical Corporation, Consultant December 15, 2008 Written Comments</p>	<p>Agree in part. Agree with comment praising the chronic pain medical treatment guidelines. Commenter's specific comments will be addressed in connection with the specific proposed regulations sections discussed.</p>	None.
9792.24.2 General Comment Chronic Pain Guidelines	<p>Commenter endorses Dr. Phil Lippe's comments and suggestions regarding DWC's Chronic Pain Medical Treatment Guidelines. Commenter finds Dr. Lippe's comments and suggestions insightful and right on target.</p>	<p>Moustapha Abou-Samra, M.D. President California Association of Neurological Surgeons, Inc. December 17, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Philipp M. Lippe, M.D., Medical Corporation, Consultant, dated December 15, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines, above.</p>	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 1. Pain Outcomes and Endpoints	<p>Commenter refers to the Division's proposal to strike from the discussion of Pain Outcomes and Endpoints the sentence "Moreover, '[t]he desired end point in pain management is return to function rather than complete or immediate cessation of pain.'" (Page 8) Commenter states that the decision to remove "return of function" as the immediate goal effectively makes pain management the desired outcome for injured workers with chronic pain, not returning them to work. Such a shift in philosophy is not supported by the evidence and the potential impacts of that are not explained. There are countless studies that support the</p>	<p>Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment</p>	<p>Disagree. The chronic pain medical treatment guidelines are not intended to abandon the goal of returning the injured worker to meaningful employment. Moreover, see response to comment submitted by Jeffrey S. Harris, MD, dated December 15, 2008, on the issue of Section 9792.24.2, General Comment, Chronic Pain Guidelines – Outcomes, above.</p>	None.

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	value to the individual of returning to function and to work.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction	<p>Commenter suggests that the division insert the word “pain” before the word “complaint” in paragraph 1, sentences 2 and 4 of the Introduction.</p> <p>Commenter states that this insertion will clarify that this guideline specifically addresses pain complaints.</p>	Philipp M. Lippe, M.D. Medical Corporation, Consultant December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Moreover, it is important to assess all complaints, not just pain complaints as to ignore non-pain-related symptoms would be clinically inappropriate. The addition of the word “pain” before the word “complaint” would prevent evaluating the patient as a “whole.”	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction	<p>Commenter suggests that the division modify the 5th and 6th sentences of paragraph one as follows:</p> <p>If the patient continues to have pain that persists beyond the anticipated time of healing, without plans for definitive treatment, such as surgical options, the chronic pain medical treatment guidelines apply, <u>unless there are definitive plans for alternative treatment.</u> This provides a framework to manage all chronic pain conditions, <u>regardless of whether or not even when</u> the injury is not addressed in the clinical topics section of the MTUS.</p> <p>Commenter states that the 5th sentence as written is potentially confusing and does not clearly articulate when the chronic pain medical treatment guidelines apply. Chronic pain frequently results in neuropathic pain (as adequately described in the literature and in these guidelines). Such neuropathic pain represents a neurobiological disease in itself with pathophysiological, histological, neuro-chemical and other tangible alterations. As such treatment of neuropathic or chronic pain is “definitive” and often includes</p>	Philipp M. Lippe, M.D. Medical Corporation, Consultant December 15, 2008 Written Comments	Agree in part. See response to comment submitted by Brenda Ramirez, Claims and Medical Director, Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.23.1(d), Neck and Upper Back Complaints, above.	See action taken in connection with comment submitted by Brenda Ramirez, Claims and Medical Director, Michael McClain, General Counsel and Vice President, California Workers’ Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.23.1(d), Neck and Upper Back Complaints, above.

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	<p>surgical options. Hence to state that these guidelines apply when there are no plans for definitive treatment or surgical options is circular and confusing. Hence the sentence has been modified to read:</p> <p>“If the patient continues to have pain that persists beyond the anticipated time of healing, the chronic pain medical treatment guidelines apply, unless there are definitive plans for alternative treatment”.</p> <p>Commenter believes that this revision clarifies the language and the intent of the original document.</p> <p>Commenter states that the suggested change to sentence 6 is a grammatical change intended to clarify the meaning of the sentence.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction Overview</p>	<p>Commenter suggest that the following language be reinstated to the first paragraph, fourth sentence under the subject <i>Overview</i>, at page 1 of the Introduction.:</p> <p>Therefore, effective early care is paramount in managing and potentially preventing chronic pain.</p> <p>Commenter suggests that the words “and potentially preventing” be inserted to restore the concept contained in the original document. Commenter opines that while effective early care is certainly important in managing acute nociceptive pain it also serves an important function of preventing the multiple changes in the nervous system that ultimately result in neuropathic and chronic unrelenting pain. This occurs in animal models as well as human subjects. This phenomenon is well documented in copious literature and also is described in the CP MTUS itself on multiple occasions; e.g., “Evidence suggests that generation and subsequent maintenance of chronic pain” may involve “changes in central pain</p>	<p>Philipp M. Lippe, M.D. Medical Corporation, Consultant December 15, 2008 Written Comments</p>	<p>Disagree. Commenter references the first paragraph, fourth sentence under the subject <i>Overview</i>, at page 1 of the Introduction. That sentence was modified during the 1st 15-day Notice period to substitute the word “managing” for the word “preventing,” which was contained in the 45-day Notice draft. The modification resulted from a public comment indicating that early recognition of chronicity is important to provide effective care. DWC agreed with the comment that the use of the concept “prevention” is not correct because it is difficult to certain in any given case that a worse outcome would have occurred absent the intervention. DWC decided that the concept of “management” is a better concept</p>	<p>None.</p>

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	processing mediated through mechanisms of neural plasticity and ultimately leading to hyper-excitability of central structures in the spinal cord and brain”.		because early recognition of chronicity does change the management approach in treating the chronic condition. Thus, the sentence was modified to state, “Therefore, effective early care is paramount in managing chronic pain.” DWC is still persuaded that the concept of “management” is a better concept under the circumstances, and disagrees with commenter’s proposed edits.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction Acute vs. Chronic Pain Model	<p>Commenter suggests that the following language be reinstated to the second paragraph, second sentence, under the subject Acute vs. Chronic Pain Model, at page 3:</p> <p>However, continued activation of nociceptors with less than adequate pain control can lead to peripheral and central sensitization, a risk factor for persistent pain leading to a neuropathic pain state with prolonged disability, delayed return to baseline function, and delayed return to work.</p> <p>Commenter suggests reinserting the words “leading to a neuropathic pain state” from the original text for clarity and accuracy. Commenter opines that these words are not redundant or superfluous. Commenter alleges that persistent inadequately treated nociception leads to a variety of changes in the nervous system including peripheral and central sensitization that culminates in the neuropathic pain state. Commenter states that the first part of the sentence describes the means by which the end result in the last part of the sentence is achieved.</p>	Philipp M. Lippe, M.D. Medical Corporation, Consultant December 15, 2008 Written Comments	Disagree. This phrase was removed during the 1 st 15-day notice. The Notice of Modification to Text of Proposed Rulemaking, Appendix A1—Chronic Pain Medical Treatment Guidelines, indicted at p. 6 that the “phrase is deleted as superfluous because it carries the same meaning as the phrase “lead to peripheral and central sensitization” which is already used in the sentence. DWC remains persuaded that the sentence, as drafted, sufficiently communicates the concept intended, and further modifications are not necessary.	None.
9792.24.2(a) Chronic Pain	Commenter suggests that the third paragraph, third sentence, under the subject Acute vs. Chronic Pain	Philipp M. Lippe, M.D.	Agree. The third paragraph, third sentence, under the subject Acute	The third paragraph, fourth sentence, under the subject

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<p>Medical Treatment Guidelines Part I: Introduction Acute vs. Chronic Pain Model</p>	<p><i>Model</i>, at page 4, be revised as follows:</p> <p>Evidence suggests that generation and subsequent maintenance of chronic pain, as opposed to acute pain, <u>may involve</u> involves changes in central pain processing mediated through mechanisms of neural plasticity and ultimately leading to hyper-excitability of central structures in the spinal cord and brain.</p> <p>Commenter states that persistent inadequately treated acute pain leading to maintenance of chronic pain, usually, but not always, results in changes in the nervous system giving rise to neuropathic pain. Hence, commenter opines that the wording “may involve” is more accurate than “involves.”</p>	<p>Medical Corporation, Consultant December 15, 2008 Written Comments</p>	<p>vs. Chronic Pain Model, at page 4, is modified to insert the word “may” before the word “involve” and to strike the “s” at the end of the word “involves.” Agree with comment that persistent, inadequately treated acute pain does not always result in changes in the nervous system giving rise to neuropathic pain, hence the word “may involve” is more accurate than the word “involves. Thus, as modified, the sentence states, “Evidence suggests that generation and subsequent maintenance of chronic pain, as opposed to acute pain, may involve changes in central pain processing mediated through mechanisms of neural plasticity and ultimately leading to hyper-excitability of central structures in the spinal cord and brain.”</p>	<p><i>Acute vs. Chronic Pain Model</i>, at page 4, is revised as follows:</p> <p>“Evidence suggests that generation and subsequent maintenance of chronic pain, as opposed to acute pain, <u>may involves</u> changes in central pain processing mediated through mechanisms of neural plasticity and ultimately leading to hyper-excitability of central structures in the spinal cord and brain.”</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction Functional Restoration Approach to Chronic Pain Management And Part I: Introduction</p>	<p>Commenter suggests the following language be restored to the fifth paragraph, eighth sentence, under the subject <i>Functional Restoration Approach to Chronic Pain Management</i>, at page 8:</p> <p>There are no drugs that have been proven to reverse, cure, or “heal” chronic pain <u>or neuropathic pain.</u></p> <p>Commenter requests that the Division re-insert the deleted words, restoring the original text with clarification. Commenter states that peripheral and a central sensitization are the pathophysiological mechanisms resulting in neuropathic pain.</p>	<p>Philipp M. Lippe, M.D. Medical Corporation, Consultant December 15, 2008 Written Comments</p>	<p>Disagree. The phrase “or neuropathic pain,” and the word “neuropathic” were both removed during the 1st 15-day notice. The phrase “or neuropathic pain” was deleted for clerical error, and the word “neuropathic” was substituted with the word “chronic” for clarification purposes. DWC is still persuaded that the edits were appropriate within the context of the sentence and the entire Introduction of the chronic pain medical treatment</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Conclusion</p> <p>Clarification of Neuropathic pain</p>	<p>Commenter suggests the following revision to the first sentence of the first paragraph under “Conclusion”:</p> <p>We now have an appreciation that chronic neuropathic pain is associated with structural and functional changes of the peripheral and central nervous system.</p> <p>Commenter requests that the Division strike the word “chronic” and re-insert “neuropathic” returning to the original text. Commenter states that chronic pain is not synonymous with neuropathic pain.</p> <p>Commenter provides the following argument and references to support the requested revisions:</p> <p>Pain can be transient, short lived, acute; or it can be unrelenting, persistent, and chronic. The terms “nociceptive” and “neuropathic” define pathophysiologic mechanisms on a neurobiological axis. Nociceptive pain is a normal physiological response to a noxious stimulus. It is a symptom. Neuropathic pain is a path-physiologic process related to changes in the plasticity of the nervous system. It represents a neurobiological disease. Acute pain, though usually nociceptive, may also be neuropathic; e.g., thalamic pain following a stroke. Chronic pain though usually neuropathic may also be nociceptive; e.g., arthritic pain resulting from chronic activation of nociceptors.</p> <p>For clarity see the following diagrammatic representations. Also see references:</p> <ol style="list-style-type: none"> 1. Basbaum, A and Bushnell, c. 2009. Science of Pain, Elsevier. 2. The concept that persistent pain may be dysfunctional parallels other observations in medicine 		<p>guidelines.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>of bodily responses, initially adaptive, that may malfunction to produce pathological states. Examples of the latter include autoimmune diseases, or aberrant cell growth resulting in unwanted scarring or adhesions, or neoplasia. Further in analogy to other medical conditions such as heart failure, hypercoagulability, immune deficiency, or pulmonary disease, persistent pain regardless of the specific triggering etiology is associated with a common group of stereotypical changes [Yaksh]. In the peripheral nervous system, nociceptive afferent activity becomes self-sustaining even in the absence of ongoing tissue injury. Mechanisms contributing to this ongoing nociceptive afferent activity include the over expression of phenotypically abnormal sodium channels and excitatory adrenergic receptors. In the spinal cord, an enhanced response to nociceptive afferent traffic (“sensitization”) takes place together with structural reorganization and rewiring, the latter often producing pain in response to normally nonpainful stimuli such as light touch. Cortical and subcortical biochemical abnormalities in persistent pain help to explain the increased risk of depression and anxiety [Siddall, Stanwell et al]. The persistence of this constellation of responses transforms an appropriate pain signal, warning of impending tissue damage (“eudynia”), into a chronic neurobiological disease (“maldynia”) [Siddall and Cousins]. Sufferers from chronic pain score lower on measures of quality of life than patients with most other medical conditions. Population-based surveys in developed countries document a pervasive burden of chronic pain that encompasses absenteeism as well as “presenteeism” (i.e., continuing to work but with diminished productivity), the cost of medical care, and time spent by family members sharing the burden of care. Most of the major conditions that the WHO recognizes as contributing to the global burden of</p>			

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	<p>disease (e.g., cancer, HIV/AIDS, trauma, musculoskeletal disease, psychiatric illness, and diabetes) detract from quality of life by causing chronic pain in their sufferers [Bond and Breivik]. The multidimensional nature of maldynia mandates that effective rehabilitation be based upon comprehensive, multimodal treatment. Dan Carr, MD</p> <p>3. Bond M, Breivik H. Why pain control matters in a world full of killer diseases. In: Wittink HM, Carr DB (eds). Pain Management: Evidence, Outcomes and Quality of Life. New York: Elsevier, 2008: pp 407-411.</p> <p>4. Siddall PJ, Cousins MJ. Persistent pain as a disease entity: implications for clinical management. Anesth Analg 2004; 99: 510-520.</p> <p>5. Siddall PJ, Stanwell P, Woodhouse A, Somorjai RL, Dolenko B, Nikulin A, Bourne R, Himmelreich U, Lean C, Cousins MJ, Mountford CE. Magnetic resonance spectroscopy detects biochemical changes in the brain associated with low back pain: a preliminary report. Anesth Analg 2006; 102: 1164-1168.</p> <p>6. Yaksh TL. Physiologic and pharmacologic substrates of nociception after tissue and nerve injury. In: Cousins MJ, Carr DB, Horlocker TT, Bridenbaugh PO (eds). Cousins and Bridenbaugh's Neural Blockade in Clinical Anesthesia and Pain Medicine, 4th ed. Philadelphia: Lippincott Williams & Wilkins, 2009: pp 693-751.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction General Comment</p>	<p>Commenter thanks the Division for the inclusion of the biopsychosocial model in the current revision and finds this very appropriate in assisting the chronic pain patient. Commenter states that the emphasis on individual treatment is fantastic. Commenter agrees that the unrealistic "curative view" does lead to repeated failures and unnecessary delays in treatment and to further disability. Commenter states that the emphasis that being declared permanent and</p>	<p>Ruth L. S. Miller, RN, MSN December 1, 2008 Written Comments</p>	<p>Agree in part. Commenter's suggestion regarding need for education is acknowledged. However, education is better accomplished via conferences, training programs, etc., not as a requirement in the regulations.</p>	<p>None.</p>

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	stationary does not negate further treatment is welcomed. Commenter states that some injured workers' have been denied treatment even when rated 100% disabled. Commenter finds it interesting that, according to the draft, only physicians need to be educated about the false impression that chronic pain is curable. Commenter knows a claims adjuster that indicated to her that once the patient completed a pain management course the pain would be gone. Commenter suggests emphasizing the need for education among all persons, including but not limited to physicians, insurance personnel, patients, support systems, etc.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction Risk Stratification Patients with Intractable Pain	Commenter states that according to California Health and Safety Code 124960, if the chronic pain patient failed the pain course or does not qualify for a pain course, the he or she <u>should</u> have proper access for their pain. Commenter finds the emphasis on attending a functional restoration program welcomed. However, commenter questions what constitutes failing a pain management course? Commenter points out that other areas of the proposed guidelines accentuate individual focused treatments, yet here one has to either not qualify or fail the functional restoration program in order to receive individual focused treatment.	Ruth L. S. Miller, RN, MSN December 1, 2008 Written Comments	Disagree. The chronic pain medical treatment guidelines, as adapted from the ODG guidelines, provide guidelines to determine if a candidate is qualified for a chronic pain program. Furthermore, the guideline provides criteria for when a functional restoration program is determined to be unsuccessful.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Complex Regional Pain Syndrome	Commenter believes that the various treatment steps under "Complex Regional Pain Syndrome (CRPS)" are communicated well. Commenter continues to state that when physical therapy is restricted to 26 sessions for life, the number of psychological sessions limited or that Fosamax is the <u>only</u> bisphosphone medication permitted, the person with CRPS is set up for failure and possibly a life with limited function resulting in possibly becoming wheelchair, home and or bed bound. Commenter requests that the Division consider rewording the CRPS section to indicate that modalities (PT, psychological intervention, etc.) may	Ruth L. S. Miller, RN, MSN December 1, 2008 Written Comments	Disagree. Commenter suggests that DWC consider rewording the CRPS section to indicate that modalities (PT, psychological intervention, etc.) may be need for life, depending upon the unique needs of each individual with CRPS. Physical therapy under Labor Code section 4604.5(d)(1) provides for a 24-visit cap. DWC has no authority to expand a statute through regulations. Further, the	None.

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	<p>be need for life, depending upon the unique needs of each individual with CRPS. Commenter continues by stating that this is especially true if an intervention is successful as indicated in the progress reports by the respected discipline. Commenter states Fosamax is one of several disphosphonate medications. Commenter questions what happens if the patient cannot tolerate disphosphonate? Is the treatment for osteopenia or osteoporosis omitted? (Bisphosphates are also used to treat osteoporosis, which commenter opines should be included in the guidelines.) Commenter request that the Division not limit treatment to one specific medication. Commenter realizes that she may be construed as splitting hairs, however she states that there are some (physicians, insurance personnel, and other health care professionals) who have taken previous guidelines and denied treatments based on seeming insignificant issues such as these. Finally, commenter requests that the Division emphasize consistency with accentuating individual focused treatments base on the unique needs of each individual even if it means falling outside of the recommended guidelines.</p>		<p>chronic pain medical treatment guidelines provide in its individual treatment guideline topic on “complex regional pain syndrome,” as adapted from ODG, criteria for the need for psychological sessions. ODG in its evidence based review, found that Adendronate (Fosamax®) given oral doses of 40 mg a day (over an 8 week period) produced improvements in pain, pressure tolerance and joint mobility. (Manicourt DH, 2004). Additionally, ODG did include the class name for the category of drugs, i.e., Bisphosphonates, and therefore other drugs of the same category can be considered under utilization review, especially if the patient does not tolerate Adendronate. Further, the chronic pain medical treatment guidelines does not include guidelines to treat osteopenia and osteoporosis as this conditions are not related to chronic pain.</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction Functional Restoration Approach to Chronic Pain Management</p>	<p>Commenter is an interventional pain management physician and director of a successful Functional Restoration Program (www.scpwc.com), and wishes to stress the importance of the FRP model.</p> <p>Commenter states that he has spent the past 17 years as an interventional pain management physician doing close to 30,000 procedures on patients. Commenter indicates that those who did not improve were simply placed on chronic narcotics. Commenter has experienced a "reawakening" on how chronic pain</p>	<p>Sam Maywood, MD Diplomate, American Board of Anesthesiology Medical Director Southern California Pain & Wellness December 17, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice.</p>	<p>None.</p>

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	<p>patients should be treated since he started his FRP.</p> <p>Commenter states that he has been astonished as to how well people do without narcotics. Commenter indicates that until now, his San Diego physicians had no options in detoxifying patients and improving their function to have them return to a productive life. Commenter states that having the referring physicians simply write an opinion in an AME or QME report that states a patient should be off narcotics was never feasible. Commenter adds that unless these people are provided with the tools, coping skills, and support to have them change their lifestyles, they will simply find another physician who will give them their drugs.</p> <p>Commenter states that no one currently can provide any solid guidelines for these types of programs, and proposes that they be included as an option which would allow the success of each individual program to speak for itself. Commenter opines that the carriers will quickly know which programs get results and which do not. Commenter opines that this is why the commenter's program has thrived in San Diego having been open for only 4 months.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines</p> <p>General Comment</p>	<p>Commenter would like to express that the draft Chronic Pain MTUS is an excellent document. Commenter continues that those of his professions, practicing interventional pain management in California are proud of the work the Administrative Director, Dr. Searcy and the [MEAAC] Committee has done.</p>	<p>Sandiford Helm, MD Medical Director Pacific Coast Pain Management Center December 18, 2008 Written Comments</p>	<p>Agree.</p>	<p>None.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines</p> <p>Part I: Introduction</p>	<p>Commenter indicates that the purpose of the "postsurgical physical medicine period", in subdiv. (a)(3) is not apparent. Commenter states that if such a period has a purpose, clarification must be provided as to how these time periods were determined. Commenter indicates that the Global Period provided</p>	<p>Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments relating to the</p>	<p>None.</p>

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<p>Models <u>Acute vs. Chronic Pain Model</u></p>	<p>in the CPT and the OWC's OMFS for each surgical procedure might bear looking at and be utilized if it is evidence based. Commenter adds that the fact that all but a very few of the post-surgical periods are six months makes them appear to be arbitrarily set. Commenter opines that this apparent arbitrary time setting is further demonstrated by the statement that any unnamed procedure in the guideline will have a six month "postsurgical physical medicine period."</p> <p>Commenter states that all of the periods appear to extend for months beyond the additional physical medicine course of therapy. Commenter is concerned that extending the "postsurgical physical medicine period" beyond the "General Course of Therapy periods" will result in the number of visits listed in the Frequency/ Duration column becoming the floor rather than the expectation for recovery and additional visits will then be requested to continue throughout the "postsurgical physical medicine period." Commenter recognizes that functional improvement must be shown to request continued visits, but states that improvement can be in the eye of the beholder or the reporter. Commenter states that there is no level of required improvement that must be met for continued therapy, so insignificant or truly non-existent progress could be used to justify continued therapy.</p> <p>Commenter's concern is amplified by the deletion of the word "quantifiable" in Sec. 9792.20(f).</p>	<p>Written Comments</p>	<p>"postsurgical physical medicine period" during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart. Moreover, Disagree. See response to comment submitted by Brenda Ramirez, Claims and Medical Director and Michael McClain, General Counsel and Vice President, California Workers' Compensation Institute (CWCI), dated December 18, 2008, on Section 9792.20(f), Functional Improvement Definition, above. It is further noted that therapy beyond the initial course of treatment, requires functional improvement and this will be reviewed by utilization review.</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction Functional Restoration</p>	<p>Commenter quotes the following sentence from this section:</p> <p>"If the physician prescribes a medication for an indication not in the approved FDA labeling, he or she had the responsibility to be well informed about the medication and that its use is scientific and evidence based."</p>	<p>Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments</p>	<p>Disagree that the use of the language quoted by commenter "will act as carte blanche for off-label prescribing." The guideline requires that the use be scientific and evidence-based. The MTUS provides information regarding its use, for example some of the</p>	<p>None.</p>

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Approach to Chronic Pain Management	Commenter is concerned that the permissive nature of this statement will act as carte blanche for off-label prescribing.		antiepileptic drugs for neuropathic pain are used off label but the guideline provides the evidence-base supporting their use. For off label use not addressed by the MTUS, other evidence is needed.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part I: Introduction Pain Outcomes and Endpoints	<p>Commenter points out that the following sentence has been deleted:</p> <p>Moreover, “[t]he desired end point in pain management is return to function rather than complete or immediate cessation of pain.” (ACOEM Practice Guidelines, 2nd Edition, p. 116)”</p> <p>Commenter questions this deletion as a significant departure from the previously stated goal of functional improvement as a treatment objective.</p>	Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments	Disagree. The chronic pain medical treatment guidelines are not intended to abandon the goal of returning the injured worker to meaningful employment. Moreover, see response to comment submitted by Jeffrey S. Harris, MD, dated December 15, 2008, on the issue of Section 9792.24.2, General Comment, Chronic Pain Guidelines – Outcomes, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Acetaminophen	<p>Commenter states that strategically located in the first entry of Part 2 of the proposed Chronic Pain Guidelines (p 11) is an overt attack on ACOEM’s Guidelines, as follows:</p> <p>“These ODG recommendations are contrary to the recently released update to the ACOEM Practice Guidelines, which say NSAIDs are recommended for treatment over acetaminophen, and they conclude that acetaminophen is modestly less efficacious. (ACOEM, 2008) But an independent review of these guidelines utilizing the Appraisal of Guidelines for Research and Evaluation (AGREE) ACOEM Comments to MTUS CP First 15 Day Comment Period Dec 18, 2008 instrument concluded that they scored below 30% with a recommendation from AGREE, "not recommended or suitable for use in practice." (Manchikanti, 2008) (Manchikanti2, 2008)”</p> <p>Commenter opines that in misapplying very</p>	Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment	Agree in part. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational & Environmental Medicine (ACOEM), dated December 18, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines (Rating Methodology), above. Moreover, disagree with the comment that ACOEM’s evidence review is fully consistent with the rating criteria and strength of evidence standards in section 9792.25(c)(B) as required in section 9792.26(c) of these regulations. Since the adoption of the original ACOEM strength of evidence rating methodology, ACOEM has further revised its	See action in connection with comment submitted by Barry Eisenberg, Executive Director, American College of Occupational & Environmental Medicine (ACOEM), dated December 18, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines (Rating Methodology), above.

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	<p>questionable conclusions to an acetaminophen-NSAID evidence discussion reached by a small group of interventional pain specialists, DWC appears to be supporting ODG's conclusion (based on a biased review), that ACOEM's Guidelines are "not recommended or suitable for use in practice". Commenter states that this statement is factually incorrect and is completely inappropriate for a proposed government regulation.</p> <p>Commenter states that the situation is further compounded by the assertion that this statement/recommendation can be reasonably extrapolated to all other ACOEM based Guidelines set out in the MTUS Chronic Pain proposal, as well as the revised ACOEM Low Back Chapter that is already in widespread use in California. Commenter opines that these statements are problematic for DWC and should be removed by the Division. There should be no place in regulatory language for such editorial statements. This alone underscores the need for a careful review of the entire proposal.</p> <p>Commenter states that the MTUS statement references a 2008 Cochrane review of NSAIDs and ODG commits a series of critical errors in failing to follow the adopted methodology and, more specifically, in failing to compile, analyze, critique, and grade original research data to synthesize true evidence-based guidance. Commenter opines that these errors have resulted in flawed "guidance," that is representative of a process that propagates poorly developed and unclear guidelines. Commenter further opines that unaddressed, this could result in appreciable harm to injured workers and add unnecessary costs to the workers compensation system in California.</p>		<p>methodology and the MTUS system is no longer identical to ACOEM. In ACOEM's previous version, the methodology permitted use of systematic reviews and meta analyses provided by other organizations such as Cochrane. It is common practice amongst professional organizations to rely upon systematic reviews instead of exclusively relying on original data, a position that ACOEM now takes.</p>	

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	<p>Under the subtitle, <u>Review of the Evidence</u>, commenter states that there are relatively few true comparisons of NSAIDs and either Acetaminophen or its analog, Paracetamol for treatment of low back pain or chronic pain conditions (see reference list below). Commenter states that most of the available literature combines acetaminophen (or paracetamol) with another medication such as an opioid or muscle relaxant (Sweetman 1987; Innes 1998; Emkey 2004; Parr 1989; Brown 1986; Mullican 2001; Hingorani 1971; Lloyd 1992; Perrot 2006; McGuinness 1983; Valtonen 1975; Vernon 1975; Kjæsgaard-Andersen. Pain 1990). Commenter indicates that some compare one of these medications with another completely different intervention (e.g., Hackett 1998). Commenter states that this effectively prevents a determination of the relative value of these medications compared with NSAIDs. Commenter indicates that, however, this is not true of all studies.</p> <p>Commenter states that one of the studies to directly address this question compared six different treatments (Evans 1980). Commenter states that this trial is of particular interest because it is a crossover trial, thus patients crossed over to another treatment arm, which results in effective elimination of confounding variables.</p> <p>Commenter indicates that the six treatment arms were: A. aspirin vs. B. dextropropoxyphene (a narcotic) plus paracetamol vs. C. indomethacin vs. D. mefenamic acid vs. E. paracetamol vs. F. phenylbutazone</p> <p>Commenter indicates that the daily pain scores</p>			

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	<p>documented that mefenamic acid was statistically superior to paracetamol (as well as dextropropoxyphene plus paracetamol (1.375 vs. 1.660 vs. 1.713, p<0.05). Commenter states that these data suggest that two NSAIDs are superior to paracetamol/acetaminophen: mefenamic acid and indomethacin. Commenter further states that another measure was the patient's preferences of the blinded medications, which noted that the paracetamol group was the <i>second worst</i> desired medication among all medications, with the phenylbutazone, mefenamic acid and indomethacin (all 3 NSAIDs) being the three most highly rated medications, followed by narcotics. Commenter opines that this quality study demonstrated paracetamol was inferior to mefenamic acid and suggested indomethacin was superior as well for purposes of pain relief (phenylbutazone is not currently available).</p> <p>Commenter continues that the second of the quality few quality studies to address this question compared ibuprofen versus acetaminophen versus a heat wrap in a manufacturer sponsored study that appears to have set up the conditions such that the ibuprofen arm was sub-maximal dose (400mg three times a day) versus the maximally recommended dose for acetaminophen (4,000 mg per day) (Nadler 2002). Commenter states that despite that major bias against ibuprofen the article notes that the pain relief scores on day one appear to note they were trending towards being better for ibuprofen than for acetaminophen (apparently not statistically significant). Commenter adds that reduction in muscle stiffness also appears to have favored half-maximal dose ibuprofen (see Figure 3, page 1015). Commenter adds that there was only one person dropping out of the ibuprofen group due to an adverse effect (an "upper respiratory tract infection") although some other adverse effects appear to have</p>			

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	<p>occurred, including nausea. Commenter concludes that these manufacturer-sponsored data suggest, but do not prove, that maximal-dose acetaminophen was comparable to half-maximal dose ibuprofen and suggest that maximal dose acetaminophen may therefore be inferior to maximal-dose ibuprofen.</p> <p>Commenter indicates that the third report consisted of three different experimental trials compared (i) flurbiprofen versus 3,600 mg of aspirin a day for treatment of lower extremity soft tissue injuries in soccer players, (ii) flurbiprofen versus 4,000 mg of acetaminophen for treatment of LBP, or (iii) flurbiprofen vs. 4,000 mg of acetaminophen for treatment of post-meniscectomy pain (Muckle 1986). Commenter states that this study found that in the first study, flurbiprofen out-performed aspirin in measures of pain ($p < 0.01$) and days to training fitness ($p < 0.05$). Commenter states that in the second study, it was found that flurbiprofen resulted in reduced recovery period for muscle spasm and power ($p = 0.10$). Commenter further states that in the third study, the flurbiprofen outperformed the acetaminophen in measures of pain ($p < 0.01$), resumption of full activity, flexion and knee power (most measures $p < 0.01$ or $p < 0.001$). Commenter indicates that in this last trial, those on flurbiprofen resumed full activity 22 days earlier than those on acetaminophen.</p> <p>Commenter states that even though one may always invoke a need for additional research, at this point, every quality trial directly testing this question either documents superiority of NSAIDs or contained trends in favor of an NSAID. Commenter states that quality evidence must rely on the best quality evidence available at a given point in time. Commenter concludes that there is quality evidence that acetaminophen is modestly less efficacious than</p>			

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	<p>NSAIDs (Evans 1980; Muckle 1986; Nadler 2002). Commenter indicates the evidence is that the patients and workers were right: acetaminophen is not as good as NSAIDs for relief of pain, such as Low Back Pain. Commenter concludes that the ACOEM Guidelines correctly analyzed this topic and produced accurate guidance that ODG and the California MTUS appears to have subsequently discounted.</p> <p>Commenter opines that the implications of these conclusions are that:</p> <ol style="list-style-type: none"> 1) The ODG guidance on this topic is wrong. 2) The California draft MTUS does not rely on evidence-based medicine and instead, reproduces an error from a proprietary source for guidelines that would instead mislead California physicians, other healthcare providers and workers, and 3) The Cochrane review from 2008 made an error on this point. <p>Commenter states that one could argue whether this specific question is material. Commenter indicates that considering the magnitude of low back pain and other musculoskeletal pain that afflict almost the entire working population in a lifetime and most of the time, on multiple occasions, it is clear that quality guidance on such a simple topic is critical.</p> <p>Commenter opines that this error is an example of damaging problems that can emerge from not relying on original data and instead relying on non-evidence-based data and reports. Commenter also opines that this problem appears replicated throughout the proposed MTUS, which does not appear to be substantially improved from prior versions. Commenter states, without reference, that in some instances it appears that even more errors have been</p>			

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	<p>introduced.</p> <p>Commenter includes the following Citations and Quality as an example of how graded evidence is used to develop evidence based independent recommendations that, in his opinion, should be the standard for MTUS guidelines. Commenter states that ACOEM's grading is fully consistent with the rating criteria and strength of evidence standards in section 9792.25(c)(B) as required in section 9792.26(c) of these regulations.</p> <p><u>Citations (ACOEM Quality Scores)</u></p> <p><u>NSAID versus Acetaminophen</u> Evans. Curr Med Res Opinions 1980; 6(8):540-547. 6.0/11 Muckle. Am J Med 1986; 80(3A):76-80. 6.0/11, 5.0/11, 5.0/11 Nadler Spine 2002; 27(10):1012-1017. 6.0/11</p> <p><u>NSAID versus Acetaminophen combined with opioid or similar</u> Innes. J Emerg Med 1998; 16(4):549-556. 8.0/11 Emkey. J Rheumatol 2004; 31(1):150-156. 6.5/11 Parr. Br J Clin Pharmac 1989; 27: 235-242. 6.5/11 Brown. 1986;9 Suppl C: 52-58. 5.0/11</p> <p><u>Acetaminophen combined with opioids or muscle relaxant</u> Mullican Clin Therapeutics 2001; 23(9):1429-1445. 8.0/11 Hingorani. Br J Clin Practice 1971; 25(5):227-231. 6.0/11 Lloyd. Cur Med Res Opinion 1992; 13(1):37-48. 6.5/11 Perrot. Clin Therapeut 2006; 28(10):1592-1606. 7.5/11</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>McGuiness J Intl Med Res 1983;11:42-45 6.5/11 Valtonen. Ann Clin Res 1975; 7(2):85-88. 3.5/11 Vernon. Curr Therapeut Res 1972; 14(12):801-806. 4.0/11</p> <p><u>Acetaminophen/paracetamol versus same plus opioid</u> Kjæsgaard-Andersen. Pain 1990; 34:309-318. 6.0/11</p> <p><u>Other</u> Mefanamic acid vs. chlormezanone-paracetamol versus ethoheptazine-aspirin-meprobamate Sweetman Br J Clin Pract 1987; 41(2): 619-624. 4.0/11 Electroacupuncture vs. paracetamol Hackett. The Practitioner 1998; 232:163-164. 4.0/11</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Acetaminophen</p>	<p>Commenter would like to add his endorsement to comments submitted by Barry Eisenberg of the American College of Occupational and Environmental Medicine, also dated Dec 18, regarding the proposed revisions.</p> <p>Commenter is particularly concerned regarding the embedding, within the section on Acetaminophen (pg. 11 of the draft revisions), of the section questioning the suitability of the ACOEM guidelines. Commenter believes that in addition to containing highly subjective statements, this language could present an opportunity for legal challenges to the entire MTUS. Commenter points out that no guideline rating system, including the AGREE criteria referred to in this paragraph, has been shown to produce guidelines that create superior clinical outcomes. Marketing language such as this in not appropriate in this context.</p>	<p>David C. Deitz, MD PhD, Vice President & Medical Director Liberty Mutual Insurance Company December 18, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational & Environmental Medicine (ACOEM), dated December 18, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines (Rating Methodology), above.</p>	<p>See action in connection with comment submitted by Barry Eisenberg, Executive Director, American College of Occupational & Environmental Medicine (ACOEM), dated December 18, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines (Rating Methodology), above.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines</p>	<p>Commenter states that the comments regarding the AGREE instrument lack clarity. Commenter states that it is not clear whether they relate to Acetaminophen or the NSAIDS. Commenter is also</p>	<p>Steven Suchil, Assistant Vice President American Insurance</p>	<p>Agree in part. See response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational</p>	<p>See action in connection with comment submitted by Barry Eisenberg, Executive Director, American College</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments <i>Acetaminophen</i>	concerned with the allusions to a difference of opinion with the ACOEM guideline. Commenter believes that this is inappropriate and sets up the potential for litigation on the issue of conflicting guidelines.	Association December 18, 2008 Written Comments	& Environmental Medicine (ACOEM), dated December 18, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines (Rating Methodology), above.	of Occupational & Environmental Medicine (ACOEM), dated December 18, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines (Rating Methodology), above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Actiq®</i>	Commenter is concerned about deleting the word “addictive” from this caption. Commenter states that there is no question that this is a highly addictive substance and he believes that this warning should be retained.	Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments	Disagree. The individual treatment guideline on the topic of Actiq® is clear that the drug is not recommended for musculoskeletal pain. It describes the guideline as “a fast-acting highly potent ‘lollipop’ pain killer.” It clarifies that the drug is contraindicated in acute pain; is not for use in chronic pain; and has a Black Box warning for abuse potential. Further, the guideline is clear that is indicated “only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” Although the word “addictive” was removed, the expanded language is meant to clarify the nature of the drug in more detail.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Acupuncture</i>	Commenter states that this section refers the reader to title 8 C.C.R Sec. 9792.24.1, which simply refers the reader, yet again, to the definition of Chronic Pain. Commenter states that this is not helpful in determining the frequency/duration/intensity of this treatment.	Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Moreover, the Acupuncture Medical Treatment Guidelines, as moved due to the MTUS reorganization to Section	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			9792.24.2 (originally contained in Section 9792.21(a)(2)), were approved by formal regulation effective June 15, 2007. The definition of “chronic pain” the Acupuncture Medical Treatment Guidelines is consistent with the definition of “chronic pain” as defined in the Chronic Pain Medical Treatment Guidelines, and the frequency, duration, and intensity of the treatment are clearly set forth in the Acupuncture Medical Treatment Guidelines.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Acupuncture</i> <i>[DWC]</i>	Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision quotes a California regulation and not scientific data. No data, reference or sources are provided. Commenter states that the ACOEM Chronic Pain Update provides 3 recommendations, is 8 pages long and references 28 high or moderate grade randomized controlled trials.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice.	None.

<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Antiepilepsy drugs (AEDs)</i></p>	<p>Commenter states that, contrary to the proposed guideline, there is high-quality evidence for the use of topiramate. Commenter indicates that the proposed recommendations state that there is insufficient evidence to recommend for or against AED for chronic, nonspecific low back pain based upon a recent review article and limited references for topiramate. Commenter states that in fact, there are three high-quality studies of topiramate in chronic pain that has led ACOEM to recommend it as a fourth or fifth line agent in nonradicular chronic low back pain.</p> <p>Commenter opines that this point raises the question of whether the proposed chronic pain guideline could ever be considered “presumptively correct” since it is proposed for adoption at a time when the higher quality evidence exists, but has not been considered by ODG, DWC or the MEEAC.</p>	<p>Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment</p>	<p>Disagree. Following its evidence-based review, ODG indicates under the individual treatment guideline topic of “Antiepilepsy drugs (AEDs),” as adapted into the chronic pain medical treatment guidelines, that “Topiramate (Topamax®, no generic available) has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of ‘central’ etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard.” Thus, ODG’s analysis as set forth in the individual treatment guideline topic of “Antiepilepsy drugs (AEDs),” is comparable to ACOEM’s conclusion that Topiramate is a fourth or fifth line agent. Moreover, disagree with commenter regarding the existence of higher quality evidence at the time of adaptation into the chronic pain medical treatment guidelines, and the effect on the presumption of correctness. Treatment guidelines will always lag new research as the pace of new developments is high and the updating cycle varies amongst guideline producers. The MTUS provides a mechanism to rebut the presumption when there is new evidence, as contained in Section 9792.21(c).</p>	<p>None.</p>
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MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Antiepilepsy drugs (AEDs)</i></p>	<p>Commenter points out the following reference: (Gabapentin) states that this drug has been shown to be effective for treatment of diabetic painful neuropathy, and is considered as a first-line treatment for neuropathic pain, as well as pointing out the fact that there is fairly good evidence that the use of Gabapentin and Gabapentin-like compounds results in decreased opioid consumption.</p> <p>Commenter opines that neuropathic pain can be very difficult to treat with only some 40-60% of patients achieving partial relief. Commenter indicates that deciding on the best treatment for individual patients challenges both the art and science of medicine. Commenter states that attempts to synthesize scientific studies into best practices are limited by such factors as differences in reference populations and a lack of head-to-head studies. Commenter adds that there are few studies evaluating treatment combinations or the special needs of children.</p> <p>Commenter states that it is common practice in medicine to designate classes of medication according to their most common or familiar use e.g., as "antidepressants" and "anti-epileptic drugs" (AED's). These drugs have alternate uses to treat pain because the human nervous system employs common mechanisms for different functions, for example ion channels for impulse generation and neurotransmitters for cell-to-cell signaling.</p> <p>Commenter states that in addition to the work of Dworkin, O'Connor and Backonja et al., cited above, there have been several recent attempts to derive guidelines for pharmacological therapy. Commenter indicates that these have combined evidence from randomized controlled trials with expert opinion.</p>	<p>Tom Van Auken Deutsche Medical Services December 9, 2008 Written Comment</p>	<p>Agree in part. Commenter provides a general statement regarding the use of antiepileptic drugs in treating chronic pain. Commenter appears to agree with the individual treatment guideline on the topic of "Antiepilepsy drugs (AEDs)," and specifically the recommendation on Gabapentin.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that favored treatments are certain antidepressants e.g. tricyclics and selective serotonin-norepinephrine re-uptake inhibitors (SNRI's), anticonvulsants, especially pregabalin (Lyrica) and Gabapentin (Neurontin), and topical lidocaine. Commenter indicates that opioid analgesics and tramadol are recognized as useful agents but are not recommended as first line treatments.</p> <p>Commenter states that any of the pharmacologic treatments for chronic neuropathic pain decrease the sensitivity of nociceptive receptors, or desensitize C fibers such that they transmit fewer signals.</p> <p>Commenter adds that according to the ACPA, American Chronic Pain Association Medications Supplement 2008, page 34-35. "Anticonvulsant medications have been found to be widely effective in various neuropathic pain conditions.", "Gabapentin (Neurontin) is widely utilized and has proven to be effective in many people for nerve injury or neuropathic pain."</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Chronic pain programs (functional restoration programs)</i></p>	<p>Commenter opines that the changes to this version of the proposal appear to be mostly "padding the text" with references, whether they apply or not, and whether they meet reasonable scientific criteria or not. Commenter indicates that in the behavioral/psychological and functional areas, there is a glaring disconnect between the literature cited and the recommendations, and there is little attention paid to the quality of evidence. Commenter opines that much of the text just appears to be "made up" without any high grade or even low grade support. Accordingly, the 'guidance' remains vague, arbitrary, and confusing.</p>	<p>Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter offers no substantive or specific comment in connection with his allegation that the individual treatment guideline on "Chronic pain programs (functional restoration programs)" is "vague, arbitrary and confusing."</p>	
<p>9792.24.2(a) Chronic Pain</p>	<p>Commenters state that they have some concerns regarding the current ODG Guidelines which</p>	<p>Allen Kaisler-Meza, MD, Co-Medical</p>	<p>Disagree. Labor Code section 5307.27 requires that the Medical</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Chronic pain programs (functional restoration programs)</i></p>	<p>indicates that programmatic treatment duration should be limited to an arbitrary number of days. Commenters indicate that under the section for pain treatment, chronic pain programs (functional restoration programs) ODG states that:</p> <p>“Total treatment duration should generally not exceed 20 full-day sessions (or the equivalent in part-day sessions if required by part-time work, transportation, childcare, or comorbidities). (Sanders, 2005) Treatment duration in excess of 20 sessions requires a clear rationale for the specified extension and reasonable goals to be achieved. Longer durations require individualized care plans and proven outcomes, and should be based on chronicity of disability and other known risk factors for loss of function;...”</p> <p>Commenters state that reviewing the reference upon which this statement is made (Sanders, 2005), it should be noted that there is no substantial medical evidence in this article that supports a limit of 20 sessions. [See below: Sanders SH, Harden RN, Vicente PJ. Evidence-Based Clinical Practice Guidelines for Interdisciplinary Rehabilitation of Chronic Nonmalignant Pain Syndrome Patients. World Institute of Pain, <i>Pain Practice</i>, Volume 5, Issue 4, 2005 303–315. Siskin Hospital’s Center for Pain Rehabilitation, Chattanooga, Tennessee.]</p> <p>Commenters add that it should be highlighted that the ODG lists the following notation in regard to the Sanders article in the following way: “Note: This issue of this journal was not accepted into Medline, and therefore it is not part of the primary evidence based used for ODG, but it includes a helpful reference list.”</p>	<p>Director Darrell S. Bruga, D.C., Program Director Kimeron Hardin, Ph.D, Director of Behavioral Medicine Michael C. Prost, MD, Co-Medical Director Ronald J. Fuimoto, DO., Co-Medical Director Scott Standage, MD Diplomate SpineOne Rehabilitation Programs December 18, 2008 Written Comment</p>	<p>Treatment Utilization Schedule “address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases.” Thus, the individual treatment guideline topic on “Chronic pain programs (functional restoration programs)” is intended to address the requirements of the statute. Moreover, the individual treatment guideline topic on “Chronic pain programs (functional restoration programs)” does not present an absolute. The guideline would allow more than 20 sessions if (1) they were not full-time; or (2) other factors exist justifying more sessions. The individual treatment guideline topic on “Chronic pain programs (functional restoration programs)” states: "Total treatment duration should generally not exceed 20 full-day sessions (or the equivalent in part-day sessions if required by part-time work, transportation, childcare, or comorbidities).” The individual treatment guideline topic on “Chronic pain programs (functional restoration programs)” further provides that “Treatment duration in excess of 20 sessions requires a clear rationale for the specified extension and reasonable goals to be achieved. Longer durations</p>	

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	<p>Commenters also state that ODG guidelines under references, state:</p> <p>Per ODG Reviewers:</p> <p>“With regards to the Sanders article... as the Abstract points out, this is the third iteration of this "guideline," and contains updated references... it is published in a relatively low-impact journal of questionable peer review (an uncertain indexing in Index Medicus). This is a "pragmatic guideline," based on a highly selective review of the pain literature.... it does not focus on chronic pain treatment in workers' compensation, which leaves the usual problems of subjectivity associated with the outcomes.”</p> <p>Commenters indicate that the problem surrounds the poor quality of the article and the purpose of the article. Commenters state that the Sanders paper is not a scientific article designed to study the optimal frequency and duration of a chronic pain or functional restoration programs for injured workers. Commenters add that this is merely the author’s opinion and not a scientific conclusion. Commenters conclude that the article has no relevance on chronic pain programs for injured workers and the optimal duration or frequency for such programs.</p> <p>Commenters indicate that to date there are no such guidelines with recommendations based on scientific studies. Commenters add that some guidelines have attempted to make recommendations for duration and frequency, but they are based on opinion only.</p> <p>Commenters state that typical functional restoration programs (FRPs) in Northern and Southern California consist of approximately 200+ hours of treatment. Commenters indicate that it is unclear how the</p>		<p>require individualized care plans and proven outcomes, and should be based on chronicity of disability and other known risk factors for loss of function;...” Furthermore, as the evidence-base is developed, and new studies are published, DWC will update the guidelines to reflect the evidence-base. If ODG updates individual treatment guideline topic on “ Chronic pain programs (functional restoration programs)” before the chronic pain medical treatment guidelines of the DWC is updated, the treatment may be provided under Section 9792.21(c).</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>duration of treatment can be arbitrarily limited to 20 days if not supported by peer reviewed medical evidence. Commenters opine that there is no magic in 20 days and by the same token one could argue that there is no magic in 200 hours. Commenters further state that California health care providers that have experience working in FRPs know that the injured worker population they treat are some of the most difficult in the system. Commenters indicate that during the program it takes substantial time to shift misguided beliefs about chronic pain and disability, improve functional capacity for work and help them overcome obstacles to recovery.</p> <p>Commenters opine that based on their experience this it is rare to accomplish this in 20 days. Commenters state that in fact, they follow patients completing a 200 hour program for an additional 6 months at no additional charge to ensure that progress continues. Commenters state essentially provide the equivalent of an 8-9 month program. Commenters further state that the duration of a program must be substantial in order to achieve an optimal outcome which includes return to work and decreased utilization of the health care system. Commenters indicate that their outcomes are based on a 40 day 200 hour program.</p> <p>Commenters state that should new scientific evidence come to light in the future on the optimal dose and duration of a chronic pain program, they would consider modifying our program to reflect that new evidence and knowledge. Commenters add that in the meantime, they strongly recommends eliminating any opinion based language pertaining to frequency and duration until further evidence is available. Commenters state that the current consensus in administering programs is based on experience with outcome and the needs of the individual patient.</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenters further state that the FRPs in California have a similar design and we feel this should not be changed until quality scientific evidence becomes available or common sense dictates. Commenters conclude that they hope DWC will consider their position so that injured workers continue to receive the necessary care they need to become productive citizens in life and work.</p>			
<p>Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Chronic Pain Programs</i></p>	<p>Commenter would like to address the issues cited with respect to the use of special interdisciplinary programs in the treatment of chronic pain and to restore lost function:</p> <p>Commenter states that certain specific guidelines recommended can be considered outdated based on the most recent review of the use of interdisciplinary pain programs. Please reference:</p> <p><i>"Evidence-Based Scientific Data Documenting the Treatment and Cost-Effectiveness of Comprehensive Pain Programs for Chronic Nonmalignant Pain" Gatchel and Okifuji, The Journal of Pain, Vol 7, No 11 2006, pp 779-793</i></p> <p>Commenter states that such programs are underutilized in our health care system in comparison to alternative, traditional treatment options. Commenter states that there is not a consensus standard, when considering outcomes from programs across the globe, to suggest validity to the recommendation that treatment should be based on two week increments. Commenter opines that long-term measurable gains may require more than two weeks of treatment in catastrophically impaired cases.</p> <p>Furthermore, commenter states that there is a lack of support to the recommendation that treatment should be no more than 20 days. Such limitations would</p>	<p>Peter Abaci, MD Medical Director Bay Area Pain and Wellness Center December 5, 2008 Written Comments</p>	<p>Disagree. See response to comment submitted by Allen Kaisler-Meza, MD, Co-Medical Director, et.al., SpineOne Rehabilitation Programs, dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Chronic pain programs (functional restoration programs), above.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>affect outcomes in a profoundly adverse way. For example, of the two credible comprehensive programs available in California currently, both offer treatment over a span of 6-8 weeks. In addition, treatment time often is done in conjunction with opioid detoxification. Commenter states that such complex care would be expected to fall outside of any 20 day window, and this is ignored in what has been posted so far.</p> <p>Lastly, commenter states that measurements and reports are typically generated on a weekly basis, not a bi-weekly basis.</p> <p>Commenter opines that unfortunately, strict adherence to the guidelines, as posted, would lower positive outcomes including functional gains, diminished medication use, and return to work rates and therefore would not optimally serve the injured worker.</p>			
<p>Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Chronic Pain Programs – Criteria for the general use of multi-disciplinary pain management programs</i></p>	<p>Commenter acknowledges that the Division has clearly begun to take appropriate action based on numerous comments regarding the implication of advising a specific interim milestone for authorization of care within a pain management program. The admonishment, currently within the proposed guideline,</p> <p><i>“However, it is also not suggested that a continuous course of treatment be interrupted at two weeks solely to document these gains, if there are preliminary indications that these gains are being made on a concurrent basis,”</i></p> <p>represents an appropriate step in the correct policy direction. Unfortunately, commenter finds the sentence directly following it,</p>	<p>Stephen J. Cattolica AdvoCal December 18, 2008 Written Comments</p>	<p>Disagree. See response to comment submitted by Allen Kaisler-Meza, MD, Co-Medical Director, et.al., SpineOne Rehabilitation Programs, dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Chronic pain programs (functional restoration programs), above. Moreover, disagree with commenter’s argument that in lieu of establishing a reporting timeframe, the regulation should enable the treating physician and the claims administrator to establish an appropriate length of</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>“Total treatment duration should generally not exceed 20 full-day sessions (or the equivalent in part day sessions if required by part-time work, transportation, childcare, or co morbidities). (Sanders, 2005),”</i></p> <p>Commenter states that this has the effect of completely negating any positive effect the preceding statement may have intended. Commenter stands behind his previous written comments on this subject and anticipate the same result, despite the current proposal:</p> <p>“...we are concerned that in practice, carriers will only allow two week authorization periods yet make it impossible to communicate to obtain a timely extension. We appreciate that a pain program shouldn't keep injured workers who are not improving, but from a practical standpoint, we anticipate great problems obtaining continued authorization when the recommended two week reporting period and the end of authorized treatment coincide.”</p> <p>Commenter opines that modifying the length of time to 20 sessions will do nothing to curb inappropriate use of the time frame. All of the negative outcomes resulting from ensuing delays will still manifest.</p> <p>In addition, commenter believes that the source for the 20 day recommendation (Sanders) is referenced by ODG as follows:</p> <p>“With regards to the Sanders article... as the Abstract points out, this is the third iteration of this "guideline," and contains updated references... it is published in a relatively low-impact journal of questionable peer review (an uncertain indexing in Index Medicus). This</p>		<p>authorization within the frame work of appropriate reporting. Under commenter’s proposal, there still remains a need for communication and reporting of progress from the provider to the claims administrator. If this communications require negotiating the length of the program in each case, the result will be disagreement and dispute. DWC believes that it is a better policy to define a program duration and have the provider communicate to the claim administrator the progress made and goals that are expected if the program is to be extended beyond 20 days.</p>	

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	<p>is a "pragmatic guideline," based on a highly selective review of the pain literature.... it does not focus on chronic pain treatment in workers' compensation, which leaves the usual problems of subjectivity associated with the outcomes.”</p> <p>Commenter states that the “study” appears to be arbitrary and have no application to workers’ compensation medicine.</p> <p>Commenter urges the Division to reconsider any such specific time frame. Commenter believes that the regulation should enable the treating physician and the claims administrator to establish an appropriate length of authorization within the frame work of appropriate reporting and that the mere suggestion of a specific time frame, especially one whose foundation is suspect, will have the effect of creating an inappropriate and potentially deleterious rule, not a guideline. Commenter opines that in this era of utilization review and network medicine, the result will be poorer treatment, not better.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Chronic pain programs (functional restoration programs)</i></p>	<p>Commenter offers the following comments and states that he has special expertise as Dr. Searcy (DWC’s former medical director) had requested his input early on in the development of these Guidelines. Further, commenter is an ODG Medical Advisor and also was an Associate Editor to the ACOEM 2008 Chronic Pain Chapter Update.</p> <p>Commenter is particularly concerned with what appears to be the arbitrary designation of 20 days of treatment in a functional restoration chronic pain program. There is no legitimate evidenced based medicine to back this “20 day” limit up. Commenter has been a practicing pain specialist for over 35 years and has gained some respect in the workers’ compensation community over the years as a</p>	<p>Steven Feinberg, MD December 17, 2008 Written Comments</p>	<p>Disagree. See response to comment submitted by Allen Kaisler-Meza, MD, Co-Medical Director, et.al., SpineOne Rehabilitation Programs, dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Chronic pain programs (functional restoration programs), above. Moreover, commenter provides physician/patient experience as evidence that six (6) weeks are necessary for the chronic pain programs to be</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recognized AME in this area of chronic pain. Commenter is an Adjunct Clinical professor at Stanford and teaches in the Pain Service. Commenter runs a functional restoration pain program.</p> <p>In northern California, the pain programs run from six to eight weeks full time. Commenter states that it is rare for a patient to be discharged in four weeks from a full time functional restoration pain program. Commenter states that at times he discharges patients in four or less weeks but that is the exception. The great majority of injured workers that are admitted for treatment need to be detoxified and rehabilitated and this cannot be accomplished in four weeks time.</p> <p>Commenter believes that there is no legitimate reason for injured workers to be treated in intensive pain programs if they can be successfully treated in a less intense environment.</p> <p>Commenter opines that the problem is that some payers typically will use any excuse they can to cut off care and a 20 day statement creates a terrible problem for the good pain programs.</p>		<p>successful. Physician/patient experience alone outside of a controlled environment evidence does not meet the requirements of the statute that the guideline be evidence-based.</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Chronic pain programs (functional restoration programs)</i></p>	<p>Commenter is a pain management physician by way of anesthesia. Commenter applauds the efforts to improve patient care as it pertains to the ever complicated workers compensation system.</p> <p>Commenter is a graduate of the Stanford Pain Management Fellowship program. As a fellow, he was exposed to a variety of pain management modalities, including intensive inpatient comprehensive pain programs, multidisciplinary and interdisciplinary outpatient programs and several functional restoration programs. With the help of his colleagues, commenter has been fortunate enough to create a successful functional restoration program.</p>	<p>Joel E. Mata, M.D. Medical Director Southern California Pain and Wellness Center December 17, 2008 Written Comment</p>	<p>Disagree. See response to comment submitted by Allen Kaisler-Meza, MD, Co-Medical Director, et.al., SpineOne Rehabilitation Programs, dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Chronic pain programs (functional restoration programs), above.</p>	<p>None.</p>

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	<p>Although the program has been in existence for less than a year, commenter has experienced significant success helping patients improve their lives, return to work and reduce the financial burden on the workers compensation system. Due to the relative lack of guidelines, some insurance companies have been easier to work with than others. For example, some patients who commenter feels are appropriate for his comprehensive program is being denied on the grounds that their case has been open to long and “something like this should have been initiated earlier”. Others who commenter has wanted to put into an early intervention program have been denied citing that commenter has not exhausted “other options” prior to enrolling the patient into his program.</p> <p>Commenter does not agree with an arbitrary 10 day or two week initial authorization as is at a loss for where the rationale for this time line came from. The same can be said for the 20 day limit. Commenter states that those of his peers practicing in this field know all too well, arbitrary “cut offs” in complex cases with psychological overlays often times places significant stressors on patients and staff. While the intent is to improve outcomes, these timelines may have dramatic negative results. Failures can exacerbate feelings of worthlessness, self-loathing and aggravate perceptions of pain. Commenter opines that while 20 days may be ample for some patients, it is clearly not sufficient in others, particularly complex patients who would clearly benefit from enrollment in a comprehensive multidisciplinary program.</p> <p>Commenter agrees that there should be a standardization process providing incentive to establish and maintain a well run program. Commenter does not want to rush to create arbitrary</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>guidelines without well supported data, in the name of standardization, which may have the unintended consequence of delaying or denying authorization.</p> <p>For many patients where surgery is no longer an option, opioids have failed and overall ability to accomplish tasks lessen each year, commenter states that a quality functional restoration program may provide a means to improve their quality of life while reducing their dependence on the healthcare system. In addition to the comprehensive multidisciplinary programs, which should be offered to qualified injured workers, early intervention programs have been proven to aid less complex, less severe cases from becoming biopsychosocial catastrophes. Commenter proposes that we not only standardize these programs, but make them standard practice.</p>			
<p>Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>CRPS, spinal cord stimulators (SCS)</i></p>	<p>Commenter states that there is more recent evidence available for spinal cord stimulators (SCS).</p> <p>Commenter states that in addition to the evidence already cited within the section on spinal cord stimulators (as based on the October 2008 version of ODG), he would like to draw attention to newly published data on the long-term effectiveness of spinal cord stimulation (SCS) in patients with failed back surgery syndrome (FBSS). Commenter states that these data, from the Medtronic sponsored PROCESS study, demonstrate sustained pain relief, functional improvement, quality of life improvement and patient satisfaction with spinal cord stimulation. (Kumar, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery. 2008 Oct;63(4):762-70.) Commenter states that this evidence has already been incorporated into the online ODG version of their Chronic Pain</p>	<p>N. William Fehrenbach Reimbursement Director Medtronic December 18, 2008</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Moreover, see response to comment submitted by Barry Eisenberg, Executive Director, American College of Occupational, ACOEM, dated December 18, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2, Pain Intervention and Treatments, Antiepilepsy drugs (AEDs), above.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>chapter. Commenter submits the following excerpts:</p> <ul style="list-style-type: none"> • “In an as treated analysis, 34 (47%) patients who received SCS plus conventional medical management (CMM) achieved the primary outcome (>50% leg pain relief) versus 1 (7%) who received CMM alone (p = 0.02). • “69% of the SCS+CMM patients continuing therapy at 24 months achieved \geq 30% leg pain relief. • “Compared to baseline, patients continuing SCS+CMM at 24 months experienced statistically significant enhancement in health-related quality of life (HRQoL) in 7 out of 8 domains on the SF-36 (p \leq 0.01) • “Compared to baseline, patients continuing SCS+CMM at 24 months experienced statistically significant improvement in functional capacity (p = 0.0002). • “ 93% of patients continuing SCS+CMM at 24 months declared that “based on their experience so far, they would have agreed to treatment.” • “Of the 42 patients continuing SCS+CMM at 24 months, 19 patients (45%) experienced a total of 34 SCS-related complications. For 13 patients (31%), a surgical revision was required to resolve the event. <ul style="list-style-type: none"> ➢ “Of those who underwent a surgical revision for an SCS-related complication, 89% stated that “based upon their experience so far, they would have agreed to treatment.” <p>Commenter states that the following has been included in the ODG Chronic Pain chapter:</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>“Recent research: New 24-month data is available from a study randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone. At 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. All 100 patients in the study had undergone at least one previous anatomically successful spine surgery for a herniated disk but continued to experience moderate to severe pain in one or both legs, and to a lesser degree in the back, at least six months later. Conventional medical therapies included oral medications, nerve blocks, steroid injections, physical and psychological therapy and/or chiropractic care. (Kumar, 2008)”</i></p> <p>Commenter opines that while inclusion of this evidence does not directionally change DWC’s recommendation regarding spinal cord stimulation, it nonetheless makes it more current and comprehensive. Commenter encourages DWC to cite this new and compelling study data about spinal cord stimulation to the proposed regulations. (Commenter offers a copy of this manuscript upon request.)</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Complex Regional Pain Syndromes (CRPS)</p>	<p>Commenter states that the Chronic Regional Pain Syndromes (CRPS) [sic] treatment guideline in the original draft of the DWC Chronic Pain Medical Treatment Guidelines is 4 pages long and it is an extremely superficial discussion of a complicated matter. Commenter adds that the Chronic Regional Pain Syndromes (CRPS) [sic] treatment guideline in the ACOEM Chronic Pain Update is an entire multi-page section and contains multiple recommendations.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment</p>	<p>James E. Lessenger, MD December 07, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Guidelines provides an expanded discussion.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Cytokine DNA Testing for Pain [DWC]</i>	Commenter states that all three guidelines do not recommend the use of <i>Cytokine DNA Testing for Pain</i> .	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Detoxification</i>	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision recommends <i>Detoxification</i> for the treatment of chronic pain. Commenter states that the treatment is recommended “as indicated below.” Commenter makes no reference to the discussion below. Commenter adds that the ACOEM Chronic Pain Update also recommends <i>Detoxification</i> . He indicates that the guideline contains a long discussion under this recommendation.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Drug Testing</i>	Commenter states that both versions of the DWC Chronic Pain Treatment Guideline and the ACOEM Chronic Pain Treatment Guideline recommends drug testing. Commenter states that DWC’s original draft gives no discussion while the revised November 8, 2008 version provides a short discussion. Commenter points out the ACOEMS revised Chronic Pain Treatment Guidelines give guidance on frequency and criteria.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and	Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines recommends <i>Education</i> in connection with the treatment of chronic pain. Commenter observes that discussion is 10 lines. Commenter adds that the ACOEM Chronic Pain Update also recommends	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatments <i>Education</i>	<p>Education in connection with the treatment of chronic pain. Commenter observes that discussion is extremely detailed.</p> <p>Commenter states that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines recommends Education in connection with the treatment of chronic pain and cites the Colorado Guidelines. However, commenter opines that this version contains a confusing discussion of the Alexander technique and that the recommendation is unclear.</p>		comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Epidural steroid injections (ESIs)</i>	<p>Commenter submitted a chart comparing the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision with the Chronic Pain Update to Chapter 6 of the Occupational Medicine Practice Guidelines, 2nd Edition, (ACOEM Practice Guidelines). Under the <u>Representative Specific Recommendations</u> heading, commenter offers the following comments:</p> <p>Commenter states that the original draft of the DWC Chronic Medical Treatment Guideline recommends epidural steroid injections (ESIs) for radicular pain, is less than half of a page long and has 4 references of which at least one is consensus.</p> <p>Commenter states that the November 8, 2008 revised draft of the DWC Chronic Medical Treatment Guideline recommends ESIs for radicular pain, recommends no more than 2 treatments and cites 4 papers including a consensus statement.</p> <p>Commenter states that ACOEM’s Chronic Pain Update recommends ESIs for radicular pain in certain circumstances and has 4 recommendations in 5 pages. The recommendation is based upon 13 RCTs, 12 systemic reviews, 3 guidelines, 6 low quality RCTs</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. Comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter’s comparison between ACOEM’s chronic pain guideline and DWC’s chronic pain medical treatment guideline on the topic of “Epidural steroid injections (ESIs)” is not clear as it does not address the substance of the guideline, and commenter offers no substantive suggestion to improve the guideline.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	and 2 other studies.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Exercise</i>	<p>Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines recommends <i>Exercise</i>, but the discussion is ½ a page. Commenter adds that the ACOEM Chronic Pain Update recommends <i>Exercise</i>. He indicates that the section has 18 recommendations in 15 pages, which contain 6 subcategories.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines recommends exercise and quotes a “low quality study on page 48 when other high quality studies are available.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Functional restoration programs (FRPs)</i>	<p>Commenter quotes the introductory sentence in the original draft of the DWC Chronic Pain Medical Treatment Guidelines on the <i>Functional restoration programs</i>, which states as follows: “Recommended, although research is still ongoing as to how to most appropriately screen for inclusion in these programs.” Commenter then questions whether the sentence means that it will be recommended if an appropriate screen is developed and used. Commenter adds that the ACOEM Chronic Pain Update recommendation on <i>Functional restoration programs</i> consists of 3 pages, with 2 recommendations. Commenter adds that the recommendation is based upon 2 RCTs, 2 systemic reviews, 1 review, 2 low quality RCTs, and 1 other study.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines recommends this treatment and provides a short discussion with the treatment not recommended for more than 2 weeks.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2(a) Chronic Pain	Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines does not	James E. Lessenger, MD	Disagree. The comment does not address the substantive changes	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Glucosamine (and Chondroitin Sulfate) [DWC]</p>	<p>recommend Glucosamine in connection with the treatment of chronic pain. Commenter observes that discussion is 4 lines. Commenter adds that the ACOEM Chronic Pain Update also recommends Glucosamine in connection with the treatment of chronic pain. Commenter observes that discussion is half page.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines does recommend this treatment and provides a ½ page discussion.</p>	<p>December 07, 2008 Written Comments</p>	<p>made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	
<p>Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Implantable drug-delivery systems (IDDSs)</p>	<p>Commenter states that both the original draft of the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision recommend treatment “only as an end-stage treatment alternative for selected patients for specific conditions indicated below, after failure of at least 6 months of less invasive methods and following a successful temporary trial.” Commenter points out that the November 8, 2008 revision contains typographical errors that need correction.</p> <p>Commenter states that the revised ACOEM Chronic Pain Guides, Chapter 12, does not recommend this treatment.</p>	<p>James E. Lessenger, MD December 07, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart. Regarding the alleged typographical errors in the guideline which need correction, commenter does not specifically point to those typographical errors. Inasmuch as DWC is able to find typographical errors in the guidelines during its review, they will be corrected.</p>	<p>None.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Intrathecal drug</p>	<p>Commenter appreciates the consideration DWC provided in reviewing their initial comments and making changes to the proposed section concerning coverage guidelines for Prialt® (ziconotide intrathecal infusion). These changes appear on pages 130 – 131 of the current draft of the Chronic Pain Treatment Guidelines and the language now indicates that PRIALT (ziconotide intrathecal infusion) is</p>	<p>Nick Poulos, Ph.D., Vice President, Pricing & Reimbursement Strategy Elan Pharmaceuticals December 18, 2008 Written Comment</p>	<p>Agree in part. Commenter agrees with the recommendation in the individual treatment guideline on the topic of “Ziconotide (Prialt®,” wherein the guideline indicates “Recommended for use after there is evidence of a failure of a trial of intrathecal morphine or</p>	<p>Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Intrathecal drug delivery systems, medications, is modified at page 57, line 12, subtopic</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p><i>delivery systems, medications</i></p>	<p>“recommended for use after there is evidence of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid), and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects.”</p> <p>Commenter states that under the section titled, “Intrathecal Drug Delivery Systems, Medications” on pages 56-57 of the Chronic Pain Medical Treatment Guidelines, PRIALT is recommended 3rd stage after documentation of a trial of intrathecal morphine AND hydromorphone (Dilaudid). Commenter would like to inform the DWC of the inconsistencies between the “Intrathecal Drug Delivery Systems, Medications” and the “Ziconotide” sections within the Chronic Pain Medical Treatment Guidelines. Commenter is also concerned that these inconsistencies will create confusion within the provider community and at the Workers’ Compensation Carriers that administer and process these medical claims.</p> <p>Furthermore, commenter believes that since the coverage guidelines for PRIALT (ziconotide) require a failure of morphine OR hydromorphone (dilaudid) as stated under the ziconotide coverage section, then this drug should be moved from the currently recommended 3rd stage to the recommended 2nd stage therapy under the Intrathecal Drug Delivery Systems, Medications section as described on page 56. Commenter opines that this minor modification, in addition to the language change that commenter previously has recommended, will further eliminate the inconsistencies between the language contained within these two sections.</p> <p>In summary, commenter agrees with the modification to the “Zinconotide” section of the Chronic Pain Medical Treatment Guidelines; however, commenter</p>		<p>hydromorphone (Dilaudid), and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects.” Commenter notes that this change should have been transmitted to the individual treatment guideline on the topic of “Intrathecal drug delivery systems, medications,” where in reference to specific recommendations for “Ziconotide (Prialt®,” it is stated: “See also Ziconotide (Prialt®), which is recommended after documentation of a failure of a trial of intrathecal morphine and <u>or</u> hydromorphone (Dilaudid).” DWC agrees with the commenter. Due to clerical error the word “or” as contained in the individual treatment guideline on the topic of “Ziconotide (Prialt®” was not transmitted to the individual treatment guideline on the topic of “Intrathecal drug delivery systems, medications.” The individual treatment guideline on the topic of “Intrathecal drug delivery systems, medications” is corrected for clerical error to state: “See also Ziconotide (Prialt®), <u>which is recommended</u> after documentation of a failure of a trial of intrathecal morphine and <u>or</u> hydromorphone (Dilaudid).”</p>	<p>“Recommended 3rd stage,” as follows:</p> <p>The individual treatment guideline on the topic of “Intrathecal drug delivery systems, medications” is corrected for clerical error to state: “See also Ziconotide (Prialt®), <u>which is recommended</u> after documentation of a failure of a trial of intrathecal morphine and <u>or</u> hydromorphone (Dilaudid).”</p>

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	<p>recommends that these changes also be incorporated into the “Intrathecal Drug Delivery Systems, Medications Section.” Specifically he respectfully recommends that the word “AND” in the “Intrathecal Drug Delivery Systems, Medications” section be changed to the word “OR” (refer to page 57) to be consistent with the updated changes made to the “Ziconotide” section (refer to page 131).</p>		<p>Commenter believes that since the coverage guidelines for PRIALT (ziconotide) require a failure of morphine OR hydromorphone (dilaudid) as stated under the ziconotide coverage section, then this drug should be moved from the currently recommended 3rd stage to the recommended 2nd stage therapy under the Intrathecal Drug Delivery Systems, Medications section. Disagree with the comment because “Clonidine” is a better choice as an addition to an opioid, for the 2nd stage. For 3rd stage, adding both clonidine and bupivacaine to opioids, or ziconotide alone, which should be the next choice only, "in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects. Ziconotide is FDA-approved in patients for whom intrathecal therapy is warranted and who are intolerant of other treatments. This medication is meant to be an option for patients who are intolerant and/or refractory to intrathecal morphine. Current case reports have described many challenges in converting from morphine to ziconotide, including inadequate analgesia, adverse medication effects, and opioid withdrawal symptoms. Prialt has been</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			associated with severe central nervous system-related adverse effects, and a black-box warning has been issued in this regard. Prialt is contraindicated in patients with a pre-existing history of psychosis."	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Intrathecal drug delivery systems (IDDSs)</i>	<p>Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines recommends <i>Intrathecal drug delivery systems</i>. Commenter states that the recommendation lists three stages: 1st stage: Morphine including a non-FDA approved medication, 2nd stage using clonidine (no reference is given for this), and 3rd Baclofen (cites recommendations from a consensus conference and articles from a non-peer reviewed journal). Commenter adds that the ACOEM Chronic Pain Update does not recommend <i>Intrathecal drug delivery systems</i>, and indicates, and that “no recommendation” is based upon 2 high quality RCTs, 3 systemic reviews, 5 reviews, 17 other studies. The recommendation contains no consensus data. Commenter further adds that Baclofen contains a guideline of “No recommendation,” and that the section cites high grade crossover trial that was equivocal.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines state that it is “Recommended as indicated below.” Commenter states that the division uses consensus conference as a reference authority and recommends lower doses to avoid granulomas at the tip.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart. Moreover, see comment submitted by Jeffrey S. Harris, MD, dated December 15, 2008, on Section 9792.24.2, General Comment, Chronic Pain Guidelines – Use of Material not Generally Considered Evidence, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not recommend <i>Low-Level Laser Therapy</i> , and observes that the	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 2. Pain Intervention and Treatments <i>Low-Level Laser Therapy (LLLT)</i>	guidelines cite 9 references. Commenter adds that the ACOEM Chronic Pain Update does not recommend <i>Low-Level Laser Therapy</i> , and indicates that the guideline contains two recommendations of “not recommended.” Commenter further observes that the guidelines cite 8 high quality RCTs, 4 systemic reviews, 1 guideline, 3 low grade RCTs, and 1 other study.		Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Manual therapy & manipulation</i>	<p>Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines recommends <i>manual therapy & manipulation</i>. Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommend <i>manual therapy & manipulation</i> for chronic pain if caused by musculoskeletal conditions and manipulation is specifically recommended as an option for acute conditions. He indicates that the guidelines quote the Colorado Guidelines. Commenter also states that the guideline does not give the recommendations for acute therapy. He further observes that there is no mention of who is going to do the recommending. Commenter opines that this is essentially a meaningless statement. He observes that the guideline is ½ page in length and uses only one reference; the Colorado Guideline. Commenter further opines that this is clearly a political statement. Commenter adds that the ACOEM Chronic Pain Update recommends <i>manual therapy & manipulation</i>. Commenter observes that the recommendation is 8 pages long, it contains 8 recommendations based on 25 RCTs, 14 systemic reviews, 2 guidelines, 10 low quality RCTs, and 1 other study.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines recommends the treatment and provides a longer discussion that cites consensus studies and guidelines.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Methadone</i>	Methadone is a dangerous drug. There is no evidence to support its use as a second line drug in moderate to severe pain. This recommendation is a vestigial listing of the original text that included listing for acute and sub acute pain. The text is clearly ambiguous and would be assumed to have a role in the management of chronic pain when clearly it should only be considered in acute situations which are not intended to be part of the proposed regulations.	Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment	Disagree. Commenter appears to state that the individual treatment guideline topic on “Methadone” recommends the use of methadone without proper information. The individual treatment guideline topic on “Methadone” recommends methadone as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The guideline warns that the FDA reports that they have received reports of severe morbidity and mortality with the medication. The guideline further warns that methadone should only be prescribed by providers experienced in using it, sets forth the drug’s adverse effects, and provides a detailed criteria for its use.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Muscle relaxants</i>	Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines recommends <i>Muscle relaxants</i> . Commenter quotes a portion of the guideline as follows: “Recommended non-sedating muscle relaxants with caution as a second-line option for acute LBP [lower back pain] and for short-term pain relief in patients with chronic LBP, but benzodiazepines are not recommended.” Commenter questions the use of the words “with caution.” Commenter wants to know what it means in the context of the guideline. He questions whether it means that everybody uses or is supposed to use caution. He opines that this is a meaningless recommendation and will be of no use in utilization review or as a reference. Commenter adds that the ACOEM Chronic Pain Update recommends <i>Muscle relaxants</i> . Commenter observes that the	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommendation uses is 3 pages long, contains 4 recommendations, references 9 RCTs, 3 systemic reviews, 1 guideline, 2 low quality RCTs.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines recommends muscle relaxants for the initial second line option for short-term pain relief in patients with exacerbation of low back pain and provides a longer discussion.</p>			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Nucleoplasty</i>	<p>Commenter states that both the original draft of the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision does not recommend <i>Nucleoplasty</i>. Commenter adds that the guidelines quote company sales literature. Commenter adds that the ACOEM Chronic Pain Update does not recommend <i>Nucleoplasty</i>, and indicates that the subject is covered in chapter 12.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Nutritional Supplements</i>	<p>Commenter would like to request the addition of language to the proposed regulations that further clarify the treatment guidelines as they relate to nutritional supplements in combination with pharmaceuticals as well as the paragraph on page 3 of the proposed regulation in the California Code of Regulations, Section 9792.20 that deals with "nutritional supplements...foods or dietary supplements." The language is currently stated as follows:</p> <p>"Another area identified by the MEEAC which does not conform to the framework of the MTUS in the herbal therapies and nutritional supplements. Herbal therapies and nutritional supplements are not considered drugs by the FDA, rather they are considered foods or dietary supplements."</p>	Elisa Gottlieb December 16, 2008 Written Comment	Disagree. It is noted that the 45-day chronic pain medical treatment version did not contain any individual medical treatment topic on medical foods. Medical foods, herbal remedies, and nutritional supplements are addressed in ODG's October 23, 2008 updated version. Upon review of ODG's October 23, 2008 updated version, DWC determined that these recommendations do not specifically address their use in chronic pain. These references were not included in the ODG October 23, 2008 version, as adapted by DWC, because they do not relate to chronic pain. This	None.

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	<p>There are currently prescription medications such as generic Vicodin, generic Norco, and generic prescription NSAIDS, etc being packaged in a single box that contains two separate bottles-one bottle contains a nutritional supplement called "Theramine" (a combination of amino acids such as choline, L-arginine, L-histidine, L-Glutamine, L-Serine, GABA, Whey Protein, Grape Seed Extract, Ginkgo Biloba, Cinnamon, and Cocoa) The Second bottle in the package contains the actual therapeutic pharmaceutical medication such as generic Vicodin, etc. The prepackaged bottles are called "copacks" or "medical foods". Each "copack" has its own NDC # and is being dispensed as one unit item (two bottles in one box). Apparently the average wholesale price (AWP) for the copack is extremely high. When the carrier processes the claim, they find that there is no "therapeutic equivalent" due the addition of the "nutritional supplement" (i.e. Theramine) in the package. Since it has its own unique NDC #, the carrier is then forced to pay 83 percent of the high AWP as per Section 9789.40 Pharmacy which was passed on March 1, 2007 regarding pharmaceuticals. This area should be specifically addressed to create less confusion in the new regulation since nutritional supplements are not considered "drugs" by the FDA, Due to the nature of the packaging, the carrier will be forced to reimburse for the nutritional supplement as well as the generic pharmaceutical at a much higher rate (i.e. up to 10 fold) as compared to the reimbursement of the pharmaceutical if it were dispensed alone in a traditional manner with this "nutritional supplement"</p>		<p>action is specified in the MTUS, 1st 15 Day Notice, Appendix A1, November 2008, pp. 15-16, in relevant part, as follows:</p> <p><u>“4. Deletion of an ODG individual treatment topic or relevant portions of a topic when the treatment recommendation does not relate to chronic pain.</u></p> <p>The individual treatment topics, or relevant portions of a topic, when the treatment recommendations do not relate to chronic pain were omitted from the chronic pain medical treatment guidelines as the text in the guidelines was not directly related to chronic pain. ... Further, with regard to reviewing individual medical foods, ODG did not specify how these medical foods are used for chronic pain conditions. Without such specification, these medical foods are deleted.</p> <p style="text-align: center;">***</p> <p>(10) Medical Foods (a) Choline (b) Glutamic Acid (c) Gamma-aminobutyric acid (GABA) (d) L-Serine (e) L-Arginine (See, 1st 15 Day Notice, Appendix A1, November 2008, pp. 15-16.)</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Moreover, it is noted that commenter raises the issue of costs associated with medical foods and how they are packaged with other drugs. Disagree that the MTUS regulations are intended to control costs associated with dispensing packaged drugs. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Opioids	The use of Opioids in chronic pain situations should be considered only after other; multiple options have been tried or considered, not as an alternative to first line options. The increasing availability of opioids in many forms has been linked to excess mortality in Utah and West Virginia and many rural areas and should result in stricter regulations not looser as in the proposed guidelines. The increasing problem of diversion is becoming epidemic.	Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment	Disagree. The individual treatment guideline on the topic of “Opioids,” as adapted from the October 23, 2008 ODG updated version, provides extensive precautionary recommendations prior to the initiation of opioid therapy such as to identify indicators and predictors of possible misuse of controlled substances and/or addiction. Moreover, the individual treatment guideline on the topic of “Opioids” contains language that Opioids are not first line treatment, but rather are prescribed after failure of other treatments. See, , the individual treatment guideline on the topic of “Opioids,” subsection “Opioids for	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			neuropathic pain,” where it states: “Not recommended as a first-line therapy.” In the subsection <i>Opioids for chronic pain</i> it states “In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm).”	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Opioids</i>	Commenter points out that the document states that short acting opioids are recommended for chronic pain. In fact, most of these medications have mood elevating side effects and are therefore not recommended for chronic pain in most evidence-based guidelines. Commenter opines that they are often used intentionally or unintentionally used to treat co-existing mood disorders. Commenter believes they are not appropriate drugs for that purpose. This statement poses many problems and should be changed. There are other statements emphasizing the use of long acting medications, creating conflict.	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree with commenter as DWC believes there is role for both short acting opioids and long acting opioids in the treatment of chronic pain. Chronic pain can be intermittent, continuous, or continuous with exacerbations. In this regard, the individual treatment guideline on the topic of “Opioids,” as adapted from the October 23, 2008 ODG updated version, provides the following recommendations. In the subsection entitled “Initiating Therapy,” at p. 80, the recommendation for “intermittent pain” is to “start with a short-acting opioid trying one medication at a time.” For “continuous pain,” however, the recommendation is “extended-release opioids.” The guideline further provides that “patients on this modality may require a dose of ‘rescue’ opioids. The need for extra opioid can be a guide to determine the sustained release does required.”	None.

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9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Opioids</i>	<p>Commenter states that the Opioids treatment guideline in the original draft of the DWC Chronic Pain Medical Treatment Guidelines is 15 pages and thorough. Commenter observes that the treatment guideline includes an entire section lifted from a State website. Commenter adds that the Opioids treatment guideline in the ACOEM Chronic Pain Update contains 6 recommendations, 1 table, and the references are: 46 high quality RCTs, 13 systemic reviews, 5 reviews, 3 guidelines, 1 low quality RCT, 5 others. Commenter also notes that the appendix is over 40 pages (plus references), and is comprehensive.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines recommends opioids and now has an expanded set of recommendations and indications. The revised section contains dosing material and is a lot more detailed.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Physical Medicine [ODG]</i>	<p>Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines recommends <i>Physical Medicine</i>. Commenter states that the DWC guideline contains a short, half page discussion on one of the major areas in pain treatment. He further states that it contains only two references. He opines that the recommendation is extremely superficial, and that it presents “physical medicine guidelines” without any citation. He further observes that there is no mention of any specific modality and it is far too general to be of use in utilization review. Commenter adds that the ACOEM Chronic Pain Update recommends <i>Physical Medicine</i>. Commenter observes that the recommendation is 6 pages long, contains 6 recommendations, and 4 modalities.</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Guidelines contains the same recommendation of its predecessor; however, it now has a paragraph supporting active treatment modalities instead of passive modalities.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Psychological evaluations</i>	Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines and the November 8, 2008 revision recommends <i>Psychological evaluations, testing and treatment</i> . Commenter states that the guideline is ¾ of a page, and includes a listing without discussion in a paragraph of various tests. Commenter adds that the ACOEM Chronic Pain Update recommends <i>Psychological evaluations, testing and treatment</i> . Commenter observes that the guideline contains 6 pages of recommendations and discussion. Commenter also states that the guidelines have a 40+ page appendix that includes a comprehensive list and discussion of each test.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Return to work</i>	Commenter states that the DWC Chronic Pain Medical Treatment Guidelines and the November 9, 2008 revision recommends <i>Return to work</i> . He observes that only 9 lines are used to discuss return to work. Commenter adds that the ACOEM Chronic Pain Update also recommends <i>Return to work</i> but offers three (3) pages of discussion on the matter.	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment	None.

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9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Spinal cord stimulators (SCS)</i>	Commenter opines that some of the evidence is not correctly interpreted, possibly due to the lack of critical analysis. Commenter provided a list of such problems in several of the sets of initial 45 day comments. One such example is the recommendation for spinal cord stimulators. Some of those studies are mis-rated, since the design is in fact not as listed in PUBMED, and some have significant methodological flaws and are therefore unacceptable as evidence.	Jeffrey S. Harris, MD December 15, 2008 Written Comments	period chart. Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised similar arguments with respect to ODG's rating methodology during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Spinal cord stimulators (SCS)</i>	<p>Commenter states that the DWC Chronic Pain Medical Treatment Guidelines recommends <i>Spinal cord stimulators</i>. He observes that it is recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. He indicates that the guidelines use 15 references, which include citations of 2 consensus groups. Commenter adds that the ACOEM Chronic Pain Update also recommends <i>Spinal cord stimulators</i>. He indicates that the discussion in the subject is 3 pages long, that there are 2 recommendations, and that it is recommended in CRPS. He also states that the guidelines include a table with selection criteria. He states that the sources for the recommendations are 2 Random Control Trials, 5 systemic reviews, 2 guidelines, and 9 other studies.</p> <p>Commenter points out the November 8, 2008 revised version of the DWC Chronic Pain Medical Treatment Guidelines have the same recommendation as the first draft but provides a longer discussion that contains citations from 4 consensus groups, including specialties that will financially benefit from the revised version.</p>	James E. Lessenger, MD December 07, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

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<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter opines that the Division is dangerously inserting itself into the physician-patient relationship, which could have far-reaching consequences. Commenter asserts that physicians work with their patients to determine when compounded medications are appropriate and, if they are, work with pharmacists to design individualized treatments to meet their patients' needs –needs that are unmet by off-the-shelf, one-size-fits-all, mass-produced pharmaceuticals.</p> <p>Commenter states that doctors often prescribe manufactured products. Commenter adds that some doctors determine that those products are inappropriate for their patients and prescribe compounded medications tailored to meet a patient's individual needs.</p> <p>Commenter points out that the Division's discussion states, "the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required."</p> <p>Commenter opines that the division seems to be contending or implying that physicians and pharmacists do not have knowledge regarding the pharmacologic and pharmacodynamic activity of the agents being used, either alone or in combination with one another, in compounded topically administered analgesic preparations. Commenter states that it is well known that physicians and pharmacists are trained in this area and are in the best position to determine what is appropriate or inappropriate for their patient's therapeutic success. Commenter fears that by adopting this position, patients receiving benefit from these compounded preparations may go without therapy, and be forced to use a different and</p>	<p>Robert Nickell, PharmD, Nickell Group, December 10, 2008 Written Comment</p>	<p>Agree in part. Labor Code section 5307.27 requires the Administrative Director (AD) to adopt a medical treatment utilization schedule (MTUS), which among other things, is evidence-based. Labor Code section 4604.5(a) provides that upon adoption of the MTUS, the recommended guidelines set forth in the MTUS are presumptively correct. The MTUS serves as a basis for utilization review (UR), whereby a treatment request made by a physician is reviewed and a determination is made as to whether the treatment meets the requirements of the presumptively correct guidelines. (Lab. Code, 4610(c).)</p> <p>Topical analgesics must be distinguished from transdermal agents. Topical drugs work near or on the surface, place, or location where the agent is applied. This is different from transdermal drugs which enter the body through the skin but are expected to cause a systemic effect throughout the body, far beyond the surface, place, or location where the agent is applied. Oral and parenteral (intravenous, subcutaneous, or intramuscular) administration of drugs is generally expected to produce a systemic effect, i.e. an action that is delivered to the</p>	<p>Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, <i>Topical Analgesics and Topical Analgesics, compounded have been modified as follows:</i></p> <p>“Topical Analgesics</p> <p>“Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist,</p>

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	<p>potentially less appropriate therapeutic modality, be at risk for increases in morbidity and, in the end, be a greater financial burden on the healthcare system.</p> <p>Commenter opines that compounded medications involve an intimate relationship between the prescriber, patient and pharmacist that is predicated on an individual patient's needs. Intervening in the patient-prescriber pharmacist relationship could have dire consequences for the health of individual patients.</p> <p>Commenter states that pharmacy compounding is a long-standing, safe and well-regulated practice that serves the needs of many Americans with unique health requirements which off-the-shelf prescription medicines cannot meet.</p> <p>Commenter points out that state boards of pharmacy, state medical boards, the Food and Drug Administration, the Federal Trade Commission, the Drug Enforcement Agency, and other federal and state agencies each have some degree of oversight over compounding practice. The U.S. Pharmacopeia and the Pharmacy Compounding Accreditation Board also play critical roles. Together, they have constructed a web of regulations and standards that protect patients.</p> <p>Commenter states that the DWC rationale quotes an old FDA warning about potential dangers of compounding topical medications containing local anesthetics. However the commenter believes that the circumstances triggering FDA's warning are outside the normal prescriptive use of these types of preparations. With regard to topically applied analgesics that are used in the workman's comp arena, anesthetics are not the primary agents employed.</p>		<p>whole body. The site of action for pain drugs is often in the nervous system (spinal cord or brain) and far away from the site of injury. Therefore a systemic drug effect is necessary if the mechanism of action involves the nervous system. Since the purpose of transdermal drug delivery is intended to have a systemic effect, transdermal agents should act similarly to an orally or parenterally administered drug. Topical agents, on the other hand, are expected to have a desired action that is local at or near the surface of the skin where the drug is applied. Drugs that work by mouth may not work when applied directly to the skin because the target of the drug effect may not be nearby under the skin. Therefore, each topical agent must be tested for effectiveness because the hypothesis is that the mechanism of action is local and clinical efficacy needs to be proven. (Note that there are hypotheses that for some topical agents the mechanism of action might involve a retrograde transport to act more centrally). Thus NSAIDs are more likely to have a local effect, but anticonvulsants such as gabapentin is more likely to have a central effect.</p> <p>The series of comments below</p>	<p>adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many these agents. <u>Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.</u> The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. <u>[Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic® (fentanyl transdermal system).]</u></p> <p><u>“Non-steroidal antiinflammatory agents (NSAIDs):</u> <u>The efficacy in clinical trials for this treatment modality has been inconsistent and most studies</u></p>

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	<p>When they are used, it is not at the same concentrations and combinations that were used in the preparations triggering the FDA's warning.</p> <p>Compounded topical analgesics are critical to many patients in his practice and he requests that the Division reconsider the "not recommended" status for this class of drugs.</p> <p>Commenter's particular concern is the MTUS relating to the decisions surrounding "recommended" and "not recommended" substantiation. Commenter believes that the format in which the content for the guidelines are presented will be misinterpreted by the industry as a whole, specifically as it relates to topical compounds.</p> <p>Commenter appreciates the fact that the guideline is created to help control costs associated with the practice of medicine in the workers compensation arena, however, to control costs while limiting patient access, or to control costs while prohibiting the practice of medicine is disingenuous and most likely unconstitutional.</p> <p>Commenter states that as a pharmacist and former adjunct professor at USC School of Pharmacy teaching pharmaceutical compounding, he believes that it is short sighted for the Division to unilaterally declare "Topical Compounds" as not recommended.</p> <p>Commenter states that there are over 1000 various combinations of topical compounds in use across the USA. Compounded medications are used by every practice specialty, every type of disease state and type of patient. Compounds are utilized daily in hospitals, hospice, medical groups, private physician practice, independent pharmacies, chain pharmacies, and other</p>		<p>addressed the chronic pain medical treatment guidelines' individual treatment guideline on <i>"Topical Analgesics, compounded."</i> Compounding pharmacy is a practice whereby a pharmacist or physician mixes or prepares batches of one or more therapeutic agents that are customized to the needs of a patient. Like any other pharmaceutical products, compounded drugs are prescribed pursuant to physician's orders. Compounding pharmacy is opposite from commercial manufactured drugs which are available in limited forms. Compounding allows adjustments to be made to the concentration, flavorings, allergen-free components, etc. Commercial formulations of drugs including commercial topical agents require FDA approval as these drugs are mass produced. Compounding of small batches of drugs customized to the patient does not require FDA approval as this is a professional practice and the FDA does not consider compounding pharmacists to be drug manufacturers. Commercial manufactured topical agents require scientific review by the FDA. Compounding pharmacy practice requires that the practitioner is licensed and based on the professional standards, compounding is permitted without</p>	<p><u>are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical</u></p>

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	<p>types of clinics across the country. Commenter opines that there is so much more to topical compounding than the paragraph declaring the category "not recommended".</p> <p>Further, commenter believes that the evidenced based search process was not complete. Searching for topical compounds for pain is not going to reveal much to the researcher, however, if they were to search for individual active ingredients used topically, or transdermally, the researcher would discover hundreds of articles that would fit the criteria for EBR. Commenter states that searching beyond active ingredient, combination of active ingredients, strengths, and therapeutic categories will reveal even more.</p> <p>Commenter states that there is at least as many if not more, class C substantiated EBRs in favor of various topical compounds as there are for unsubstantiated claims, which renders the decision not proving or disproving efficaciousness at this time, in essence, "under study" and thus the decision to prescribe a topical compound should remain with the physician treating the patient with the most tools available without compromise.</p> <p>Throughout the narrative, and after reviewing countless articles as presented in the MTUS, commenter opines that "off-label" use, and use other than that in which the drug is FDA indicated is acceptable within the Division. Commenter questions why then would topical compounds simply be negated based on poor research and a warning letter released by the FDA referencing topical lidocaine as used by laser surgery centers for hair removal?</p> <p>Commenter opines that the choice of medication</p>		<p>demonstrating safety and efficacy of the treatment as the FDA does not regulate compounding pharmacy practice.</p> <p>As previously indicated, the Labor Code requires the guidelines set forth in the MTUS be evidence-based as they are presumptively correct by statute. Given that topical drugs are not expected to work in the same way as orally or parenterally administered drugs, efficacy for topical agents cannot be extrapolated from data when the same agent is given by another route. In order to meet the requirements of the statute, topical agents are not excluded from evidence-based review. Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence). In practice, several</p>	<p><u>NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren® Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren® package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug</u></p>

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	<p>therapy should be left to the physician as they are deemed competent as the treating physician and the surgeon by the carrier. Compounded pharmaceuticals are the cornerstone of the practice of pharmacy and have been in existence for thousands of years. Compounding is recognized as a legitimate standard of medical care by the FDA, BOP, Board of Medicine, and the DEA.</p> <p>In the spirit of the Division attempting to regulate compounding, commenter strongly advises that it not be regulated by a paragraph on a guideline that universally discounts the use of compounded medications as a whole, but instead establish an OMFS specifically for compounds.</p>		<p>pharmaceutical agents are often combined to produce a multi-drug mixture that is applied topically. However, combinations of agents cannot be presumed to be more effective than the single agents applied separately. At a minimum, each agent in a mixture requires evidence of effectiveness. Proof that multiple agents, when combined, have a complementary effect require rigorous study to test how the combination is superior to single agents or control groups.</p> <p>Physicians are defined by the Labor Code (Lab. Code, § 3209.3). Licensed prescribing physicians give orders. Pharmacy carry out physician orders. It is beyond the scope of the MTUS to address professional practices, and to expand their scope of practice. As indicated above, the MTUS is presumed to be correct on the issue of extent and scope of medical treatment. (Lab. Code, § 4604.5(a)) Thus, there is no longer a primary treating physician's presumption. In adopting the MTUS as required by Labor Code section 5307.27, the Administrative Director is complying with the requirements of the law, and is not the intention of the MTUS to interfere with the doctor-patient relationship. However, because the primary</p>	<p><u>depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000)</u></p> <p><u><i>“Lidocaine Indication: Neuropathic pain</i></u> Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post herpetic neuralgia. <u>Topical lidocaine, in the formulation of a dermal patch (Lidoderm®) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as</u></p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>treating physician’s presumption is no longer available to the physicians, these physicians are required to comply with the requirements of the MTUS in providing treatment to injured workers. In that regard, the MTUS serves as a basis for utilization review (UR), whereby a treatment request made by a physician is reviewed and a determination is made as to whether the treatment meets the requirements of the presumptively correct guidelines. (Lab. Code, 4610(c).)</p> <p>Further, it is not the intention of the DWC by adapting the individual treatment guideline on <i>“Topical Analgesics, compounded”</i> to ban topical compounded. DWC disagrees with comments that the purpose of the regulation is to shut down a practice. Rather, the MTUS requires evidence-based review. Agree, however, with comments that the that Topical Analgesics and Topical Analgesics, compounded guidelines may be confusing to the public. The DWC added the individual treatment guideline on <i>“Topical Analgesics, compounded”</i> in the chronic pain medical treatment guidelines to supplement the existing ODG individual treatment guideline on <i>“Topical Analgesics.”</i> The</p>	<p><u>local anesthetics and anti-pruritics.</u> Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. <u>In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine.</u> <u>Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings.</u> <u>Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended.</u> (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) <u>Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no</u></p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>individual treatment guideline on <i>“Topical Analgesics, compounded”</i> was added because ODG’s individual treatment guideline on <i>“Topical Analgesics”</i> did not address mixing multiple compounded agents. It is clear that the public finds the two sections confusing. Taking into consideration the public comments submitted, ODG has conducted its own evidence-base review, and has updated its the individual treatment guideline on <i>“Topical Analgesics.”</i> In the revised individual treatment guideline on <i>“Topical Analgesics,”</i> ODG has clarified the guideline by stating that the scientific evidence is lacking and not all topical agents are proven effective. Therefore, if a mixture of compounding agents is to be prepared, all the active ingredients need to be proven effective. If the mixture contains a not recommended drug agent, then the entire mixture is not recommended. Since compounding pharmacy practices create preparations on a customized basis, adjustments to the compounding pharmacy practice can be made to utilize only mixtures where every active ingredient is supported by the available scientific evidence. Because the individual treatment guideline on <i>“Topical Analgesics”</i> was clarified, ODG removed the</p>	<p><u>superiority over placebo. (Scudds, 1995)</u></p> <p><i>“Capsaicin:</i> Recommended only as an option in patients who have not responded or are intolerant to other treatments. <u><i>Formulations:</i></u> <u>Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy.</u> <u><i>Indications:</i></u> <u>There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose</u></p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>text of the individual treatment guideline on “Topical Analgesics, compounded” and indicated below the guideline title, “See, Topical Analgesics.” DWC agrees with the updated version and proposes to adapt the updated version in the chronic pain medical treatment guidelines.</p> <p>Commenter appears to confuse the issues of medical treatment guidelines vs. costs. Disagree with the comment that the MTUS regulations are intended to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b).</p>	<p><u>pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004)</u> See also Capsaicin.</p> <p>“Other agents: Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post herpetic neuralgia, and both studies showed encouraging results. Topical elonidine has published reports in animal studies only. Topical gabapentin has no published reports.</p> <p><u>“Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen.</u></p> <p><u>“Other muscle relaxants: There is no evidence for use of any other muscle</u></p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				<p><u>relaxant as a topical product.</u></p> <p><u>“Gabapentin: Not recommended. There is no peer-reviewed literature to support use.</u></p> <p><u>“Other antiepilepsy drugs: There is no evidence for use of any other antiepilepsy drug as a topical product.</u></p> <p><u>“Ketamine: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined. (Gammaitoni, 2000) (Lynch, 2005) See also Glucosamine (and Chondroitin Sulfate): & Topical analgesics, compounded.</u></p> <p><u>“Non neuropathic pain (soft tissue injury and osteoarthritis).</u></p> <p><u>“NSAIDS: The efficacy in clinical trials for this treatment modality have</u></p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				<p>been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2 week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Ketoprofen is under study in a patch formulation for treatment of ankle strain and for tendonitis/bursitis of the elbow, shoulder and knee in phase II clinical trials in Europe.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				<p>“Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. See also Capsaicin.”</p> <p>“Lidocaine: There are no randomized controlled trials evaluating the use of topical lidocaine for treatment of low back pain or osteoarthritis, and treatment with this modality is not currently recommended.”</p> <p>“Other agents: Topical glucosamine, chondroitin and camphor showed significant pain relief for osteoarthritis of the knee after 8 weeks compared to placebo. (Cohen, 2003) See also Glucosamine (and Chondroitin Sulfate). For non-neuropathic low back and myofascial pain there are few published studies. (Argoff, 2006)”</p> <p>“Topical Analgesics, = Compounded [DWC]”</p> <p><i>“See Topical analgesics. Not recommended. There is no mixed evidence that about whether compounding topical medications, such as</i></p>

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				<p>adding an anti-inflammatory agent to capsaicin, is more efficacious than the single medication. Furthermore, the a recent FDA has issued warnings warning on about the potential dangers of compounding topical medication containing local anesthetics supersedes any recommendation (U.S. Food and Drug Administration, FDA News, December 5, 2006, FDA Warns Five Firms to Stop Compounding Topical Anesthetic Creams. (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01516.html) The FDA warns, that Exposure to high concentrations of local anesthetics, like those in compounded topical anesthetic creams, can cause grave reactions (including seizures, and irregular heartbeats and death). At least two deaths have been connected to compounded topical anesthetic creams. (FDA Advisory 12/05/06) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local</p>

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				<p>anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006). There is little to no research to support the use of many of these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required.”</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical compounds</i></p>	<p>In regards to topical medications, there is an incredible profit margin associated with most of those which are compounded and commenter has witnessed that the physicians who most vociferously object to their exclusion are the ones who regularly prescribe them, many of whom have their own compounding pharmacy arrangements. As they and their applicant attorneys attempt to game the worker’s compensation system to maximize their revenue streams, I would strongly encourage whoever reviews the modifications to consider this aspect before unleashing a loophole in the system that allows these providers to prescribe such treatments in unfettered fashion.</p>	<p>Frank Hall, MSN, RN, CMM Supervisor U.R. & Nurse Case Management December 18, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, disagree with the comment that the MTUS regulations are intended to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b).	
Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical compounds (Salicylate topical)</i>	Commenter states that while indicating that a Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in acute and chronic pain, this document then states on page 71 that Topical Analgesics are recommended as an option, but not recommended when they are compounded as per the DWC comments. Commenter states that although an OTC medication may be used to relieve chronic and acute pain, they can be less effective than a compounded medication. Commenter indicates that compounded medications are by their nature designed to address a specific treatment regime. Commenter states that for example, the compounding of methyl salicylate, Capsaicin, Camphor, menthol, and Cyclobenzaprine (Flexeril) into a single typical applied compound medication. Each of these drugs is individually recommended for the treatment of pain in topical form by the ACPA.	Tom Van Auken Deutsche Medical Services December 9, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical analgesics – Compounded [DWC]</i>	Commenter has noted that a number of physician and pharmacy interest groups are protesting the lack of treatment guideline recommendations for compounded multi-agent topical creams and most compounded topical agents. As a physician who has been active in OccMed treatment, medlegal evaluations, and UR, commenter is well aware of the use of these agents. Commenter states that they are generally dispensed by physicians who provide no specific indications and provide no specific evidence of benefit. Commenter opines that the vast majority of patients, if not all, exhibit no benefit from these agents. Commenter believes that any recommendation for these agents should be based on specific medical	Paul Manchester,MD, MPH – Occupational Medicine December 16, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. With regard to the issue of medical foods, The comment does not address the substantive changes made to the proposed regulations	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>evidence, just like other treatments. Commenter indicates that testimonials of patients, dispensing doctors and pharmacists, should not be considered as valid medical evidence. Commenter states that the so-called "medical foods" are usually dispensed by the same kind of physicians who dispense topical compounded agents, and are equally lacking in medical evidence. Medical foods should also be "not recommended" unless there is good medical evidence. Commenter opines that it is remarkable how quickly a number of physicians have rushed to dispense topical compounded agents and medical foods, in light of the absence of medical evidence. Commenter observes that other factors are clearly motivating in this case, but enthusiasm by those who profit from these items does not constitute medical evidence or provide an adequate basis for recommending these items in a treatment guideline.</p>		<p>during the 1st 15-day notice. The issue was raised during the 45-day comment period, and was appropriately addressed in the 45-day comment period chart. Medical foods were deleted from the chronic pain medical treatment guidelines as adapted from the October 23, 2008 ODG version. (See, 1st 15 Day Notice, Appendix A1, November 2008, pp. 15-16.)</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical analgesics – Compounded [DWC]</i></p>	<p>Commenter submits her organization's position paper on topical compounded pain medications:</p> <p>DECEMBER, 2008 The American Pain Foundation (APF) has been following the actions of the California Division of Workers' Compensation who are planning to adopt a new policy that classifies topical compounded pain medications as "not recommended" which will therefore not be covered by Worker's Compensation. Such a change would create significant hardships for individuals who benefit from these medicines and who have no alternative options for pain relief. APF wishes to voice our concern about the Division's attempt to impede access to pain treatment options.</p> <p>For some people with pain, topical compounded pain medicines are necessary and the only effective treatment option for their pain. There are legitimate clinical reasons to utilize topical compounded</p>	<p>Tina Register, Communications Manager American Pain Foundation December 18, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>analgesic medicines and the inability to access these will impede appropriate pain relief for those in need. There are many people who cannot tolerate therapeutic dose levels of pain medicines in oral forms who show significant benefit from topical or transdermal use of these medicines. To deny them access to this form of medicine is to condemn them to unnecessary and often debilitating pain.</p> <p>According to a statement in the Chronic Pain Treatment Guidelines outlined by the agency: “Continuation or modification of pain management depends on the physician’s evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. When prescribing controlled substances for pain, satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life (http://www.medicines.ca.gov/pain_guidelines.html).” This statement emphasizes the importance of the patient/physician relationship in treating an individual’s pain. The document continues: “[t]he use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required” (MTUS, Chronic Pain Medical Treatment Guidelines, p.117). This is the specific responsibility of the prescribing physician and compounding pharmacist.</p> <p>Access to pain treatment options that include topical compounded medications must be protected for people affected by pain. On behalf of the approximate 9 million Californians who report a problem with pain, APF respectfully requests that the California</p>			

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	Division of Workers' Compensation reconsider their decision and protect access to this important pain treatment option. There is no "one-size-fits-all" pain treatment option and protecting access to all pain treatments is important for all who live with pain.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical analgesics And Topical analgesics – Compounded [DWC]</i>	<p>Commenter believes that these two sections contradict each other and offers the following argument:</p> <p>Commenter states that under the heading Topical Analgesic, a listing of recommended given; with the statement, "Largely experimental in use with few randomized controlled trials to determine efficacy or safety."</p> <p>Commenter indicates that in fact they are not largely experimental. The art of pharmaceutical compounding has ancient roots. Commenter states that hunter-gatherer societies had some knowledge of the medicinal properties of the animals, plants, molds, fungus and bacteria as well as inorganic minerals within their environment. Commenter indicates that ancient civilizations utilized pharmaceutical compounding for religion, grooming, keeping the healthy well, treating the ill and preparing the dead.</p> <p>Commenter adds that these ancient compounders produced the first oils from plants and animals. They discovered poisons and the antidotes. They made ointments for wounded patients. Commenter states that the modern age of pharmacy compounding began in the 19th century with the isolation of various compounds from coal tar for the purpose of producing synthetic dyes. Commenter indicates that from this one natural product came the earliest antibacterial sulfa drugs, phenolic compounds made famous by Joseph Lister.</p> <p>Commenter indicates that in 2006, over 30 million</p>	Tom Van Auken Deutsche Medical Services December 9, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>compounded prescriptions were dispensed, not counting all the admixtures and injectable drugs compounded in America’s hospitals. “These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Commenter states that many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006).”</p> <p>Commenter observes that the statement is made that topical gabapentin has no published reports. This is not accurate. There are three studies that have been done on topical gabapentin. Further in this section several examples of medications used typically for the treatment of pain are given.</p> <p>Commenter indicates that in the next section Topical Analgesics – Compounded [DWC], they are listed as not recommended and states that there is no evidence that compounding topical medications, such as adding an anti-inflammatory agent is more efficacious than the single medication. Commenter states that a reference is made to an FDA warning on the potential dangers of compounding topical medication containing local anesthetics. This contradicts ACOEM and distorts the facts. Commenter indicates that the FDA advisory was specifically directed at five pharmacies and does not even list the specifics of the issues (e.g. dosage).</p> <p>Commenter states that the International Academy of</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Compounding Pharmacists states that "Congress, the U.S. Supreme Court, and each of the 50 state boards of pharmacy that regulate compounding have long recognized the value of pharmacy compounding, yet the FDA has contended for nearly 20 years that compounded medications are illegal. Compounded medications are not new, unapproved drugs and pharmacies dispensing them act only under a doctor's prescription. To the extent that there are patient safety issues, state boards of pharmacy are well equipped to deal with them." Recent court rulings, such as <i>Medical Center Pharmacy v. Gonzales</i> (2006) support the position taken by IACP.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter states that there seems to be many positive guidelines incorporated into this new schedule but feels that the Compounded guidelines should be adjusted in order to properly reflect many of the positive outcomes that are achieved through the use of compounding medication.</p> <p>As a pharmacist in California commenter truly understands that cost-cutting measures are necessary to enhance the current workers compensation system. However, due to rogue outfits that corruptly bill for topical medications under Usual and Customary prices and completely abuse the system, this should not affect the entire compounding community as your proposal does and will. Compounding medications is one of, if not, the earliest form of medical treatment. Commenter opines that the knowledge that Prescribers and Pharmacists use to work together to create helpful drug regimens should not be overlooked and neither should their efficacy. It is noted in the proposed guidelines that "The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required." Pharmacists in commenter's company work hand in</p>	<p>Gerald R. Laxer, Prph, Pharm D., PIC KLE Inc. December 17, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. It is noted that commenter adds articles on vulvodynia which is not a condition which falls under the MTUS. It is noted that commenter adds articles on topical gabapentin for the treatment of vulvodynia a condition which does not fall under the MTUS and the results of these studies cannot be generalized to chronic pain related to common work injury conditions. Moreover, commenter states that he has knowledge of studies that are about to be published for topical gabapentin. Treatment guidelines will always lag new research as the pace of new</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>hand with doctors to create medication regimens that are truly unique and are all about helping patients recover faster. The regimens are not about bilking the system for unwarranted amounts of reimbursements.</p> <p>Commenter kindly requests to see a change in proposal that further clarifies that if a Doctor and Pharmacist, who have specific knowledge of a desired analgesic effect, prepare a regimen it will be RECOMMENDED based off of their expertise in the area of topicals as long as documentation and studies exist to corroborate their assumptions.</p> <p>Commenter states that all of the topical medications the commenter's company creates are billed for with NDC numbers based off of the Medi-Cal fee schedule adopted by the DWC in 2005. His company does not ever bill usual and customary prices that seem to be the issue here. Commenter states that companies billing for questionable "Wasabi" creams that are burning through workers' compensation dollars with unfounded charges should be targeted. Pharmacies that practice proper and safe medication should not be targeted. Because of these few questionable practices do not let a thriving and effective industry be cancelled out completely. Rather, commenter opines that the Division should go after companies who are abusing the system.</p> <p>Commenter is happy to see that the DWC does acknowledge the benefit of topical NSAIDS, Ketamine & Lidocaine. However commenter has attached one study to his email in regards to the effectiveness of topical Gabapentin which has showed very promising results. [A copy of this study is included in the complete comment section of the formal MTUS rulemaking file and is available for inspection upon request.] Commenter adds that, in</p>		<p>developments is high and the updating cycle varies amongst guideline producers. The MTUS provides a mechanism to rebut the presumption when there is new evidence, as contained in Section 9792.21(c).</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>October of 2008, Dr. Lori Boardman published her work on the efficacy of Topical Gabapentin in Vulvodynia with amazingly strong and consistent results over a five-year trial period. Also note that the University of Michigan is working on two independent studies regarding the use of topical Gabapentin with early and encouraging results. Their work should be published early [2009]. It is noted in the DWC proposal that “These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate.” In addition, commenter has also attached PCCA’s study of the delivery of the base Lipoderm and its effectiveness in skin penetration further proving the ability of these medications to penetrate positively. [A copy of this study is included in the complete comment section of the formal MTUS rulemaking file and is available for inspection upon request.] Commenter states that Lipoderm is such an advanced base that it is able to carry even the largest molecules through skin as proved in the study with Lipoderm as the vehicle and Promethazine as the active chemical (attached). Promethazine molecularly is one of the largest active ingredients that could be used and it penetrates the skin extremely effectively. Commenter believes that this further supports the assumption of Topical applications and their ability to penetrate skin and deliver medication to the point of attack at a more concentrated level than that of oral administration while curtailing many of the systemic problems associated with oral applications. Commenter agrees with DWC that some forms of Topical medications have been abused; however, he strongly supports DWC adjusting the MTUS to reflect many of the positive sides of topical compounding. Commenter believes that the truth is there are many studies that support the use of Topicals; he does feel that the</p>			

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	<p>DWC also did not invest enough time in finding all of the supportive literature, rather stuck to literature that refuted efficacy. Commenter has offered to supply the Division with over 300 pages of documentation and studies that support the use of various Topical Analgesics (at your request of course). Commenter believes that DWC and Practitioners must acknowledge published data, both good and bad, that support the uses of topical applications. Commenter's Pharmacy would also be able to provide DWC with a list of over 175 Practitioners who support the use of topical medications and routinely prescribe them with very effective results.</p> <p>One piece of information commenter believes has also been left out is the use of topicals in the private insurance world. The private insurance carriers are known for their stringent adherence to formularies as well as effective medicine. Over 70% of all private health insurance carriers including: Blue Cross, Health Net, Pacificare, Blue Shield, Aetna, and Caremark, reimburse at some level for many topical compounded medications, especially NSAIDS, Gabapentin, and Muscle Relaxants. These insurance carriers reimburse based off of their fee schedules, which is similar to the Medi-Cal fee schedule currently in place for the DWC. Commenter believes that if these agents were not effective or not FDA approved they would not be contained in their fee schedules. In addition, prior authorizations would need to be obtained prior to a prescription fill, which is not necessary. All medications in the Medi-Cal fee schedule should be reimbursable based off of their inclusion. This is why there is a special compounded formula for medications built into the Med-Cal system.</p> <p>Commenter requests the omission of the referenced</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>FDA warning regarding topical anesthetics. Commenter states that this in no way pertains to the practices of compounding currently being utilized in the Workers Compensation system today. Commenter requests that the Division not confuse the term Anesthetic and Analgesic. The FDA warning was in regards to the marketing and use of high concentrations of “Caines” in the Cosmetic Surgery area of medicine. This practice was completely out of control and the FDA had to step in to stop Pharmacists and Doctors from compounding unfounded and unsupported levels of medications. This is why, as referenced above, he feels that Pharmacists and Practitioners with extensive analgesic knowledge as well as documentation to support regimens should be given the ability to obtain authorization and or recommendations based off of an application designed for a patient and supported with literature.</p> <p>As commenter represents a compounding pharmacy, he sees firsthand the effectiveness of these medications. His company currently has a working file of over 15,000 active patients receiving some form of a topically applied medication. While workers compensation makes up a small percentage of their overall volume, they still actively treat 800-1000 workers compensation patients a month. The most telling information we have, in regards to efficacy, come in their retention reports post workers compensation cases being closed. The leader of pharmaceutical retention post claim is of course Pain medications at an almost 82% rate. However, the next highest medication retention is their patients being treated with topical NSAIDS at 58% and then a topical Gabapentin formulation at just over 50%. These are patients who are now choosing to pay out of pocket for these medications and their efficacy. If</p>			

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	<p>commenter had the time he could put together a list of well over 3000 workers compensation patients who would testify to the efficacy of their topicals (remember we are just one small pharmacy). In addition, commenter believes that the retention rate should be considered amazing considering the high frequency of fraud and overall patient lack of adhering to medication regimens.</p> <p>Commenter states that one glaring omission by the DWC with the proposed MTUS is that of compounded medications in other forms. Why is it that there is no mention of orally compounded, troche compounds, injection compounds, or suppository compounds? Commenter suspects that the reason is that most pharmacies who engage in these practices play by the rules and do not abuse the system, which brings him back to the point of punishing those who abuse the system, rather than the practice itself. All of these utilize the same principals of Topicals with a different delivery method. All of these methods are effective just like Topical delivery is effective. There is never a question about efficacy when commenter's pharmacy compounds an orally administered liquid application of a medication for patients who cannot take pills. The delivery method is of course different yet the outcome is the same, similar to topicals utilizing a different delivery method. Commenter is positive that this lack of clarification will further damage the compounding industry as a whole. Commenter points out that when a pharmacist in a hospital mixes an IV pain medication prior to administration it is considered compounding. Commenter is positive that DWC is not going to curb that practice as well if the cost of IV's is on the rise. Commenter requests that DWC to also review these methods and add this to the current version of the MTUS in order to further clarify the term of</p>			

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<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>compounding and its efficacy</p> <p>Commenter states that in the final draft medical utilization schedule (MTUS) for chronic pain treatment published by the Division of Workers' Compensation (DWC), the DWC is asserting that compounded topical analgesics are not understood by the medical community, are not effective and are unsafe.</p> <p>Commenter is concerned that by DWC adopting this position, patients receiving benefit from these compounded preparations may go without therapy, be forced to use a different, and potentially less appropriate therapeutic modality, be at risk for increases in morbidity and, in the end, be a greater financial burden on the healthcare system as well as have a diminished quality of life.</p> <p>Commenter states that pharmacy compounding is a long-standing, safe and well-regulated practice that serves the needs of many patients with unique health requirements not met by ordinary medications. Commenter indicates that there are many instances that the patient may not be able to tolerate any forms of medications other than topical. In these cases, adherence to the medication regimen is achieved by compounding topical analgesics.</p> <p>Commenter states that the combination of analgesics plus pain adjuvants means better levels of analgesia and, therefore, a better quality of life. Commenter adds that compounded topical analgesics are critical to the care of our patients. The status of "not recommended" is unacceptable and will negatively affect our patient's pain control.</p> <p>Commenter requests, on behalf of the California Pharmacists Association's Academy of Compounding</p>	<p>Dana B. Nelson, Rph, Pharm. M.S., F.A.S.C.P., Chair Academy of Compounding Pharmacists California Pharmacists Assn. December 18, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Pharmacists, that the Division intercede to guarantee that our patients have access to medication that alleviates their pain and ensures their quality of life. Commenter requests that the Division please reconsider, and reverse the decision for the "not recommended" status for this class of drugs.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Topical Analgesics - compounded	<p>Commenter understands that the final draft of the medical treatment utilization schedule (MTUS) for chronic pain medical treatment guidelines would effectively remove the option of utilizing custom compounded medications for treating patients.</p> <p>Commenter has been contacted by pharmacists and physicians who are troubled by this, as it does not address similarly constructed commercial topical pain relievers that have also been beneficial in patient care. Commenter states that two separate topical pain relieving formulations have entered the market in the past year (Flector and Voltaren Gel); claims for these agents have seldom raised any objection as to their appropriateness.</p> <p>Commenter points out that the need to have a skilled and capable compounding pharmacist to prepare patient-specific therapies often arises in many physicians' practices. Commenter opines that having the option to employ a formula that may improve compliance, reduce unwanted side effects, eliminate or reduce the need for narcotic analgesics, and possibly reduce the number of medications is necessary to treat secondary conditions as well as a practical necessity, and simply put is "good medicine."</p> <p>Commenter request the Division to meet with a group of pharmacists and physicians by contacting Robert Nickell R.Ph and urges the reconsideration to remove the language "not recommended" from the proposed</p>	Christine Kehoe, Senator – 39 th Dist. CA State Senate December 9, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, disagree with the comment that the guideline effectively removes compounding. It is noted that the guideline provides for two separate topical pain relieving formulations, which are FDA approved and based on evidence. The MTUS is presumptively correct and evidence-based. Good medicine is to use effective medication and to not prescribe inappropriate treatments that are not proven to work (i.e. do not have a research basis to demonstrate efficacy). Many agents that are compounded are used off label, and off label use is acceptable, if there is evidence for safety and efficacy.	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

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<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>guidelines and support the use of topical analgesics.</p> <p>Commenter is writing in response to the California Worker’s Compensation Division’s (CWCD) proposed policy to classify topical compounded analgesics as “not recommended.” Commenter opposes the policy due to its potential negative impact on worker’s compensation claimants who may rely on these medications to treat their unique medical conditions.</p> <p>Commenter states that compounding pharmacists play an essential role in their patients’ lives by allowing physicians to prescribe customized medication therapy to best meet the needs of their patients. Compounding allows physicians to prescribe and pharmacists, utilizing their medication knowledge and expertise, to produce tailored medications that meet a patient’s individual needs. In providing compounding services, pharmacists work hand-in-hand with physicians to solve health care problems not addressed by the commercial marketplace.</p> <p>Commenter states that DWC’s proposed policy proposes to disrupt the patient-pharmacist-physician triad relationship. Commenter opines that physicians, who determine what medications are appropriate for their patient's therapeutic success, would no longer have access to these drug products as a covered benefit even if the product is the only treatment option for the patient. Commenter adds that this restriction would not exist if the same patient with the same medical needs had been injured off of the work site.</p> <p>Commenter indicates that because there are numerous cases each day in which compounded medications are essential to patient health, he believes that a broad sweeping denial of reimbursement of compounded medications has the potential affect of jeopardizing</p>	<p>John A. Gans, PharmD, Executive Vice President American Pharmacists Association, December 18, 2008, Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that the DWC has considered every comment received in connection with the individual treatment topic guideline on Topical Analgesics, compounded. The DWC has also considered studies submitted by the commenter’s in support of their comments. For further discussion on these studies see, Memorandum to the Rulemaking File, dated November 26, 2008, which addresses the individual treatment guideline on “Topical analgesics – Compounded [DWC].” The November 26, 2008 Memorandum to the Rulemaking file was adopted and incorporated as part of the 45-days comments rulemaking chart, and specifically addresses studies submitted in connection with the individual treatment topic guideline on Topical Analgesics, compounded.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>patient health. For example, compounded topical preparations can be used to deliver the medication directly to the intended site of action and avoid systemic side effects that could result from taking the same medication orally. Compounded topical products can also be used as an alternative when commercially available products fail to achieve the intended effect such as pain relief. Commenter's compounding pharmacist members report that their patients and the physicians with whom they work are greatly appreciative of the services provided and the effect they have on improving patient care, as evident by patients frequently refilling these prescriptions.</p> <p>Commenter opines that intervening in the patient-prescriber-pharmacist relationship could have dire consequences for the health of individual patients. Commenter urges the Division to strongly consider and incorporate the comments, evidence and examples that have been submitted by pharmacists and physicians in regard to this section. Hundreds of patients have found relief from compounded therapies that have been prescribed by their physician and compounded by a licensed pharmacist. Commenter respectfully urges the Division to consider the impact DWC's broad-sweeping, proposed policy would have on these patients.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter states that the American Pain Foundation is dedicated to improving the quality of life of people affected by pain. Commenter is very concerned about the proposed DWC's regulations classifying topical compounded analgesics as "not recommended."</p> <p>Commenter states that there are many people living with severe, debilitating pain conditions who have adverse reactions to many oral pain remedies. For many, the only effective choice for pain relief is compounded topical pain medications. To restrict</p>	<p>Will Rowe, Chief Executive Officer American Pain Foundation December 17, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	access to these medicines for these people will condemn these people to living with unrelieved, debilitating pain. Commenter asserts that their access to this one effective path to relief needs to be protected. Commenter strongly urges the Division of Workers' Compensation to support pain patients' access to these treatments.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	As a compounding pharmacist in Wisconsin, commenter finds the Division's proposed <i>anticompounding</i> rules frightening. Commenter requests that before the Division activates these rules, that there is a need to get out in the field (behind the Rx counter) and talk to the patients and their doctors. Commenter is aware of hundreds of women who would tell you topical hormone replacement has saved their lives-both business and marriage.	Wayne Loveland, Pharmacist Prescription Center December 9, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, the goal of hormone replacement therapy is for a systemic effect and therefore does not represent a topical treatment but rather a transdermal treatment. Also, there are numerous FDA approved transdermal hormone replacement therapies. It is unlikely that hormone replacement will be a topic covered under the MTUS (except Testosterone replacement for hypogonadism (related to opioids)).	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	Commenter is a compounding pharmacist in Pittsburgh and opposes the new draft guidelines stating that topical compounded analgesics are "not recommended" by the DWC. Commenter states that topical compounds have helped thousands of patients and are utilized in most modalities of medicine including pain, orthopedics, sports medicine, hospice care and rheumatology. Commenter believes that the pharmaceutical industry would like compounding	Susan Merenstein, Pharmacist/Owner Murray Avenue Apothecary December 9, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and

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	abolished since it cuts into their profits and opines that this is no doubt motivated by them. Commenter indicates that compounding only encompasses 2% of all scripts filled, but she believes that the drug companies want it all. Commenter requests that the Division reconsider its decision.			Treatments, Topical, compounds, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Topical Analgesics - compounded	<p>Commenter is a board certified orthopedic surgeon. Commenter states that approximately 25 to 30 percent of his practice is related to work related injuries and that he finds topical compounded medications valuable in his treatment armamentarium. Commenter has substantially reduced the use of narcotic medications in his practice because of instituting these medications. Commenter finds the mixture of ketoprofen, capsaicin, and gabapentin to be most useful in diminishing the need for narcotic analgesics. The dosages that he uses for the compounded medications are much lower than traditional measures such as therapeutic dose, let alone lethal dose. Commenter indicates that greater than 80 percent of patients who receive compounded medications have a favorable response.</p> <p>The only complication commenter had noted from using the compounded medications include a few mild cases of contact dermatitis. Overall, the benefits have outweighed the risks. Commenter has also noted an improved ability to get patients back to work quicker and at higher functional capacity. Many employers will not take patients back to any work as long as the patients that are taking oral analgesics or narcotics. Because patients are not taking mind altering narcotics, they can return to work faster and be more useful.</p> <p>Many patients have problems with gastritis secondary to the use of oral anti-inflammatories. By using compounded medications, commenter is able to give</p>	Sohail Ahmad, MD December 11, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT,	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>patients anti-inflammatories with much lower risks in relation to gastric complications. Compounded medications also allow the use of the product directly on the site of injury with less risk of systemic complications. Systemic risks of gastric bleeding from oral salicylates or constipation from oral narcotics are almost nonexistent with the use of compounded medications.</p> <p>Commenter has previously prescribed these topical agents separately (i.e., ketoprofen alone or capsaicin alone). He believes, however, the efficacy was less beneficial. Commenter states that the same patients who used the agents singularly noted much greater benefit when combining the agents. Commenter believes there seems to be a synergistic beneficial effect to combination therapy with compounded medications. Commenter states this is not surprising since numerous medications have potentiating effects in the body.</p> <p>In summary, commenter states that using compounded topical medications have decreased his need for writing narcotic prescriptions, improved his ability to get patients back to work quicker and at higher functional capacity, and reduced the incidence of systemic complications since the medications can be applied directly to the site of injury. Commenter believes that compounded agents work better than using the agents singularly because of potentiating synergism. The only problem has been a few cases of contact dermatitis that resolved from abstinence.</p> <p>Commenter states that overall, he and his patients are happy with using these useful and safe medicines. Commenter offers to provide more information or patient testimonials if needed.</p>		see strength of evidence).	

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<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter states that the efficacy of topical pain control medication has been well established. Commenter opines that the deletion of these medications from the DWC formulary is a major error on the Division's part. The FDA has allowed a number of these medications to the market after the stringent scrutiny with which we all are familiar. In addition, many compounded formulae have proven their efficacy through studies done with pharmacists and physicians in collaboration. Commenter offers to provide these for the Division's consideration. Commenter opines that the loss of these medications from pain management armamentarium will result in more internal medications being prescribed with their attendant side effects and excessively high costs, especially the brand name single source products. Commenter encourages the Division to seriously reconsider its position on this subject.</p>	<p>Santo Garro, R.Ph. Garro Drug Store of Utica, Inc. December 10, 2008 Written comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that the DWC has considered all studies submitted by commenters relating to the individual treatment guideline topic of Topical Analgesics, compounded. For further discussion on these studies see, Memorandum to the Rulemaking File, dated November 26, 2008, which addresses the individual treatment guideline on "Topical analgesics – Compounded [DWC]." The November 26, 2008 Memorandum to the Rulemaking file was adopted and incorporated as part of the 45-days comments rulemaking chart, and specifically addresses studies submitted in connection with the individual treatment guideline topic of Topical Analgesics, compounded.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics</i></p>	<p>Commenter is very distressed to hear that consideration is being given to eliminating the use of compounded creams for injured workers. Commenter is a practicing Neurosurgeon and has found these creams to be very helpful in treating patients in his practice. They are well accepted by the patients who in many cases do not accept oral meds for fear of side effects, etc. Commenter has found that the</p>	<p>Roger W. Shortz, M.D., F.A.C.S. December 18, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds,</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
- <i>compounded</i>	<p>compounds provide significant relief and improved function in the vast majority of the patients, frequently allowing a reduction in addictive oral medications such as Norco, etc. In over two year’s use of these compounds in hundreds of patients, commenter has never seen a serious adverse reaction, only occasional skin rash.</p> <p>Commenter considers the compounded creams to be one of the most useful tools for treating patients to become available in many years. Commenter urges the Division not to remove them from available treatment alternatives. Commenter understands that abusive prescribing may have occurred in some instances; however , commenter believes that this can be addressed by reasonable limits on prescribing, i.e. no more than two creams simultaneously, etc.</p>		<p>above. Moreover, disagree with the comment that the MTUS regulations are intended to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b).</p> <p>Here, commenter “understands that abusive prescribing may have occurred in some instances,” and he “believes that this can be addressed by reasonable limits on prescribing, i.e. no more than two creams simultaneously, etc.” Commenter is correct that there are instances where a compounded mixture contains more than one active ingredient and the evidence-base may not support the efficacy of each active ingredient. Thus, the revised individual treatment guideline on the topic of “Topical Analgesics,” addresses that problem by stating: “Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.”</p>	2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter believes the proposed changes in the MTUS to be reflective of considerable effort and deliberation, and that they should prove to be beneficial to all stakeholders in the workers compensation arena. Commenter states that the operational clarification of many outstanding issues in the management of chronic pain and in the provision of post-surgical treatment represent significant improvements.</p> <p>Commenter relates an issue that has reportedly become contentious is that of compounded topical preparations, which are not supported within the draft of the MTUS. The issue of compounded medications is actually broader than topical preparations, and he would like to recommend that there be consideration of inclusion of guidance regarding compounding of medications.</p> <p>Commenter continues that an area of potential abuse that has become increasingly widespread over the past year is that of custom compounded medications. The use of compounded medications to achieve therapeutic benefit at lower dosages and with fewer side effects is well-supported and a long standing practice within medicine. Commenter states that many compounded preparations have been shown to be of significant benefit, and some of these compounded preparations are readily available in mass-produced form. Commenter states that perhaps the most readily recognized such compounded medication is Tylenol with codeine, a compounded medication that is known within and outside the health care community.</p> <p>Commenter states that custom compounded medications could be reasonably necessary in those instances where a combination of materials is known to be safe and effective for a particular condition, but</p>	<p>Robert Ward Clinical Director CID Management December 18, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Disagree with the comment that the MTUS regulations are intended to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b).</p> <p>Further, commenter states that “[m]aterials for which there is no known evidence of efficacy for any condition and/or combinations of materials with no known efficacy are routinely being prescribed.” DWC agrees. There are instances where a compounded mixture contains more than one active ingredient and the evidence-base may not support the efficacy of each active ingredient. Thus, the revised individual treatment</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>the incidence of that condition is sufficiently low that there is no financial viability to the mass production of the product. In these very unusual situations, commenter believes that the preparation of a custom compounded material should be made available to the injured worker, and the skill and care required to produce that custom compounded material should be associated with an appropriate value on fee schedules.</p> <p>Commenter opines that the situation that is at play in the workers compensation community with regard to compounded medications is not reflective of this situation. Materials for which there is no known evidence of efficacy for any condition and/or combinations of materials with no known efficacy are routinely being prescribed. Commenter states that while it is not possible to know the motivations of the providers making these prescriptions, there is an appearance that the motivation is to achieve billing for medication that exceeds the established fee schedules. Commenter indicates that the current situation is very reminiscent of the practice of prescribing medications in non-standard quantities that was experienced until 2007, and tends to involve the same providers.</p> <p>Commenter states that a significant proportion of treatment requests in the workers compensation arena include requests for custom compounded materials. As claims administrators became aware of the practice of compounding multiple medications in topical and began denying those requests from an evidence-based perspective, providers began to shift towards prescribing a single-ingredient topical, but with custom “compounding” at a concentration that was not available mass produced. Requests for custom compounded oral medications are now found in approximately 1 in 50 treatment requests. Many of these requests involve compounding with a food</p>		<p>guideline on the topic of “Topical Analgesics,” addresses that problem by stating: “Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.”</p> <p>Regarding commenter’s request that the DWC consider that the MTUS include recommendations on the appropriate use of custom compounding of medicinal materials of all types, DWC will consider additional areas as suggested by the commenter when reviewing and updating the MTUS via formal rulemaking.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>substance called theramine, and it is not unusual to see requests for 4 or 5 different standard medications each separately compounded with the same amount of theramine and to be provided to the patient concurrently.</p> <p>Commenter requests consideration of his suggestion that the MTUS include recommendations on the appropriate use of custom compounding of medicinal materials of all types.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter opposes that the DWC is not recommending topical compounded analgesics. Commenter states this is a proven product that has helped many people, often times substituting for stronger narcotic use. Commenter states that the goal is the overall well being of the patient and the workers return to work. Commenter supports the “triad” of patient-doctor-pharmacist working together to solve problems and improve patient outcome, and not to have some board dictate medicine.</p>	<p>Robert Lima, RPh. December 10, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics</i> <i>- compounded</i>	<p>Commenter states that as a treating physician for injured workers, he has occasions to prescribe analgesic medications compounded by a local pharmacy.</p> <p>Commenter states that this combination of medicine has proven effective and convenient for use by the patients. It has given significant pain relief and avoided the problems of oral medication (GI upset). It is an alternative delivery system for useful medication. Commenter urges the Division not to list such compounded medication as "not recommended"</p>	Robert G. Aptekar, M.D. December 9, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter believes that the final draft medical utilization schedule (MTUS) for chronic pain treatment recently published by the Division of Worker's Compensation (DWC), is compromising the physician-patient relationship, by dictating physician prescription writing practices.</p> <p>Currently, physicians work with their patients to determine when compounded medications are appropriate. An "one-size fits all" approach to patient treatment does not achieve optimum patient outcomes. While working with pharmacists to design individualized treatments, patient recovery times improve and work days missed are reduced. Doctors often prescribe manufactured products that sometimes do not meet patient needs. Currently doctors can successfully prescribe compounded topical analgesics for pain management. These topical preparations may reduce the patient's dependency upon Schedule II narcotics or opiates, lessening the likelihood of possible abuse and/or dependency. Such dependencies only place a greater burden upon the healthcare system.</p> <p>As a compounding pharmacist who has been serving the local community for over 30 years, commenter attests to the number of patients who have achieved outstanding results from compounded medications and who are grateful for an alternative to standardized therapy. Commenter opines that intervening in the physician, patient, and pharmacist relationship would severely compromise the delivery of health services to my patients.</p> <p>Commenter attests that prescription compounding is a safe, well-regulated practice and believes that workers' compensation patients should not be discriminated against by eliminating their ability to</p>	<p>Richard W. Motske December 17, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, disagree with the comment that the individual treatment guideline topic of Topical Analgesics, compounded intervenes with the "physician, patient, and pharmacist relationship." Like any other pharmaceutical products, compounded drugs are prescribed pursuant to physician's orders. Physicians are defined by the Labor Code (Lab. Code, § 3209.3). Licensed prescribing physicians give orders. Pharmacy carry out physician orders. It is beyond the scope of the MTUS to address professional practices, and to expand their scope of practice.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>receive effective, alternative therapies for their work-related injuries.</p> <p>Commenter requests that the Division please reconsider the "not recommended" status for compounded medications.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter understands that the Division is contemplating stopping payment for compounded topical pain medications. Commenter believes that this would be a very big mistake. Commenter has observed that hundreds of patients over the years have gotten relief from these very same preparations that they could not get by taking oral pain meds. Commenter reviewed the backup documentation that the Division is using from the FDA and opines that the Division is comparing apples to oranges. Commenter suggests that the Division revisit the documentation from the FDA and approach it from a less jaundiced viewpoint. Commenter instructs the Division to "Do your homework--help your constituents" and that the present course of action is an unwise one.</p>	<p>Richard Brisson, R.Ph Pharmahealth Pharmacies December 19, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter would like to point out to the Division that the FDA has recently approved Brand Voltaren Gel® 1% (Diclofenac Sodium Topical Gel) manufactured by Novartis. Its NDC number is 0067-6215-97 (100gm Net Wt)</p> <p>Commenter states that the Division's draft reads "Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, ?-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, ? agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many [of] these agents.</p>	<p>Rakesh Patel, R.Ph WELLHealth Rx December 9, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, commenter brings to the attention of DWC that "the FDA has recently has recently approved Brand Voltaren Gel® 1% (Diclofenac Sodium Topical Gel) manufactured by Novartis. Its NDC number is 0067-6215-97 (100gm Net Wt)." The updated</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required”.</p> <p>As part of FDA drug approval, Voltaren Gel® must undergo both safety and efficacy studies in this country. Voltaren Gel® is a monotherapy NSAID.</p> <p>Commenter points out that the Division’s draft also reads “There is no mixed evidence that about whether compounding topical medications, such as adding an anti-inflammatory agent to capsaicin, is more efficacious than the single medication.”</p> <p>Commenter finds it hard to believe that the FDA approved Voltaren Gel® without compelling evidence to its safety and efficacy. Commenter requests that when the Division makes broad drafts such as this, that it has its facts in order first. Commenter states that he would happy to answer any questions that the Division may have.</p>		<p>individual treatment guideline on the topic of “Topical Analgesics” contains the approved topical agent. The guideline provides as follows: “<i>FDA-approved agents: Voltaren® Gel 1% (diclofenac):</i> Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren® package insert).”</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter would like to provide the Division with information regarding compounded creams used in pain control of injured patients. Commenter opines that patients hate taking pills/medications. In certain situations, anti-inflammatory medications can lead to bleeding ulcers. Commenter states that every year, 16,500 people die due to oral NSAID use. Commenter indicates that topical compounded creams offer a means of delivering medications through the skin, as opposed to the gastrointestinal tract. Psychologically, patients prefer to rub creams on their skin, as opposed to taking medications. Commenter states that a large portion of patients are already taking medications (heart, cholesterol, blood pressure, diabetes, ...) so to add more pills for pain control and anti-inflammation, makes it more challenging for patients to be compliant</p>	<p>Raffy Mirzayan, MD Department of Orthopaedics December 11, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>with their anti-inflammatory medications. Commenter speaks from personal experience of prescribing compounded medications that patients love them and are much more compliant with the compounded creams as opposed to pills. He states they are also happy with the results of pain reduction.</p> <p>Commenter urges the Division to NOT to classify topical compounded analgesics "not recommended" as it will be a hard pill to swallow for his patients when they can no longer be offered compounded creams.</p>		<p>might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter requests that the Division reconsider its proposal to reclassify 'topical compounded analgesics' into the 'not recommended' category. Commenter states that topical analgesics, both commercial and compounded, have provided great relief to millions of people, without the expense and adverse reactions associated with oral or injectable pain medications.</p> <p>Commenter indicates that topical analgesic compounds are recognized as legal by the FDA, the Board of Pharmacy, and the Board of Medicine, and are an accepted standard of practice.</p>	<p>R. P. Marshall, R.P. Vital Care Pharmacy of Norfolk December 10, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter is a physician practicing in the field of industrial medicine. After reviewing the proposed changes to the DWC rules wording regarding the use of compounding topical agents, he objects to the wording "not recommended" and "no" evidence...etc..with respect to the effectiveness of compounds. Commenter states that there have been many anecdotal successful treatment outcomes in his, as well as in others, professional practice with</p>	<p>Quynam Nguyen, M.D., December 13, 2008, Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>compounding topical usage. In his field, respectively, the use of compounds has cut down on the usage of narcotic and non-narcotic oral pain pills by at least 25 percent, as a conservative estimate. Commenter has no doubt that this has decreased not only the pharmacy costs but also to the cost of treating the untoward medical and metabolic side effects of oral medications...e.g. liver function abnormalities and GI tract disorders.</p> <p>Furthermore, commenter states that there have been peer-reviewed articles on the use of topical analgesics and anti-inflammatory agents--although few, that have pointed to the efficacy on their use for both acute and chronic pain relief. Commenter opines that compounding topical agents are effective when used properly and as principle or adjunctive treatment for acute and chronic pain syndromes and that they are also cost effective.</p> <p>Commenter requests that DWC re-think its position on this matter, as it will negatively affect on patient care and is that not what the DWC was created to do when it was formed? To look out for the welfare of injured workers and offer them the treatment within standard of medical practice so they may be able to return and be productive at their jobs?</p>			<p>Treatments, Topical, compounds, above.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter has been using these medications for the past several months and has been very impressed with their efficacy. Commenter started out slowly giving samples, but his patient's really responded well and asked for more.</p> <p>Commenter opines that for some reason, utilization review has been running utilization review on the medicine even though he never requested utilization review for the medicine. It makes him wonder if some utilization review companies have done a literature</p>	<p>Peter Gleiberman, M.D. – Orthopedic Surgeon December 8, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>search and have authorized the medication. Commenter states the patient's were very happy. Commenter adds that, however, other utilization review companies have done a review and felt that it was dangerous because there have been one or 2 reported deaths and the FDA told 5 companies [pharmacies] to stop. Commenter opines that the utilization review companies therefore came to a conclusion that compounded medicines should not be given out. Commenter states that it should be noted that the FDA did not prohibit compounding at all.</p> <p>From the standpoint of a treating physician, commenter finds that there is better compliance with the compounded medication then with the p.o. (by mouth) medication. Commenter states that patients that would rather apply an ointment did not take the pill. Commenter notes that many patients are apprehensive about taking additional pills so they do not want to take the medication that they need. Commenter believes that the treating physician should have this as a treatment modality.</p> <p>Commenter has had patients taking pills that have not responded but did respond to the ointments that have been compounded and he is not sure that they could have gotten better without this treatment option. Commenter has also had patients on whom the compounded medication did not work so he cannot claim that it is 100% effective, but feels that he should have the option of using the medication.</p> <p>Commenter points out that some of the utilization review companies have gone through literature and feel that this is an appropriate treatment modality. Commenter states that with all due respect to those utilization companies that feel that it is dangerous, commenter would like to point out that there are over</p>			

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	<p>15,000 deaths per year in the United States just from the use of p.o. (by mouth) anti-inflammatory medication. Commenter states that these deaths are from gastrointestinal bleeding and are not caused by topical compounded medication.</p> <p>Commenter states that any medication that a physician prescribes carries risk. Commenter indicates that as long as physicians are careful and closely follow the patient, then they have been managing that risk in any way that will help the patient. Commenter asks "Is compounded medication risk-free?" Commenter answers, "Of course not" but does state there have been a few deaths and therefore to conjecture that people should not use a medication / is to ignore the fairly significant risk we take with the traditional p.o. (by mouth) medications.</p> <p>Commenter stresses there over 15,000 deaths from gastrointestinal bleeds in United States every year and Commenter does not observe utilization review companies trying to stop the use of Motrin or Naprosyn or Voltaren. Commenter believes that the compounded medication helps patients and that physician should still have the medicine available for those patients that need it.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter submitted a presentation (PowerPoint) for the Division to consider before completing the final draft treatment guidelines for treatment of chronic pain. [A copy is in the complete rulemaking file and is available upon request.]</p> <p>Commenter hopes that the Division's new guidelines indicates for "TOPICAL ANALGESICS, COMPOUNDED" either recommended or no comment at this time.</p> <p>Commenter currently works with pharmacists and</p>	<p>Michael Rudolph, Pharm.D. Executive Director Community Pharmacy Practice USC School of Pharmacy December 3, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>physician practices in creating alternative treatments for pain with resulting increase in positive outcomes for patients and reduction in adverse side effects. Commenter's presentation focuses on the use of topical medications for pain resulting in :</p> <ul style="list-style-type: none"> • Treating the direct source of the pain, inflammation or neuropathy • Avoiding the gastrointestinal tract and side effects. • Providing more immediate relief than oral medications Combining more than one medication in a prescription to optimize therapy • Topical treatment for various neurological conditions especially useful in the Elderly <p>Commenter states that in response to the 2006 incident with 5 compounding pharmacies, commenter believes that this is a regulatory issue for the boards of pharmacy and the profession has reacted accordingly. Commenter opines that this incident should not affect the status of a class of medications that can improve patient care. Commenter points out that there is a reference list in his presentation which has numerous articles regarding the use of topical compounded medications.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter is discouraged to see that there is a push to rid the general population of compounded topical pain medications that improve the quality of life of so many pain riddled patients in the state.</p> <p>Commenter states that the FDA warnings regarding topical anesthetics are taken widely out of context, and were not meant to address use by patients seeking relief from pain. Commenter adds that these patients were self administering high doses anesthetic cream without physician's care. Commenter notes that this reference is over 2 years old and has been addressed numerous times in compounding practices.</p>	<p>Mayank Shah December 10, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter points out that this statement contradicts ACOEM (American College of Occupational and environmental medicine) and distorts the facts. Commenter indicates that the FDA advisory was specifically directed at 5 pharmacies and does not list the specifics of the issue (dosage used) or what was being treated.</p> <p>Commenter states that the use of the addressed compounded agents requires knowledge of the specific analgesic effect of each agent, and how it will be useful for the specific therapeutic goal required. Commenter believes that this statement should be considered a positive support for topical compounded analgesics allowing the physician and pharmacist to create a patient specific treatment plan. Commenter states compounded medications involve an intimate relationship between the prescriber, patient and pharmacist that is predicated on an individual patient's needs and the available science to support the use of a product. The FDA does not prohibit compounding in a pharmacy.</p> <p>Commenter states that the following are the benefits that would be stripped from patients if compounded topical treatments are taken away from patient access:</p> <ol style="list-style-type: none"> 1. Limited systemic side-effects such as drowsiness, sleepiness, NSAID induced ulcers, etc. 2. Higher concentration of drug at site of pain leading to more pain relief and decrease narcotic usage as well as abuse 3. Quicker recovery time, and decreases time away from work. <p>Commenter requests that the Division take the time necessary to listen to patients who have received so much by the use if a compounded topical pain</p>		<p>correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	medication that was designed exclusively for them to meet their pain needs.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter is a compounding pharmacist who has multiple patients receiving topical analgesics for post herpetic neuralgia, rheumatoid/osteoarthritis and general back pain associated with sciatica. Commenter states that these patients have responded very well to topical therapy after being treated with intervertebral steroid injections, opiates, muscle relaxants, anti-seizure medications, etc without any significant improvement in overall quality of life. Commenter states that after the initiation with topical Gabapentin/ketamine/ketoprofen/baclofen, all of these patients have shown rapid increase in mobility, decrease in pain from a 7-9, to a 2-3 on a pain scale of 1-10, 10 being severe pain.</p> <p>Commenter questions how the Division can remove these very useful treatment modalities from a very short list of treatment options for these patients? Commenter states that “We Can Not!!!” Commenter opines that unless the Division can provide documented side effects that caused harm or resulted in a greater risk than benefit to these patients then there is no way we can justify this action!</p>	Mark LeRoy, MD Quality First Compounding Pharmacy December 9, 2008 Written Comments	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.
9792.24.2(a) Chronic Pain Medical Treatment	Commenter opines that DWC’s final draft of the MTUS and its exclusion of compounded medications for the treatment of pain will result in the pain and	Mark Burger, Pharm.D Health First!	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group,	See action taken in connection with comment submitted by Robert Nickell,

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<p>Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>suffering of patients with chronic pain conditions. Topical bupivacaine/lidocaine/tetracaine, transdermal clonidine, piroxicam, ketoprofen, ibuprofen, amitriptyline, gabapentin and others, alone and in combination have improved the quality of life for many of their patients with pain.</p> <p>Commenter states that the reasoning given for this exclusion is spurious, distorted, outdated and outright inaccurate. The transdermal lidocaine death was over 2 years ago and has been addressed. The allusion to the necessity of a prescribing physician having a working knowledge of the analgesics involved is a given. In the traditional “Triad” of physician, pharmacist and patient, the benefits and risks of these therapies are foremost in their collaborations.</p> <p>Commenter states that compounding is a legal activity under FDA and State Law. Commenter request that the Division not let this exclusion become another stone aimed at the venerable and necessary profession of pharmacy and the life-saving practice of compounding.</p>	<p>Pharmacy December 5, 2008 Written Comment</p>	<p>dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	<p>PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics</i></p>	<p>After reading the final draft of the medical utilization schedule (MTUS) for chronic pain treatment, commenter is extremely troubled by the possible ramifications.</p> <p>Commenter states that compounding is a safe, effective, and well-regulated area of pharmacy that has helped numerous patients who do not respond</p>	<p>Marc Gasca, MD December 15, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds,</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
- <i>compounded</i>	<p>well to oral medication therapy. Commenter opines that the physician-pharmacist-patient relationship is at its best using compounded medications that is tailored specifically to fit an individual patient's needs. This "triad" of interaction allows for the best possible outcome for the patient.</p> <p>Commenter would like to stress that pharmacists are EXPERTS in medication therapy and that the pharmacist has specific insight to the effects of each compounded agent and how it will be useful for the specific therapeutic goal required. Commenter opines that if changes are not made to the final draft, thousands of patients will not have the best treatment options available. This may lead to a longer duration of therapy and thus an increase in medical costs.</p> <p>Commenter requests that the Division reconsider the final draft and allow for compounded medications to be recommended agents for patient therapy.</p>		<p>above. Moreover, disagree with the comment that the individual treatment guideline topic of Topical Analgesics, compounded interferes with the “the physician-pharmacist-patient” relationship. Like any other pharmaceutical products, compounded drugs are prescribed pursuant to physician’s orders. Physicians are defined by the Labor Code (Lab. Code, § 3209.3). Licensed prescribing physicians give orders. Pharmacy carry out physician orders. It is beyond the scope of the MTUS to address professional practices, and to expand their scope of practice.</p>	<p>2. Pain Intervention and Treatments, Topical, compounds, above.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics</i> - <i>compounded</i></p>	<p>Commenter states that the removal of compounded medications for patients by the DWC and that the state is moving into a very dangerous zone when it comes to Doctor knowing the patient needs.</p> <p>Commenter opines that this move will ultimately put a burden on the health care industry since not all the patients require the same strength for their treatments. The pharmacists and the doctors know exactly the patient needs hence they know and understand the pharmacology and pharmacodynamics and their benefits of compounded medications. Products that are on the shelf are good but will not cause the same impact as custom made medications for the patients. Since the products that are on the shelf are for general use, commenter opines that they will either cause harm to patients or will not produce the desired effect on people who need them, thus elongating their</p>	<p>Luis Marquez December 15, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, disagree with the comment that the individual treatment guideline topic of Topical Analgesics, compounded interferes with the “the physician-pharmacist-patient” relationship. Like any other pharmaceutical products, compounded drugs are prescribed pursuant to physician’s orders.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recovery status and possibly weakening their health.</p> <p>Commenter states that pharmacy compounding is a long-standing, safe and well-regulated practice that serves the needs of many Americans with unique health requirements which off-the-shelf prescription medicines cannot meet. Commenter adds that state boards of pharmacy, state medical boards, the Food and Drug Administration, the Federal Trade Commission, the Drug Enforcement Agency, and other federal and state agencies each have some degree of oversight over compounding practice. The U.S. Pharmacopeia and the Pharmacy Compounding Accreditation Board also play critical roles. Commenter indicates that together, they have constructed a web of regulations and standards that protect patients.</p> <p>Commenter opines that compounded pharmacies have been inspected by the FDA and different organizations and they all agree that compounded medications in the only way to prevent a burden on the health care. Commenter believes that doctors and pharmacists know their patients and know exactly what they need as these are the people who actually work with the patient on a one to one basis.</p> <p>Commenter states that the division is just using a published by the FDA but not information obtained from actual field studies. Commenter states that this is what makes a difference. One to one relation, doctor to patient, or pharmacist to patient. Commenter states that these people know what it takes and what is needed for the patient to recover.</p>		<p>Physicians are defined by the Labor Code (Lab. Code, § 3209.3). Licensed prescribing physicians give orders. Pharmacy carry out physician orders. It is beyond the scope of the MTUS to address professional practices, and to expand their scope of practice. Further, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines	Commenter would like to raise his strong objection to the California Division of Worker’s Compensation’s (DWC) new policy classifying topical compounded analgesics as “not recommended.” This policy would	L. D. King Executive Director, EVP International	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group,

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<p>Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>deny critical medications to worker’s compensation claimants who may rely on these medications to treat their unique medical conditions.</p> <p>Commenter opines that with this new guideline, the DWC is dangerously inserting itself into the physician-patient relationship, which could have far-reaching consequences for California worker’s compensation claimants. In all cases, physicians work with their patients to determine when compounded medications are appropriate and, if they are, they work with pharmacists to design individualized treatments to meet their patients’ needs – needs that are unmet by off-the-shelf, one-size-fits-all, mass-produced pharmaceuticals. Physicians are uniquely qualified to make determinations about what medications are appropriate or inappropriate for their patient’s therapeutic success. Commenter stresses that doctors often prescribe manufactured drugs. Some doctors, however, determine that those products are inappropriate for their patients and prescribe compounded medications tailored to meet a patient’s individual needs.</p> <p>Commenter states that there are numerous cases each day in which compounded medications are essential to patient health and that a broad sweeping denial of reimbursement of compounded medications has the adverse affect of jeopardizing patient health. For example, if a patient is allergic to a dye or other ingredient in a commercially available drug, a pharmacist can compound the medication without the dye for the specific patient.</p> <p>Further, commenter asserts that pharmacy compounding is a long-standing, safe and well-regulated practice that serves the needs of many Americans with unique health requirements which</p>	<p>Academy of Compounding Pharmacists (IACP) December 10, 2008 Written Comment</p>	<p>Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, disagree with the comment that the individual treatment guideline topic of Topical Analgesics, compounded interferes with the “the physician-pharmacist-patient” relationship. Like any other pharmaceutical products, compounded drugs are prescribed pursuant to physician’s orders. Physicians are defined by the Labor Code (Lab. Code, § 3209.3). Licensed prescribing physicians give orders. Pharmacy carry out physician orders. It is beyond the scope of the MTUS to address professional practices, and to expand their scope of practice. Further, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment</p>	<p>dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>off-the-shelf prescription medicines cannot meet. State boards of pharmacy, state medical boards, the Food and Drug Administration, the Federal Trade Commission, the Drug Enforcement Agency, and other federal and state agencies each have some degree of oversight over compounding practice. The U.S. Pharmacopeia and the Pharmacy Compounding Accreditation Board also play critical roles. Together, they have constructed a web of regulations and standards that protect patients.</p> <p>Commenter states that the DWC rationale on topical compounded analgesics quotes an old FDA warning about potential dangers of compounding topical medications containing local anesthetics. However, with regard to topically applied analgesics that are used in the worker's compensation arena, commenter understands that anesthetics are not the primary agents employed and that, when they are used, it is not at the same concentrations and combinations that were used in the preparations triggering the FDA's warning. Thus, commenter opines that this warning is being applied far outside of its scope. Compounded medications involve an intimate relationship between the prescriber, patient and pharmacist that is predicated on an individual patient's needs. Commenter warns that intervening in the patient-prescriber-pharmacist relationship could have dire consequences for the health of individual patients.</p> <p>Commenter urges the Division to strongly consider and incorporate the comments, evidence and examples that have been submitted by compounding pharmacists and physicians in regard to this section. Commenter would like to stress that as the division promulgates these regulations to consider the implications of the new policy, and to remember that millions of patients have found relief from</p>		<p>outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	

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	compounded therapies that have been prescribed by their doctor and compounded by a licensed pharmacist.			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Topical Analgesics - compounded</p>	<p>Commenter states that the following information is possibly the most important point of all regarding this subject:</p> <p>"Mike Pavlovich, a member of the American Pharmacy Association's Board of Trustees who supports reimbursement for compounded topical analgesics, explained in an e-mail to pharmacists that the purpose of the FDA release was not to discredit compounded topical analgesics, but to denounce pharmacies' mass-marketing of compounds that are not necessarily prescribed by physicians.</p> <p>Pavlovich highlighted the following text from the FDA release:</p> <p>"By contrast, FDA is concerned that the five firms receiving warning letters are behaving like drug manufacturers, not traditional compounding pharmacies, because they produce standardized versions of topical anesthetic creams for general distribution."</p> <p>“***He also pointed out that the FDA's news release was neither evidence-based nor peer reviewed, and is instead a policy statement by the agency. This, Pavlovich contended, conflicts with the DWC's written policy stating that only ‘evidence-based, peer-reviewed research concerning the efficacy of a treatment can be the basis for recommending or not recommending a treatment***.’ ” (Emphasis added.)</p> <p>Commenter states that this letter also pointed out the many benefits of compounded topical analgesics, which include the reduction of the need for narcotic analgesics and a potential overall reduction of</p>	<p>Keith Hunt December 15, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>unwanted side effects and secondary conditions. Commenter criticizes the Division as taking the position of "do as we say, not as we do" -- mandates disguised as guidelines, all based upon non-peer reviewed material, underlying which is anecdotal information generated by a completely different cohort of treaters.</p> <p>Commenter states that if the Division wants to manage the prescriptions of compounded pharmaceuticals, then the Division should create cogent guidelines for their appropriate use, and not just use junk science to cement their opposition to this effective adjunct treatment.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter is an Orthopaedic Surgeon who treats a large Hispanic population. Commenter states that he has numerous patients who respond fantastically to topical medications. Patients who do not respond are discontinued without ill effect. Commenter believes there is a sociological bias in the Hispanic population in favor of the use of "Topicals". Commenter states that to strike them from use in the MTUS just takes away one more non-operative method of treating a large group of patients.</p> <p>Commenter requests that the Division not let big pharmaceutical corporations dictate how he treats patients.</p>	<p>Jonathan Cohen, MD Stanislaus Orthopaedic and Sports Medicine Clinic December 9, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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			outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter urges the Division to reconsider the "not recommended" status for topical compounded analgesics.</p> <p>As a pharmacist, commenter has seen the success and advantages of using compounded medications versus traditional oral therapy. Commenter states that the physician is able to tailor each compounded medication according to each patient's specific needs. He adds that rather than prescribe multiple oral medications for a patient, the physician is able to work closely with the pharmacist in order to produce topical compound medication that suits the patient's needs. Commenter believes that this single medication allows for a higher probability of patient adherence to the medication regimen. Commenter opines that with a greater likelihood of patient adherence, there comes a greater possibility of a decrease in patient recovery time (thus allowing for a decrease in treatment costs). Commenter states that the patient also experiences less side effects with these topical compounded medications. Commenter indicates that a decreased amount of medication enters the blood stream, causing less side effects. From his experience, a patient is more likely to continue treatment if medication side effects are minimized.</p>	John Sempre December 16, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.
9792.24.2(a) Chronic Pain	Commenter is the owner of a compounding pharmacy and has been involved in patient care with this	John K. Hart CPT Inc.	Agree in part. See response to comment submitted by Robert	See action taken in connection with comment

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<p>Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>industry for over 8 years. Commenter understands that there are concerns from the Division’s viewpoint. Although not mentioned, commenter is aware that there are pharmacies that abuse the unregulated system in workers compensation regarding compounding medications and its prices. Commenter urges the Division to make a decision in the interest of patient care, not just a cost based one. Each time he hears from claim adjusters, it is more about the price from other compounding pharmacies, not the product. Commenter states that his pricing is fair and that he is often disgusted at some of the prices that are submitted by other pharmacies making the same products.</p> <p>Commenter states that compounding is a practice of medicine that is recognized by the FDA. Not every pain patient is a candidate for topical creams; however, there are patients that have conditions that may warrant the trial or use of compounded medications. There are studies about topical medications for patients. Commenter has heard stories ranging from his cancer patients to injured worker patients that have had effective relief from compounded medications. They do not have to take as many of their oral pain medications, which improves their quality for life and is cost effective. Commenter challenges the Division to look into the issue further before making a blanket statement that will prevent a payment for compounding.</p> <p>As stated in the Division’s proposed guidelines, "The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required." This statement is a positive support for topical compounded analgesics allowing the physician and pharmacist to create a patient specific treatment</p>	<p>December 9, 2008 Written Comment</p>	<p>Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, disagree with the comment that the individual treatment guideline topic of Topical Analgesics, compounded interferes with the “the physician-pharmacist-patient” relationship. Like any other pharmaceutical products, compounded drugs are prescribed pursuant to physician’s orders. Physicians are defined by the Labor Code (Lab. Code, § 3209.3). Licensed prescribing physicians give orders. Pharmacy carry out physician orders. It is beyond the scope of the MTUS to address professional practices, and to expand their scope of practice. Further, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological</p>	<p>submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>plan. Commenter states that compounded medications involve an intimate relationship between the prescriber, patient and pharmacist that is predicated on an individual patient's needs and the available science to support the use of a product. Commenter point out that the FDA does not prohibit compounding in a pharmacy.</p>		<p>effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter opines that to say that compounds used in topical pain relief is "not recommend" is silly. At University Compounding Pharmacy commenter's organization compounds 10's of thousands of transdermal prescriptions a year and has not had problems with patients. Commenter states that they are extremely effective and many patients have no other choice because manufactured tablets do not work for everyone. Commenter opines that the Division will be doing a great injustice to his patients by not allowing them access to topical transdermal pain relief. In the 15 years he has used them including with the use of lidocaine he has experienced no adverse reactions. Commenter states that manufactures also make topical pain relief including anesthetic medications, so he questions why a topical compound not be recommended.</p> <p>Commenter questions the Division's rational? Commenter believes that the Division is not properly informed. Commenter stresses that the warning from the FDA was for patients using topical anesthetic for cosmetic laser treatment not for pain relief. Commenter requests that the Division not confuse the 2 issues. Commenter requests that the Division look into this thoroughly before hurting patients by removing their transdermal pain relief.</p>	<p>Joe Grasele RPH University of Compounding Pharmacy December 5, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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			outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	Commenter states that compounded pain management products are a valuable tool for prescribers and she believes that if access to these medications is restricted, higher economic burdens on the State and poorer patient outcomes will result. From commenter's professional experience, many manufactured for the control of pain are much more costly and have many more adverse effects than compounded products. Commenter opines that manufacturers have lead payors down the road to higher costs and worse outcomes and pharmacists have a vested interest and community providers to not only provide quality products but to collaborate with prescribers to find products that will work for each patient's particular ailment. Commenter strongly urges the Division to continue to support compounded medications as treatment alternatives for your covered lives.	Jodi Ettare, Pharm.D. Valley Compounding Pharmacy December 9, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT,	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			see strength of evidence). Further, disagree with the comment that the MTUS regulations are intended to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Topical Analgesics - compounded	<p>Commenter is concerned that this proposed draft would effectively remove the option of utilizing custom compounded medication for treatment patients.</p> <p>Commenter states that two separate NSAID formulations have entered the market in the past year (Flector and Voltaren Gel), and topical lidocaine (Lidoderm) has been used for several years. Claims for these agents have seldom raised any objection to their appropriateness.</p> <p>Commenter has been prescribing compounded medications for patients for several years and has found the results to be positive for helping to relieve, and in many cases, resolve, the symptoms related to the injuries sustained by patients.</p> <p>Commenter states the need to have a skilled and capable compounding pharmacist to prepare patient-specific therapies often arises in his practice. Having the option to employ a formula that may improve</p>	James P. Tasto, MD Rina Jain, MD Steven Tradonsky, MD Jonathan J. Myer, MD San Diego Sports Medicine and Ortopaedic Center December 10, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

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	<p>compliance, reduce unwanted side effects, eliminate or reduce the need for narcotic analgesics, and possible reduce the number of medications necessary to treat secondary conditions as well is practical necessity. Commenter states that the limited array of commercial formulations to address the specific needs of his patients often fall short in many regards.</p> <p>Commenter states that topical analgesic compounds of many types have been used effectively by orthopedists and pain management specialists for workers' compensation patients, and by physicians in many areas of specialty practice, including hospice, sports medicine, neurology, and rheumatology among others. Commenter opines that to dismiss topical analgesic compounds as "not recommended" is extremely short-sighted and unfair. Commenter states that there is a wealth of clinical data to support their proper utilization. Commenter can provide a litany of peer-reviewed, evidence-based studies to support his assertions. While there may be several cases of ill-advised treatment and fatal results stemming from over-administration of high potency local anesthetics, commenter states that the number of annual fatalities due to oral administration of NSAIDs or narcotics is far greater in magnitude.</p> <p>Commenter continues that orally administered NSAIDs also are implicated in causing serious GI complications that greatly impact morbidity and mortality. It is estimated that the mortality rate of patients who are hospitalized specifically because of NSAID-induced upper GI bleeding is approximately 5% to 10%. Topically administered NSAIDs have demonstrated systemic block levels as little as 5% of those administered orally while local issue concentrations can be considerably higher.</p>		<p>effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence). Although commenter submits that "there is a wealth of clinical data to support their proper utilization ... [and] can provide a litany of peer-reviewed, evidence-based studies to support his assertions," commenter has not submitted this evidence with his comment.</p>	

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	<p>As a qualified and board-certified treating physician, commenter fully expects to utilize all lawful and recognized therapeutic means available for the benefit of his patients. Commenter stresses that topical analgesic compounds are recognized as legal by the FDA, the Board of Pharmacy, and the Board of Medicine, and are an accepted standard of practice.</p> <p>Commenter strongly urges reconsideration of the proposed guidelines and calls for full reinstatement of the use of compounded topical analgesics as an accepted treatment modality.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter objects to the proposed language of the draft for medical treatment utilization schedule (MTUS) for chronic pain medical treatment guidelines. Commenter is a pharmacist and has seen the benefits of compounded topical analgesics from the patient's point of view and the physician's point of view.</p> <p>Commenter states that topical compounds are recognized as legal and as an accepted standard of practice by the FDA, Board of Pharmacy, DEA, and Board of Medicine. Commenter opines that every physician should fully expect to utilize any and every lawful and recognized prescription based treatment available to ensure the most appropriate treatment for their patients. Commenter adds that often, these patients cannot tolerate the debilitating and potentially dangerous side-effects of many oral meds. Commenter indicates that they are too caustic on the GI tract and others have potential for addiction or worse. Commenter states that topical analgesics give the physician a choice in treatment to help these patients.</p> <p>Commenter opines that to simply say that Topical Compounds are "not recommended" based upon a two</p>	<p>Christine Givant R.Ph December 8, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, the Labor Code requires the guidelines set forth in the MTUS be evidence-based as they are presumptively correct by statute. (Lab. Code, §§ 5307.27, 4604.5(a).) Also, the Labor Code requires that the medical treatment provided to injured workers be "based upon the guidelines adopted by the administrative director pursuant to Section 5307.27." Given that topical drugs are not expected to work in the same way as orally or parenterally administered drugs, efficacy for topical agents cannot be extrapolated from data when the same agent is given by another</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>year notice by the FDA with regards to inappropriate use of lidocaine by Med Spas, and to further state, that there is little to no evidence to a plethoric list of ingredients is disingenuous to say the least.</p> <p>Commenter states that there are many evidences based peer reviewed articles to substantiate the choice of a physician to work with an experienced compounding pharmacist to create a customized treatment plan to ensure the best possible outcome for the patient. Physicians with 10-12 years of medical school and specializing in a specific area of medicine know what is best for their patients. Commenter state that compounding is what pharmacy is based on and was started from and continues to be cutting edge care to expedite healing and potentially cut costs.</p>		<p>route. In order to meet the requirements of the statute, topical agents are not excluded from evidence-based review. Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment.</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter was recently informed that there are new guidelines being made regarding discontinuation of the use of compounding medications for the Worker Compensation patients.</p> <p>Commenter was very surprised to hear that, since he has been using these on my patients with great deal of success. Commenter states that as a Hand and Upper Extremity surgeon, he routinely uses the Ketoprofen/gabapentin/capsacin on his patients with pain around their hands and wrists, he can confidently say it relieves their pain in 70-80% of the time, allowing them to remain at work and perform their work duties. Furthermore, they take less oral NSAIDS, which can potentially cause gastric ulcers. Commenter adds that patients who already cannot take oral NSAIDS secondary to gastric ulcers or erosions are the perfect candidates for these compounding medications.</p>	<p>Christopher A.Zahiri, M.D. Orthopedic Hand and Upper Extremity Surgery December 21, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>Commenter hopes that the committee will reconsider making a change in this policy, as it will be a significant detriment to the care of the injured workers.</p>		<p>are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>In reading the latest draft, commenter believes there is important information that was not taken into account when the research was being conducted for the base of the Department of Workers Comp recommendation. Commenter requests that the Division please consider the following points and refer to the attached literature in regards to the use of compounded topical analgesics. Commenter believes that it will help fill in the gaps in the research...</p> <p>* The draft discussion focuses on a "recent FDA warning about potential dangers of compounding topical medications containing local anesthetics."</p> <p>This reference is over 2 years old and has been addressed numerous times in compounding practices. This statement contradicts ACOEM (American College of Occupational and environmental medicine) and distorts the facts. The FDA advisory was specifically directed at 5 pharmacies and does not list the specifics of the issue (dosage used).</p> <p>* The draft discussion states "The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will</p>	<p>Cort Colbert Western Pharmaceutical Management Office December 9, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, ODG has conducted its own evidence-base review, and has updated its individual treatment guideline topic on <i>“Topical Analgesics, compounded.”</i> ODG has updated this guideline based on its evidence-based review findings which meet the evidence-based requirements of the statute. In order for commenter’s submitted studies to be included in the guideline, they have to meet the evidence-based criteria. If they are not included in the evidence-based review, they do not meet this criteria.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>be useful for the specific therapeutic goal required."</p> <p>This statement should be considered a positive support for topical compounded analgesics allowing the physician and pharmacist to create a patient specific treatment plan. Compounded medications involve an intimate relationship between the prescriber, patient and pharmacist that is predicated on an individual patient's needs and the available science to support the use of a product. The FDA does not prohibit compounding in a pharmacy.</p> <p>To aid in completed research, commenter attached brief articles from Compounding Education Resource in regards to compounded topical analgesics. [Note: These articles are a part of the official rulemaking file and are available for inspection upon request.]</p> <p>Their website is (www.compoundingeducationresource.org) and contains a complete library of articles addressing compounds.</p> <p>In his conversations with physicians and patients commenter has only heard positive reactions to their use. Commenter believes that the Division is incorrect in its statements used for the draft Medical Treatment Utilization Schedule (MTUS), and all the research he has come across in his career supports their use (especially when compared to oral medications).</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics</i></p>	<p>Commenter is a practitioner who states that the Division is misinformed because of not recommending topicals. Commenter opines that this is an egregious error that will deny appropriate patient care. Commenter states that topicals improve compliance, bypass potential GI problems and allow better participation in therapeutic exercise regimens.</p>	<p>Daniel Capen, MD December 9, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds,</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part</p>

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- <i>compounded</i>	<p>Commenter speculates that insurance carriers - who are reaping profits and perhaps raping individual injured workers with the fact that essentially they are making all the rules - simply ignore a body of evidence in support of topicals when it seems inconvenient to them. Commenter urges the Division reformulate the position on topicals which he states are of significant benefit to patients.</p>		<p>above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence). Further, disagree with the comment that the MTUS regulations are intended to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured</p>	<p>2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter states that this issue is about access. Topical Compounded creams are an alternative to treating pain. Commenter is a Compounding Pharmacist and has had a number of success stories when treating patients with topical Ketamine, Gabapentin and Ketoprofen. Commenter stresses that the proper strength of the creams must used in order to get a therapeutic response. Commenter states that there is a study that compares Ketamine 1% and Amitriptyline 1-3% to placebo. In one study it showed no significant difference. Commenter states that the prescription topical creams he makes are stronger and do make a significant difference to his patients. Commenter questions if the real question here is cost of care? Are practitioners over charging for their prescriptions or is this about market share?</p> <p>Commenter questions if the Drug Companies competing with the Compounding Pharmacists for market share? Commenter points out that there seems to be a number of new Brand products out in the market place: Lidoderm Patch, Flector Patches and Voltaren Gel. Commenter states that there is no question that topical pain creams and patches work. Commenter states that compounded creams are very effective but do not have a long expiration date, generally about 180 days. Patients are only given a 30 day supply. Many of the patients using these creams are taking or have taken many Oral Pain Medications such are Oxycontin, Methadone, or Morphine. Commenter points out that Oxycontin is very expensive and costing the Workers' Compensation system Millions of dollars. Commenter states that many of his patients have been able to wean themselves off of the oral pain meds to lower doses by using alternative topical pain creams.</p>	<p>Dr. David Smith December 18, 2008 Written Comment</p>	<p>workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b).</p> <p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence). Further, disagree with the comment that the MTUS regulations are intended to control costs associated with</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>Commenter requests that the Division not take access away from patients by not paying for Topical Compounded pain creams.</p>		<p>medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b).</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter is a certified orthopedic surgeon in practice for 32 years and has never found a product with as much pain relief and so few complications and side effects as he observes with the use of topical analgesic compounds. Commenter has over 400-500 patients using topical GKL(gabapentin, ketoprofen and lidocaine). Commenter has only had one patient experience a slight rash. All of the other patients find a great deal of relief and love the product. Commenter personally uses it twice a day to relieve the pain his hands and neck following complications of cervical spinal surgery. Commenter opines that it would be a travesty to allow this compounded topical analgesic medication to be withheld from patients. The dosage is known and can be adjusted. The side effects are nil. Commenter states that the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The topical lidocaine numbs the area, the ketoprofen decreases the inflammation and the gabapentin decreases the nerve responses thereby decreasing the perceived pain. Commenter has compared GKL to the FDA approved Voltaren Gel and finds that the GKL works better. Commenter has also compared the GKL to FDA approved Lidoderm patches and finds the GKL works</p>	<p>Elliot Gross, M.D. December 18, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	better. Commenter requests that the Division not succumb to insurance company pressure and take this effective therapeutic treatment away from our workers compensation patients.		Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter is disappointed with the Division’s decision to label compounded medications as “not recommended” for patients experiencing pain from work related injuries. Commenter would like to point out that other practices such as Chiropractics and Acupuncture which at some point in time were deemed as little more than quackery? Today, these practices are regarded as viable alternatives for pain in the medical community and millions of people have found the answer to their pain related conditions with the help of these once denounced practices.</p> <p>Commenter opines that real question here is “what is really being challenged? Is it the medications? Is it the compounds or the manner in which the medication is delivered to the affected area?” Commenter states that looking at the active ingredients in many of the compounded medications it should be obvious that much of the medicines found in prescription compounds have been in use for quite some time and he opines that what is really being questioned here is the delivery method of the medications.</p> <p>Commenter opines that those opposed to compounded medications, specifically compounded creams, would argue that this type of delivery method may cause any number of unwanted or undesired side effects. Commenter offers the example the tried and true orally delivered method wherein a patient takes a pill every few hours. Commenter opines that everyone has heard many times over the unwanted and</p>	Eric Cervantes Rx Financing December 12, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that Topical analgesics must be distinguished from transdermal agents. Topical drugs work near or on the surface, place, or location where the agent is applied. This is different from transdermal drugs which enter the body through the skin but are expected to cause a systemic effect throughout the body, far beyond the surface, place, or location where the agent is applied. Oral and parenteral (intravenous, subcutaneous, or intramuscular) administration of drugs is generally expected to produce a systemic effect, i.e. an action that is delivered to the whole body. The site of action for pain drugs is often in the nervous system (spinal cord or brain) and far away from the site of injury. Therefore a systemic drug effect is	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>undesirable side effects of many of these oral pain medications; for example “addiction” and not to mention “overdose”, “gastric upset”, “violent allergic reactions” and “death” yet no one mentions these as issues when it comes to treating patients. Commenter continues that not only do many medications carry these side effects but they also tend to make the patient slow, lethargic and unable to operate machinery, drive a car or be focused and alert.</p> <p>Commenter opines that this is quite contradictory to the goal of returning the patient back to work as quickly and efficiently as possible. Commenter states that while it may be true that compounded creams may have some undesired side effects in SOME individuals just like oral medications have some side effects for SOME individuals; the difference is that while a patient is using compounded creams, they remain alert and focused because the medication is only applied to the affected area leaving the brain and other organs virtually unaffected by the mind numbing effects of some of the more popular anti pain medications.</p> <p>Commenter questions if this seem like a novel idea for workers’ compensation? A method in which a patient gets relief from their pain yet does not suffer the more common side effects of many of these orally introduced medications such as lethargy, sleepiness and mind numbing? Commenter questions why the Division is considering removing a tool that could help doctor’s better treat millions of injured workers whose only desire is to get back to work as quickly as possible?</p> <p>Commenter points out that the actual practice of compounding has been in use since the first pain medication was introduced to the public. Commenter</p>		<p>necessary if the mechanism of action involves the nervous system. Since the purpose of transdermal drug delivery is intended to have a systemic effect, transdermal agents should act similarly to an orally or parenterally administered drug. Topical agents, on the other hand, are expected to have a desired action that is local at or near the surface of the skin where the drug is applied. Drugs that work by mouth may not work when applied directly to the skin because the target of the drug effect may not be nearby under the skin. Therefore, each topical agent must be tested for effectiveness because the hypothesis is that the mechanism of action is local and clinical efficacy needs to be proven. (Note that there are hypotheses that for some topical agents the mechanism of action might involve a retrograde transport to act more centrally). Thus NSAIDs are more likely to have a local effect, but anticonvulsants such as gabapentin is more likely to have a central effect.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>states that compounding is exactly what the first pharmacists used to do; a patient would bring a prescription to a pharmacist and that pharmacist would then compound that medicine into whatever form the doctor requested on his prescription whether that be an injectable, topical or oral concoction.</p> <p>Commenter stresses that compounds are not “new”; the art of compounding has been around since the beginning of pharmaceutical practice. Commenter opines that it would be folly to completely disregard a different delivery method simply because it is not a pill.</p> <p>Commenter requests that the Division not judge what could potentially be a very practical and useful tool for doctors to treat patients in a fast, efficient way based on outdated and under funded research; but instead focus a little more research before a hasty decision is made.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter represents a practice of ten orthopaedic surgeons who prescribe topical compounded analgesics to their patients. These medications are prescribed with the same indications and thought processes that any other medications are given. Commenter has found these medications to be especially beneficial to patients who want relief at a specific body part and do not want to medicate their entire system. Further many patients do not want to experience systemic effects from the additives in oral medications. Commenter observes daily the benefit that topical compounded analgesics provide to their patients. Commenter opines that to refuse to pay for this alternative or take this treatment regimen away from patients would be an uncaring and cruel act. Commenter requests that the Division reconsider its position and allow physicians to decide the best course of drug therapy for their patients.</p>	<p>Frank J. Martelli, RRT, MBA Administrator Orthopaedic Specialists of North County, Inc. December 9, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter believes that eliminating the ability of physicians and pharmacists to dispense topical analgesics due to "lack of knowledge" is incomprehensible and irresponsible.</p> <p>Commenter observes the benefits every day in patients being able to apply these preparations topically directly to the painful area and avoiding having to swallow a higher dose that is then partially broken down in the stomach and possibly causing side effects that are not seen by local topical application.</p>	Gene Samborsky, MD December 16, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

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			required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>As a pharmacist and a patient who uses compounded topical medications, commenter believes that topical compounded medications provide alternatives for patients in whom first-line agents have failed or cannot be used. Commenter states that compounded topical agents avoid having to be metabolized by the liver and it also bypasses the stomach thereby avoiding many of the side effects associated with oral medications. Commenter states that for example, oral NSAIDs have a potential for causing stomach bleeding which will require treatment with more medications such as H2 blockers or PPI – worst case scenario a patient may need to be hospitalized to treat the stomach bleeding – all these things will increase treatment cost. Commenter states that in contrast, topical medications avoid having to go through the gastrointestinal tract and therefore have no effect on the stomach. Commenter indicates that compounded topical agents work by the drug concentrating at the site of application therefore there will be less drugs in the patients’ blood and more drug in places where it needs to be – this will decrease side effects and also increase patient compliance to the medications.</p> <p>Commenter states that the warnings about the potential dangers of compounding topical medications that contain local anesthetics have been addressed</p>	Gul Khwaja, PharmD December 11, 2008 Written Comment	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

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	<p>numerous times in the compounding practice and this particular reference is over 2 years old. Commenter states that it is true that compounding requires knowledge of the analgesic effects provided from each agent. Hence, pharmacists are in the front lines in coming up with formulas and making sure physicians and patients are informed with the effects and outcomes with the compounded medications. Commenter adds the FDA does not prohibit compounding in a pharmacy. Commenter believes that compounded topical agents play a very vital role in pain management. Commenter has patients who tell him how great topical NSAIDs that he has compounded for them have worked and how they are able to entirely stop taking oral pain medications.</p>		<p>outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter is an Orthopaedic Surgeon doing Workman's Compensation Complex shoulder surgery for the past 38 years. Commenter is impressed with the pain relief obtained in his patients with selective compounding drugs containing analgesic and anti-inflammatory medications and that his patients tolerate these drugs much better than the oral meds and the side effects are less. Commenter has not seen any dangers from using local anesthetics in these drugs. The FDA warning about the dangers of compounding local anesthetics is over two years old and contradicts the SCOEM advice.</p> <p>Commenter states that the use of these compounding drug combinations enables the treating physician to create a specific treatment plan for patients based on the patient's individual problem and needs.</p> <p>Commenter indicates that in his practice, these compounding medicines are safe and effective. Every day patients thank him for the relief they obtain from these meds without the side effects.</p>	<p>James C. Esch, MD Orthopaedic Surgeons of North County December 14, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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			required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>As an orthopaedic nurse practitioner, commenter sees many patients with musculoskeletal injuries associated with both acute and repetitive injuries. Many of these patients recover to some degree and are able to return to work, often at the same activities that caused their injury.</p> <p>Commenter finds that the use of topical analgesics has proven invaluable for many of his patients for a variety of reasons, including:</p> <ul style="list-style-type: none"> - underlying medical conditions such as gastrointestinal, kidney, or neurological problems for which oral medications are contraindicated - inability to tolerate particular side effects of oral medications - concern about long term systemic side effects of oral medications used for chronic pain - preclusions from using oral medications which interfere with the ability to drive or use machinery - history of substance abuse which contraindicates use of narcotics <p>Commenter states that careful assessment of each patient's situation, their condition, medical history, and prognosis is the first step in developing a treatment plan that will allow them to return to their highest level of comfort and function. Commenter adds that the second step is considering all of the</p>	<p>A.J. Benham Warbritton & Associates December 15, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>treatment alternatives available and working with the patient to design a program that best fits their needs.</p> <p>Commenter states that based upon his 10 years of experience working with this population, it is his opinion that eliminating an effective delivery system for medications that would otherwise be unavailable to a large number of patients will only serve to keep many of them from successfully returning to work. Commenter strongly recommends that the proposal to limit or eliminate reimbursement for topical medications be withdrawn.</p>		<p>environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter states that topical analgesics are needed by patients and that the selection of the topical analgesic should be left to the discretion of the physician who best knows the individual patient. Commenter believes that anytime a physician determines that a product is needed by a patient, the physician should first consider those products that are commercially available. This is applicable to all products, including topical analgesics. Commenter indicates that there will be occasions when a manufactured product will not work for a specific patient. In that occasion, commenter states the physician should have the prerogative of ordering a compounded preparation. Topical analgesics should not be excluded from this process.</p> <p>Commenter states that physicians are trained to diagnose and prescribe and that he/she is the only person who knows the patient and what product should be prescribed. Commenter opines that in the final draft medical utilization schedule (MTUS) for chronic pain treatment recently published by the Division of Worker's Compensation (DWC), the Division is inserting itself into the physician-patient relationship and that this is a dangerous precedent.</p>	<p>William Blair, M.D. December 15, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment.</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>Commenter states that compounding is a long-standing, safe and well-regulated practice and is recognized by every state and the federal government. Compounding serves the needs of many Californians with unique health requirements which off-the-shelf prescription medicines cannot meet. Commenter strongly urges the Division of Worker's Compensation to not disrupt this process by denying patients the use of topically, compounded preparations.</p>		<p>Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence). Moreover, disagree with the comment that the individual treatment guideline topic of Topical Analgesics, compounded interferes with the “the physician-patient” relationship. Like any other pharmaceutical products, compounded drugs are prescribed pursuant to physician’s orders. Physicians are defined by the Labor Code (Lab. Code, § 3209.3). Licensed prescribing physicians give orders. Pharmacy carry out physician orders. It is beyond the scope of the MTUS to address professional practices, and to expand their scope of practice.</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Under the subtitle, <u>Compounded Formularies: Recommendation</u>, commenter states that she is concerned with the issue of pharmaceutical "compounding" and its practice in the treatment of injured workers. Since the initial public comment period, the use (actually misuse, in commenter’s opinion) of compounding has grown ever-greater; and, thus, she respectfully proposes that the DWC take this opportunity to further address the issue of compounded formularies (in general) in the MTUS/Chronic Pain Guidelines by outlining under what, specific, conditions compounding is deemed beneficial, or recommended (as supported by evidence-based reviews), and pointedly</p>	<p>Denise Niber-Montoya, Sr. Claims Adjuster Contra Costa County Risk Management December 9, 2008 Written Comment</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Further, disagree with the comment that the MTUS regulations are intended to control costs associated with medical treatment. Issues related to costs are properly addressed by medical</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommending against pharmacist compounded formularies* [<i>* In referring to "pharmaceutical compounding" and "pharmacist compounded formularies," Commenter is specifically discussing formularies that are custom-compounded by pharmacists (or pharmaceutical labs), as distinguished from readily-available (OTC or prescription) manufactured products, and FDA approved medications, such as Vicodin (which is, technically, a "compounded" medication).</i>] in all other instances.</p> <p>Under the heading, <u>Background / Reasoning</u>, commenter states that the Chronic Pain Guidelines address the issue of compounding as it relates to topical analgesics (use of compounded topical analgesics are "not recommended", Pg. 117); but the MTUS is silent concerning the issue of other pharmaceutical compounding, and silent on the appropriate use of compounded formularies, in general. Commenter applauds the DWC for addressing the issue of compounding as it relates to topical analgesics, but she respectfully submits that, in order to fully carry out the mandate of LC 5307.27, the DWC needs to go further.</p> <p>Commenter observes that since the inception of the Pharmaceutical Fee Schedule, claims administrators are seeing occupational treaters dispense various compounded formularies, topical and oral (topical analgesics; topical anti-inflammatories; compounded capsules [capsules that combine two {or more} prescriptions, or a combination of prescriptions and supplements, into one capsule]; and co-packaged medical foods and drugs ["co-packs" of a conventional generic pharmaceutical compounded with a proprietary medical food]).</p>		<p>fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” (Lab. Code, 4604.5(b).)</p> <p>Regarding commenter’s request that the DWC consider that the MTUS include recommendations on the appropriate use of compounded formularies other than for topical analgesics, DWC will consider additional areas as suggested by the commenter when reviewing and updating the MTUS via formal rulemaking in the future.</p> <p>With regard to the issue of medical foods, The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. The issue was raised during the 45-day comment period, and was appropriately addressed in the 45-day comment period chart. Medical foods were deleted from the chronic pain medical treatment guidelines as adapted from the October 23, 2008 ODG version. (See, 1st 15 Day Notice, Appendix</p>	

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	<p>Commenter submits that compounded formularies (topical and oral) have become "commonly" used in workers' compensation, and, as such, the use of compounded formularies needs to be ("shall be") addressed.</p> <p>Under the subtitle, <u>Proof Source for Assertion that Compounded Formularies are "Commonly" Used in Workers' Compensation Treatment</u>, commenter states that she requested that Comprehensive Industrial Disability Management (CID Management)** [** Commenter states if needed commenter can provide, outside this public forum, the contact (source) who can attest to the accuracy of this data] , to supply data. CID Management reviewed treatment requests from November 2008 (a sampling of 500) from a client whose practice is to submit all requests to formal utilization review. Commenter states that of that sampling, compounded formularies (topical and oral) represented 6.7% of all treatment requests. (2% of all treatment requests were for compounded oral formularies.)</p> <p>Commenter believes that the data offered supports her assertion that compounded formularies are, indeed, "commonly" used in workers' compensation." As such, commenter believes that it would appear that Labor Code section 5307.27 mandates that compounded formularies (topical and oral) be addressed in the MTUS/Chronic Pain Guidelines. [Note: the data submitted by commenter is part of the official rulemaking file and is contained in her comment but not summarized in this chart.]</p> <p>Under the subtitle, <u>the Scheme of Compounded Formularies</u>, commenter states that she recognizes the benefit, necessity and legality of compounding as a part of the pharmacist's role, based on the specific</p>		<p>A1, November 2008, pp. 15-16.)</p> <p>Regarding the comment relating to "Co-packs," see response to comment submitted by Elisa Gottlieb, dated December 16, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Nutritional Supplements, above.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>needs of particular patients. Commenter indicates that pharmaceutical compounding is an important practice for many patients who cannot take traditional medication such as pediatric patients, hospice patients, and patients with allergies to common dyes and fillers.</p> <p>Commenter believes that what is going on in our workers' compensation system is, by and large, the illegitimate use of compounding -- an inappropriate use driven by the profit it generates, as opposed to specific patient need. Indeed, compounding has come under increasing regulatory scrutiny over the past ten to fifteen years due to risks involved in the practice. Commenter states that the indiscriminate use of pharmaceutical compounding by numerous occupational treaters is a practice that elevates provider profit above patient care.</p> <p>Commenter believes that the "players in the compounded scheme" are the compounding pharmacists, the intermediaries and the industrial physicians-- all of whom get a substantial piece of that rich, compounded "pie." Commenter states that it starts with the compounding pharmacist (or pharmaceutical lab) that produces (often, mass-produces) the compounded meds ... who then mass markets to (through) various channels (including "billing services")... Commenter states that the compounded meds are then supplied to the real drive behind the industry: the industrial treaters who dispense at will to their work comp patients. Commenter indicates that the real "compounding" is in the billing-- with medications being billed up to 1000% higher than need be if the sole goal were patient care and medical necessity (as opposed to lucrative profit). Commenter states that there is "profit" in this scheme, but questions whether there is</p>			

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	<p>a benefit to the injured worker and to our workers' compensation system.</p> <p>Commenter states that those involved in the scheme of creating and dispensing meds that fall outside the Pharmacy Fee Schedule (compounded creams, compounded capsules and medical food "co-packs") are essentially thumbing their collective noses at the noble intent of both SB899 and the Pharmacy Fee Schedule. Commenter believes that one just needs to look at http://www.OccMeds.com to glean the intent of these "billing services. " Commenter states that OccMeds.com specifically markets Physician Therapeutics' (tm) "medical foods and drugs," but marketers and "billing services" associated with compounded topicals and compounded capsules are most certainly no different in their objective.</p> <p>Commenter states that at the OccMeds.com website you will find the caption (next to the picture of a smug-faced, white-cloaked, physician lookalike) that reads, "I win!"... There you will also find a telling graphic: A pill bottle... filled with money! (Commenter thanks to OccMeds.com for making obvious what every astute claims examiner already knows: Profit, not patient care, is the primary drive behind physicians dispensing meds that fall outside the Pharmacy Fee Schedule.)</p> <p>Under the subtitle, <u>Medical Safety & Efficacy Concerns</u>, commenter urges the division to read Dr. Bouts' article over viewing the legitimate and questionable uses of pharmaceutical compounding, and his reasons for concern. http://www.quackwatch.org/01QuackeryRelatedTopics/compounding.html</p> <p>Commenter states that a review of the FDA's website</p>			

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	<p>will support Dr. Bouts' assertions. Commenter indicates that as Dr. Bouts points out, the FDA requires manufacturers to meet stringent quality control measures. Commenter indicates that compounded formularies, however, may vary significantly in dosage and absorption characteristics, with no independent check of quality or variation.</p> <p>Commenter states that in 2003, the US General Accounting Office concluded,</p> <p>"While drug compounding is important and useful for patient care, problems that have occurred raise legitimate concerns about the quality and safety of compounded drugs and the oversight of pharmacies that compound them." [Heinrich J. "Prescription Drugs: State and Federal Oversight of Drug Compounding by Pharmacies." GAO-04-195T, Oct., 23, 2003]</p> <p>Commenter states that it can be argued that all compounded formularies are new drugs-- newly created (as in "compounded") drugs that are not FDA approved or regulated. Since such formularies are not subject to the stringency and scrutiny afforded manufactured (FDA approved and regulated) products, they should be used with discretion, employed only when absolutely necessary. Commenter states that at its worst, compounded medications have been tainted, they have caused harm, and, at times, even death. [See FDA Warning Letters- FDA website]</p> <p>Under the subtitle, "<u>Medical Foods</u>" & "<u>Dietary Supplements</u>," commenter states that one could argue that the contours of the statutory definition of "medical foods" -- as defined in Section 5(b) of the Orphan Drug Act -- have long been blurred. In light of</p>			

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	<p>this, the FDA has provided some guidance concerning products that fall within this category. [http://www.cfsan.fda.gov/~dms/medfguid.html]. Commenter states that the issue of what constitutes a "medical food" is an important one since medical foods are exempted from nutrition and labeling requirements. Commenter adds that medical foods are also exempted from the labeling requirements for health claims and nutrient content claims.</p> <p>Commenter states that since the Workers' Compensation Fee Schedule seemingly limits the reimbursement of "dietary supplements" to very specific conditions, *** [<i>*** "Dietary supplements such as minerals and vitamins shall not be reimbursable unless a specific dietary deficiency has been clinically established in the injured employee as a result of the industrial injury or illness."</i>] [8 CCR Sec. 9789.11(a)(1), eff. 7/1/04], the AD may believe that the use of "medical foods" has already been sufficiently addressed by the Fee Schedule, and, therefore, need not be specifically, and comprehensively, discussed in the MTUS. Commenter disagrees.</p> <p>Commenter states that as with everything in our system, too much is subject to interpretation (and arguments over semantics). Commenter states that the manufacturers/marketers of Physician Therapeutics' (tm) "co-packs" argue that their products are <i>not</i> "dietary supplements," but are instead "convenience packed medical foods and drugs." Commenter adds that these co-packs can be viewed as "compounded" formularies in that they contain a prescription generic that has been combined with a proprietary "medical food."</p> <p>Commenter states that the proprietary (trademarked)</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>medical foods "Theramine" (NDC 68405-10-0803) and "Gabadone" (NDC 68405-10-0402) are listed in the Medi-Cal database-- with a very hefty charge. "Theramine" and "Gabadone" are packaged along with generic pharmaceuticals (co-packaged and distributed by Physician Therapeutics. (Commenter indicates parenthetically, these packaged products are labeled with NDC's that are not found in either the Medi-Cal database or the NDC database available online, causing one to wonder if these are valid NDC numbers. But that level of understanding is beyond commenter's scope of expertise).</p> <p>Under the subtitle, <u>"Theramine" and "Gabadone" (TM) & "Convenience Packed Medical Foods and Drugs" (aka "Co-packs")</u>, commenter states that the industry is commonly seeing "Theramine" and "Gabadone" utilized (as ingredients in the "co-packs" previously mentioned). Commenter states that these proprietary "medical foods" are co-packaged with prescription pharmaceuticals and marketed under various trademarked names, common ones seen being "Theracodophen," "Therafeldamine," "Theratramadol," "Gabitidine," and "Prazolomine."**** [**** If needed, commenter will gather data concerning the billing (and, therefore, the utilization) of these co-packs.] (Reference: http://OccMeds.com and http://PhysicianTherapeutics.com for a comprehensive list of all "co-pack" products by Physician Therapeutics).</p> <p>Under the subtitle, <u>Recommendation</u>, commenter recommends that the appropriateness of both "medical foods" and "dietary supplements" be thoroughly discussed. Commenter respectfully recommend that the MTUS/Chronic Pain Guidelines address: "Dietary supplements"; "Medical foods" in general; The</p>			

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	<p>appropriateness of the specific medical foods; "Theramine" and "Gabadone"; and The efficacy and appropriateness of "convenience packed medical foods and drugs."</p> <p>Under the subtitle, <u>Addressing Patient Need as It Relates to Compounded Formularies</u>, commenter opines that the use of compounded formularies should be the exception, not the rule. Commenter states that when an over-the-counter or prescription formulary exists that meets the patient's needs (whether in monotherapy or polypharmacy), that formulary (or formularies) should be employed instead of a compounded med. Compounding should be done based on patient need, not a treater's practice-- as this is the only legitimate, appropriate, use of compounded formularies. Commenter opines that codifying this basic tenet would help ensure treater, and prescription, integrity.</p> <p>Under the subtitle, <u>QUERY</u>, commenter raises the following questions: "Other than for legitimate care-based reasons, why should our workers' compensation system condone a practice that allows treaters to indiscriminately prescribe and dispense non-FDA approved, and non-FDA regulated, drugs?; "Why should injured workers be treated as a class of patient that does not require the same care and protection that nonworkers' compensation patients enjoy?" and "Why should our system allow providers to place provider profit above patient care?"</p> <p>Under the subtitle, <u>RECOMMENDATION</u>, commenter urges the DWC to address the utilization of compounded formularies, specifically delineating the (limited) appropriate medical reasons for their use. Commenter request this for the betterment of our system -- for the integrity of provider treatment and</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the drugs they dispense, and for the protection of our injured workers.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical analgesics – Compounded [DWC]</i>	Commenter supports DWC’s proposal that topical compounded analgesics are not recommended. A claims administrator still has the ability to consider authorization for these types of treatments where medical necessity is demonstrated by the requesting physician with nationally recognized scientific evidence.	Marie W. Wardell Claims Operations Manager – State Compensation Insurance Fund December 18, 2008 Written Comments	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	Commenter are patients that currently uses topical compounded analgesics for pain and experiences great relief where oral medication has failed. Commenters strongly urge the Division to find other ways to manage the costs of compounded medications and allow quality providers to continue to prescribe these medications as an alternative to appropriately treat pain.	Arthur Whitney December 17, 2008 Brittany Lewis December 9, 2008 Deb Hubers December 8, 2008 Don Langworthy December 9, 2008 Erin DeAngelis-Duffy December 10, 2008 Evelyn Timmons December 9, 2008 Jason Hanson December 15, 2008 John Cruz December 12, 2008	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, disagree with the comment that the MTUS regulations are intended to control costs associated with medical treatment. Issues related to costs are properly addressed by medical fee schedules, not treatment guidelines. Treatment guidelines are intended to “assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and ... constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” Lab. Code, 4604.5(b). Further, it is noted that in order to	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		<p>Joseph Kosnosky December 15, 2008</p> <p>Karen Koenig December 9, 2008</p> <p>Kerry McLeod December 11, 2008</p> <p>La Mona December 9, 2008</p> <p>Melanie Walsh December 11, 2008</p> <p>Paul Stevenson December 10, 2008</p> <p>Pepper K. Mintz December 9, 2008 December 10, 2008</p> <p>Rebecca Bartling December 9, 2008</p> <p>Robert Schwartz December 16, 2008</p> <p>Roberta Valdez December 11, 2008</p> <p>Robin Digby December 9, 2008</p> <p>Suzy Brown December 9, 2008</p> <p>Toraye Izatt</p>	<p>meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	

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		December 9, 2008 Valerie Clement December 16, 2008 Will Shepard December 9, 2008		
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenters have suffered injuries at work and Dr. Satish S. Kabada and Los Angeles Orthopedics provided commenters with topical compounds that have been very beneficial for commenters' recovery to return to work. Commenters state that the use of these creams have given commenters great relief without the usual side affects that come from taking different oral pain medications.</p> <p>Commenters have been informed that the Division is trying to stop physicians from prescribing these compounds and do not understand the reasoning behind this. Commenters state that topical compounds are approved by Medi-Cal, approved for use by private insurance, hospitals, and are used by doctors to treat pain throughout the United States, and are not habit forming or addictive.</p> <p>Commenters believe that it is unfair and discouraging that someone on welfare is allowed to obtain these medications at tax payers' expense and that because commenters are injured workers, they will be denied a medication that would otherwise be available to someone with private insurance. Commenters state that as injured workers, they deserves to have the proper treatment to heal their injuries and return to work as soon as possible. If commenters are not longer allowed to receive these medications, they will be bringing this up to their attorneys and employers.</p>	Adrian Valdovinos Agustin Gutierrez Alfredo Sanchez Amadita Cano Ana N. Becerra Anthony Navarro Antonio Fonseca Bernardo Hernandez Blanca Valdez David Mendoza Diana Melendez Juarez Domingo Hernandez Eduardo de la Vega Eduardo Medina Enrique Herrera Erick D. Farley Florencio Flores Gabriel Hernandez- Nunez Gilda Ramirez Isaias Camargo- Jimenez Jesus Medina Jesus Ramos Jhony Velasquez Jorge Lopez Jorge Pulido Jose Guardado Jose Quintanilla Leticia Escarsega	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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		Letty Espinosa Lucia Herrera Luz E. Orozco Martha Ambriz Moises Perez Maria Vargas Melissa Levandis Minerva Cortez-Hernandez Noe Prieto Oscar Paez-Ramirez Raul Gonzalez Rosa Torres Ruth R. Cox Salvador Valle-Hernandez Salvador Vargas Telesia Tarver Travis Dreiling	Randomized Control Trial (RCT, see strength of evidence).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	Commenters are employees for a multi-specialty medical clinic that treats injured workers who have sustained a work related injury. Commenters have seen patients who were prescribed the typical name brand medications, such as Vicodin, Soma, etc. Commenters state that after taking these medications for more than a year, it is not unusual for the patients to start experiencing gastrointestinal symptoms. Commenters' clinic prescribes topical compounds to help treat their injuries. Commenters state that the clinic's ability to treatment these patients has been severely limited by SB 899 and has made a speedy recovery for injured workers very difficult. Commenters find that these topical medications have enabled injured workers to increase their daily function by decreasing their pain. Commenters have witnessed that these patients do not experience any of the side effects of taking oral medications, which can cause drowsiness, fatigue, and confusion which, in	Form letters were submitted by Ida Solivar, Legal Dept. Cal Care Medical Institute December 18, 2008 [Note: The majority of signatures are illegible but are included in the rulemaking file.] The legible signatures are as follows: Isiria Arreola Erica Zamoza Adriana Arreola	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>turn, significantly diminishes their quality of life.</p> <p>Commenters understand that the Division is once again attempting to change the medical treatment guidelines for chronic pain, indicating that topical compounded analgesics should not be recommended treatment. Commenters do not understand why a medicine that is approved by Medi-cal, approved for use by hospitals, and private insurance and is used by doctors for pain all over the USA is not recommended in the Division's Chronic Pain Treatment Guidelines. Commenters state that topical analgesics are less addictive than the typical commercially available medications by allowing the patient to use the topical cream directly on the affected area. Commenters respectfully request that the Division strongly consider allowing topical analgesics to be part of the treatment guidelines.</p>	<p>Maria Banelez Lorenzo Gonzalez Julia Bobedill Anna Ramy Dr. Montez Maria Orbe Cynthia Dettanda Sonia Hernandez Jessica Agredano Allen Brenner Michelle Santos Monica Santillanes</p>	<p>treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenters are patients that have been prescribed topical compounds by their physician, Scott Goldman, M.D., to help treat their injuries. Commenter feels immediate and great relief from using this medication. Commenters understand that the Division is attempting to remove the ability for their physicians to prescribe this therapy to them. Commenters do not understand why a medication that is approved for Medi-cal, approved for use by hospitals, and private insurance, and is used by doctors for pain all over the USA is being considered to be denied as a benefit to them.</p> <p>Commenters believe that this is unfair and will not allow them to properly heal from their injuries. Commenters state that they will be reviewing this issue with their attorney if they are no longer allowed to receive the treatment that they deserves.</p>	<p>Andrew Lucifora Cheryl Thompson Diane Lopez George Negrette Gloria Nunez Larry Backer Larry Flores Marlene Breen Nancy Millet Noemi Corral Stephen Chavez Teresa Whited Theresa Guzman</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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			are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenters are Orthopedic Surgeons who have been in practice for several years. Commenters are responding to recent issues concerning the prescription of compounded medications and the attempt to have this category of medication deemed “not recommended” for California workers’ compensation patients.</p> <p>Commenters indicate that in their practice, they have prescribed compounded medications over this last year. Commenters state that the results have been positive in helping to relieve pain and restore function in their patient population. When used as a supplement to oral medication, there has been a marked decrease of patient related complaints. The overwhelming majority of those patients who have received these compounded medications report beneficial results. Commenters continue that for many, it help to allow them to keep working without the risk of unwanted side effects from other pain medications such as gastritis or excessive sedation.</p> <p>From commenters’ standpoint, the use of compounded topical medication results in a decreased need for oral NSAIDS and/or narcotic medication. Commenters</p>	<p>Diokson Rena, MD</p> <p>Fred F. Naraghi, MD</p> <p>Joe W. Renbaum, MD</p> <p>Joel Weddington, MD</p> <p>Paul Roache, MD</p> <p>Rakesh Dixit, MD</p> <p>Richard Fernandez, MD</p> <p>Varsha Sikka, MD</p> <p>William Robert Campbell, DO</p> <p>December 17, 2008</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>state the most frequent comment from their patients is that the compounded topical medical has been the most beneficial of any medication the have been prescribed and on with the least amount of unpleasant side effects. Commenters indicate that topical compounds are used not only in orthopedic and pain management subspecialties, but are used as well successfully by physicians in other areas, including HMO's, PPO's, hospitals, professional sports, sports medication, etc. Commenters believe that the treating physician should be fully allowed to utilize lawful and recognized and accepted prescription based treatments. Topical compounds are an accepted standard of practice by the FCA, Board of Pharmacy, DEA, and Board of Medicine.</p> <p>Commenters indicate that after reviewing the proposed arguments to have these medications "not recommended" and other miscellaneous recent notice on this issue, they observe that much discussion or basis has been focused on "...recent FDA warning about potential dangers of compounded topical medications including local anesthetics...". When reviewed in its entirety, commenters note that the FDA advisory was specifically directed at five pharmacies. Commenters also note that it did not disclose specifics of the issues and that this "recent" warning is over two years old. Commenters believe that such statements distort the facts. Commenters strongly urge the Division to consider this information and allow more time for input from experienced health professionals on this subject.</p>		<p>responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and</p>	<p>Commenters state that in the final draft medical utilization schedule (MTUS) for chronic pain treatment recently published by the Division of Worker's Compensation (DWC), the DWC is dangerously inserting itself into the physician-patient relationship, which could have far-reaching</p>	<p>The following physicians submitted this form letter: Adeyemi Omilana Ahron Greenwald</p>	<p>Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines,</p>	<p>See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a),</p>

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<p>Treatments <i>Topical Analgesics - compounded</i></p>	<p>consequences.</p> <p>Commenters indicate that in all cases, physicians work with their patients to determine when compounded medications are appropriate and, if they are, work with pharmacists to design individualized treatments to meet their patients' needs --needs that are unmet by off-the-shelf, one-size-fits-all, mass-produced pharmaceuticals.</p> <p>Commenters state that doctors often prescribe manufactured products. Some doctors, however, determine that those products are inappropriate for their patients and prescribe compounded medications tailored to meet a patient's individual needs. Commenters state that the DWC's discussion states, "the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required."</p> <p>Commenters opine that the Division seems to be contending or implying that physicians and pharmacists do not have knowledge regarding the pharmacologic and pharmacodynamic activity of the agents being used, either alone or in combination with one another, in compounded topically administered analgesic preparations. Commenters argue that it is well known that physicians and pharmacists are trained in this area and are in the best position to determine what is appropriate or inappropriate for their patient's therapeutic success. Commenters state that by adopting this position, patients receiving benefit from these compounded preparations may go without therapy, be forced to use a different and potentially less appropriate therapeutic modality, be at risk for increases in morbidity and, in the end, be a greater financial burden on the healthcare system. Commenters indicate that compounded medications</p>	<p>Akira Aoyama Alan Gross Alan Ivar Amber Tsao Anjana Mehta Austin Walk Bach Pham Bart Nelson Betsy Priker Bill Harris Brent F. Wilson Carina Lomeli Charles Bonner Charles Mee Cherylee Gardea Christene Del Pozo Christine Givant Clay Hammett Corina Yang Curtis Hague Dan Wills Dana Gordon Daniel Gelber Dara Saghafi David M. Smith Deanne Archw Deb Hubers Debby Johnson Daisy Melchor Dennis Christensen Destry Setser Dionne Cue Douglas J. Mills Elson Cornelius Farbod Melamed Erin Falconer Frank Maseguerra Gina Potter</p>	<p>Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	<p>Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

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	<p>involve an intimate relationship between the prescriber, patient and pharmacist that is predicated on an individual patient's needs. Commenters state that intervening in the patient-prescriber pharmacist relationship could have dire consequences for the health of individual patients.</p> <p>Commenters state that pharmacy compounding is a long-standing, safe and well-regulated practice that serves the needs of many Americans with unique health requirements which off-the-shelf prescription medicines cannot meet. Commenters indicate that state boards of pharmacy, state medical boards, the Food and Drug Administration, the Federal Trade Commission, the Drug Enforcement Agency, and other federal and state agencies each have some degree of oversight over compounding practice. Commenter states the U.S. Pharmacopeia and the Pharmacy Compounding Accreditation Board also play critical roles. Commenters indicate that together, they have constructed a web of regulations and standards that protect patients. Commenters argue that the DWC rationale quotes an old FDA warning about potential dangers of compounding topical medications containing local anesthetics. Commenters continue to argue that the circumstances triggering FDA's warning are outside the normal prescriptive use of these types of preparations. Commenters state that with regard to topically applied analgesics that are used in the workers' compensation arena, anesthetics are not the primary agents employed. Commenters indicate when they are used, it is not at the same concentrations and combinations that were used in the preparations triggering the FDA's warning.</p> <p>Commenters state that compounded topical analgesics are critical to many patients in his/her practice and request that the Division reconsider the "not</p>	<p>Glenn Ballantyne Gloria Serrano Helen Ferry Iqtadar Malik Jack Castaldo Jeffrey Goad Jennifer Tate John Sowinski Judy Wong Julie Anez Karen Floyd Kaye Gornall Kenton Crowley Kim Tafolla Kimberly Hansen Kimberly LeTourneau Kristen Everett L. Ottmann Laura Chavers Leah Accola Lauren Papa Lawrence Weil Leo Blais Lilliana Gutierrez Lisa Faast Lisa Padilla LoiTrinh Ly Nguyen Margaret Cheng Mark Contreras Marshall Hankin Martha Torres Martin Miller Masoud Rashidi Matthew Walk Mayank Shah Melissa Durham</p>		

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	recommended" status for this class of drugs.	Mervyn Miller Michael Rudolph Michelle Crabtree Mike Edmondson Mike Pavlovich Najy Abifadel Nicolas Izatt Nicole Meng Patricia Hammett Patrick LeRoy Paul Lofholm R. Wayne Blackburn Richard Brisson Robert Brensel Robert Tyson Robert Villapania Robin Johnson Ronald McGuff Ronald Miller Sarah Fenner Shannon Towle Shannon Wong Sharon Amos Sharon Steen Sherry Cochran Si Pham Sidney Cobos Suchandra Turner Susan Merenstein Svetislav Milic Terry O'Rourke Waheed Ebrahim		
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and	Commenters are injured workers recovering from a workplace injuries and have been prescribed topical compounded medications by their physicians to help treat their injuries. Commenters state that these medications give them immediate and significant relief and improve the quality of their life because	Adela Rojas Aida Carillo Alberto Solis Alfredo Campos Amina Adem Ana Del Valle	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines,	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a),

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Treatments <i>Topical Analgesics - compounded</i></p>	<p>they do not experience any of the side effects normally associated with taking oral medications, such as fatigue and confusion.</p> <p>Commenters have been informed that the Division is attempting to remove the ability of their physician to prescribe this therapy to them. Commenters do not understand why a medication that is approved for use by Medi-Cal, hospitals, and private insurance companies is being removed as a treatment option for him/her merely because he/she is an injured worker. Commenters state that these medications are prescribed by doctors all over the country to treat pain because they are not habit forming or addictive. Commenters state that is not ethical that they are being denied treatment that would otherwise be available to someone with private insurance or eligible for Medi-Cal benefits.</p> <p>Commenters will be addressing this issue directly with their attorneys and employers if they are no longer allowed to receive the course of treatment that they deserve as a result of being injured on the job. Commenters find it discouraging that someone on welfare can obtain these medications at taxpayers' expense while they, injured while working, are denied such beneficial treatment. Commenters submitted the letter after receiving form letter in the mail from their pharmacist, Robert Nickell.</p>	<p>Ana Rosales Angel Garcia Anne Clancy Arsenia Liwang Arturo Rodriguez Audrell Wiggins Audry Lea Young Banadin Gonslaves Basilio Fabbri Beatrice Williams Benito Ibarra Bennie Stephens Betty Tidwell Brenda Sharp Carlos Fuentes Carlos Mendez Carol Cieminis Carol Dighton Carole D. Katrinak Cecil Sebastian Charles Ericson Charles Hutchenson Charon A. Williams Christine Pradere Cinda Johnson Claudia Alvarez Curleen Green Curtis Goodwin Danny J. Sr Yarbrough Dany O'Bryan Darnell Broadwater David Pepe Deborah Wartenbe Denise Ross Dennis Poole Derrick Liang Diana Clemons</p>	<p>Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	<p>Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		Diane Keith Dolores Spanousian Domingo Perez Donna Jones Donna Van Son Duane Delcomber Edmund J. Beck Efren Curiel Elaine Byrd Elis A. Moreno Ezequiel Martinez Florence Austin Francisco Guterrez Frank Cotto Gary Takata Gilberto Contreras Greg Campbell Gwendolyn Battles Hector Gonzalez Helen Lancaster Heng Chreng Hsiu Chu Wang Huguette Lemonnier Irene Herrera Irene Yoorra Isolda Huaman Ivonne Rodriguez Janet Favors Janet Robinson Javier Jr. Garcia Jayette Jones Jesus Castillo Jesus Cisneros Jimmy Madril Jo Ann Dawson Joelle Berenger John Adame John Sterns		

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		John Van Dyke Jorge Lomeli Jorge Pliego Jose Luis Alvarez Jose Luis Varas Josephine Holloman Joyce Greer Juan Soria Judy Life Julian Gallardo Julio Lozano Juniaty L. Prawoto Kathleen Olivas Kathleen Rink Kathy Ross Kathy Sunia Kelsey Stevens Kim Kastel Laurie Furgeson Leigh Bennett Lenard Pederson Liza Boone Lugardita Mossadaq Lyudmila Ostrovsky Marcus Meriott Maria Esparza Maria Perez Maria Reyes Maria Sanchez Marie Politowski Martina Felder Mary Encinas Michael Jays Michael Manley Michelle Payne Michelle Robinson Miguel Castro Miho Morgan		

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		Mohammed Anvarikhachkini Nancy Frank Natalie Applebee Neffiterri Hearnes Nelson Inafuku Nick Stewart Noelle Eskridge Nora Veloz Norma Torres Ofelia Arjon Oscar Ortega Pablo Manzano Pamela Thompson Patricia Bagley Paul Corral Peggy Watkins Pete Navarro Peter Munoz Phyllis Estes Phyllis Shilaos- Barrett Rafael Marvilla Randy Pawloski Raul Castenda Raul de la Cruz Raymond Crawford Renee Vardi Ricardo Green Richard Ming Richard Zambrana Rita Martin Robert Hall Robert Schappals Roberto Salazar Rogelio Sandoval Ronald Lewis Rossco Cahill		

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		Ruby Martin Ruby Torres Shirley Beckett Shirley Keys Stephanie Hoang Stephen Lathan Steven Jacques Susan Dixon Susan Vigil Suzanne Mack Shirley Davidson Stacey Borges Thomas Sperduto Thomas Valencia Tony Hernandez Valerie West Vivet Maragh Willie Goodwin		
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenters are concerned about the proposed regulation change in the Division of Workers' Compensation that would designate topical compounded topical analgesics as "not recommended." Commenters opine that such a change would create significant hardships for individuals who benefit from these medicines and who have no alternative options for pain relief. Commenters indicate that there are many people who cannot tolerate therapeutic dose levels of pain medicines in oral forms who show significant benefit from topical or transdermal use of these medicines. Commenters opine that to deny them access to this form of medicine is to condemn them to unnecessary, debilitating pain.</p> <p>Commenters note that according to a statement placed in the Chronic Pain Treatment Guidelines outlined by the division: "Continuation or modification of pain management depends on the physician's evaluation of</p>	Ana Espana Anne Mosbergen Annie Borgenicht April Boyd Brian Dodd Brian Lewis Candie Duenas Carl Cardey Charles L. Krugman Christine Garner Christine Leiendecker Cindy Ross Clay Hammett Dana Nelson Darlene Matthews David Ellison Debbie Nelson Diane Goltz Dona Van Bloemen	Agree in part. See response to comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above. Moreover, it is noted that in order to meet the requirements of the statute, topical agents are not excluded from evidence-based review and the presumption of correctness. (Lab. Code, §§ 5307.27, 4604.5(a).) Often, physician and patient experiences might suggest that a topical agent or compounded agent is effective. However, unblinded open label treatment is subject to bias as there	See action taken in connection with comment submitted by Robert Nickell, PharmD, Nickell Group, dated December 10, 2008, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical, compounds, above.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. When prescribing controlled substances for pain, satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life (http://www.meddbd.ca.gov/pain_guidelines.html)."</p> <p>Commenters opine that this statement emphasizes the importance of the patient/physician relationship in treating an individual's pain. Commenters point out the Division also states in this document, "[t]he use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required (MTUS, Chronic Pain Medical Treatment Guidelines, p.117). Commenters indicate this is the specific responsibility of the prescribing physician and compounding pharmacist.</p> <p>Commenters indicate that as individuals who know first-hand the debilitating nature of unrelieved pain, they urge the Division of Workers' Compensation to protect access to this necessary treatment option.</p>	<p>Donna DuFrane, RN Douglas Beadle Dennis Rogers Dennis Shue Dennis Tanenbaum Edward Manougian Elizabeth Baird Elizabeth Schaeffer Emily Bredehoft Erin Null Eva Diltz Frank Miceli Gail Bailleaux Gloria Badella Gwen Dawson Jean Kennerson Jeannette Monroe Jeffrey Matisoff Jeff Hogrefe Jeffrey Millman Jennifer Blackburn Jenny Falcon Jitka Parmet Joan Bush Jose Llontop Joseph Szabo Judi Soderstrom Judith Gremer Judy Rowles Julee Moron Kathy Gregg Keni Horicuhi Kenneth Walden Ianna Rank Leigh Blankenship Lena Jones Linda Charlton Lynn Nolan</p>	<p>are expectancy effects that may exceed true pharmacological effects. Special methods are required to assess treatment outcomes based on subjective responses to treatment. Physician/patient experience alone outside of a controlled environment cannot be considered scientific evidence. The only way to assess for effectiveness is a Randomized Control Trial (RCT, see strength of evidence).</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		Lynne Pryde Lynnette Flores Marcia Puppo Margaret Buckley-Brown Margaret Gipson Mariana Mendez Marion Perez Marlene Head Mayssa Sultan Michael Dunn Michael Mejia Michelle Kennington Mikella Kievman Mohan Val Nicole Thompson Paul Whitson Pete Hernandez Ray Disperati Richard Kerr Robert Cassell Robert Shaver Robin Gemmill Roland Esquivel Rossann Grimm Sarita Bissett Shalona Pendley Sharon Candler Sheryl Sutterfield Tapati McDaniels Tifini Powers Tristam Savage Venus Savage Vicki Kuells Wendy Paley William Whitener		
9792.24.2(a) Chronic Pain	Commenter states the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines	James E. Lessenger, MD	Disagree. The comment does not address the substantive changes	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Transcutaneous Electrotherapy [DWC]</i> <i>H-wave stimulation (devices) [ODG]</i></p>	<p>state that this is “Not recommended as an isolated intervention, but a one-month home-based trial of H-Wave stimulation may be considered as a noninvasive conservative option for diabetic neuropathic pain or chronic soft tissue inflammation if used as an adjunct to a program of evidence-based functional restoration, and only following failure of initially recommended conservative care, including recommended physical therapy (i.e. exercise) and medications, plus transcutaneous electrical nerve stimulation (TENS).” Commenter alleges that this guideline cites multiple low quality studies. However the ACEOM Chronic Pain Update states this treatment is “not recommended” as there are no RCTs to evaluate.</p>	<p>December 07, 2008 Written Comments</p>	<p>made to the proposed regulations during the 1st 15-day notice.</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Transcutaneous Electrotherapy [DWC]</i> <i>Interferential Current Stimulation [ODG]</i></p>	<p>Commenter states that the original draft of the DWC Chronic Pain Medical Treatment Guidelines recommendation on <i>Interferential Therapy Units</i> states “Not generally recommended....” Commenter inquires as to the meaning of this statement. Commenter adds that there is no definition as to what “generally” means. Commenter references page 77 of the guidelines. Commenter adds that the ACOEM Chronic Pain Update does not recommend <i>Interferential Therapy Units</i>. The guideline contains “Two recommendations [and] 2 moderate quality RCTs.”</p> <p>Commenter points out that the November 8, 2008 revision of the DWC Chronic Pain Medical Treatment Guidelines states that this therapy is “Not recommended as an isolated intervention.” Commenter opines that there is no quality of evidence of effectiveness except in conjunction with recommended treatments, including return to work, exercise and medications and limited evidence of improvement on those recommended treatments alone.</p>	<p>James E. Lessenger, MD December 07, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Transcutaneous Electrotherapy [DWC]</i> <i>Interferential Current Stimulation [ODG]</i></p>	<p>Commenter points out that there is an inconsistency in this section. In the Interferential Current Stimulation (ICS) electrotherapy session, the October 23, 2008 ODG Guidelines initially state “Not recommended as an isolated intervention.”</p> <p>ODG later states in this same section “While not recommended as an isolated intervention, Patient selection criteria if Interferential stimulation is to be used anyway: ...”</p> <p>The DWC proposed guideline for this same latter section says “While not recommended, Patient selection criteria if Interferential stimulation is to be used anyway: ...”</p> <p>Commenter points out that the DWC proposed guideline did not incorporate the phrase “as an isolated intervention...” as consistently stated in ODG nor did Appendix A1 detail the reason for this omission.</p> <p>Commenter opines that it may have been an oversight but suggests that for consistency within the Interferential Current Stimulation (ICS) electrotherapy section, the guidance needs to be the same in both sections of the regulation, otherwise there is a conflict in guidance. Commenter requests that we maintain consistency with ODG and change the regulation to state:</p> <p>“While not recommended as an isolated intervention, Patient selection criteria if Interferential stimulation is to be used anyway: ...”</p>	<p>Robert R. Thauer President Alliance December 15, 2008 Written Comments</p>	<p>Agree. The commenter is correct that the individual treatment guideline topic on “Transcutaneous Electrotherapy [DWC] Interferential Current Stimulation [ODG]” contains a clerical error, at page 126, wherein the phrase “as an isolated intervention” is missing. The individual treatment guideline topic on “Transcutaneous Electrotherapy [DWC] Interferential Current Stimulation [ODG]” is modified for clerical error. The text of the individual treatment topic guideline for Interferential Current Stimulation (ICS) is modified, at page 126, for clerical error, to insert the phrase “as an isolated intervention” at the second full paragraph. This phrase was left out from the October 23, 2008 ODG version due to inadvertence.</p>	<p>Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Transcutaneous Electrotherapy [DWC] Interferential Current Stimulation [ODG] is modified. The text of the guideline is modified, at page 126, to state as follows:</p> <p>While not generally recommended <u>as an isolated intervention</u>, Patient selection criteria if Interferential stimulation is to be used anyway:</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment</p>	<p>Contrary to the ODG recommendations and the MTUS position there is no quality evidence that electrical stimulation in the form of added electrical</p>	<p>Barry Eisenberg Executive Director American College of</p>	<p>Disagree. The chronic pain medical treatment guidelines provides for “unique clinical</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Guidelines Part 2. Pain Intervention and Treatments <i>Transcutaneous electrical nerve stimulation (TENS)</i> And 9792.24.1(2) Acupuncture – Electrical Stimulations</p>	<p>therapy to acupuncture, percutaneous electrical nerve stimulation or interferential current stimulation is routinely more efficacious than less costly treatments. Such procedures should be considered only in unique clinical situations.</p>	<p>Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment</p>	<p>situations” recommendations with regard to electrical stimulation in the form of “Percutaneous electrical nerve stimulation,” and “Interferential current stimulation.”</p> <p>The individual treatment guideline on the topic of “Percutaneous electrical nerve stimulation,” recommends use according to the following criteria: “Not recommended as a primary treatment modality, but a trial may be considered, if used as an adjunct to a program of evidence-based functional restoration, after other non-surgical treatments, including therapeutic exercise and TENS, have been tried and failed or are judged to be unsuitable or contraindicated.”</p> <p>Furthermore, the individual treatment guideline on the topic of “Interferential current stimulation,” recommends use according to the specified criteria below:</p> <p>“While not recommended, Patient selection criteria if Interferential stimulation is to be used anyway:</p> <p>“Possibly appropriate for the following conditions if it has documented and proven to be effective as directed or applied by the physician or a provider licensed to provide physical</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>medicine:</p> <ul style="list-style-type: none"> - Pain is ineffectively controlled due to diminished effectiveness of medications; or - Pain is ineffectively controlled with medications due to side effects; or - History of substance abuse; or - Significant pain from postoperative conditions limits the ability to perform exercise programs/physical therapy treatment; or - Unresponsive to conservative measures (e.g., repositioning, heat/ice, etc.). <p>“If those criteria are met, then a one-month trial may be appropriate to permit the physician and physical medicine provider to study the effects and benefits. There should be evidence of increased functional improvement, less reported pain and evidence of medication reduction. A “jacket” should not be certified until after the one-month trial and only with documentation that the individual cannot apply the stimulation pads alone or with the help of another available person.”</p> <p>Thus, commenter is incorrect in stating that these guidelines do not recommend use in “unique clinical situations.” With regard to the comment that the chronic pain</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			medical treatment guidelines does not provide for “unique clinical situations” recommendations with regard electrical stimulation in the form of Acupuncture with electrical stimulation, it is noted that the comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice.	
9792.24.2(e) Chronic Pain Medical Treatment Guidelines – Appendix D	<p>Commenter points out that the amendments in this new subdivision propose to add a modified version of the ODG for Chronic Pain to the Medical Treatment Utilization Schedule. Commenter is opposed to this change. While the referenced material is a fine overview of the great number of issues and treatment modalities concerning chronic pain, and can perform well as an educational tool, commenter does not believe that it will function adequately as a treatment guideline.</p> <p>Commenter alleges that this addition does not meet the criteria found in Labor Code Sec. 5307.27 which states that the Medical Treatment Utilization Schedule “...shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases.” The ODG give an appropriateness rating of Recommended, Under Study, or Not Recommended but rarely provides recommended/allowable frequency, duration, or intensity indications.</p> <p>Further, while the numerous citations are very helpful for research, without an indicator of where the studies fall within the ACOEM hierarchy of evidence, commenter states that they are not entirely useful in the context of these rules. Commenter believes that</p>	Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart. Moreover, it is noted that the incorporation of Appendix D to the regulations was done pursuant to the same commenter’s request during the 45-day comment period, wherein commenter stated: “Commenter states a number of important documents have been given as appendixes to the Initial Statement of Reasons. Commenter believes these appendixes should instead be incorporated into the regulations. Commenter states that these include Appendixes B, C, D, and E.”	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>the rating of evidence is beyond the scope of the lay public and that as MEEAC is charged with this duty, they should include the results of their reviews in the guideline for each treatment.</p> <p>Commenter strongly recommends that a decision on the addition of the ODG Chronic Pain Guideline be delayed pending inclusion of both frequency/duration/intensity amounts and strength of evidence ratings. Without both additions, commenter does not believe this guideline meets statutory or current regulatory requirements.</p>			
9792.24.3 General comment – Post Surgical Treatment Guidelines	<p>Commenter opines that the modifications have not corrected the basic problem with the proposed Postsurgical Treatment Guidelines. Commenter further opines that although Labor Code § 4604.5(b) requires the MTUS to be scientifically and evidence-based, nationally recognized and peer reviewed, the proposed guidelines are not based on any scientific studies regarding the need for physical medicine following surgery.</p> <p>Commenter adds that it appears that ODG headings have been revised and adopted from the ODG’s guidelines on physical medicine (Note: not on post-surgical physical therapy guidelines) but the introductions to the body parts and the numbers of visits, and the time periods are not based on evidence regarding postsurgical physical medicine treatment. Commenter notes that in the proposed postsurgical treatment guidelines, the DWC has supplemented the ODG-based guidelines on surgeries with “additional surgeries” and provided in the Initial Statement of Reasons Appendix C, evidence based reviews performed per the MTUS standards. Commenter states that these evidence based reviews also found insufficient evidence on which to base any</p>	<p>Brenda Ramirez Claims and Medical Director</p> <p>Michael McClain General Counsel and Vice President</p> <p>California Workers’ Compensation Institute (CWCI) December 18, 2008 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommendations for postsurgical physical medicine treatment. Commenter indicates that in fact, in Appendix C – Postsurgical Treatment Guidelines Evidence-Based Reviews, the DWC noted “There were no studies on the need for postsurgical physical therapy” for each of the body part sections under the “Individual Medical Treatment Guidelines” headings: Ankle and Foot; Elbow and Upper Arm; Forearm, Wrist and Hand; Hip, Pelvis and Thigh (femur); Knee; and Low Back. Under the headings: Carpal Tunnel Syndrome; Forearm; Head; Hernia; Neck and Upper Back; and Shoulder, the DWC stated “No Evidence Based Reviews Conducted.”</p> <p>In the Notice of Modification the Division suggests that ODG guidelines are evidence based because RAND considers them so. However, as noted on page 4 of these comments, RAND study panelists did not review the evidence-base* [*Nuckols, T., Wynn, B., Lim, Y., Shaw, R., Mattke, S. Wickizer, T., Harber, P., Wallace, P., Asch, S., MacLean, C., Hasenfeld, Garland, R., Evaluating Medical Treatment Guideline Sets for Injured Workers in California,, RAND (Prepared for the Commission on Health and Safety and Workers’ Compensation and the Division of Workers’ Compensation, California Department of Industrial Relations), 2005, page 50] nor were they reviewing the version of the guidelines proposed in these regulations. Commenter opines that it is incorrect for the DWC to declare this proposed version of the postsurgical treatment guidelines as evidence-based.</p> <p>Commenter further adds that while the current MTUS contains individual treatment guidelines that are graded as ‘Insufficient’ (I) because there is inadequate scientific evidence supporting a recommendation (commenter is presumably referring to the adopted</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>ACOEM chapters), the notion of adding an entire guideline for a complete condition or course of care that is based on insufficient medical evidence turns the statute on its head. Commenter argues that the proposed post-surgical physical medicine guideline that notes insufficient evidence supporting the recommendations for each surgery listed elevates these insufficient recommendations to the level of minimum legal requirements merely by being included in Labor Code section 5307.27. Commenter further argues that by including these unsupported guidelines, the AD will give them false weight by operation of the presumption contained in section 4604.5. Commenter opines that the proposed guidelines fail the statutory test of section 5307.5 and, in her opinion, cannot be included as part of the Medical Treatment Utilization Schedule.</p> <p>Commenter makes reference to AB 1073, stating that it added Labor Code section 4604.5 (d), paragraph (1), setting a cap of 24 physical medicine visits for injuries sustained after 2003, notwithstanding the MTUS. Commenter further states that per paragraph (2), that cap does not apply to postsurgical physical medicine and rehabilitation services provided in compliance with a postsurgical treatment utilization schedule established by the Administrative Director in accordance with Labor Code section 5307.27.</p> <p>Commenter states that the Administrative Director appears to have two possible options to address this, in her opinion, conundrum. Commenter states that one option is to wait to adopt postsurgical guidelines until there are scientific medical studies on which to base guidelines that can address, at a minimum, the frequency, duration, intensity, and appropriateness of all commonly performed postsurgical physical medicine and rehabilitation procedures and</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>modalities. Commenter states that the other option is to modify the proposed language in the postsurgical treatment guidelines to allow post-surgical physical medicine and rehabilitation services in accordance with the MTUS clinical topic sections 9792.23.1 through 9792.24 without regard to the 24-visit caps.</p> <p>Commenter argues that in order to accomplish the second option, (allow post surgical physical medicine and rehabilitation services in accordance with the MTUS clinical topic sections without regard to the 24-visit caps) the Administrative Director can adopt the changes recommended by the Commenter in written testimony submitted on August 12, 2008.</p> <p>Commenter recommends that the Administrative Director modify the proposed language to allow postsurgical physical medicine and rehabilitation services in accordance with clinical topic sections 9792.23.1 through 9792.24 without regard to the 24 visit limitations imposed on injuries sustained after 2003 by Labor Code section 4604.5(d)(1). Alternatively, commenter recommends that the Administrative Director wait to adopt postsurgical guidelines until there are scientific medical studies on which to base guidelines that can address, at a minimum, the frequency, duration, intensity, and appropriateness of all commonly performed postsurgical physical medicine and rehabilitation procedures and modalities.</p>			
9792.24.3 General comment – Post Surgical Treatment Guidelines	Commenter endorses the comments expressed by Brenda Ramirez and Michael McClain of the California Workers’ Compensation Institute (CWCI).	Keith T. Bateman Property Casualty Insurers of America December 18, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raises similar arguments which were raised during the 45-day comment period. This comments were appropriately	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			addressed in the 45-day comment period chart.	
9792.24.3 General Comment Postsurgical Treatment Guidelines	Commenter alleges that there is no evidence on the use, quantity, frequency and duration of post-operative therapy, however, the ODG numbers have been incorporated. Commenter states that there is no discussion of their origin. Commenter points out that typically such numbers are generated by an open multidisciplinary panel or are based on claims data use of resources versus functional recovery time. Commenter states that there is no evidence that this was done. Commenter opines that lack of a clearly described process and lack of consideration of population data undermines this proposed guideline.	Jeffrey S. Harris, MD December 15, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raises similar arguments which were raised during the 45-day comment period. This comments were appropriately addressed in the 45-day comment period chart.	None.
9793.24.3(b)(1) Postsurgical Treatment Guidelines	Commenter objects to reverting back to any unused pre-surgical visits after the postsurgical period without demonstrating the potential for further functional improvement.	Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.3(c)(1) Postsurgical Treatment Guidelines	Commenter is concerned with what he believes to be removing patient management from the primary treating physician. Commenter opines that the surgeon and the primary treating physician should discuss treatment and that the primary treating physician should submit the request, as with all other types of requests from secondary providers. Commenter states that claims administrators are trained to be vigilant about watching for Requests for Authorization via the PR-2. Commenter indicates that with the surgeon sending the Request for Authorization in on virtually any document, it could easily be missed, creating a lag in the authorization and treatment for the patient. Commenter cites Tit. 8 C.C.R. Sec. 9785 (a) (4),	Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>stating that it indicates that it is the Primary Treating Physician who is responsible for the "scope and extent of the employee's continuing medical treatment." Commenter cites subdivision (b) (1) of the same section, which states that, "An employee shall have no more than one Primary Treating Physician at a time."</p>			
<p>9792.24.3(c)(5)(A) Postsurgical Treatment Guidelines</p>	<p>Commenter recommends that section 9792.24.3(c)(5)(A) be amended as provided below. Commenter states that without these "quantifiable, functional goals" being required, demonstrating functional improvement is difficult, if not impossible and can be expected to lead to disputes. Thus, commenter's changes are recommended as follows:</p> <p>"The surgeon who performed the operation, a nurse practitioner or physician assistant working with the surgeon, or physician designated by that surgeon, the therapist, and the patient should shall establish quantifiable, functional goals achievable within a specified timeframe."</p>	<p>Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>
<p>9792.24.3(c)(5)(C) Postsurgical Treatment Guidelines</p>	<p>Commenter recommends the following change in order to make this subsection comply with the Ground Rules in the Official Medical Fee Schedule and current thinking in the medical world, which believes active procedures to have a significantly greater benefit to the passive modalities. Commenter states that this is also espoused in Section II of the proposed Chronic Pain Guideline under Physical Medicine. Thus, commenter's changes are recommended as follows:</p> <p>"Modalities (CPT codes 97010 through 97039) should shall only be performed in conjunction with other active treatments. Although these modalities are occasionally useful in the post surgical physical medicine period, their use should be minimized in favor of active physical rehabilitation and independent</p>	<p>Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

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	self-management."			
9792.24.3(d)(1) Postsurgical Treatment Guidelines <i>Carpal Tunnel Syndrome</i>	<p>Commenter is concerned that the “VAS improvement greater than four” example of “objective improvement” could be interpreted by utilization review doctors to require a four point improvement, regardless of the scale used. Commenter states that the Visual Analog Scale (VAS) is a 100 point scale. Commenter adds that in contrast, most doctors of chiropractic use a Numerical Rating Scale (NRS), which is an 11 point scale. Commenter states that a four point improvement on a NRS is significantly more improvement than a four point improvement on a VAS. Commenter opines that if these regulations are enacted, surely some UR doctor will use the four point improvement example to insist on a four point improvement of the NRS scale.</p> <p>Commenter suggests amending the regulation to allow a “VAS improvement greater than four, <i>or a similar percentage improvement using a different rating scale.</i>”</p>	David Benevento, DC, President California Chiropractic Association December 18, 2008 Written Comment	Disagree. The postsurgical treatment guideline, subtopic “Carpal Tunnel Syndrome” provides that: “Continued visits should be contingent on documentation of objective improvement, i.e., VAS improvement greater than four, and long-term resolution of symptoms.” The language in the guideline is explicit in stating that the Visual Analog Scale (VAS) is required and it will not be confused with the numeric rating scale (NRS). Because the language is clear, it is not expected that it will cause confusion with utilization review.	None.
9792.24.3(d)(1) Postsurgical Treatment Guidelines <i>Carpal Tunnel Syndrome</i>	<p>Commenter points out that currently, post surgical treatment visits are limited to 3 to 5 visits after carpal tunnel surgery. Commenter would like to recommend that the language regarding post surgical treatment of carpal tunnel syndrome be changed to provide up to 12 treatment visits based on the client’s needs and the occupational therapists clinical judgment. Commenter opines that depending on the severity of the client’s post-surgical condition, the client may need up to 12 treatment visits to optimally recover and prevent further disability after a carpal tunnel release surgery.</p> <p>Commenter states that the certified hand therapists within his organization have provided input that 3 to 5 post-surgical visits are not sufficient to treat these patients and have them make a successful return to</p>	Shawn Phipps, MS, OTR/L – President Occupational Therapy Association of America December 10, 2008 Written Comments	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice.	None.

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	work. Commenter further states that surgically incised tissue takes four to six weeks to heal, and injured workers need to regain range of motion and strength in order to return to their previous job duties. Commenter points out that the current language recommends 20 treatment visits for cubital tunnel release surgery and 9 visits for digital nerve repair.			
9792.24.3(d)(1) Postsurgical Treatment Guidelines Low Back	<p>Commenter is concerned about the statement regarding massage being a sham therapy is not accurate. Massage is not a “sham” therapy (see citations from ODG below and attached 2008 article from the <i>Spine Journal</i>). Commenter suggests that the first paragraph be amended to delete everything after the first sentence.</p> <p>Massage Recommended as an option in conjunction with recommended exercise programs. Manual massage administered by professional providers has shown some proven efficacy in the treatment of acute low back symptoms, based on quality studies. Mechanical massage devices are not recommended. (Furlan-Cochrane, 2002) (Werners, 1999) (Cherkin, 2001)(Cherkin-Annals, 2003) (Sherman, 2004) See Manipulation for recommended frequency and duration of treatment. (ODG Low Back)</p> <p>Massage Therapy Recommended as an option as indicated below. This treatment should be an adjunct to other recommended treatment (e.g. exercise), and it should be limited to 4-6 visits in most cases. Scientific studies show contradictory results. Furthermore, many studies lack long-term follow-up. Massage is beneficial in attenuating diffuse musculoskeletal symptoms, but beneficial effects were registered only during treatment. Massage is a passive intervention and treatment dependence should be avoided. This lack of</p>	David Benevento, DC, President California Chiropractic Association December 18, 2008 Written Comment	Agree in part. DWC agrees with the commenter that it is incorrect to refer to massage therapy as sham therapy. Accordingly, the introductory text leading to the specific postsurgical physical medicine guidelines in the Low Back topic is modified to remove the description of “sham therapy” to refer to “massage.” Further, the introductory text leading to the specific postsurgical physical medicine guidelines in the Low Back topic is modified for clerical error to delete the word “physical” immediately preceding the word “therapy” in two instances in the introductory text. The modification is to clarify that “therapy” in these guidelines can be either “physical therapy” or “occupational therapy” because “physical medicine” in these regulations encompasses both, physical therapy and occupational therapy. Moreover, disagree with commenter recommending that the first paragraph of the guideline be amended to delete all the language after the first sentence based on the argument that “massage is not	Section 9792.24.3(d)(1), Low Back is modified as follows: The introductory text leading to the specific postsurgical physical medicine guidelines in the Low Back topic now states: Low Back <u>As compared with no therapy, physical therapy (up to 20 sessions over 12 weeks) following disc herniation surgery was effective. Because of the limited benefits of physical therapy relative to “sham” therapy (massage), it is open to question whether this treatment acts primarily physiologically, but psychological factors may contribute substantially to the benefits observed. (Erdogmus, 2007)</u>

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	<p>long-term benefits could be due to the short treatment period or treatments such as these do not address the underlying causes of pain. (Hasson, 2004) A very small pilot study showed that massage can be at least as effective as standard medical care in chronic pain syndromes. Relative changes are equal, but tend to last longer and to generalize more into psychologic domains. (Walach 2003) The strongest evidence for benefits of massage is for stress and anxiety reduction, although research for pain control and management of other symptoms, including pain, is promising. The physician should feel comfortable discussing massage therapy with patients and be able to refer patients to a qualified massage therapist as appropriate. (Corbin 2005) Massage is an effective adjunct treatment to relieve acute postoperative pain in patients who had major surgery, according to the results of a randomized controlled trial recently published in the <i>Archives of Surgery</i>. (Mitchinson, 2007) The efficacy of massage as a stand-alone and as multimodality treatment is uncertain, according to this Cochrane review. (Haraldsson, 2007) (ODG Pain Chapter)</p>		<p>sham.” The language as contained in the guideline is necessary because sets forth the evidence that serves as the basis for the guideline.</p>	
<p>9792.24.3(d)(1) Postsurgical Treatment Guidelines</p>	<p>Commenter believes that the individual procedures in the Post-Surgical Treatment Guideline should have the Strength of Evidence rating included here as part of the regulation, so that they are evident to the regulated community and the WCAB. Commenter notes that in the Initial Statement of Reasons Appendix C that each and every procedure is marked with an ACOEM Strength of Evidence score of 1 and with the following "No Evidence Based Reviews Conducted" or "There were no studies on the need for post-surgical physical medicine." Commenter states that it is difficult to understand how this being the case, [when] these quite generous levels of therapy are being proposed as scientifically and evidence-based, peer reviewed and meeting a nationally recognized standard.</p>	<p>Steven Suchil, Assistant Vice President American Insurance Association December 18, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice. RCTs refers to Randomized Controlled Trials. (See Section 9792.25(c)(1)(A), Table A.)</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter also points out that the Postsurgical Treatment Guidelines-Ankle and Foot refers to “this RCT”. Commenter is not familiar with the acronym and does not see it defined elsewhere. In the interest of clarity, commenter requests that this acronym be defined.</p>			
<p>9792.25 (c)(1)(B) Table B – Strength of Evidence Ratings</p>	<p>Commenter is generally very supportive of the Division’s use of the Official Disability Guidelines (ODG) for chronic pain. Commenter is concerned, however, with what he perceives to be the narrow definition of “evidenced based medicine” that ODG relies upon. Along these same lines he would also like to point out that the DWC evidence rating scale is in conflict with CMA’s own mission statement which reads in part; “Promote the science and art of medicine, the care, and well-being of patients, the protection of the public health, and betterment of the med-cal profession...”</p> <p>Commenter requests that Table B be amended. Commenter does not disagree that randomized controlled trials (RCT) provide reliable medical evidence, but believes that the current DWC evidence rating system should not depend exclusively on RCT, as doing so is seriously and perhaps dangerously flawed. Commenter states that the failure to recognize “published consensus statements by nationally recognized specialties” in particular potentially limits the inclusion of safe and efficacious treatments. It also fails to acknowledge how quality medical care is provided today.</p> <p>Commenter states that admittedly, there is disagreement within the medical community over the definition of “evidence based medicine.” Commenter states, that however, the DWC’s evidence rating methodology sets a threshold for what does and does</p>	<p>Frank Navarro Associate Director Center For Economic Service – California Medical Association December 18, 2008 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

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	<p>not constitute “evidence based” so high that it may make some medically necessary treatments unavailable to injured workers.</p> <p>Commenter indicates that given the absence of qualifying studies, especially in areas such as pain management, he believes it is imperative that some weight be given to published consensus statements by nationally recognized specialty societies. For these reasons, commenter urges the Division to consider taking either of the two following actions:</p> <p>Commenter suggests that the strength of evidence rating include published consensus statements by nationally recognized specialties** [**(D) Level D. No research-based evidence, no RCTs. Published consensus statements by nationally recognized specialties exist.].</p> <p>In the alternative, commenter requests that DWC adopt ODG’s 30-step alphanumeric rating system. Commenter indicates that the ODG 30-step alphanumeric rating system for each individually referenced study is far more robust than ACOEM or the DWC’s evidence rating scale. Commenter indicates that it describes and summarizes the entire body of medical evidence within the Procedure Summary topic, as support for the overall ODG recommendation on a topic, rather than using a simplistic alphanumeric rating system for the body of evidence. Commenter opines that this is important for utilization review. Commenter notes that in states that have mandated ODG, where a clear unambiguous ODG recommendation is required, providers still have an opportunity to view and fully understand the complete body of evidence along with the relative quality of studies in support of a particular topic.</p>			

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	<p>Commenter adds that summarizing the body of evidence in this fashion allows ODG to take into consideration other factors in addition to study quality, such as: (1) trade-off between risks versus benefits; (2) magnitude of effect of an intervention; (3) availability of dependable sources of the treatment; (4) education and experience of providers; (5) consistency of study outcomes, and (6) variability of treatment parameters being studied.</p> <p>Commenter states that given the DWC's use of ODG as the basis for these proposed chronic pain guidelines, and having indicated its intent to follow ODG for the DWC low-back treatment section, CMA believes that it makes sense to replace, by total substitution, the DWC evidence rating scale with the ODG's 30-step alphanumeric rating system. Commenter believes that this move will allow physicians to provide the injured workers of California high quality medical care.</p>			
9792.25(c)(1)	<p>Commenter states that ACOEM's strength of evidence rating methodology is based largely - - if not exclusively - - on the randomized controlled trial (RCT). Commenter indicates that an 11-point scale is used to rate the quality of a randomized controlled trial as high (8-11 points), intermediate (4-7.5), or low (3.5 or less). Commenter opines that while the RCT offers important advantages, such as providing a means of balancing known and unknown factors between groups, and ranks near the top of the evidence "pyramid", there are several other types of studies that can and should contribute to the body of evidence for a therapy – and constitute evidence in their own right but nonetheless appear to be dismissed by ACOEM. Commenter states that these include observational studies that may be in the form of a case-control study, a cohort study, a prospective or</p>	<p>N. William Fehrenbach Reimbursement Director Medtronic December 18, 2008</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

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	<p>retrospective case series, and others. Commenter adds that the expert medical opinion of physicians is often considered another level of evidence but appears not to be considered by ACOEM. Commenter indicates that ACOEM only considers RCTs and systematic reviews or meta-analyses thereby including only the “tip of the iceberg.” Commenter adds that the ACOEM rating scale is rooted in the ability of the clinical study to blind patient and provider, which may not be possible for some device trials - - thereby inadvertently and unfairly misjudging the higher levels of implantable device evidence that do exist.</p> <p>Commenter states that their analysis of the 2008 ACOEM Low Back and 2008 ACOEM Chronic Pain drafts demonstrate, while ACOEM evidence ranking system does not appear to consider “medical consensus opinion,” a clear majority of “Recommendations” are based on evidence which is deemed to be “Insufficient” and there by definition rely on “consensus.” Commenter states that specifically, 36% of the <i>positive</i> ACOEM recommendations in the Low Back chapter are based on what ACOEM themselves deemed as insufficient evidence. Commenter indicates that if they were to abide by their own guidelines for evidence, they would lose over one-third of recommended treatment options.</p> <p>In addition to commenter’s concern with ACOEM, several others in the field of interventional pain medicine have taken opposition. Commenter states that for example, the following excerpt from a recently published article in Pain Practice states, “[a]n independent critical appraisal of both chapters of the ACOEM guidelines showed startling findings with a conclusion that these guidelines may not be applied in patient care as they scored below 30% in the majority</p>			

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	<p>of evaluations utilizing multiple standardized criteria.” Commenter indicates that a reassessment of the evidence synthesis using both ACOEM’s criteria and the quality of evidence criteria developed by the U.S. Preventive Services Task Force (USPSTF) resulted in the following: “The results of reassessment are vastly different from the conclusions derived by the ACOEM guidelines. The differences in strength of rating for the diagnosis of discogenic pain by provocation discography and facet joint pain by diagnostic facet joint nerve blocks is established with strong evidence. Therapeutic cervical and lumbar medial branch blocks and radiofrequency neurolysis, therapeutic thoracic medial branch blocks, cervical interlaminar epidural steroid injections, caudal epidural steroid injections, lumbar transforaminal epidural injections, percutaneous and endoscopic adhesiolysis, and spinal cord stimulation qualified for moderate to strong evidence.” (Manchikanti, et al. Pain Physician 2008;11(4):393- 482.)</p> <p>Commenter indicates that in strong contrast to ACOEM’s ranking system, several other well-respected and widely-used methods for rating the strength of evidence for a single study and/or the body of evidence for a therapy do exist and should be considered. Commenter states that though those alternatives may have their limitations regarding potentially failing to fully consider significant and unique challenges that one faces regarding the development and execution of device trials, these alternatives nonetheless are all significantly superior to ACOEM’s evidence grading scale. Commenter encourages the Administrative Director and her staff to review this text, and the related appendix and consider choosing one of these approaches instead.</p> <p><u>Option 1: Oxford</u></p>			

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	<p>The Oxford Centre for Evidence-Based Medicine (OCEBM) was established in 1995 to develop, teach and promote evidence-based health care. They produce a bi-monthly journal, Evidence-Based Medicine, in partnership with McMaster University and the British Medical Journal (BMJ). The Centre staff has published numerous articles and book chapters on evidence based medicine. OCEBM utilizes a Levels of Evidence document that considers all forms of evidence including systematic reviews, randomized controlled trials, cohort studies, outcomes research, case-control studies, case series, expert opinion and bench research. (http://www.cebm.net/)</p> <p><u>Option 2: ECRI</u> ECRI Institute, a nonprofit organization which was established over 40 years ago, dedicates itself to using applied scientific research to understand which devices, drugs, and processes are best for patient care. They pride themselves in their unique ability to blend practical experience and uncompromising independence with thorough and objective evidence-based research. They are both a Collaborating Center of the World Health Organization (WHO) as well as an Evidence-Based Practice Center for the U.S. Agency for Healthcare Research and Quality (AHRQ). In conducting a health technology assessment, ECRI includes clinical studies of both prospective and retrospective design. Therefore, ECRI's internal validity scale and strength of evidence assessments allow for more than one type of study design to be included in their analysis. Recognizing that the methodological rigor of retrospective studies is typically lower than that of RCTs, ECRI does state that retrospective studies must be comprised of a consecutive series of patients or randomly selected patients to minimize the threat of bias. (https://www.ecri.org/Products/Pages/htais.aspx)</p>			

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	<p><u>Option 3: AHRQ</u> In 2002, The U.S. Department of Health and Human Services AHRQ collaborated with experts from the private and public sector to identify evidence classification methods and systems and provided recommendations. As a part of this report, the authors identified 19 generic systems to assess study quality that fully addressed all key quality domains. Only three of these systems were used for both RCTs and observational studies. While RCTs have the ability to minimize important potential bias, some experts prefer using studies with larger aggregate samples or studies with more diverse populations or different practice settings, which are typical of observational studies. Therefore, AHRQ recognizes the value of both categories of study design and offers key quality domains for systematic reviews, randomized controlled trials, observational studies, and diagnostic test studies. http://www.ahrq.gov/clinic/epcsums/strengthsum.htm)</p> <p><u>Option 4: SORT</u> The editors of the US family medicine and primary care journals (i.e., <i>American Family Physician</i>, <i>Family Medicine</i>, <i>Journal of Family Practice</i>, <i>Journal of the American Board of Family Practice</i>, and <i>BMJ-USA</i>) and the Family Practice Inquiries Network (FPIN) collaborated to develop a unified taxonomy for the strength of recommendations based on a body of evidence called SORT This taxonomy recognizes and is in keeping with the recommendations of the AHRQ report mentioned above. Their instrument to rate the quality of a study takes systematic reviews, RCTs, case-control studies, cohort studies, consensus guidelines, bench research, and opinion into account. (Ebell MH, et al. J Am Board Fam Pract 2004;17:59–</p>			

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	<p>67.)</p> <p>Commenter states that the foregoing evidence supports that the ACOEM ranking system is markedly different than other, more widely respected and accepted scales as delineated above. Commenter has provided a side by-side comparison of these various scales which makes the significant differences even more compelling. Commenter opines that experimental studies (RCTs) and observational studies (non-randomized) should be considered complimentary. Commenter indicates that the former offers internal validity, the latter external validity. Commenter further adds that the former tests a research hypothesis, the latter takes the hypothesis and injects it into a “real world” setting. Commenter states that observational studies allow for longer-term follow-up of effectiveness, economic analysis of alternate treatments, and more. Commenter believes that excluding this body of evidence prohibits an exhaustive, fair and balanced review of treatment options, which commenter believes to not be in the best interest of patients.</p> <p>Commenter requests that California delete reference and use of ACOEM’s evidence ranking system, and instead insert one of the alternatives highlighted in his submission.</p> <p>Commenter acknowledges that as this evidence ranking scale has already been incorporated previously into regulations, and that the division may not be inclined to consider these changes at this time. Commenter states, however, that given the significant impact this will have on patient access to proven therapies that are not already appropriately included in DWC’s new MTUS, commenter urges that the division give it consideration at this time. Commenter</p>			

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	requests that if the division decides not to address this issue now, the Division to do so in the near future under separate rule promulgation.			
9792.25(c)(1)	<p>Commenter states that during the course of the public hearing held by the Division on the original 45 day version of the draft of the Medical Treatment Utilization Schedule, several presenters chose to be critical of ACOEM in their verbal remarks and in press comments. Commenter opines that it is unfortunate that rather than providing constructive comments that might improve the proposed schedule, some chose to use the hearing as an opportunity to misinform the Division in order to advance their own special interests. As commenter's organization is a partner in guideline development and, as an organization with extensive experience in the development of evidence based guidelines for treatment of injured workers with chronic pain, commenter appreciates the opportunity to share ACOEM's perspective on some of the most important misleading/inaccurate statements that have come to his attention.</p> <p>Under the subtitle, <u>Evidence Ranking</u>, commenter notes that several commenters asked the Division to reopen the MTUS to revise the evidence ranking scale that the Division proposed and that became effective on July 15, 2007. [The MTUS evidence ranking methodology is drawn from ACOEM's methodology which was developed by a 6-person <u>multidisciplinary committee</u> with representatives from the American Academy of Orthopedic Surgeons, the American Physical Therapy Association, and ACOEM.] Commenter states that two commentators at the Los Angeles public hearing share nearly identical verbiage: "The comments relate to a concern regarding inclusion by DWC of ACOEM's evidence ranking scale. . . A third commenter, the California</p>	Patrick O'Connor Kent & O'Connor December 18, 2008 Written Submission of letter from Barry Eisenberg to Anne Searcy dated September 18, 2008	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p> <p>Commenter states that it is an incorrect statement to state that the recommendation as used in the ACOEM guidelines "Not Recommended" means that the treatment is "disallowed." Commenter argues that it means that quality evidence does not support the intervention or there is not quality evidence supportive to overcome significant potential for adverse effects. Commenter states that ACOEM's guidelines are explicit in expressing their view that such interventions should still be considered, particularly if a physician's judgment concludes that the injured worker presents an extra-ordinary clinical situation. Commenter in essence states that when the treatment is "not recommended" in the ACOEM guidelines, the recommendation may still be obtained based on the</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Society of Industrial Medicine and Surgery (CSIMS), reportedly provided written comments to the Division objecting to the “use of ACOEM’s strength of evidence rating methodology.” [These CSIMS arguments were also made in 2007 which the Division rejected.]</p> <p>Commenter opines that the hierarchy of medical evidence – the grading system that stratifies conservative, high quality evidence from lower quality, less reliable evidence is the backbone of the MTUS. Commenter notes that it is based on ACOEM’s methodology which incorporates the highest scientific standards for reviewing evidence-based literature, thus ensuring the most rigorous, reproducible, and transparent occupational health guidelines available. Commenter states that that methodology, while having some unique attributes, share a basic foundation that is widely found throughout quality evidence based guidelines.</p> <p>Commenter is concerned that those who now suggest that DWC drastically alter it “evidence ranking” foundations lack an understanding of the principles of evidence based medicine, demonstrate a possible bias against evidence based guidelines, and overall may reflect a movement toward a system whereby the methodology can constantly change to “fit the evidence.”</p> <p>Commenter states that by suggesting that the “Criteria Used to Rate Randomized Control Trials” or the “Strength of Evidence Ratings” adopted by the Division are proprietary, as claimed by CSIMS, is simply wrong. Commenter states that both the “Criteria...” and the “Strength...” are widely available and can be adapted for use by any organization. Both are freely available on ACOEM’s</p>		<p>treating physician’s opinion. Commenter, in fact, ignores the statutory presumption attributed to the MTUS. The Labor Code provides that the MTUS is presumed to be correct on the issue of extent and scope of medical treatment. (Lab. Code, § 4604.5(a)) Thus, there is no longer a primary treating physician’s presumption. Because the primary treating physician’s presumption is no longer available to the physicians, the guidelines have to be clear in their recommendations, as to “recommended,” “not recommended,” or when there are unique situations where there is an exception. This facilitates utilization review. It is important to note that the MTUS serves as a basis for utilization review (UR), whereby a treatment request made by a physician is reviewed and a determination is made as to whether the treatment meets the requirements of the presumptively correct guidelines. (Lab. Code, 4610(c).)</p>	

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	<p>website http://www.acoem.org/guidelines_methodolgy.aspx), and on the Division’s website and have been published extensively.</p> <p>Commenter also adds that both the “Criteria...” and “Strength...” are based on commonly recognized, and valid, principles of evidence based medicine. Commenter notes that the “Criteria...” uses a modification of the most recent assessment scheme proposed by the Cochrane Collaboration Back Group. Commenter states that the “Strength...” uses a process that is similar to that used by AHCPR to develop recommendations and by the RAND Corporation in developing quality indicators.</p> <p>Under the subtitle, <u>Bias</u>, commenter states that it is clear to him that there has been a continual and coordinated effort to impugn the integrity of ACOEM and the Occupation Medical experts who serve, without compensation, on the ACOEM Evidence Based Panels. Commenter indicates that for example, a leading California interventional pain physician was reported to have suggested at the hearing, “It appears there’s something of an agenda at ACOEM.” Commenter urges that the Division requests that this person document his claim.</p> <p>Commenter states the reality is that ACOEM goes to great lengths to eliminate the potential bias from its Guidelines, as the AGREE Collaboration recommends: “There should be an explicit statement that all group members have declared whether they have any conflict of interest.”</p> <p>Commenter states that members of his organization’s evidence-based panels are required to publicly disclose any potential financial conflicts of interest</p>			

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	<p>which are published in their updates. Commenter states that they are not aware of other guidelines with other comparable disclosure policies, including the Medical Evidence Evaluation Advisory Committee. Commenter urges the Division to seek and disclose similar such statements from other guideline sources under consideration.</p> <p>Commenter opines that bias in a treatment guideline can come from those who have a vested interest in a therapy or device. Commenter alleges that while ACOEM panelists have no such interests, the same is not true for others who have commented on the proposed schedule. Commenter indicates that for example, there is an ongoing investigation by the U.S. Senate Finance Committee of medical-device makers for payments that might influence doctors to use their products, including sponsorships of medical-education seminars. One medical device company agreed to pay the federal government \$40 million to settle accusations that its spinal-implant division paid kickbacks to prominent spine surgeons to induce them to use its devices. The Justice Department has accused the manufacturer of paying doctors thought “sham consulting agreements, sham royalty agreements and lavish trips to desirable locations” from 1998 to 2003. Kickbacks to doctors “are incompatible with a properly functioning health care system,” said Peter D. Keisler, assistant attorney general for the civil division in a statement. “They corrupt physicians’ medical judgment and they cause overutilization and misallocation of vital health care resources.”</p> <p>Commenter is of the understanding that the Senate Finance Committee has been asked to expand its investigation to include the workers’ compensation system. Commenter continues that bias also comes</p>			

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	<p>when an external funding source with a vested interest in therapy or device becomes involved with treatment guidelines. Commenter points out that ACOEM receives no funding from therapy or device manufacturers, but that is not the case for others. Commenter alleges that one of ACOEM's most vocal critics, who claims unbiased evidence based guidelines, receives a generous annual contribution from a major device manufacturer.</p> <p>Under the subtitle, <u>Misinformation</u>, commenter alleges that in his verbal statement, the current President of the California Society of Interventional Pain Physicians (CSIPP) made several statements that are inaccurate. To the extent that the Division intends to consider any of his statements, commenter requests that the Division invite him to provide documentation for all of his assertions. Commenter would like to respond to two particular points. First the CSIPP President commented that "50 percent of treatment recommendations are disallowed under the ACOEM guidelines." Commenter alleges that this is an incorrect statement and that "Not Recommended" (as used in the ACOEM guidelines) does not mean "disallowed." It means that quality evidence does not support the intervention or there is not quality evidence supportive to overcome significant potential for adverse effects. Commenter states that ACOEM's guidelines are explicit in expressing their view that such interventions should still be considered, particularly if a physician's judgment concludes that the injured worker presents an extra-ordinary clinical situation.</p> <p>Second, commenter states that the CSIPP President asserted that the ACOEM process did not include input from relevant "expert" medical societies, include his national organization. Commenter states</p>			

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	<p>that this assertion is clearly false, as he later contradicts himself by referring to a “volley” of letters between ACEOM and these “expert societies.” Commenter states that in reality, there were lengthy discussions (both written and verbal) between ACOEM’s Chronic Pain panel and these “expert societies,” which they now prefer not to acknowledge. Commenter states that ACOEM actually delayed the publication of its pain update to consider their comments and many of their suggested changes are reflected in the final update. Commenter points out that they did not change their guideline recommendations as they would have preferred, in any manner that would have violated ACOEM’s commitment to the highest standard of evidence based guideline development.</p>			
9792.25(c)(1)	<p>Commenter states that he has been deeply involved with the issue of evidence ranking through a variety of venues, most recently with the writing of systematic reviews, in which he needed to comprehensively review and rank the literature. Commenter indicates that in his writing, he uses the Cochrane criteria for randomized controlled trials and the AHRQ criteria for observational studies. Commenter opines that an easier approach for the DWC would be adaptation of the ODG criteria. Commenter states that since the ODG is the basis for the Chronic Pain MTUS, commenter believes that the adoption of similar criteria for review of evidence has the obvious advantage of intellectual consistency with the MTUS. Commenter states the alternative would be to use the ACOEM criteria. Commenter strongly opposes the use of the ACOEM criteria. Commenter believes that the ACOEM criteria suffers from a simplistic view of the literature, with an over emphasis on randomized controlled trials. Commenter opines that while RCTs are important, particularly in terms of providing information on placebo effect, they are extremely</p>	<p>Sandiford Helm, MD Medical Director Pacific Coast Pain Management Center December 18, 2008 Written Comments</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Comments relating to the strength of evidence rating were raised during the 45-day comment period. Commenter raises similar comments during the 1st 15-day notice. These comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

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	<p>difficult to perform on interventional procedures. Commenter states that for example, RCTs dealing with thermal annular procedures, such as IDET, were unable to recruit sufficient patients to power the studies at the planned levels: they have fewer high quality RCTs than we would like. Commenter states that however, they have multiple observational studies which can be very valuable in determining effectiveness of a procedure. Commenter indicates that these studies can be assessed as to quality and the data pulled together in systematic reviews. Commenter notes that, however, the ACOEM criteria does not admit this valuable evidence. As such, commenter believes that the ACOEM hierarchy is inadequate to meet the needs of the DWC. Commenter recommends that the ODG method of rating evidence should be adopted over the ACOEM method.</p>			
9792.25(c)(1)	<p>Commenter states that Section 9792.25 of the MTUS provides that if treatment is not covered by the MTUS, ACOEM's strength of evidence rating methodology should be used in evaluating the evidence invoked as the basis for treatment. Commenter requests that the regulations clarify how the issue should be resolved when a treating physician invokes one set of guidelines to support treatment while a UR physician invokes a different set to deny treatment. Commenter asks which set of guidelines would hold sway. Commenter also inquires as to who determines that. Commenter further questions could one of the parties appeal that determination, and how would the process affect normal UR timeframes.</p> <p>Commenter also requests that the DWC formally deploy the ACOEM strength of evidence rating methodology in evaluating and comparing chapters for possible inclusion in MTUS. Commenter opines that it seems wholly appropriate and consistent to</p>	<p>Steven C. Schumann, MD, Legislative Chair Western Occupational & Environmental Medical Association (WOEMA) December 18, 2008 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart.</p>	<p>None.</p>

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	<p>amend MTUS using the same methodology being used in the field to evaluate the appropriateness of non-MTUS treatments.</p> <p>Commenter requests that the Division’s process for adopting new MTUS chapters include an opportunity for the authors of treatment guidelines – ACOEM, ODG, others – to formally present their chapter on the subject to the Medical Evidence Evaluation Advisory Committee. Commenter states that for guidelines authors, the process would likely lead to better shared understanding of the Division’s needs regarding timing and content. Commenter opines that this process would involve absolutely no expense for DWC, and would give MEEAC members the chance to directly raise their specific questions.</p> <p>Commenter believes that these changes would likely strengthen the overall scientific validity of MTUS, while making the regulations more useful to providers and payors.</p>			
Appendix D – Chronic Pain and Medical Treatment Guidelines	<p>Commenter inquires as to whether the DWC will be screening the research articles contained in the appendix for the following:</p> <p>a.) Are any of the authors (lead authors OR co-authors) of these articles also providers or vendors in the California Worker’s Compensation system who will stand to gain monetarily or otherwise by a favorable interpretation and implementation of the study conclusions? If so, commenter opines that this represents a study bias and threat to the validity of the study. Commenter opines that these studies must be rejected from consideration and I am notifying you of my objection to their inclusion in your review process.</p> <p>b.) Do any of these authors quote their own studies? Do any of the articles cross-reference the same</p>	Frank Hall, MSN, RN, CMM Supervisor U.R. & Nurse Case Management December 18, 2008 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 1 st 15-day notice. Commenter raised the same arguments during the 45-day comment period, and his comments were appropriately addressed in the 45-day comment period chart. Moreover, in selecting a guideline, DWC is required to evaluate the guideline to determine whether the guideline meets the requirements of the statute that the guideline is evidence-based, peer-reviewed, and nationally recognized. (Lab.	None.

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	<p>author? If so, commenter opines that this represents a study bias and threat to the validity of the study. Commenter opines that these studies must be rejected from consideration. Commenter states that he is notifying the division of his objection to their inclusion in the review process.</p> <p>c.) Has the DWC screened these studies to ensure they have been replicated by a separate researcher and study which has been determined to possess rigorous objectivity, reliability, and non-involvement with the prior study?</p> <p>2.) Due to the comments made about authors of studies in item # 1, has the DWC screened for all the different conflict of interest laws in California and the ways in which they have been interpreted by the courts and by published opinions of the Attorney General? Commenter states that conflict of interest laws are grounded on the notion that government officials owe paramount loyalty to the public, and that personal or private financial considerations on the part of government officials should not be allowed to enter the decision making process. Commenter states that this could easily extend to those participants in the workers' compensation system who have a vested interest and are paid by or stand to gain by that system, particularly if the information such participants supply are done so under the guise of non-biased objectivity.</p>		Code, § 5307.27.) When this determination is made, DWC is not require to analyze each individual study as contained in the guidelines to determine bias, rigor, and reproducibility. This subject was analyzed and responded to in the 45-day comment period chart under various subject headings.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Botulinum toxin	Commenter states that a recommendation for the use of Botulinum toxin in chronic low back pain if there is a favorable initial response is based on low-quality evidence when in fact there is a RCT showing reduced efficacy over time. (Foster 2001). Commenter alleges that the proposed recommendation is again based upon a third party recommendation (repeating a level of evidence rating with no explanation). Commenter	Barry Eisenberg Executive Director American College of Occupational & Environmental Medicine (ACOEM) December 18, 2008 Written Comment	Disagree. The evidence base reflects that there is scientific support for the use of botox for low back pain. The Naumann, 2008 article reflects the findings of a systematic review by the American Academy of Neurology.	None.

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(Botox)	opines that given the potential side effects (including death) and cost, any extension of a “may be considered” third party finding to a “recommended” status, as is being proposed, is scientifically incorrect.			