

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.20 (Definitions)	<p>Commenter requests that this section be amended to include definitions of the following: cure, curative treatment, and therapist. Commenter believes that “cure” is a superior term to the previous, definitive treatment. Commenter states that it still requires a definition or needless disputes and litigation will result. Commenter indicates that the Notice of Modification to Text of Regulation states that changing the term “physical therapist” to “therapist” is necessary to include occupational therapists. Commenter does not object to this inclusion, but believes it must be specific because there are many other “therapists” of one kind and another. Commenter believes that without specificity “therapist” could open up treatment opportunities for all sorts of theretofore unauthorized practitioners.</p>	<p>Steven Suchil Assistant Vice President American Insurance Association February 20, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice. It is noted that Subdivision 9792.23(b)(1) was modified pursuant to the 2nd 15-day notice to substitute the phrase “definitive treatment” with the word “cure.” It is this term (cure) and the phrase “curative treatment” which commenter alleges should be defined. The Notice of 2nd 15-Day Changes to Proposed Rulemaking, issued February 2009, set forth the reasoning behind this modification. The Notice indicated that modification resulted from public comments requesting that the phrase “definitive treatment” be defined. After analyzing these comments, DWC decided that 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,” it was pertinent not to add another definition to the regulations related to the term “medical treatment.” DWC decided to extract from the definition of the term “medical treatment” the word which best described the phrase “definitive</p>	<p>None.</p>

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			<p>treatment” in the context of subdivision 9792.23(b)(1), which makes reference to the identification of a chronic condition. DWC determined that the word “cure” was the appropriate word to substitute for the phrase “definitive treatment” because when there is an “absence of any cure 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. This analysis is based on the definition of “medical treatment” as set forth in Labor Code section 4600(a), which encompasses the concept of “cure” when it states the employer shall provide the injured worker “medical treatment.” The medical treatment to be provided, under this statute, is medical treatment which is “reasonably required to <i>cure</i> or relieve the injured worker from the effects of his or her injury.” The terms “cure” or “relieve” are common terms used in the workers’ compensation practice in relation to the definition of the term “medical treatment” for over a decade, and a definition at this time is not necessary. Further, with regard to the request for a definition of the term “therapist,” the regulations are clear that the</p>	

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			reference is to “physical therapy” and “occupational therapy,” consistent with Labor Code section 4604.5(d).	
9792.23(b)(1)	<p>Commenters state that the term “cure” is not defined in these regulations and has several possible meanings, including the following ones found in the Merriam-Webster dictionary:</p> <ul style="list-style-type: none"> • recovery or relief from a disease • something (as a drug or treatment) that cures a disease • a course or period of treatment • a complete or permanent solution or remedy • a process or method of curing <p>Commenters state that “cure” is most commonly used to describe a complete recovery. Commenters indicate that since injured employees are treated but are sometimes left with residual disability, they suggest replacing the term “cure” with “curative care” here and in every other place it appears in the regulations. Commenter states that the Notice of Modification refers to Labor Code section 4600(a) where treatment to “cure or relieve” appears to mean curative treatment and palliative treatment. Commenter state that curative care refers to medical care provided with the intent to cure or improve the patient's condition. Commenters add that palliative care, by contrast, is medical care intended to provide relief, but not to cure or improve the patient's condition. Commenters state that while the term “curative care” is clearer, defining the term in the regulation will eliminate potential disputes. Commenters believe that if the term “cure” is retained, as definition is necessary.</p> <p>Commenters recommend replacing the term “cure” with the phrase “curative care” in section (b)(1) and</p>	<p>Brenda Ramirez Claims and Medical Director California Workers’ Compensation Institute (CWCI)</p> <p>Michael McClain General Counsel & Vice President California Workers’ Compensation Institute (CWCI)</p> <p>February 20, 2009 Written Comment</p>	<p>Disagree. With regard to the comment requesting that the term “cure” be replaced with the term “curative care,” see response to comment submitted by Steven Suchil, Assistant Vice President, American Insurance Association, dated February 20, 2009, above. Further, disagree with the comment “that the language ... that states guidelines in the MTUS shall supersede other applicable guidelines, ... must be removed because it prohibits considering other guidelines in rebuttal, which is directly contradictory to the statute.” The statute is clear that “[u]pon adoption by the administrative director of a medical treatment utilization schedule pursuant to Section 5307.27, the recommended guidelines set forth in the schedule shall be presumptively correct on the issue of extent and scope of medical treatment.” (Lab. Code, §4604.5(a).) Thus, every guideline which is adopted into the MTUS, as approved through formal rulemaking, becomes presumptively correct. The “superseding” language is intended to make it clear that the guidelines, as contained in the MTUS, are</p>	None.

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	<p>wherever the term “cure” was added during this rulemaking.</p> <p>Commenters further state that Labor Code section 4604.5(a) specifically states that the presumption afforded to the MTUS “is rebuttable and may be controverted by a preponderance of the scientific medical evidence...” Commenters argue that the language here that states guidelines in the MTUS shall supersede other applicable guidelines, and similar language elsewhere in these regulations, must be removed because it prohibits considering other guidelines in rebuttal, which is directly contradictory to the statute.</p> <p>Commenters also request removal of the wording “supersede any applicable guidelines” language in section (b)(1) and similar language elsewhere in these regulations that prohibits considering other guidelines in rebuttal which is in direct conflict with the statutory language.</p> <p>Pursuant to their discussion, commenters propose the following revisions:</p> <p>(1) In providing treatment using other guidelines pursuant to subdivision (b) above, and in the absence of any cure curative care 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 and supersede any applicable chronic pain guideline in accordance with section 9792.23(b).</p> <p>(2) In providing treatment using other guidelines pursuant to subdivision (b) above and if surgery is performed, the postsurgical treatment guidelines in section 9792.24.3 for postsurgical physical medicine</p>		<p>afforded the presumption of correctness. This avoids conflict between the MTUS and other guidelines as this language makes it clear than when the injured worker is treating under the MTUS, for example for chronic pain, or for acupuncture treatment, the chronic pain medical treatment guidelines, or the acupuncture medical treatment guidelines of the MTUS apply. However, the MTUS is clear that “if the condition or injury is not addressed in the MTUS,” then other “nationally recognized” guidelines which are “scientifically and evidence-based, [and] peer-reviewed” apply. (See, Section 9792.21(c).) This language is consistent with the statute wherein Labor Code section 4604.5(e) provides, in relevant part, that “[f]or all injuries not covered by the ... official utilization schedule after adoption pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence-based medical treatment guidelines generally recognized by the national medical community and that are scientifically based.” Labor Code section 4604.5 further provides that “[t]he presumption is rebuttable and may be controverted by a preponderance of the evidence establishing that a variance from the guidelines is reasonably</p>	

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	shall apply together with any other applicable treatment guidelines found in the MTUS or in accordance with section 9792.23(b). The postsurgical treatment guidelines supersede any applicable postsurgical treatment guideline in accordance with section 9792.23(b).		required to cure and relieve the employee from the effects of his or her injury, in accordance with Section 4600. The presumption created is one affecting the burden of proof.” Commenters’ argument ignores that Labor Code section 4604.5(e) applies when the condition or injury is not addressed by the MTUS. This would include cases when there is new evidence, or when there is a guideline at variance with the MTUS. However, as set forth in Labor Code section 4604.5(a), the presumption can be rebutted by showing better evidence (i.e., a preponderance of the evidence establishing that a variance from the guidelines is reasonably required to cure and relieve). Merely presenting another guideline does not overcome the presumption. Rather, if another evidence review demonstrates better evidence, it is the showing of the better evidence that allows it to overcome the presumption. If, on the other hand, the condition or injury is addressed by the MTUS, then the presumption of correctness applies, and the “superseding” language aids in the application of the MTUS, and prevents internal inconsistencies.	
9792.23(b)(2)	Commenter notes that this subdivision states that the Postsurgical Guideline shall supersede any postsurgical treatment guideline in accordance with	Steven Suchil Assistant Vice President	Disagree. With regard to the comment objecting to the postsurgical treatment guidelines	None.

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	9792.23(b). Commenter believes that this addition lacks statutory authority. Commenter states that the MTUS requires evidence and clinically based, peer-reviewed, nationally recognized medical guidelines. Commenter argues that this clearly does not meet any of the statutory criteria.	American Insurance Association February 20, 2009 Written Comment	as not meeting the requirements of the statute, the comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice. Commenter raised the same arguments during the 1 st 15-day and 45-day comments periods, and his comments were appropriately addressed in the 45-day comment period chart. Moreover, disagree with the comment objecting to the “supersede” language in this section for the reasons set forth in the response to the comment submitted by Brenda Ramirez, Claims and Medical Director, Michael McClain, General Counsel & Vice President, California Workers’ Compensation Institute (CWCI), dated February 20, 2009, above.	
9792.23.3 (ACOEM Elbow Disorders)	<p>Commenter would like to bring attention to two specific areas that will be problematic if the ACOEM Guidelines directed toward the area of the elbow and the ulnar nerve are adapted without change.</p> <p>Under the subtitle, “<u>Electrodiagnostic Studies</u>,” commenter states that a firm recommendation requiring electrodiagnostic confirmation of ulnar neuritis is a potential problem. Commenter states that 80% of patients with compression neuropathy will show electrodiagnostic confirmation. Commenter adds that, however, the medical literature does indicate that there is a 20% false negative in electrical testing. Commenter indicates that regardless of individual professional expertise, 20% of patients with an ulnar neuropathy will not show positive</p>	Richard M. Braun, M.D. February 19, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.

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	<p>electrodiagnostic studies.</p> <p>Commenter states that it is important to understand that there are three basic mechanisms involving ulnar neuritis at the elbow. Commenter indicates that these include chronic compression, friction or abrasion on the nerve passing behind the epicondyle in the fiber osseous canal and traction or distraction of the nerve with elbow flexion, wrist extension and small finger extension. Commenter adds that this places a distracting force on the nerve which is frequently forced in the bone posterior to the elbow.</p> <p>Commenter states chronic compression cases usually do result in positive electrodiagnostic confirmation. Commenter adds that, however, cases involving friction or abrasion may show only nerve irritation that does not slow conduction. Commenter indicates that these cases are symptomatic, frequently show areas on numbness in the hand, but do not always show muscle weakness or delay in conduction at the elbow. Commenter states that this is also true for subluxation which occurs when the nerve snaps over the medial epicondylar bone causing a direct impact injury as well as abrasion. Commenter observes that these cases frequently show normal electrodiagnostic studies while producing clinical evidence for subluxation and obvious need for ulnar nerve transposition.</p> <p>Commenter states that traction on the ulnar nerve in some individuals causes nerve injury resulting in neuritis. Commenter indicates that these cases probably do not show electrodiagnostic evidence of nerve compression. Commenter states that in these cases there is no specific compression but, rather, distraction of the nerve or stretching of the nerve tissue, which causes pain and numbness.</p>			

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	<p>Commenter states that in cases that involve abrasion (friction), nerve subluxation, or distraction injuries, there is less likelihood to have confirmatory electrical studies. Commenter further states that this probably explains why 20% of cases with positive clinical findings have no evidence of significant electrical abnormality.</p> <p>Under the subtitle <u>“The Concept of “Simple Decompression,”</u> commenter states that he has already begun to see authorizations for “simple decompression” in the area of the elbow. Commenter indicates that based on over 30 years of experience, he would like to stress that there is nothing in the medial aspect of the elbow regarding the ulnar nerve that is “simple.” Commenter states that he will enclose a few references to the literature suggesting some of the difficulties that are encountered in evaluating the ulnar nerve behind the elbow. Commenter indicates that the anatomy sites are numerous involving compression, abrasion or traction injuries. As he noted in enclosed items, these may involve the ligament of Struthers, the medial head of the triceps, the medial intermuscular septum, the medial epicondylar bone, the cubital tunnel, an abnormal muscle involving the anconeus epitrochlearis, an arcuate ligament in flexor carpi ulnaris and involvement of the nerve in the deep forearm musculature. Commenter states that the numbers are of variables involving combinations of these factors, provides a huge number of possibilities. Commenter stresses that this is not a simple subject.</p> <p>Commenter believes that the choice of an operation along the medial aspect of the elbow must be left to the operating surgeon. Commenter states it is unreasonable to specify one type of operation or</p>			

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	<p>another, when there is no proof that one operation is any better than another, and it is likely that a mandatory authorization for one operative procedure will result in a serious problem if the patient has a situation that requires another operation.</p> <p>Commenter would like to reference a specific article written by an obvious international expert, Dr. David G. Kline, Professor of Neurosurgery at Louisiana State University. Commenter observes that Dr. Kline reported on page 654 ulnar nerve lesions in the <u>Journal of Neurosurgery</u>, Volume 98, pages 993-1004. Commenter states the article was written in 2003. Commenter further states that in this magnificent contribution, Dr. Kline outlines the many variables that are necessary in evaluating the procedure. Commenter notes that in his large series, Dr. Kline used intra-operative testing to identify areas of conduction delay that were not found in clinical tests using electrodiagnostic protocols that are standard for this condition. Commenter states these cases were considered “false negatives” based on preoperative tests. Commenter adds that nevertheless, confirmation of abnormality was proven when intra-operative methods were applied directly to the nerve.</p> <p>Commenter indicates that Dr. Kline’s preferred ulnar nerve operation is anterior transposition , a procedure that has also been endorsed by numerous other experts including Dr. Richard Gelberman, Professor of Orthopaedic Surgery at Washington University in St. Louis and past President of the American Society for Surgery of the Hand.</p> <p>Commenter states that in some cases, these variables must be addressed in performing ulnar nerve decompression along the medial aspect of the elbow. Commenter adds that some patients require</p>			

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	<p>decompression of a compressed nerve, removal of friction or abrasion sources along the medial aspect of the elbow and prevention of distraction forces from placing traction onto the nerve. Commenter indicates that in these cases, the ulnar nerve must be moved anteriorly by a knowledgeable surgeon who is able to pursue appropriate technique.</p> <p>Commenter states that it is extremely important for the ACOEM Guides to leave this decision making to experienced upper extremity surgeons, neurosurgeons, knowledgeable plastic surgeons and others who have the expertise to deal with the situation that presents many variables and should not be direct from a text that is not designed as a surgical decision making treatise, but rather a “guideline” for dealing with problems in the elbow.</p> <p>[Note: commenter did not include any attachments with his correspondence.]</p>			
9792.24.2 Chronic Pain Medical Treatment Guidelines (General Comment)	<p>Commenter wishes to express his opinion that the ODG "Pain" chapter (or any other portions of ODG) NOT be adopted as part of the MTUS.</p> <p>Commenter is an occupational medicine physician performing UR on a full-time basis. Commenter states that although the recommendations of ODG are generally reasonable and appropriate, he has a serious concern that adopting certain portions of ODG to supersede portions of the ACOEM guidelines will lead to increasing fractionation of the MTUS. Commenter states that ultimately, increasing confusion among treating physicians and UR reviewers is likely to result.</p> <p>Commenter recommends that the State of California continue to use the ACOEM guidelines as the primary</p>	Jay Westphal, M.D. February 5, 2009	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.

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	<p>MTUS, allowing only the existing Acupuncture Medical Treatment Guidelines as the sole exception. Commenter opines that ACOEM has an ongoing, robust method to revise and update existing chapters using evidence-based medicine.</p>			
<p>9792.24.2 Chronic Pain Medical Treatment Guidelines (General Comment)</p>	<p>Commenter would like to know more about these materials. He is a former manufacturing engineer and if he can do anything from his home it would be his pleasure. He can usually spend a few hours a week doing phone calls or computer work. Commenter is a frustrated hard worker who wishes every day he could work. It has taken him years to accept that it isn't going to happen. It was a very painful lesson. Commenter thanks God for what the Division is trying to do. So many people who suffered serious injuries, like commenter has suffered, had to go without treatment or lose all access to medical treatment for serious injuries. Commenter has been lucky to have access to most of his medical care. In fact, he is thankful for what workers comp benefits he still has access to. But most others have suffered horribly. Commenter obtained a lifetime medical benefit settlement which was in place when our new Governor took office. His settled suit was thrown out and he had no means to contest that change. The loss of income is another issue that kills commenter every week when he sees the price of everything going up so fast. I don't know if there is any way to deal with that. Again commenter lucked out and he gets almost \$21,000 a year from SS disability. Not close to the \$100,000 he would be earning. He is thankful for all that he has been blessed with but it could be a little better. Commenter thanks the Division for the incredible battle it is fighting. Commenter didn't think anyone would be able to help the thousands of people whom nobody really cares about.</p> <p>Commenter thinks that most people think that injured</p>	<p>Richard Kerr February 4, 2009 Written Comment</p>	<p>Agree in part. Agree with comment approving the chronic pain medical treatment guidelines. DWC cannot delegate work on these regulations to the public other than to request public comments and to consider those comments. Commenter has appropriately commented on a timely basis, and his comments have been appropriately considered.</p>	<p>None.</p>

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	workers are all looking for a way to sit at home watching Jerry Springer and Oprah.			
9792.24.2 Chronic Pain Medical Treatment Guidelines (General Comment)	<p>Commenter continues to object to the addition of the proposed Chronic Pain Guideline that does not state the level of evidence for treatments because these Guidelines are not evidence-based, as required by the statutory authority. Commenter's rationale has been submitted with earlier comments and will not be repeated. Commenter hopes his comments as to those guidelines will receive attention before the rulemaking is completed.</p> <p>Commenter's greatest concern is that the various Chronic Pain treatments are not identified with the level of evidence. Without specificity, disputes will be rampant, unnecessary treatment to some is assured, and medical costs will rise.</p> <p>Commenter states that that continued addition of guidelines that do not clearly state the level of evidence is not consistent with the goals of improved patient care and reduced expenses related to unnecessary treatments and litigation. Commenter is already seeing the cost for medical care beginning to rise. Commenter states that in the absence of fee schedule increases, this indicates increased utilization.</p>	Steven Suchil Assistant Vice President American Insurance Association February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice. Commenter raised the same arguments during the 45-day comment period, and the 1 st 15-day comment period. His comments were appropriately addressed in the 45-day comment period chart.	None.
9792.24.2 Chronic Pain Medical Treatment Guidelines (General Comment)	<p>Commenter welcomes the opportunity to respond to the proposed changes to California's Medical Treatment Utilization Schedule dated Feb 2nd, 2009.</p> <p>Commenter notes the minimal differences of the proposed regulations dated Feb 2nd, 2009 compared to November 25th, 2008 and reiterate our comments that the use of Work Loss Data Institute's Official Disability Guidelines Treatment in Worker's Comp – Chapter on Pain (Chronic) ODG's Chronic Pain Chapter as the basis of the chronic pain utilization schedule violates the legislature's mandate of an</p>	Barry Eisenberg Executive Director ACOEM February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice. Commenter raised the same arguments during the 45-day comment period, and the 1 st 15-day comment period. His comments were appropriately addressed in the 45-day comment period chart. Moreover, regarding commenter's objection to the language that the	None.

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	<p>evidence-based guideline process. Furthermore, commenter again recommends the adoption be suspended until the Governor appoints a permanent medical director.</p> <p>Commenter points out that a methodology that relies on selected meta-analyses and systemic reviews, and not on original research, results in many errors of fact and science that he has previously documented. In particular, while the acetaminophen recommendation has been rewritten, the reliance on other reviews and not an original, complete evaluation of high quality evidence still results in an incorrect conclusion.</p> <p>Proposed opioid recommendations represent another concern worth repeating. The proposed recommendations are vague and confusing, where ACOEM’s methodology has resulted in a clearly defined set of recommendations that opioids should be considered only after other multiple options have been considered. This is remarkably similar to a recent evidence-based guideline from the American Pain Society and the American Academy of Pain Medicine:</p> <p>“Clinicians should consider a trial of COT for CNCP when potential benefits are likely to outweigh risks, and there is no alternative therapy that is likely to pose as favorable a balance of benefits to harms.” [The Journal of Pain, Vol. 10, No 2 (February), 2009: pp 113-130]</p> <p>Commenter strongly suggests that DWC replace the ODG based opioid recommendations with either ACOEM’s recommendation or suggest that ODG base their recommendations on the recent APS/AAPM guidelines.</p> <p>Other examples of recommendations based upon</p>		<p>chronic pain medical treatment guidelines “supersede any applicable chronic pain guideline in accordance with section 9792.23(b),” See response to comment submitted by Brenda Ramirez, Claims and Medical Director and Michael McClain, General Counsel & Vice President, California Workers’ Compensation Institute (CWCI), dated February 20, 2009, on Section 9792.23(b)(1), above. Further, it is noted that the MTUS originally adopted ACOEM’s methodology, and at that time ACOEM’s methodology considered well-conducted systematic reviews and meta-analyses as high quality evidence. ACOEM has since changed their methodology to exclude systematic reviews and meta-analyses, which is now at variance with the MTUS. However, it remains a standard practice amongst other organizations to rely on systematic reviews and meta-analyses as evidence to produce evidence-based guidelines.</p>	

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	<p>ODG’s methodology that relies on non-original research have been previously shown. The inclusion of several electrical therapies that have little evidence of efficacy, commenter opines that to define them as “presumed correct” only serves to include additional cost into a system that has trouble paying for truly efficacious treatments.</p> <p>Commenter also strongly questions that the proposed chronic pain schedule “supercedes” chronic pain guidelines contained in other injured body part guidelines. Commenter finds that this position is arbitrary and presumes that better, more specific evidence is not available for truly evidence-based recommendation – which is false. Commenter recommends that body specific, chronic pain recommendations apply as the evidence allows and evolves.</p> <p>In closing, commenter looks forward to continued collaboration with the Division and the State of California to ensure that injured workers receive quality medical care in a timely and appropriate manner.</p>			
9792.24.2 Chronic Pain Medical Treatment Guidelines (General Comment)	<p>Commenters are disappointed that the most basic flaws in the proposed regulations have not been addressed and recommends that the DWC reconsider the recommendations and comments previously submitted.</p> <p>Commenters’ greatest concerns are:</p> <ul style="list-style-type: none"> As written, the proposed ODG-based Chronic Pain and Postsurgical Treatment Guidelines will often function as exit ramps from the existing high-quality, scientific hierarchy of evidence-based medicine, and lead the injured worker back towards the 	<p>Brenda Ramirez Claims and Medical Director California Workers’ Compensation Institute (CWCI)</p> <p>Michael McClain General Counsel & Vice President California Workers’ Compensation Institute (CWCI)</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice. Commenters raised the same arguments during the 45-day comment period, and the 1st 15-day comment period. Their comments were appropriately addressed in the 1st 15-day comment period chart and the 45-day comment period chart. Moreover, commenters reference CWCI Bulletin No. 09-03, dated February 23, 2009,</p>	None.

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	<p>treating physician presumption, and inadequate, substandard, unnecessary or deleterious care.</p> <ul style="list-style-type: none"> • It will be difficult or impossible to ensure injured employees receive prompt, effective treatment and are not subjected to substandard treatment because the proposed ODG-based guidelines often fail to provide specific recommendations for treatment, include vague, ambiguous language to qualify their conclusions, and fail to apply the Strength of Evidence and Rating methodology previously adopted for the treatment schedule. • 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, and triggering disputes. • Proposed Postsurgical Treatment Guidelines are not based on any scientific studies on the need for physical medicine following surgery. • While it is virtually impossible to price out the scale of the economic impact of the proposed ODG-based guidelines because of the lack of specific recommendations, thresholds and limitations for treatment, it is certain that utilization of ineffective medical services and their related costs will escalate and the overall quality of care for California’s injured workers will be diminished. <p>Commenters also recommend that the Division review and revise its proposed guidelines on opioids in light of the Federal Government’s most recent expressions</p>	<p>February 20, 2009 Written Comment</p>	<p>submitted with their comments and request “that the Division review and revise its proposed guidelines on opioids in light of the Federal Government’s most recent expressions of concern regarding the inappropriate prescribing and growing abuse of powerful narcotics” DWC notes that the CWCI Bulletin No. 09-03, refers to a Federal Drug Administration’s (FDA) initiative to meet with manufacturers of opioid drug products. The FDA announcement is contained at http://www.fda.gov/cder/drug/info/page/opioids/default.htm. In addressing the FDA program in its Bulletin, CWCI sets forth the purpose of the FDA program, in relevant part, as follows: “In announcing the plan last week, Dr. John K. Jenkins, Director of the Office of New Drugs at the FDA’s Center for Drug Evaluation and Research, said the intent is to assure that physicians who prescribe these medications are trained in their safe and proper use and that only those physicians are allowed to prescribe these drugs. Thus, physicians could be required to obtain additional training before being allowed to prescribe these medications. Lists of the brand name and generic opioid products that may be subjected to the REMS program are on the second page of</p>	

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	<p>of concern regarding the inappropriate prescribing and growing abuse of powerful narcotics. [Commenters submitted as an attachment CWCI Bulletin No. 09-03 dated February 23, 2009. This bulletin is part of the official rulemaking file and is available upon request.]</p> <p>Commenters request that if the Administrative Director decides to move forward with adding the terms “cure,” “therapy,” and “therapist” to these regulations, that the division add definitions for each of those terms.</p> <p>Discussion According to Government Code section 11349(c): "Clarity" means written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them. Under CCR, Title 1, section 16(a), a regulation shall be presumed not to have complied with the clarity standard if:</p> <p>The regulation can, on its face, be reasonably and logically interpreted to have more than one meaning and the varying interpretations cannot be harmonized by settled rules of construction;</p> <p>An important purpose of the Administrative Procedures Act is to ensure that the rules and regulations adopted by state agencies are easy to understand. In establishing the clarity standard, the Legislature made the following finding (Government Code section 11340(b)):</p> <p>"The language of many regulations is frequently unclear and unnecessarily complex, even when the complicated and technical nature of the subject matter is taken into account. The language is often confusing to the persons who must comply with the regulations..."</p>		<p>this Bulletin. As a first step in developing the program, the FDA will begin meeting next week with manufacturers, patient consumer advocates, and the public to gather information and suggestions on how to best implement the program.”</p> <p>DWC notes that the FDA is beginning its program and it yet has to define a specific implementation of the program. A developing step which is mentioned in the FDA announcement, as well as in the CWCI Bulletin, is further physician education so that the physician is properly trained to prescribe controlled substances. DWC acknowledges that opioids have abuse potential and that treatment guidelines need to be balanced to provide for the treatment of pain, while at the same time mitigate the risks of the treatment. A review of the individual treatment guideline on the topic of “Opioids,” including subsections, contain abundant cautionary language that guides the clinician to the appropriate use of opioids. The guideline contains language which aids the clinician in detecting when opioids are being used inappropriately, when drug diversion is suspected, or when there is other drug abuse.</p>	

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	<p>The following terms of art have been added to the proposed regulations and their definitions will significantly alter the meaning of the affected regulations: cure; therapy; therapist; and manual therapy. Commenters opine that without a clear, specific definition for each of these terms, the standards contained in the MTUS will become vague and ineffectual. The MTUS is required to be used by utilization review organizations and all medical reviewers as the standard of medical care for injured workers in California. The failure to follow the dictates of the MTUS will result in penalties for reviewers. If key language in this schedule has multiple meanings with significantly different consequences, commenters fear the standards will quickly become meaningless and impossible to follow.</p>		<p>The cautionary language warns against inappropriate use of opioids, and at the same time provides guidance in treating pain.</p> <p>Further, the MTUS is designed to take into consideration other California statutes that govern physicians prescribing opioids for pain (see, Business and Professions code sections 2241 and 2241.5, and Health And Safety Code sections 124960-124961), and to avoid internal or external conflicts. With regard to physician education, California law requires medical physicians, as a one-time requirement, to complete 12 hours of continuing medical education in pain management and the treatment of terminally ill and dying patients. (Business and Professions Code, § 2190.5.) Until the FDA provides further guidance on how to promote appropriate use and to guard against abuse of opioids, the MTUS provides for a balanced approach to the appropriate use of opioids in treating work injuries.</p>	
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 1. Introduction</p>	<p>Commenters state that the MTUS is intended to ensure that injured employees receive high-quality, cost-effective medical care available. Commenters opine that the recommended change to the first paragraph of the Introduction of the Chronic Pain Medical Treatment Guidelines will ensure all evidence-based curative treatment options are considered before exiting the clinical topic sections of</p>	<p>Brenda Ramirez Claims and Medical Director California Workers' Compensation Institute (CWCI) Michael McClain</p>	<p>Disagree. Labor Code § 4604.5(a) provides that the MTUS is “presumptively correct on the issue of extent and scope of medical treatment.” Labor Code § 4604.5(b) provides that the “guidelines shall be designed to assist providers by offering an</p>	<p>None.</p>

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	<p>the MTUS. Commenters opine that it is insufficient to exit simply because there are no plans to provide curative treatment. Commenters recommend the following modification:</p> <p>“.... If the patient continues to have pain that persists beyond the anticipated time of healing, without plans for and <u>all</u> curative treatment <u>options have been exhausted, such as surgical options,</u> the chronic pain medical treatment guidelines apply...”</p>	<p>General Counsel & Vice President California Workers' Compensation Institute (CWCI)</p> <p>February 20, 2009 Written Comment</p>	<p>analytical framework for the evaluation and treatment of injured workers, and shall constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.” The sentence in the Introduction of the Chronic Pain Medical Treatment Guidelines stating, “If the patient continues to have pain that persists beyond the anticipated time of healing, without plans for curative treatment, such as surgical options, the chronic pain medical treatment guidelines apply,” is intended to provide the treating physician “an analytical framework for the evaluation and treatment of the injured worker” as to determine when the case has reached a chronic status and treatment may be provided pursuant to the chronic pain medical treatment guidelines. The requirement that “all curative treatment options be exhausted” as suggested by commenters interferes with the treating physician’s clinical judgment, and does not take into consideration the patient’s comorbidities and the specific facts of the case. One example under this scenario is the patient who declines surgery. Under the application of the commenters’ suggested edits, the injured worker may not be able to receive chronic pain treatment because a claims administrator</p>	

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			<p>may determine that the injured worker has not “exhausted all curative treatment options (i.e., surgery).”</p> <p>Moreover, the MTUS is designed to take into consideration other California statutes that govern physicians prescribing opioids for pain (see, Business and Professions code sections 2241 and 2241.5, and Health And Safety Code sections 124960-124961), and to avoid internal conflicts or external conflicts with these statutes. Specifically with regard to commenters’ opinion “that it is insufficient to exit simply because there are no plans to provide curative treatment,” commenters ignore the California Pain Patient’s Bill of Rights. In that regard, the Health And Safety Code section 124961, states “[n]othing in this section shall be construed to alter any of the provisions set forth in the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient’s Bill of Rights. (a) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her severe chronic intractable pain. (b) A patient who suffers from severe chronic</p>	

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			intractable pain has the option to choose opiate medications to relieve severe chronic intractable pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.”	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 1. Introduction	The Chronic Pain Chapter accessible off the DWC web site contains, on page 2, line 3, a reference to Merskey and Bugduk 1994. The correct spelling is Bogduk.	Standiford Helm, II, M.D. – Medical Director – Pacific Coast Pain Management Center February 6, 2009 Written Comment	Agree. The clerical error contained in the spelling of the citation has been corrected.	The Introduction of the Chronic Pain Medical Treatment Guidelines is corrected for clerical error at page 2, line 3, to reflect the correct name of the citation as: (Merskey and Bogduk 1994).
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Acetaminophen	Commenter recommends adding the following under the Dose requirements: According to one manufacturer, the recommended daily dose of APAP is up to 4000 mg for a duration of less than 10 days, and no more than 2600 mg daily for longer-term use. Higher cumulative doses of APAP have been shown to predispose patients to serious adverse effects including liver damage. Doses should be determined carefully in patients with risk factors including: diminished liver function, the elderly, and patients consuming greater than two alcoholic beverages per day.	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The individual treatment guideline on the topic of “Acetaminophen,” reflects the appropriate dosage based on ODG’s evidence-based review. The guideline indicates that “the recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours, with a maximum of 4g/day” as indicated by commenter. Further, the individual treatment guideline on the topic of “Acetaminophen,” contains clear warnings about	None.

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			<p>“adverse effects” based on the evidence. The guideline states, in relevant part, as follows:</p> <p>“Adverse effects: Hepatotoxicity: 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 $>3 \times$ 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 cardiovascular risk: Cohort analysis reveals that acetaminophen use is associated with hypertension but evidence</p>	

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			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)”	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Acetaminophen</i>	<p>Commenter suggests that the proposed deletion of the language related to, and the Manchikanti 2008 and Manchikanti2, 2008 citations under the individual treatment guideline topic of “Acetaminophen” be rescinded and the section kept in the document.</p> <p>Commenter does agree that within the context of the section, deleting this paragraph makes sense and does not alter the meaning of the section. However, commenter is still facing problems of inappropriate UR denial based upon ACOEM, despite the availability of evidence-based, nationally recognized guidelines which are better. Including this paragraph would add the weight of the DWC to efforts to counter these inappropriate UR denials, which are best characterized as conclusions looking for a justification.</p> <p>As a co-author of the referenced papers, commenter is well aware that these papers refer to ACOEM 2008, not ACOEM 2004. Commenter is also well aware the use of ACOEM will be supplanted by the MTUS. Despite these facts, commenter favors the inclusion of the paragraph in that its language provides an additional small tool as we struggle with UR denials.</p>	Standiford Helm, II, M.D. February 6, 2009 Written Comment	Disagree. The last two sentences of the guideline, wherein ODG discusses two <u>Manchikanti et al.</u> articles were removed from the individual treatment guideline topic of “Acetaminophen” because the text provides commentary which is off-topic and not pertinent to ODG’s recommendations in the individual treatment guideline topic of “Acetaminophen”. Further, the MTUS regulations are intended to implement adoption of the MTUS setting forth evidence-based, scientifically based, peer-reviewed and nationally recognized guidelines. (Lab. Code, §§ 5307.27, 4604.5(b).) The MTUS regulations, however, are not intended to implement utilization review standards pursuant to Labor Code section 4610. The utilization review regulations are applicable to utilization review denials, and those regulations are set forth in 8 CCR 9792.6 et. al. The utilization review regulations address commenter’s concerns, and provide for a dispute resolution	None.

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			process (8 CCR 9792.10), for assessments of penalties in connection with utilization review violations (8 CCR 9792.11 et., al.).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Actiq®(fentanyl lollipop)</i>	<p>Commenter suggests the individual treatment guideline on the topic of “Actiq®(fentanyl lollipop)” be revised as follows:</p> <p>Not recommended for musculoskeletal <u>chronic non-cancer pain patients</u>. Actiq® (oral transmucosal fentanyl citrate), a fast-acting highly potent "lollipop" painkiller produced by Cephalon, is indicated only for the management of breakthrough cancer pain in patients <u>16 and older</u> with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Actiq is not for use in chronic <u>non-cancer</u> pain; and it has a Black Box warning for abuse potential. See Opioids.</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Alendronate (fosomax®)</i>	<p>Commenter suggests the individual treatment guideline on the topic of “Alendronate (fosomax®)” be revised as follows:</p> <p>See Bisphosphonates. Bisphosphonates are a class of drugs that inhibit osteoclast action and the resorption of bone. Alendronate (Fosamax®) is in this class. <u>Recommend treatment of bone resorption with bisphosphonate-type compounds as an option for patients with CRPS Type I.</u> Not recommended for <u>other chronic pain conditions.</u></p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments	<p>Commenter suggests the individual treatment guideline on the topic of “Amitriptyline” be revised as follows:</p> <p>Recommended. Amitriptyline is a tricyclic antidepressant. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.

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<i>Amitriptyline</i>	tolerated, or contraindicated. See Antidepressants for chronic pain for general guidelines, as well as specific Tricyclics listing for more information and references. <u>These agents should be used in the lowest possible dose due to the significant anticholinergic side effects seen with this drug and this class oral doses of 10 to 150 mg/day can be used. Doses are started at a low level and gradually increased as needed and tolerated. This is an off-label, but well recognized use.</u>			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Antidepressants for chronic pain</i>	Commenter suggests the first two sentences of the individual treatment guideline on the topic of “Antidepressants for chronic pain” be revised as follows: Recommended <u>serotonin-norepinephrine reuptake inhibitors (SNRI)</u> as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics <u>and SNRIs</u> are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated.	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Antiepilepsy drug (AEDs)</i>	Commenter suggests the individual treatment guideline on the topic of “Antiepilepsy drugs (AEDs)” be revised as follows: Commenter recommends striking the following specific drug listings as he claims there is only anecdotal evidence or theoretical evidence; no well controlled studies: Lamotrigine (Lamictal®); Phenytoin (Dilantin®); Topiramate (Topamax®); Levetiracetam (Keppra®); Zonisamide (Zonegran®); & Tiagabine (Gabitril®)	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain	Commenter suggests the second paragraph of the individual treatment guideline on the topic of “Capsaicin, topical” be revised as follows: <i>Formulations:</i> Capsaicin is generally available <u>over</u>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.

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Intervention and Treatments <i>Capsaicin, topical</i>	<u>the counter</u> as a 0.025% formulation (as a treatment for osteoarthritis), and a 0.075% formulation, <u>and a 0.1% formulation</u> (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain).	Written Comment		
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Celebrex®</i>	Commenter suggests the individual treatment guideline on the topic of “Celebrex” be revised as follows: <u>Recommended only in patients at high risk for a GI bleed.</u> Celebrex® is the brand name for celecoxib, and it is produced by Pfizer. Celecoxib is a non-steroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain.	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Chronic pain programs (functional restoration programs)</i>	Commenters are experts in pain management and continue to have some concerns about some of the language in the guidelines. Commenters are also concerned that there has been no mention of the arbitrary and unscientific 20 day duration for chronic pain programs (aka. FRPs) despite numerous comments on the MTUS proposal. Commenters’ concerns are as follows: Issue 1: Functional Restoration for Shoulder and Neck Pain Commenters state that the MTUS guidelines conclude that there is little treatment evidence for patients with cervical and extremity diagnoses. Commenters indicate that the guideline states, “There appears to be little scientific evidence for the effectiveness of multidisciplinary biopsychosocial rehabilitation compared with other rehabilitation facilities for neck and shoulder pain, as opposed to low back pain and generalized pain syndromes. (Karjalainen, 2003)” Commenters would like to point out that there is scientific evidence to the contrary. Commenters state	Darrell S. Bruga, D.C. – Chief Clinical Officer Michael C. Post, M.D. Co-Medical Director Ronald J. Fujimoto, D.O. – Co-Medical Director Allen Kaisler-Meza, M.D. – Co-Medical Director Kimeron Hardin, Ph.D. – Director of Behavioral Medicine Scott Standage, M.D. SpineOne Program February 20, 2009	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.

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	<p>that the researchers from PRIDE Functional Restoration Program, the originators of functional restoration, have published two high level scientific papers on the subject as follows:</p> <p>1) Wright A, Mayer TG, Gatchel RJ. Spine. 1999 Jan 15;24(2):178-83. Outcomes of disabling cervical spine disorders in compensation injuries. A prospective comparison to tertiary rehabilitation response for chronic lumbar spine disorders. <u>Design:</u> "A subset of patients (n= 421) with work-related cervical spine disorders was compared with a group of various lumbar spine disorders (n=777). A structured clinical interview was administered 1 year after patients entered an interdisciplinary functional restoration program." <u>Results:</u> "High rates of return to work and continuation of work were recorded in the cervical and lumbar spine disorder groups, with low rates of recurrent injury, new surgery in the injured area, and use of health resources. There were no statistically significant differences between the groups." <u>Conclusion:</u> "This first large cohort study of outcomes in chronically disabled patients with work-related cervical spinal disorder produced results similar to those found in tertiary functional restoration in chronic lumbar spinal disorders."</p> <p>2) Mayer TG, Gatchel RJ, Polatin PB, Evans TH. Journal of Occupational and Environmental Medicine. Volume 41 (9), September 1999. 761-70. Outcome comparison of treatment for chronic disabling work-related upper-extremity disorders and spinal disorders. <u>Design:</u> Prospective case series cohort study. Both patient groups completed tertiary rehabilitation program. Compared UEMSD (n=163) with SD (n=163)</p>	<p>Howard Rome, Ph.D. Clinical Director East Bay Functional Restoration February 19, 2009 Written Comment</p>		

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	<p><u>Conclusions:</u> “Rehabilitation outcomes for upper extremity musculoskeletal disorders are similar to those of spinal disorders.” Sub classification analysis of UEMSD neuropathic vs. non-neuropathic showed poorer outcome for neuropathic UEMSD vs. SD.</p> <p>Commenters highly recommend that this evidence be considered in the new MTUS guidelines.</p> <p>Issue 2: 20 day limit for Functional Restoration Programs</p> <p>Commenters represent SpineOne, a comprehensive functional restoration program (FRP) located in Northern California. Commenters’ programs are staffed with a vast array of health care providers from diverse disciplines that collectively have years of experience serving individuals living with chronic pain and resultant disability. Commenters take pride in keeping current with the latest advances in “Evidence-based Medicine” and how that knowledge impacts clinical decision making including commenter’s program design. Commenters allege that their program, like many of the other functional restoration programs, is leading the way in the field of rehabilitation and disability management.</p> <p>Commenters state that upon reviewing the most recent proposal regarding the adoption and modification of the ODG Guidelines for chronic pain for the California worker’s compensation system, commenters have some concerns regarding the current ODG Guidelines which indicates that programmatic treatment duration should be limited to an arbitrary number of days. Commenters add that under the section for pain treatment, chronic pain programs (functional restoration programs) ODG states that:</p> <p><i>“Total treatment duration should generally not</i></p>			

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	<p><i>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;...”</i></p> <p>Commenters indicate that reviewing the reference upon which this statement is made (Sanders, 2005) commenters believe that 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, Pain Practice, Volume 5, Issue 4, 2005 303–315. Siskin Hospital’s Center for Pain Rehabilitation, Chattanooga, Tennessee.</p> <p>Commenters indicate that it should be highlighted that the ODG lists the following notation in regard to the Sanders article in the following way:</p> <p>“Note: This issue of this journal was not accepted into Medline, and therefore it is not part of the primary evidence base used for ODG, but it includes a helpful reference list.”</p> <p>Commenters note the following language also in the ODG guidelines under references:</p> <p>Per ODG Reviewers:</p>			

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	<p>“With regard 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 believe that the problem surrounds the poor quality of the article and the purpose of the article. Commenters allege 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 and is merely the author’s opinion and not a scientific conclusion. Commenters therefore contend 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 opine that to date there are no such guidelines with recommendations based on scientific studies. 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 to commenters how the 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.</p>			

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	<p>Commenters believe that California health care providers that have experience working in FRPs know that the injured worker populations that they treat are some of the most difficult in the system. Commenters state that during the program it takes substantial time to shift misguided beliefs about chronic pain and disability, improve functional capacity for work and help patients overcome obstacles to recovery.</p> <p>Commenters indicate that based on their experience it is rare to accomplish this in 20 days. In fact, commenters follow patients completing a 200 hour program for an additional 7 months at no additional charge to ensure that progress continues. Commenters essentially provide the equivalent of an 8-9 month program. Commenters indicate 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' outcomes are based on a 40 day 200 hour 8 week 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 their program to reflect that new evidence and knowledge. In the meantime, commenters strongly recommend eliminating any opinion based language pertaining to frequency and duration until further evidence is available. Commenters opine that the current consensus in administering programs is based on experience with outcome and the needs of the individual patient. Commenters add that the FRPs in California have a similar design and commenters believe that this should not be changed until quality scientific evidence becomes available or common sense dictates.</p>			
9792.24.2(a)	Commenter suggests the individual treatment	Ralph Kendall	Disagree. The comment does not	None.

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<p>Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>CRPS, medications</i></p>	<p>guideline on the topic of “CRPS, medications” be revised by adding the following language:</p> <p>“Several classes of medications have shown efficacy in alleviating CRPS pain, although no single agent has been found to be uniformly effective in all patients. Possible pharmacologic options listed by the CRPS Clinical Practice Guidelines include:</p> <ul style="list-style-type: none"> “• <i>Anti-inflammatory agents:</i> NSAIDs (long-term), corticosteroids (short-term: inj or oral) “• <i>Anticonvulsants:</i> most data with gabapentin; but phenytoin, carbamazepine are also used “• <i>Antidepressants:</i> specifically, low-dose amitriptyline; also consider doxepin, nortriptyline, trazodone, and the SNRI venlafaxine “• <i>For severe, refractory pain:</i> opioids (both controlled release and immediate release) “• <i>Topicals for local pain:</i> capsaicin, 5% lidocaine patch “• <i>Bisphosphonates for pain:</i> oral alendronate, pamidronate (but effects on BM.D. unknown) <p>“Vitamin C and topical DMSO may also be tried as adjuncts in therapy and have been studied with success in CRPS. The use of calcitonin to help regulate bone function and improve pain in CRPS has produced conflicting results. Other therapies to consider include clonidine and calcium channel blockers, although data is mainly anecdotal and has not been confirmed by large controlled trials. Agents that have recently generated interest include immunomodulator medications and NM.D.A receptor antagonists, which have been used in case reports and small open trials, although more studies are needed to assess efficacy and safety.</p> <p>“The dystonia that may occur with CRPS is treated</p>	<p>Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment</p>	<p>address the substantive changes made to the proposed regulations during the 2nd 15-day notice.</p>	

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	<p>with oral muscle relaxants, or for resistant cases, the use of intrathecal baclofen. Recommendations include using one of the following.</p> <ul style="list-style-type: none"> “• Tizanidine 2 mg qhs, titrate slowly to a maximum dose of 8 mg tid “• Baclofen 5 mg tid, titrate up every 3 days to a maximum of 80 mg/d divided tid or qid “• Consider referral to pain center for intrathecal baclofen for severe, intractable dystonia. <p>“Communication with the patient is key during therapy. Treatment should also include psychological aspects of CRPS. Consider all systems affected; treat osteopenia and osteoporosis accordingly. Bladder problems may be approached symptomatically.” (Commenter indicates that references are available for these recommendations.)</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments DMSO <i>(dimethylsulfoxide)</i></p>	<p>Commenter indicates that the statement “there is some evidence of efficacy for topical DMSO cream” is lightly referenced, and while there is an occasional need for it in facilitating the penetration of certain active ingredients, it is probably the most controversial agent ever studied. Commenter states that agents such as those included above are all FDA-approved for administration by one or more routes.</p>	<p>Mike Pavlovich, PharM.D. RPM Pharmaceuticals February 11, 2009 Written Comment</p>	<p>Disagree. Commenter objects to the individual treatment guideline on the topic of “DMSO (dimethylsulfoxide)” on the basis that there is little reference to the subject, asserting that “it is probably the most controversial agent ever studied.” Disagree as the comment does not substantively address the guideline. The guideline references another individual treatment guideline: Complex Regional Pain Syndrome (CRPS), CRPS, medications. Under CRPS, medications, the guideline indicates that “[t]here is some evidence of efficacy and little likelihood for harm for topical DMSO cream.” Commenter offers no further information on the individual treatment guideline</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			on the topic of “DMSO (dimethylsulfoxide).”	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Fentanyl</i>	<p>Commenter suggests the individual treatment guideline on the topic of “Fentanyl” be revised as follows:</p> <p><u>Recommended as an option for chronic pain requiring treatment with long-acting opioids not controlled by other agents.</u> Fentanyl is an opioid analgesic with potency eighty times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as fentanyl. For more information and references, see Opioids. See also Actiq® (fentanyl lollipop); Duragesic® (fentanyl transdermal system); & Fentora® (fentanyl buccal tablet).</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Flector patch</i>	<p>Commenter suggests that a new individual treatment guideline on the topic of “Flector patch” be added to the chronic pain medical treatment guidelines as follows:</p> <p>“Recommended only for acute pain and short term use of less than 14 days. The Flector Patch is a topical NSAID indicated for twice daily topical application for <i>acute</i> pain due to minor strains, sprains, and contusions. While the amount of drug reaching systemic circulation is substantially less than the oral route, topical diclofenac labeling carries the standard NSAID warnings of increased cardiovascular, gastrointestinal, and renal risks. GI and dermatological reactions are among the commonly reported adverse effects. Consequently, the prescriber is advised to weigh the benefits versus risks and, if the patch is used, prescribe the lowest effective dose/application for the shortest possible duration.”</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment	Commenter suggests the individual treatment guideline on the topic of “Gabapentin (Neurontin®)” be revised as follows:	Ralph Kendall Vice President, Clinical Services	Disagree. The comment does not address the substantive changes made to the proposed regulations	None.

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Guidelines Part 2. Pain Intervention and Treatments <i>Gabapentin (Neurontin®)</i>	<u>Recommended as a first line treatment for neuropathic pain.</u> Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain.	Healthsystems February 20, 2009 Written Comment	during the 2 nd 15-day notice.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Glucosamine (and Chondroitin Sulfate)</i>	Commenter suggests the individual treatment guideline on the topic of “Glucosamine (and Chondroitin Sulfate)” be revised to delete the first sentence of the guideline, as follows: Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007)	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Herbal medicines [DWC]</i>	Commenter suggests the individual treatment guideline on the topic of “Herbal medicines [DWC]” be revised as follows: <u>Not recommended for chronic pain.</u> See specific Sections on Boswellia Serrata Resin (Frankincense), Cannabinoids, Curcumin (tumeric), Green Tea, Pycnogenol (maritime pine bark), Uncaria Tomentosa (Cat's Claw), White willow bark	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and	Commenter suggests the individual treatment guideline on the topic of “Kadian® (morphine sulfate)” be revised as follows: <u>Not recommended as a first-line agent due to availability of Morphine ER as a less costly generic.</u>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatments Kadian® (<i>morphine sulfate</i>)	Kadian® is a brand of morphine sulfate, supplied by Alpharma Pharmaceuticals. See Opioids for recommendations and references.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Ketamine	<p>Commenter suggests the first sentence of the individual treatment guideline on the topic of “Ketamine” be revised as follows:</p> <p>Not recommended <u>for chronic pain</u>. <u>May be an option for CRPS</u>. There is insufficient evidence to support the use of ketamine for the treatment of chronic pain.</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Medications for chronic pain	<p>Commenter suggests the third and fifth sentences of the individual treatment guideline on the topic of “Medications for chronic pain” be revised as follows:</p> <p>Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects (<u>accounting for drug-drug interactions and age of the patient</u>); (3) determine the patient’s preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A <u>sufficient trial period</u> should be given for each individual medication.</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Methadone	<p>Commenter suggests the third and fifth sentences of the individual treatment guideline on the topic of “Medications for chronic pain” be revised as follows:</p> <p>Steps for prescribing methadone: (1) <i>Basic rules</i> - Weigh the risks and benefits before prescribing methadone. —Avoid prescribing 40 mg Methadone tablets for chronic non malignant pain. This product is only FDA approved for detoxification and maintenance of narcotic addiction.</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice. Commenter is incorrect in stating that Methadone 40 mg is not available. Although Methadone 40 mg is not available to treat pain, it can still be used for addiction treatment and maintenance only.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that this product is no longer available.</p> <p>Commenter further suggests adding the following language to this section:</p> <p><u>“Safety concerns regarding the prescribing of methadone for the treatment of chronic pain have been publicized in the last few years. The FDA has issued safety warnings, and black box warnings have been added to the prescribing information for methadone. This warning states that methadone treatment for analgesic therapy in patients with acute or chronic pain should only be initiated if the potential analgesic or palliative care benefit of treatment with methadone is considered and outweighs the risks. In addition, the Cardiac Expert Panel for the Center for Substance Abuse Treatment (CSAT) recently published clinical practice guidelines regarding arrhythmia risk and QT interval monitoring for clinicians prescribing methadone. This panel issued the following specific recommendations in five key clinical areas:</u></p> <p><u>“1. Disclosure. When clinicians prescribe methadone, they should inform patients about arrhythmia risk.</u></p> <p><u>“2. Clinical History. Clinicians should ask patients about any history of structural heart disease, arrhythmia, or syncope.</u></p> <p><u>“3. Screening. All patients should have a pretreatment electrocardiogram (ECG) to measure QTc interval and a follow-up ECG within 30 days and each year.</u></p> <p><u>“a. For methadone dosage > 100 mg/day, or if pts have unexplained syncope or seizures, additional ECG is recommended.</u></p>			

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	<p><u>“b. In addition, screening may be done as indicated for patients with multiple risk factors for QTc prolongation, or when patient is on another cytochrome P450 inhibitor or other QTc interval-prolonging drug.</u></p> <p><u>“4. Risk stratification. For patients in whom the QTc interval is between 450-500 milliseconds, the potential risks and benefits should be discussed, and they should be monitored more frequently.</u></p> <p><u>“a. For QTc > 500 milliseconds, discontinuing or decreasing the methadone dose should be considered, as well as eliminating other contributing factors. Use of alternative therapy may be indicated.</u></p> <p><u>“5. Drug Interactions. Clinicians should be knowledgeable concerning interactions between methadone and other drugs that tend to prolong the QT interval or to slow the elimination of methadone.</u></p> <p><u>“In light of the concerns with utilizing methadone for treatment of pain, and the cardiac safety concerns methadone is not recommended.”</u></p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Propoxyphene (Darvon®)</p>	<p>Commenter suggests the following revisions: Recommended as an option for mild to moderate pain, as indicated belowNot recommended for pain management. The most common brand names are Darvon® (propoxyphene hydrochloride), Darvon-N® (propoxyphene napsylate) or in combination with acetaminophen as Darvocet®. Generic available. Propoxyphene is structurally related to methadone. This is a synthetic opiate agonist that is ½ to 1/3 as potent as codeine. High doses are limited due to adverse effects including toxic psychosis. It is FDA approved for mild to moderate pain.</p>	<p>Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><u>Although commonly used, no data supports its therapeutic superiority to acetaminophen alone, and propoxyphene is associated with more addiction and renal toxicity than other opioids. Beers et al. places propoxyphene among the drugs inappropriate for use in the elderly due to lack of significant efficacy and high incidence of adverse effects. Despite this warning, propoxyphene-containing compounds are among the most prescribed medications in the Beers list, and use among the elderly remains high. Additionally, propoxyphene has a long half-life, and there is risk for accumulation of its toxic metabolite, norpropoxyphene. For these reasons, propoxyphene should be avoided in the management of chronic pain.</u></p> <p><u>It should further be noted that on February 28, 2006, Public Citizen petitioned the FDA to immediately begin to phase out the use and distribution of all propoxyphene containing products. These products have been associated with more than 2,110 accidental deaths since 1981, and these products are no more effective than safer alternatives. Furthermore, on January 30, 2009, an FDA advisory panel recommended that propoxyphene containing products be removed from the US market.</u></p> <p><u>The phased withdrawal in the United Kingdom of these products was announced one year ago when the British government stated that the efficacy of this product “is poorly established and the risk of toxicity in overdose, both accidental and deliberate, is unacceptable.” They further said that “It has not been possible to identify any patient group in whom the risk-benefit [ratio] may be positive.”</u></p> <p>(Commenter states that references are available for this information.)</p>			

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9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Serotonin norepinephrine reuptake inhibitors (SNRIs)</i>	Commenter recommends the following revision: See <u>dDuloxetine (Cymbalta®)</u> ; <u>venlafaxine (Effexor®)</u> ; & <u>mMilnacipran (Ixel®)</u> . See Antidepressants for chronic pain, SNRIs for general guidelines, as well as specific SNRI listing for more information and references.	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>SNRIs (serotonin norepinephrine reuptake inhibitors)</i>	Commenter recommends the following revision: Recommended as an option in first-line treatment of neuropathic pain, especially if tricyclics are ineffective, poorly tolerated, or contraindicated. See Antidepressants for chronic pain for general guidelines, as well as specific SNRI listing for more information and references. See also <u>vVenlafaxine (Effexor®)</u> ;and <u>Duloxetine (Cymbalta®)</u> ; & <u>milnacipran (Ixel®)</u> .	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	Commenters are seeing occupational physicians regularly dispense specially (pharmacist) compounded creams, capsules and co-packaged "drugs and medical foods" (boxes containing a prescription generic drug along with a proprietary "medical food"). Commenters state that this practice is starting to come to light after the Pharmaceutical Fee Schedule revision that capped pricing of repackaged drugs; and it is ever-growing. Commenters state that it is apparent that the dispensing of these compounded medications is not patient-specific. Commenters believe that since specially compounded medicines are billed (and reimbursed) at significantly higher prices than commercially available therapeutic	JaNice Kennedy Sr. Claims Examiner Cambridge February 20, 2009 Jeff Dalton Claim Supervisor Contra Costa County Risk Management February 20, 2009 Robert Wieland Sr. Claims Examiner February 20, 2009	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice. Similar arguments were raised during the 1 st 15-day comment period. These arguments were appropriately addressed in the 1 st 15-day comment period chart.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>equivalents, commenters opine that their mass-utilization is driven by the profit they generate.</p> <p>Commenters state that many of the "billing services" for these compounded medications use multiple DBA's, TINs and addresses (P.O. Boxes). Commenters question Why would that be? Might there be something to hide? Occupational treaters are being supplied with these compounded meds, just as they were with repackaged medications.</p> <p>Commenters believe that these pharmacist-compounded medications are being mass-produced and mass marketed to the industry. Commenters state that since there is no way to know if what is claimed to be in a specially compounded medication IS, they believe that this practice should be carefully scrutinized. Commenters are very concerned that profit, not patient care and medical necessity, is the primary drive behind what seems to be an indiscriminate use of pharmacist-compounded medications. As such, commenters urge the Division to address "specially compounded" (or "pharmacist-compounded") medications (creams, capsules and co-packaged drugs and medical foods) in the MTUS-Chronic Pain Guidelines.</p>	<p>Sue Karp-Simmons Adjustor – Contra Costa Risk Management February 20, 2009</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 both as a treating physician in the State of California, as well as an (inactive) registered pharmacist, it is his opinion that the role for these items is rare and infrequent. Commenter states that there are few needs not already covered by less expensive commercial products. Commenter adds that standards of cleanliness and consistency achievable in a manufacturing setting are far superior to those of a retail pharmacy. Commenter believes that there should rarely be an occasion to order such products.</p> <p>Commenter opines that the UCSF faculty would be</p>	<p>George Balfour, M.D. PharM.D. Immediate Past President California Society for Industrial Medicine and Surgery (CSMIS) February 18, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice. Similar arguments were raised during the 1st 15-day comment period. These arguments were appropriately addressed in the 1st 15-day comment period chart.</p>	<p>None.</p>

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	<p>the best source of correct billing information for custom retail compounded topicals. Commenter suspects that such charges would include the costs of materials, plus an allowance for wastage. Commenter indicates that wastage occurs with any compounding process. Commenter opines that an allowance for the time spent by the registered pharmacist at least equal to his time spent times his usual hourly rate would be reasonable and that the usual professional pharmacist fee allowed to all dispensed drugs should be chargeable.</p> <p>Commenter suspects that the above formula applied generously would result in a significant reduction in the charges presently being seen by the carriers for these items.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>1. Commenters disagree with a statement in the guidelines which states: “There is little to no research to support the use of many these agents.” Commenters state that this statement is short in stature but can be highly misinterpreted by claims adjustors and utilization review professionals. Commenters state that there is actually considerable clinical evidence and research supporting the use of such compounds. Commenters indicate that the proposed MTUS actually points to Voltaren Gel© which was released by the FDA in 2007, and the studies that made this drug available commercially precede the statement made by (Argoff 2006), which in and of itself dates the proposed MTUS before it is even accepted. Commenters question what happens later this year when new evidence is released supporting new combinations or products joining the market?</p> <p>2. Commenters would suggest alternate language for the statement in the guideline which states: “Any compounded product that contains at least one drug (or drug class) that is not recommended is not</p>	<p>Robert Nickell, Pharmacist February 14, 2009</p> <p>Scott Goldman, M.D. February 12, 2009 Written Comment</p>	<p>Disagree. Under Item No. 1, commenters object to language in the introductory paragraph of the individual treatment guideline on the topic of “Topical Analgesics,” wherein it is stated that “[t]here is little to no research to support the use of many of these agents.” Disagree with the comment. Although the introductory language states that “there is little to no research to support the use of many of these agents,” the guideline recommends the use of topical analgesics as an option as indicated in the specific sections of the guideline. The specific sections of the guideline details review of the individual agents, and sets forth the evidence-base for each agent. With respect to the comment relating to new evidence, DWC</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommended.” Commenters state that this sentence is also short in stature and it is a very powerful “double negative” and opens itself to misinterpretation by providers, claims adjustors, and utilization review personnel. Commenters state that the statement starts off with “ANY COMPOUND;” commenters believe that it should read “ANY TOPICAL COMPOUND,” since that is what the MTUS is referring to. Commenters believe that if it is left as “any compound,” it could essentially eliminate home infusion therapy, pain management pump therapy, epidurals, urologic medications, dermatology, oral combinations, etc.</p> <p>Commenters state that they do not understand the reasoning why a compound would be “not recommended” if it contains at least one ingredient that is “recommended.” Commenters state that if the patient can derive benefit from an ingredient that is recommended and the physician wishes to add another ingredient that is also beneficial, why would that invalidate the entire compound? Commenters state that if the DWC is concerned about the cost of the compound, then the most appropriate action is to address the OMFS rather than the treatment for the patient or question the judgment of the physician. Commenters recommend the following modified language, “Any topical compounded product that contains at least one drug (or drug class) that is recommended is therefore recommended.”</p> <p>3. Commenters disagree with assertions made under the subsection entitled, “Non-steroidal anti-inflammatory agents (NSAIDs): (a.) Commenters first assert that the articles being referenced did not anticipate or account for the release of Voltaren Gel © or Flector© patches, therefore the entire discussion is essentially moot; (b.) Commenters secondly assert</p>		<p>notes that 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 regulations provide a mechanism to rebut the presumption when there is new evidence such as “new combinations or products joining the market,” as contained in Section 9792.21(c).</p> <p>Under Item No. 2, commenters object to language contained in the individual treatment guideline on the topic of “Topical Analgesics,” which states: “Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Commenters first argue that the sentence incorrectly uses the phrase “any compound.” Commenters opine that the guideline should use the phrase “any topical compound,” because the use of “any compound” might apply outside of topical agents, such as home infusion therapy, pain management pump therapy, epidurals, urologic medications, dermatology, oral combinations, etc. Disagree with the commenters’ argument. The individual treatment guideline title “Topical Analgesics,” clearly indicates that the topic of the</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>that Ketoprofen is listed as a non-FDA approved agent. For the record, ketoprofen is FDA approved as an active ingredient to be used in oral, topical, or transdermal formulations. Commenters add there is a commercial formulation of ketoprofen scheduled to be released later this year, and question whether it will not be recommended upon becoming commercially available.</p> <p>4. Commenters object to the notice to consumer by the FDA being referenced as a reason to not recommend lidocaine. Commenters state that this statement by the FDA is in regard to a triple anesthetic compounded mixture that was being used by medical spas prior to laser hair removal. It is not relevant to “Chronic Pain Management.” Commenters indicate that the use of such rationale as a matter of policy would violate DWC’s own rules for promulgating regulation.</p> <p>5. Commenters object to the reference with regard to Capsaicin comparing 0.025% and 0.075% against 0.0375%. Commenters state this appears very limiting. Commenters indicate Capsaicin is a very potent active pharmacological ingredient and slight variations in percentages can result in greatly perceived outcomes for the patients. Commenters opine that on one hand the MTUS cannot only limit itself to two strengths, and on the other hand, the MTUS cannot justifiably record every strength it wishes to eliminate by not-recommending.</p> <p>6. Commenters object to the references with regard to gabapentin, muscle relaxants in general, antiepilepsy drugs in general, and baclofen as they are all listed as “not recommended.” Commenters state that some of these are listed as “little supporting evidence,” or “no evidence” or “no peer reviewed literature.”</p>		<p>guideline addresses “Topical Analgesics.” The guideline does not address home infusion therapy, pain management pump therapy, epidurals, urologic medications, dermatology, oral combinations, etc., thus commenters’ concerns are without basis.</p> <p>Commenters next recommend that the guideline be revised to state: “Any topical compounded product that contains at least one drug (or drug class) that is recommended is therefore recommended. Commenters state that if the patient can derive benefit from an ingredient that is recommended and the physician wishes to add another ingredient that is also beneficial, the entire compound should not be invalidated. Disagree with the recommendation. DWC notes that the physician who treats workers’ compensation is required to comply with the requirements of the statute that the treatment being provided is evidence-based (Lab. Code §§ 4600, 4604.5) pursuant to the MTUS which is presumptively correct (Lab. Code § 4604.5). Thus, in commenters’ scenario, if the physician wishes to add another ingredient that is also beneficial, the prescription is appropriate as long as there is demonstrated benefit (i.e.,</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenters believe that the statements are not consistent or accurate. Commenters question what happens when there is “greater supporting evidence,” and “peer-reviewed literature” available later this year to support the use of these agents in topical compounds.</p> <p>7. Commenters are concerned that the proposed MTUS is overlooking references to many other agents. Commenters state that, for example, no mention is made of methylsalicylate as a topical agent. Commenters ask if one is to assume that if an agent is not listed, it is therefore “recommended?” Or is it therefore “not recommended?”</p> <p>Commenters conclude that if DWC were to poll many of the patients who receive compounded medications prepared in his pharmacy, DWC would find a high degree of satisfaction and compliance, and a desire to continue therapies that have successfully managed their conditions and brought tremendous change in their quality of life.</p>		<p>evidence-based). However, if an ingredient has no proven benefit and lacks a scientific evidence-base to support efficacy, then such an ingredient should not be added to the compounded mixture. The pharmacist duties are those to fill the prescription as ordered by the physician who is required to follow the MTUS under California Law.</p> <p>Disagree with the comment that the guideline is intended to address costs issues. 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).</p> <p>Under Item No. 3, commenters appear to assert that the discussion contained in the guidelines is moot because the referenced articles did not anticipate or account for the release of Voltaren Gel © or Flector© patches (i.e., diclofenac) as contained in the section entitled: “Non-steroidal anti-inflammatory</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>agents (NSAIDs). Disagree with the comment. Commenters are incorrect, the articles are useful in reviewing other NSAIDs besides diclofenac. Commenters further assert that in the guideline Ketoprofen is listed as non-FDA approved agent. Commenter argues that Ketoprofen is FDA approved as an active ingredient to be used in oral, topical, or transdermal formulations. Disagree with commenters' assertion. The guideline provides that Ketoprofen is a non-FDA-approved agent for topical use. The guideline states as follows: "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 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)" Commenters offer no evidence-base to support their assertion that Ketoprofen is FDA-approved for topical or transdermal application. Again, if the product becomes commercially available based on further scientific research, the regulations provide</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>for its use as indicated in Item No. 1, above.</p> <p>Under Item No. 4, commenters object to the notice to consumer by the FDA being referenced as a reason to not recommend lidocaine. Disagree. Although the FDA permits the physicians prescribing off-label and the pharmacy practice of compounding, it does not review the efficacy of the compounded or off-label individualized treatment. On the other hand, the FDA does report all adverse effects in the product information for commercially manufactured drugs. Because of the unknown information regarding compounding and off-label medication, an FDA notice on adverse effects of a compounding practice is highly relevant in the prescribing of compounded agents. This information is not generally know to practicing physicians as there is no product information associated with the compounded product. Thus, the guideline serves the purpose of reporting known harms associated with the specific compounding.</p> <p>Under Item No. 5, commenters object to the reference with regards to Capsaicin comparing 0.025% and 0.075% against 0.0375%.</p>	

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			<p>Commenters appear to erroneously believe that 0.0375% would automatically be denied under the guidelines. Disagree with commenters' interpretation of the guidelines. It is clinically appropriate that topical compounded agents should be applied only after commercial products are considered and for some reason ruled out for the specific case. Since there are two commercially available strengths, there is evidence for both strengths to be effective, and the choice in the strength is individualized to the specific case. If for some reason, the 0.025% strength is ineffective, the 0.075% could be tried. However, if the 0.075% strength is beneficial but causes dose related adverse effects, an intermediate strength can be compounded and considered for the patient, even though that strength is not commercially available. Although there may not be studies to support an intermediate strength in head to head comparisons with other available strengths, because 0.025% and 0.075% brackets the 0.0375% strength, this should be effective against placebo. The utilization review process may then consider the compounded intermediate 0.0375% strength.</p> <p>Under Item No. 6, commenters</p>	

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			<p>object to the references with regard to gabapentin, muscle, antiepilepsy drugs, and baclofen as because they are listed as “not recommended.” Commenters question what happens when there is “greater supporting evidence,” and “peer-reviewed literature” available later this year to support the use of these agents in topical compounds. Again, if the product becomes commercially available based on further scientific research, the regulations provide for its use as indicated in Item No. 1, above.</p> <p>Finally, commenters offer their physician/patient experience to support use of compounded topicals treatment. The Labor Code requires the guidelines set forth in the MTUS be evidence-based as they are presumptively correct by statute. (Lab. Code, 4604.5.) 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</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			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).	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenters thank the Division for revising the California Division of Workers' Compensation's (DWC) policy that originally classified topical compounded analgesics as "not recommended." Commenters state that the previous wording would have denied critical medications to workers' compensation claimants who rely on these medications to treat their unique medical conditions.</p> <p>Commenters are confused by the newly revised policy that states:</p> <p>Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.</p> <p>Commenters opine that it is unclear if "not recommended" is a term that refers to the drugs that are designated by the DWC as "not recommended" or all drugs that do not fall under the DWC's listing of "recommended" therapies.</p>	<p>Adeyemi Omilana February 20, 2009 Written Comment</p> <p>Alan Gross, M.D. February 20, 2009 Written Comment</p> <p>Alan Ivar February 20, 2009 Written Comment</p> <p>Cherylee Gardea February 16, 2009 Written Comment</p> <p>Dana Gordon February 19, 2009 Written Comment</p> <p>Dara Saghafi, M.D. February 20, 2009</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.</p> <p>Moreover, it is noted that the statute is clear that “[u]pon adoption by the administrative director of a medical treatment utilization schedule pursuant to Section 5307.27, the recommended guidelines set forth in the schedule shall be presumptively correct on the issue of extent and scope of medical treatment.” (Lab. Code,</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenters believe that it is in patients' best interests to allow for prescribed therapies not yet reviewed by the DWC in which the clinical evidence overwhelmingly supports their continued use. Patients would be ill-served if physicians were unable to prescribe such treatments for lack of reimbursement. Therefore, commenters urge the Division clarify the policy to read that any compounded preparation that contains at least one drug that is designated by the DWC as "not recommended" is "not recommended." Commenters also urge the Division to revise the statement above to specifically refer to "topical compounded products" as opposed to "any compounded product." Finally, commenters request that the Division consider adding a pharmacist to the medical review board to provide another practitioner's knowledge and experience to pharmaceutical care decisions.</p>	<p>Written Comment David Matsuo February 16, 2009 Written Comment Douglas Ginter February 19, 2009 Written Comment Frank Martelli February 20, 2009 Written Comment Hootan Melamed, M.D. February 20, 2009 Written Comment</p>	<p>§4604.5(a.) Thus, every guideline which is adopted into the MTUS, as approved through formal rulemaking, becomes presumptively correct. However, the MTUS is clear that “if the condition or injury is not addressed in the MTUS,” then other “nationally recognized” guidelines which are “scientifically and evidence-based, [and] peer-reviewed” apply. (See, Section 9792.21(c); Lab. Code, § 4604.5(e).) Labor Code section 4604.5(a) further provides that “[t]he presumption is rebuttable and may be controverted by a preponderance of the evidence establishing that a variance from the guidelines is reasonably required to cure and relieve the employee from the effects of his or her injury. The presumption created is one affecting the burden of proof.” Labor Code section 4604.5(e) applies when the condition or injury is not addressed by the MTUS. This would include cases when there is new evidence, or when there is a guideline at variance with the MTUS. It would also include commenters’ concerns regarding agents not listed or not yet reviewed in the guidelines, or a treatment not found in the MTUS. Under these circumstances, the presumption of correctness does not apply, and it can be rebutted.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>by showing better evidence (i.e., a preponderance of the evidence establishing that a variance from the guidelines is reasonably required to cure and relieve). Merely presenting another guideline does not overcome the presumption. Rather, if another evidence review supports a different recommendation, the burden of proof rests on the person presenting the evidence-base to show that the new evidence is more convincing and overcomes the presumption.</p> <p>Commenters request that the Division consider adding a pharmacist to the medical evidence evaluation advisory committee (MEEAC). It is noted that ODG has pharmacists members in their editorial board that participate in formulating recommendations. Nevertheless, DWC acknowledges the suggestion and is in the process adding a pharmacist to the MEEAC as a subject matter expert.</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 have researched the use of topicals, and have found hundreds of pages from reputable medical journals that support the use of Ketoprofen, Gabapentin as well as many others that are not discussed in ODG. Commenters believe that the Division is limiting its research to ODG and ACOEM and ignoring the huge amount of literature in respected journals such as The British Medical Journal that clearly support the benefits of use as well as the efficacy.</p>	<p>Dr. Alan Gross February 20, 2009 Written Comment</p> <p>Jamie Waryck February 20, 2009 Written Comment</p> <p>Jason Kim, M.D. February 20, 2009</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded,</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>In their practice, commenters have analyzed the levels of Ketoprofen on arthroscopic synovial samples from arthroscopic procedures and has found therapeutic levels inside the knee at a much lower level of medication than when taken orally. Commenters point out that these topicals - Ketoprofen and Gabapentin are routinely used in the locker rooms of the Lakers and Kings as well as Dodgers and opines that if they are good enough for Kobe Bryant, they should be good enough for ALL worker injuries. offers to provide the Division with citations upon request.</p>	<p>Written Comment Jeffrey Goad, M.D. February 20, 2009 Written Comment Lionel Jara February 20, 2009 Written Comment Mary Walk February 20, 2009 Written Comment Matthew Walk, M.D. February 20, 2009 Written Comment Maureen Gray February 20, 2009 Michael Butcher February 20, 2009 Michael Rudolph, M.D. February 20, 2009 Written Comment Parvez Fatteh, M.D. February 20, 2009 Written Comment R. Wayne Blackburn, M.D. February 20, 2009 Written Comment</p>	<p>above. Moreover, it is noted that ODG has conducted an evidence-base review on the individual treatment guideline topic of “Topical Analgesics, compounded.” DWC believes that in as much as ODG has thoroughly reviewed the evidence, ODG would have identified “hundreds of pages from reputable medical journals that support the use of Ketoprofen, Gabapentin and other agents” if it was in the evidence base. Commenters did not submit the alleged evidence-base with their comments. Although commenter indicates that in their practice, they have analyzed the levels of Ketoprofen on arthroscopic synovial samples from arthroscopic procedures and have found therapeutic levels inside the knee at a much lower level of medication than when taken orally, their research and observations are not published in a peer-reviewed journal, and thus cannot be incorporated into the guideline. Moreover, 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</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		<p>Ray Reyhani February 17, 2009 Written Comment</p> <p>Robert Aptekar, M.D. February 20, 2009 Written Comment</p> <p>Robert Nickell February 20, 2009 Written Comment</p> <p>Robert Seiwert, M.D. February 17, 2009 Written Comment</p> <p>Sharon Steen February 16, 2009 Written Comment</p> <p>Terry O'Rourke, M.D. February 20, 2009 Written Comment</p> <p>Trisha Hatfield February 20, 2009 Written Comment</p>	<p>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 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 states that categorizing any compounded product that contains at least one drug or class that is not recommended as not recommended has broadened the classification to any compounded product, not just topical or transdermal products. Commenter opines this should also allow for the physician to add other treatments to a known recommended product without the classification becoming negative. Commenter points out that the wording of the guideline states, <i>“The physician should tailor medications and</i></p>	<p>Brent Tyndall, R.Ph. Calabash Family Pharmacy February 19, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded,</p>	<p>None.</p>

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	<p><i>dosages to the individual taking into consideration patient-specific variables such as co-morbidities, other medications, and allergies. The physician should be knowledgeable regarding prescribing information and adjust the dosing to the individual patient.</i>" Commenter hopes that with the language in mind, the division would allow any topical compounded medication that has one recommended drug or drug class be considered recommended.</p>		above.	
<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 extremely concerned about the proposed changes to guidelines concerning the use of topical analgesics. Commenters have found topical analgesics to be extremely useful in reducing pain and increasing function in patients with work-related injuries. Many of commenters' patients clinically are improved with these medications and typically request more. These medications reduce the need for additional narcotic analgesics in their patients.</p> <p>Commenters point out topical analgesics are one of the few options that patients can safely use without using sedatives while working or driving. Commenters state that their responsibility under Senate bill 899, SEC. Section 4605.5 of the Labor Code, is to "cure or relieve the injured worker from the effects of his or her injury." Commenters observe that the existing guidelines do not require that they must prove that topical analgesic medications improve function or reduce the need for other analgesic modalities.</p> <p>Commenters point out that the FDA approved commercially available topical analgesics such as Axsain, Banalog, Dendracin, and Voltaran Gel, which commenters state are cost-effective alternatives to compounded analgesics. Commenters state that these topical analgesics are either approved by the FDA or</p>	<p>Bruce R. Hoyle, M.D. February 15, 2009 Written Comment</p> <p>Dr. Silva February 19, 2009 Written Comment</p> <p>Gary Bennett, M.D. February 13, 2009 Written Comment</p> <p>Joe O'Neill Office Manager February 16, 2009 Written Comment</p> <p>John Luster, M.D. Family Practice February 16, 2009 Written Comment</p> <p>Tim Patrick President & CEO AIDAREX Pharmaceuticals LLC February 15, 2009</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.</p> <p>Moreover, disagree with commenters' opinion that under the proposed changes in the guidelines, all of the medications listed in their comment would be indiscriminately denied by the industrial carriers. If the FDA has approved the treatment, then there is an evidence base to support treatment for that indication, and the DWC guideline would be to recommend that treatment. Further, disagree with the comment that, based on the guideline as written, any commercially available topical analgesic which may contain any</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>comply with FDA regulations 21 CFR part 348. Commenters indicate that these medications also comply with ODG sections entitled “Topical Analgesics,” and “Pain; Capsaicin; Topical”, Aetna Chronic Pain Medical Treatment Guidelines, 2007, section “Topical Salicylates,” and Chronic Pain Disorder Medical Treatment Guidelines, State of Colorado, Department of Labor and Employment, Division of Workers Compensation, under the section “Topical Drug Delivery.” Commenters fear that under the proposed changes in the guidelines, all of these medications would be indiscriminately denied by the industrial carriers.</p> <p>Commenters believe that the proposed guidelines, which contains the new provision, "ANY COMPOUNDED PRODUCT THAT CONTAINS AT LEAST ONE DRUG (or drug class) THAT IS NOT RECOMMENDED IS NOT RECOMMENDED," would essentially eliminate all topical analgesics, especially, since this provision appears in the section entitled "Topical analgesics" and not in the section entitled, "Topical Analgesics, Compounded." Commenters state that any commercially available topical analgesic which may contain any active ingredients not covered by the proposed guidelines could be denied.</p> <p>Commenters indicate that topical analgesics with active ingredients such as menthol or camphor would be denied under this proposed revision because these ingredients are not in any of the recommendations but are typically added to many of the topical analgesics. Commenters believe that this provision would indirectly INCREASE the use of compounded topical analgesics in an attempt to comply with the new guidelines.</p>	<p>Written Comment Tulsi Gwalani February 17, 2009 Written Comment</p>	<p>active ingredients not covered by the proposed guidelines could be denied. If there is a commercial available treatment, then this is not a compounded agent. If there is a recommendation, for a commercial product, the guidelines would support its use. However, for compounded agents, all the active ingredients in a compounded mixture need to be effective. Also disagree with the comment that menthol or camphor would be denied under this proposed revision because these ingredients are not in any of the recommendations. If the treatment is not found in the MTUS, then other guidelines or scientific evidence may be used to support the treatment. Moreover, commercially available products are not affected by this guideline, this guideline addresses compounded agents. Disagree with commenters’ recommendations regarding monthly supply and response to treatment. This is all addressed in the guidelines.</p>	

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	<p>Commenters state that the following compromise in the Proposed guidelines should be considered:</p> <ol style="list-style-type: none"> 1) Change the proposed guidelines to state "ANY COMPOUNDED PRODUCT THAT CONTAINS AT LEAST ONE DRUG (or drug class) THAT IS RECOMMENDED IS RECOMMENDED." 2) Any topical medication that is FDA approved or complies with Federal Registry 21 CFR 348 should be authorized if indicated. This provision would include commercially available topical analgesics such as Axsain, Banalog, Dendracin, or Voltaran Gel. 3) Cap the maximum payment to \$3.00 per milliliter rather than the number or types of ingredients contained in the medication. 4) Allow a maximum 30-day prescription of no more than 120 ml per patient. 5) Follow up should contain information documenting the patient's subjective response to the topical medication using acceptable methods such as VAS but should not require evidence of functional improvement, return to work, or reduction of other analgesic modalities such as oral narcotics. 			
<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 pharmacist and has been working in regular retail pharmacy and compounding pharmacy for 25 years and has never seen a class of meds like the topical compounded analgesics make such a huge improvement in patient care. Commenter states that they eliminate the need for oral medications, which most of the time cause a plethora of problem, such as liver issues, gastric upset and gastric bleed, sedation and addiction.</p>	<p>Christine Givant La Vita Compounding Pharmacy February 9, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded,</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter recommends that the wording in the proposed new guidelines should read:</p> <p>“if there is at least one drug (or drug class) that IS recommended, then the DWC will rate this a recommended treatment.”</p>		above.	
<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 section requires polishing. Commenter advises that the Division should flip flop the wording to say that if there is one drug in the compound that is approved then it will be paid for. Commenter opines that if there is one drug that is not approved then it will not be paid for is just wrongheaded thinking. Commenter assumes that the Division is interested in helping the patient and should get on the right page. Commenter inquires if the Division understands that the FDA reasoning on this issue is wrong? The same FDA that approves drugs that hurts or kills thousands of people. Remember Vioxx and Bextra? FDA approved. Commenter requests that the Division reconsider its stance on this issue, or that it will be responsible for doing incalculable harm to many patients by withholding payment for treatment.</p>	<p>Richard Brisson, R.Ph. – PharmaHealth Pharmacy February 6, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.</p>	None.
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter refers to the statement that any compounded product that contains at least one drug [or drug class] that is not recommended is not recommended. Commenter believes that this statement should read instead as---if there is at least one drug [or drug class] that Is recommended, then the Division will rate this as a recommended treatment. Commenter states that this would allow the usage of certain compounds that are very effective which are included as recommended with other ingredients that are not included but the combination is more effective and safer for the patient.</p>	<p>Satish Kadaba February 8, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.</p>	None.
<p>9792.24.2(a) Chronic Pain Medical Treatment</p>	<p>Commenter opines that DWC has put a rush to release an updated MTUS over conducting thorough research into the recommendations that are made.</p>	<p>Cort Colbert February 17, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>1) Commenter states that within the MTUS, the following statement is made and he disagrees with the opinion expressed by it:</p> <p>“There is little to no research to support the use of many of these agents.”</p> <p>Commenter opines that this sentence is short in stature but can be highly misinterpreted by claims adjusters and utilization review professionals. Commenter states that there is actually considerable clinical evidence and research supporting the use of such compounds. Commenter requests that the Division access the peer-reviewed database of Compounding Education Resource (http://compoundingeducationresource.org) where copious amounts of data regarding compounds and their various agents can be found. Commenter indicates that even so, the proposed MTUS actually points to Voltaren Gel©, which was approved by the FDA in 2007. Commenter states that upon review the current draft of the MTUS, the studies that helped make Voltaren Gel© available commercially precede the statement made by (Argoff 2006). Commenter opines that this in and of itself dates and invalidates the draft MTUS before it is even accepted. Commenter states that the Division must consider what happens later this year when new evidence is released supporting new combinations or products joining the market.</p> <p>2) Commenter suggests alternate language for the statement:</p> <p>“Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended”.</p>		<p>February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above. Moreover, it is noted that ODG has conducted an evidence-based review on the individual treatment guideline topic of “Topical Analgesics, compounded.” DWC believes that in as much as ODG has thoroughly reviewed the evidence, ODG would have identified evidence to support the use of Ketoprofen, Gabapentin and other agents” if it was in the evidence base. Commenter did not submit the alleged evidence-base with his comments.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter opines that this sentence is also short in stature and is a very powerful “double negative” and opens itself to misinterpretation by providers, claims adjustors, and utilization review personnel. Commenter believes that this shows that the division has put little thought into the recourse of such a vague statement, or the structure of such. Commenter observes that the sentence starts off with the phrase “ANY COMPOUND.” Commenter opines that if the Division keeps this sentence, it should read “ANY TOPICAL COMPOUND” since that is what the draft MTUS is referring to in this section. Commenter adds that if it is left as “ANY COMPOUND,” it could essentially eliminate home infusion therapy, pain management pump therapy, epidurals, urologic medications, dermatology, oral combinations, etc. Commenter is hopeful that the committee meant to say “ANY TOPICAL COMPOUND” in this context. Secondly, commenter does not understand the reasoning why a compound would be “not recommended” if it contains at least one ingredient that is “not recommended.” If the patient can derive benefit from an ingredient that IS recommended and the physician wishes to add another ingredient that is also beneficial, or helps with absorption, commenter asks why that would invalidate the entire compound. If the Division is attempting to address the cost of some compounds with this statement, then the most appropriate action is to address the OMFS rather than the treatment for the patient or question the judgment of the physician in their treatment.</p> <p>Commenter states that in addressing the original language in the proposed MTUS, he recommends the following replacement language, “Any topical compounded product that contains at least one drug (or drug class) that is recommended is therefore</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommended."</p> <p>3) Commenter disagrees with assertions made in the section under "Non-steroidal anti-inflammatory agents (NSAIDs):</p> <p>First assertion: Commenter states that the articles being referenced did not anticipate or account for the release of Voltaren Gel © or Flector© patches, therefore the entire discussion is essentially moot. Commenter opines that any research that is used for or within the draft MTUS must be current and allow for future developments within the pharmaceutical community. Commenter indicates that if it does not, he believes there will have to be a new/revised MTUS every year or so in order to keep up with industry innovations. Commenter doubts that the Division will want to perform this duty.</p> <p>Second assertion: Commenter states that within the MTUS, Ketoprofen is listed as non-FDA approved agent. Commenter indicates that for the record, Ketoprofen is FDA approved as an active ingredient to be used in oral, topical, and transdermal formulations. Commenter adds that there is a commercial formulation of Ketoprofen that is scheduled to be released later this year (2009). Commenter inquires if this means it will not be recommended upon becoming commercially available? Commenter opines that the Division has not completed current research before making assertions within the draft MTUS. Commenter requests that current research be studied before a final MTUS is completed.</p> <p>4) Commenter objects to the "notice to consumer" by the FDA being referenced as a reason to not recommend Lidocaine (or any other agent for that</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>matter). Commenter states that this statement by the FDA is in regard to a triple anesthetic compounded mixture that was being used by medical spas prior to laser hair removal. Commenter opines that it is not relevant to “Chronic Pain Management,” and was directed at a select group of compounding pharmacies/locations. Commenter opines that the use of such a rationale as a matter of policy would violate the Department’s own rules for promulgating regulation.</p> <p>5) Commenter states that within the draft MTUS, the reference with regards to Capsaicin comparing 0.025% and 0.075% against 0.0375% appears very limiting. Capsaicin is a very potent active pharmacological ingredient and slight variations in percentages can result in greatly perceived outcomes for the patients. Commenter understands what the DWC is trying to do here, but believes that it may be in bad faith. Commenter opines that on one hand the MTUS cannot only limit itself to two strengths; but on the other hand, the MTUS cannot justifiably record every strength it wishes to eliminate by not-recommending.</p> <p>6) Commenter objects to the way references are being used with regard to Gabapentin, muscle relaxants (in general), anti-epilepsy drugs (in general), and Baclofen. Commenter states that within the draft MTUS, they are all listed as “not recommended.” Commenter indicates that some of these are listed as “little supporting evidence,” “no evidence,” or “no peer reviewed literature.” Commenter opines that these statements are not consistent or accurate. Commenter states that there is research available on these agents, however it is not just going to fall in the laps of the DWC, it must be part of a thorough literature review. Commenter poses the question:</p>			

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	<p>What happens when there is “greater supporting evidence”, and “peer-reviewed literature” available later this year to support the use of these agents in topical compounds?</p> <p>7) Commenter is concerned that the proposed MTUS is overlooking references to many other agents currently used in topical compounds. Commenter states that, for example, no mention is made of methylsalicylate as a topical agent. Is one to assume that if an agent is not listed, it is therefore “recommended?”</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>It is commenter’s understanding that a possible DWC regulatory language change is imminent that would be detrimental to commenter’s patients and patients in the state of California. Commenter is a compounding pharmacist in Monterey County, and currently has patients that are successfully treated with both manufactured and compounded medications. Commenter states that the latter are generally prescribed when medical necessity is warranted, often as a result of traditional treatment failure.</p> <p>Commenter opines that if such language is implemented, quality care will be severely compromised and many choices will be eliminated that are currently being successfully utilized by thousands of patients.</p> <p>Commenter, on behalf of the many patients in Monterey County, and the State of California, urges the Division to change the language or wording within the DWC to reflect the USE of topical compounded medications as "Recommended."</p> <p>"If there is at least ONE drug (or drug class) that is NOT recommended, than the DWC will rate this as a Non-recommended treatment."</p>	<p>Dana Gordon, Pharm.D. President Central Avenue Pharmacy February 9, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above. Moreover, it is noted that the physician ordering a compounded mixture that contains active ingredients that are not recommended, is likely to receive a utilization review denial for that treatment unless the treating physician can provide evidence for the treatment. Since it is a matter of the compounding pharmacist to prepare an individualized treatment for the patient, the omission of not recommended active ingredients pursuant to the doctor’s orders should be straightforward.</p>	<p>None.</p>

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	<p>Commenter states that this means that if, for example, Diclofenac is recommended, and gabapentin is not, and they are then compounded together in combination, the compound in and of itself is not recommended since it contains a bad egg (gabapentin) so to speak.</p> <p>Commenter states that this statement needs to be reversed.</p> <p>"if there is at least one drug (or drug class) that IS recommended, then the DWC will rate this a recommended 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 would like to impress upon the Division, from the practice trenches, the value of compounded medicines.</p> <p>Commenter believes that the Division is in danger of an error to assume that compounded medications should not be approved if they contain any substance not approved. Commenter opines that if it were always the case then no pill will ever be approved as some contain gel (no medical benefit) others have binders to hold the pill together-some sugars-no direct benefit. Commenter believes that direct application in chronic pain improves compliance and reduces long term systemic effects.</p> <p>Commenter states that there are compliance and efficacy studies that support use especially in long term joint disorders and chronic pain.</p> <p>Commenter states that these compounds are available for use worldwide and for the private sector and he urges their adoption into a schedule as other medications are currently. Commenter wants to confirm the value of compounded medical topicals</p>	<p>Daniel Capen, M.D. February 13, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above. Moreover, it is noted that inert agents are not the drug or drug class. It is the specific drug or drug class that is “not recommended.”</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>and suggests that the Division cannot be blind to the following:</p> <ul style="list-style-type: none"> • Benefits of topical • The rest of the free world has compounded for the last 5-10 years • All US professional sports teams rely on topical • Literature documents compliance and reduced side effects • The provider (sleaze-factor) influence to modern day care 			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>Commenter notes the guideline statement, which categorizes any compounded product that contains at least one drug or class that is not recommended as not recommended. Commenter opines that this statement unfortunately has broadened the classification to any compounded product, not just topical or transdermal products. Commenter opines that the guideline should allow for the physician to add other treatments to a known recommended product without the classification becoming negative. Commenter notes that the Division's proposal states, "The physician should tailor medications and dosages to the individual taking into consideration patient-specific variables such as co-morbidities, other medications, and allergies. Commenter opines that the physician should be knowledgeable regarding prescribing information and adjust the dosing to the individual patient." With this in mind, commenter requests that the Division allow any topical compounded medication that has one recommended drug or drug class should be considered recommended.</p>	<p>Gamze Strain, R.Ph. Granbury Drug February 18, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.</p>	<p>None.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines</p>	<p>Commenter is a practicing physician who cares for Worker's Compensation patients. Commenter has prescribed topical compounded medications for his patients with excellent results. Commenter states that</p>	<p>Gary Baker, M.D. February 20, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>many of his patients have been able to reduce or even totally eliminate the opiate pain medications they were taking. Commenter is encouraged that the DWC does see a role for this class of medications for its injured workers. Commenter encourages the division revise to the current wording to allow this class of medication if at least one of, or the primary component of the topical compound is on the recommended list. Commenter believes that this will prevent the arbitrary denial of the entire class of compounded topical medications as the current wording is in danger of doing. Commenter requests that the Division clarify the policy to read that any compounded preparation that contains at least one drug that is designated by the DWC as "recommended" is "recommended." Commenter urges the Division to revise the statement above to specifically refer to "topical compounded products" as opposed to "any compounded product."</p>		<p>Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, 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 submitted a randomized controlled trial with Dendracin topical pain lotion compared to another commercially-available topical analgesic to demonstrate the pain and functional improvements. [Note: This study is part of the official rulemaking file and is available upon request.] Commenter requests that the Division review this study and add to the evidence which favors continued prescription of FDA approved commercially available topical analgesics.</p>	<p>Gary D. Bennett, M.D. February 13, 2008 Written Comment</p>	<p>Disagree. If the MTUS does not cover this treatment, the treatment may be under “other guidelines” pursuant to Section 9792.21(c). See response to comment submitted by Adeyemi Omilana, et. al., dated February 20, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.</p>	<p>None.</p>
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain</p>	<p>Commenters are concerned that the Division is recommending a statement on Topical Compound reimbursement stating that “Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.”</p>	<p>James P. Tasto, M.D. Steven Tradonsky, M.D. Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenters request that due to the effect of the drugs and to the nature of how they work, the statement be revised to: “If there is at least one drug or drug class that is recommended, then the Division of Workers’ Compensation will rate this as a recommended treatment.”</p> <p>Not revising this would have a most negative impact on patient care. Commenters strongly urge the division to make the suggested revision.</p>	<p>Rina Jain, M.D. Jonathan J. Myers, M.D. Written Comment</p> <p>San Diego Sports Medicine & Orthopaedic Center February 10, 2009 Written Comment</p>	<p>12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above. Moreover, it is noted that the “recommended guidelines set forth in the schedule ... shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed.” (Lab. Code, §4604.5(b).) It impacts patients negatively to use treatment that are not of scientifically proven benefit.</p>	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter is writing in response to the California Worker’s Compensation Division’s (CWCD) revised proposed policy addressing topical compounded analgesics. Commenter states that the concerns of the American Pharmacists Association (APhA), expressed in the first round of this proposal, have been mitigated but not completely addressed. Commenter remains opposed to the policy due to its potential negative impact on workers’ compensation claimants who may rely on compounded products 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. Commenter adds that compounding allows physicians to prescribe and pharmacists, utilizing their medication knowledge and expertise, to produce tailored medications that meet a patient’s individual needs, which may include a particular route of administration. Commenter indicates that in providing</p>	<p>John A. Gans, PharM.D. Executive Vice President American Pharmacists Association (APhA) February 20, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice. Commenter raised the same arguments during the 1st 15-day comment period, and the comments were appropriately addressed in the 1st 15-day comment period chart. Moreover, commenter requests that the Division consider adding a pharmacist to the medical evidence evaluation advisory committee (MEEAC). It is noted that ODG has pharmacists members in their editorial board that participate in formulating recommendations. Nevertheless, DWC acknowledges the suggestion and is in the process of adding a pharmacist to the MEEAC as a subject matter expert.</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>compounding services, pharmacists work hand-in-hand with physicians to solve health care problems not addressed by the commercial marketplace.</p> <p>Commenter appreciates the Division’s ongoing efforts to ensure appropriate medical treatment of persons injured on the job. To that end, commenter supports the revisions to the proposal that would provide access to compounded topic analgesics. Commenter’s members, however, remain concerned about the limits placed on the use of these products. Commenter opines that limiting access to these compounded products disrupts the patient-pharmacist-physician triad relationship and could have dire consequences for the health of individual patients. Commenter states 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 believes that this restriction would not exist if the same patient with the same medical need had been injured off of the work site.</p> <p>Commenter opines that the medication expertise of a pharmacist appears to have been overlooked in this process. As pharmaceuticals increasingly become the first line of defense in health care, commenter believes that it is inappropriate not to engage pharmacists in the process of determining what medications work best for any patients, including worker compensation claimants. Commenter points out that other entities that make coverage determinations, such as state Medicaid programs and private health plans, include pharmacists when determining what drugs should be included in a plan’s formulary based upon a drug product’s effectiveness and cost. Commenter states that this formulary</p>			

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	management process is no different from the work of the Division of Workers' Compensation. Commenter believes that it is imperative that the expertise of a pharmacist be tapped during this process and that no one else on the health care team has the medication expertise of a pharmacist. To this end, commenter strongly encourages the Division to expand the membership of the Medical Evidence Evaluation Advisory Committee to include a pharmacist.			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter states that although this is limited to California, he is concerned about how concepts can spread or be used inappropriately by others.</p> <p>Commenter indicates that there are many issues, within the "treatment schedule" for workers compensation in California, however, the most important sentence to restructure is the following:</p> <p>It currently reads "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended."</p> <p>Commenter suggests that the wording be changed to the following:</p> <p>"Any topical compounded product that contains at least one drug (or drug class) that is recommended therefore is recommended."</p>	Mark Braun, MS, RPh February 16, 2009 Written Comment	Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter commends the Division on taking some action on changing the proposal for chronic pain medication treatment guidelines. Commenter also believes that without the assistance of some experts in the field of drugs and compounding the proposal has in itself become more confusing and troublesome.</p> <p>Commenter indicates that as an educator in this field, he can understand how this happens, but the end results can be detrimental to the Division, patients,</p>	Michael Rudoph, PharM.D. Executive Director Community Pharmacy Practice USC School of Pharmacy February 16, 2009 Written Comment	Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded,	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>and the profession of pharmacy.</p> <p>Commenter suggests that the Division solicit experts in this area to help with the background information that is needed and he would like to offer his services, if needed, to either refer the Division to experts in the area of compounded drug treatment for pain management or offer his services. The new proposed guidelines, in commenter's opinion, have numerous problems and the following are a few of the glaring issues:</p> <ul style="list-style-type: none"> • Commenter states that categorizing any compounded product that contains at least one drug or class that is not recommended is not recommended. This statement unfortunately has broadened the classification to any compounded product, not just topical or transdermal products. Commenter states that it also should allow for the physician to add other treatments to a known recommended product without the classification becoming negative. Commenter notes that the Division's proposed language states, <i>"The physician should tailor medications and dosages to the individual taking into consideration patient-specific variables such as co-morbidities, other medications, and allergies. The physician should be knowledgeable regarding prescribing information and adjust the dosing to the individual patient."</i> Commenter states that with this language in mind, he hopes this would allow any topical compounded medication that has one recommended drug or drug class should be considered recommended. • Commenter states problems with accuracy of information in the proposal exist. Commenter states that Ketoprofen is listed as a non FDA approved agent. Commenter indicates that this is incorrect since 		<p>above. Moreover, commenter requests that the Division consider adding a pharmacist to the medical evidence evaluation advisory committee (MEEAC). It is noted that ODG has pharmacists members in their editorial board that participate in formulating recommendations. Nevertheless, DWC acknowledges the suggestion and is in the process adding a pharmacist to the MEEAC as a subject matter expert.</p>	

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	<p>ketoprofen is an FDA approved drug but is currently not FDA approved for topical or transdermal application.</p> <ul style="list-style-type: none"> • Commenter states that citing an FDA release on issue of topical lidocaine appears to be used to discredit the practice of compounding. Commenter opines that if we listed all instances of problems with therapies used out of norm, we would not have enough space for any proposal. Commenter believes that the instances of problems in specific cases should be handled by licensing agencies and not be addressed in guidelines. 			
<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 are several areas where he believes further review and amendment are in order. Commenter states that those areas that specifically address compounded topical analgesics are of particular interest to him, since many of the patients he serves have been prescribed such therapies.</p> <p>Commenter notices that of all those who contributed to this document not one was listed as a pharmacist. Commenter believes the medical evidence evaluation advisory committee could have benefited greatly by obtaining the input of a pharmacist who has experience compounding at least some of the agents considered here for workers' compensation patients. Commenter is certain a volunteer could be found to fill such a position.</p> <p>Commenter objects to the continued assertions that "There is little to no research to support the use of many of these agents," or that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety." Commenter states that the MTUS is presumed to be correct on the issue of extent and scope of medical treatment and</p>	<p>Mike Pavlovich, PharM.D. RPM Pharmaceuticals February 11, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above. With regard to the comment objecting to language in the introductory paragraph of the individual treatment guideline on the topic of "Topical Analgesics," wherein it is stated that "[t]here is little to no research to support the use of many of these agents," see specifically response to Item No. 1. Further, it is noted that commenter did not submit the alleged evidence-base with his comments.</p> <p>Commenter requests that the Division consider adding a</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>diagnostic services it addresses. Commenter points out that, however, the presumption can be set aside by a preponderance of scientific medical evidence that shows a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of his or her injury. For all conditions or injuries not addressed by the MTUS, authorized treatment and diagnostic services must be in accordance with other scientific, evidence-based medical treatment guidelines that are nationally recognized by the medical community. Commenter states that he would gladly volunteer to provide copies of the many references he has collected to refute these claims.</p> <p>Commenter states that the mention of ketoprofen contains several inaccuracies or conflicting statements. <i>“Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application.”</i>...<i>“Absorption of the drug 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)”</i>. Commenter indicates that, for the record, ketoprofen has long been FDA-approved. While it may not currently exist in a commercial topical formulation, commenter states that one is on the way to market. Commenter wonders if he can expect the MTUS to change once this occurs. Ballerini, et al (1986) found Median Cmax levels in plasma to be 130-fold less than that obtained after oral intake, which would counter and precede the argument made by Krummel. Commenter agrees completely that the base utilized to deliver ketoprofen and other agents across the skin barrier is critical to success and can offer several additional studies in this regard. A competent</p>		<p>pharmacist to the medical evidence evaluation advisory committee (MEEAC). Agree in part. It is noted that ODG has pharmacist members in their editorial board that participate in formulating recommendations. Nevertheless, DWC acknowledges the suggestion and is in the process adding a pharmacist to the MEEAC as a subject matter expert.</p> <p>Commenter inquires about the complete list of the references noted in this MTUS. Commenter alleges that it is difficult to evaluate evidence presented attributed to only an author and year of publication. Commenter notes that the word document downloaded from the Division’s link omitted the list. Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice. The same issue was raised during the 45-day comment period, and this comment was appropriately addressed with changes to the regulations in the 1st 15-day Notice. At that time, Appendix D, containing the list of references for the chronic pain medical treatment guidelines, was added to the regulations as Section 9792.24.2(e).</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>compounding pharmacist should be able to provide cogent advice in this regard. Commenter states that oral delivery of NSAIDs accounts for over 16,000 deaths ANNUALLY, while no record of mortality exists to his knowledge when NSAIDs are delivered topically. Other complications from oral delivery such as peptic ulcer disease are likewise significant and avoidable. Commenter surmises the Department should have a profound interest in therapies that provide a high degree of safety. Biswal, et al., <i>J Rheumatology</i> (2006) found in a meta-analysis that there was no statistically significant correlation between efficacy and duration of treatment. This implies that the efficacy of topical NSAIDs does not diminish over time.</p> <p>With regard to lidocaine, commenter points out that the statement “Formulations that do not involve a dermal patch system are generally indicated as local anesthetics and anti-pruritics” should be amended to read “Commercially-available formulations that do not involve a dermalpatch system are generally indicated as local anesthetics and anti-pruritics.” Lidocaine can also be delivered by incorporating it into liposomal bases, such as those prepared by compounding pharmacists, resulting in a truly transdermal delivery. Commenter can produce several evidence-based studies to support this statement.</p> <p>Commenter is troubled by the use of such a statement as “In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. 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. Systemic exposure was highly variable among patients. Only FDA-approved products are</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>currently recommended.” As a matter of policy, this would violate the Department’s own rulemaking guidelines regarding such in basing the decision (in part or whole) on the FDA "press release." Commenter not only believes that the Department is misinterpreting/misusing the press release, but he believes that it is not representative of the FDA's overall approval of compounded medications.</p> <p>Commenter urges the Division to read the release. It is neither evidence-based nor peer reviewed. It is merely a policy statement by the FDA, coupled with a warning issued to several compounding pharmacies that "mass marketed" their compounds for general distribution. Commenter opines that the FDA warning has absolutely no references to any clinical studies, nor does it cite any scientific research. It is merely a policy position and a policy position that merely states that compounds should not be mass marketed. Commenter notes that, in fact, the policy paper (and that's what it is, a policy paper, not a study or a piece of scientific research), clearly states that the "<i>FDA normally permits such traditional pharmacy compounding (defined by them as: Traditional pharmacy compounding typically involves pharmacies preparing drugs that are not commercially available, such as a unique medicine for a patient who is allergic to an ingredient in a FDA-approved drug. This kind of compounding follows a physician’s decision that his or her patient has a special medical need that cannot be met by FDA-approved drugs) and the agency’s action is not targeting this practice. 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.</i>" Therefore,</p>			

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	<p>commenter asserts that the FDA is clearly not denouncing the efficacy or safety of traditional pharmacy compounding, but is denouncing compounding pharmacies that act like manufacturers, those who are mass-marketing compounds, as compared to compounding at the special request of a physician.</p> <p>Furthermore, commenter alleges that citing or excerpting this FDA "press release" as a means of discrediting compounded medications containing lidocaine or other ingredients considered "not recommended" both violates the policy of only relying on evidence-based, peer reviewed, research (which this clearly isn't), and misinterprets the FDA's findings and conclusions, which merely denounces the "mass marketing of compounds," and clearly endorses the need and efficacy of "traditional pharmacy compounding." It is commenter's assertions that this FDA piece really would lend itself to finding a "recommend" status for topical compounded analgesics, since the FDA clearly states in this "press release" that it recognizes the need, appropriateness and efficacy of "traditional pharmacy compounding," and that is what the Department is addressing here, not the issue of compounding pharmacies mass producing compounds, but whether legitimate, traditional compounding should get a "recommended," or a "not recommend."</p> <p>Commenter states that the discussion of capsaicin presents a conundrum in that 0.075% and 0.025% formulations are considered acceptable, while an intermediary potency (0.0375%) is questioned because "no studies" exist. Commenter asks if we could just leave it to the treating physician to decide what dose is appropriate for his or her patient when deciding which drug is or is not appropriate. In</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>commenter’s experience many patients have required potencies in excess of 0.075% in order to attain relief. Commenter opines that maybe no studies exist for those strengths either, but it does not mean they will not work. Tangentially, commenter has also witnessed many a hospice patient who required doses of opiates that are far above the manufacturer’s labeling limits or recommendations because they fall so far outside the norm as to escape study.</p> <p>Commenter states that the statement on gabapentin is also puzzling to him. Commenter indicates that as an oral agent it is considered first-line therapy. Commenter notes that yet, when cited in regards to topical administration the MTUS claims “There is no peer-reviewed literature to support use.” Commenter points to Swaynok J. Topical and Peripherally Acting Analgesics. <i>Pharmacologic Reviews</i>. 2003;55(1):1-20 and Vince V. Topical treatment of neuropathic pain. <i>International Journal of Pharmaceutical Compounding</i>. 2008; 12(3):183-190 as evidence to the contrary and can produce additional information if necessary. Commenter believes that the route of administration is insignificant, except that topical formulations generally require a far smaller total dose to achieve analgesia. Similar comments could be made in opposition to claims made about “other anti-epilepsy drugs.”</p> <p>Commenter states that perhaps the most objectionable statement commenter finds is “<i>Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.</i>” Commenter indicates that this statement is immediately followed by “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>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter notes that the latter infers that the guidelines will defer to the judgment and expertise of the physician.</p> <p>Commenter believes that the MTUS effectively makes his case wherein the fifth paragraph, under the subject: Functional Restoration Approach to Chronic Pain Management, at page 8, is modified to include three new sentences in the middle of the paragraph. Commenter notes that the new statement reads as follows: “Choice of pharmacotherapy must be based on the type of pain to be treated and there may be more than one pain mechanism involved. <i>The physician should tailor medications and dosages to the individual taking into consideration patient-specific variables such as co-morbidities, other medications, and allergies. The physician should be knowledgeable regarding prescribing information and adjust the dosing to the individual patient. If the physician prescribes a medication for an indication not in the approved FDA labeling, he or she has the responsibility to be well informed about the medication and that its use is scientific and evidence-based (emphasis added).</i>” Commenter states that this is precisely the premise and rationale behind the use of a compounded topical analgesic medication. Commenter concludes that the inclusion of an agent otherwise considered “recommended” should be so regardless of the route of administration.</p> <p>Commenter believes that much would be gained through the establishment of a fee schedule for compounded medication that takes into account the time, the overhead, necessary equipment and expertise of the pharmacy personnel involved in the preparation. Commenter urges and insists on the inclusion of experienced compounding pharmacists who serve workers’ compensation patients in the</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>development of any such reimbursement models.</p> <p>Commenter also encourages a mechanism for regular submission, review, and consideration of new evidence that may change the opinion or direction of the guidelines. Commenter believes that, as well, there needs to be a clear understanding among payors that these guidelines should be interpreted to benefit the patient first, and support the medical decisions made by the physician whenever possible.</p> <p>Commenter asks if it would be possible to locate a complete list of the references noted in this MTUS as it makes it difficult to evaluate evidence presented attributed to only an author and year of publication. Commenter believes that the word document he downloaded from the division's link omitted the list.</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 compounds are the future. Commenter deals with back pain every day. Commenter uses a ketorub compound and it provides him with a moment of peace. It helps commenter function as a provider for his family. Commenter cannot take oral pain meds they make him feel sick and are addictive. Commenter questions why the Division doesn't recognize that this is better medicine and better patient care. Commenter states that if there are pharmacies that are unethical that the Division should go after them -- why deny care to people who desire it?</p>	<p>Paul Stevenson February 20, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above. Moreover, 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</p>	<p>None.</p>

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			<p>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 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 individual treatment guideline on the topic of “Topical Analgesics, compounded,” which issued with 1st 15-day Notice be restored to the chronic pain medical treatment guidelines. Commenter opines that compounded topical analgesics should not be recommended for treatment in the workers’ compensation population. It appears that commenter wants to keep the <i>Topical Analgesics</i> individual treatment guideline, and the <i>Topical Analgesics, compounded</i> individual treatment guideline as two separate guidelines.</p> <p>Commenter further recommends that the following language be inserted in the new Topical Analgesics, compounded individual treatment guideline:</p>	<p>Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment</p>	<p>Disagree. The individual treatment topic guideline for “Topical Analgesics, compounded,” at pp 118-119, was modified to reference the individual treatment topic guideline “Topical Analgesics,” and by striking the entire text of the guideline. The modification resulted from many comments received from the regulated public during the 1st 15-day comment period arguing that the guideline would completely ban all topical compounded drug treatments. This</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>“Traditional pharmacy compounding involves the preparation of a drug by a pharmacist for an individual patient pursuant to a valid prescription. The need for a compounded drug is typically based on the doctor’s judgment that the patient has a special medical need for the compounded formulation which cannot be met by commercially available FDA approved drugs. Situations in which a patient has an allergic reaction to the commercially available product, or is unable to ingest the commercially available dosage form, are examples which constitute a special medical need and make the preparation of a compounded drug medically necessary.</p> <p>“It is understood that pharmacists may compound medications that were previously commercially available, but are not available in the marketplace now, or that have been removed from the market for reasons other than safety or efficacy. We support the efforts of skilled compounding pharmacists in this regard.</p> <p>“However, it is not appropriate for pharmacists to compound:</p> <p>“Drug products that are essentially copies of commercially available medications.</p> <p>“Experimental or investigational combinations of drugs that have no medical or scientific support for their safety and effectiveness.</p> <p>“New dosage vehicle forms in which the component drug(s) will have little or no beneficial effect, and there is a less expensive commercially available product that will achieve the same clinical effect.</p>		<p>was not the intention of the guideline. After reviewing the comments, ODG was consulted to evaluate the scientific evidence pertaining to the compounding pharmacy practice of mixing more than one active ingredient. From this evidence-based review, as conducted through its formal internal review, ODG determined that it was appropriate to modify its Topical Analgesics and Topical Analgesics, compounded guidelines to include language addressing compounding more than one topical analgesic. (See, ODG Topical Analgesics, compounded Guideline Update, January, 21, 2009.) DWC agreed with the modifications made to the “Topical Analgesics” and “Topical Analgesics, compounded” individual treatment guidelines, and the guidelines were modified as noticed in the 2nd 15-day notice.</p> <p>Disagree with the recommended edits in reference to the practice of compounding pharmacy. The MTUS is not intended to regulate the practice of pharmacy. Because the MTUS is not intended to regulate the practice of pharmacy, commenter’s edits in reference to what is appropriate compounding are not accepted. DWC notes that it is the physician who treats injured workers who is the one</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>“Drug products with formulation changes made as a pretext to avoid FDA enforcement of marketing an unapproved drug.</p> <p>“Drug products for which the patient has no special medical need, and there is no other medical or economic justification for the compounded product.</p> <p>“Compounded products are not reviewed by the FDA for safety and effectiveness, and their preparation is not bound by the FDA’s current Good Manufacturing Practices (cGMP) standards that would help assure product strength, identity, purity, potency, quality and stability. As such, their quality depends almost entirely on the skill of the compounding pharmacist and the cleanliness of the environment in which the product is prepared. The FDA therefore encourages patients and physicians to use FDA approved commercially available products whenever possible.</p> <p>“Please be advised that compounding pharmacies may also not imply a benefit for a compounded drug for which there is no medical or scientific basis, and they may be in violation of federal law by making false or misleading claims about unapproved therapies.</p> <p>“We are therefore obligated to take the view that the safety and effectiveness of all drug therapy, including compounded products, must be supported in the current medical literature, and the choice of drug therapy must contribute positively to the patient’s overall goals of therapy in a cost effective manner.</p> <p>“Our review of the medical literature shows that compounded products often lack:</p> <p>“• Valid and acceptable clinical evidence, especially randomized controlled trials</p>		<p>required to comply with the requirements of the statute that the treatment being provided is evidence-based (Lab. Code §§ 4600, 4604.5) pursuant to the MTUS which is presumptively correct (Lab. Code § 4604.5). The pharmacist duties are those to fill the prescription as ordered by the physician who is required to follow the MTUS under California Law.</p> <p>Disagree with the comment regarding the review of the evidence. As previously indicated, ODG conducted the evidence-based review, and the DWC has adapted their review. Further, 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).</p>	

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	<p>“• Valid safety and efficacy data, as opposed to information that is historical, anecdotal or experimental, or is extrapolated from FDA approved dosage forms</p> <p>“• A definition of the pharmacokinetic characteristics of the final product</p> <p>“• A certification of process using the FDA’s current Good Manufacturing Practices (cGMP) standards, and</p> <p>“• A tracking mechanism for reporting adverse events and toxicity resulting from the use of the product.</p> <p>“Finally, it should be noted that there are currently no standards in place for the pricing of compounded drug products. As a result, compounding pharmacies can charge exorbitant prices, which may substantially exceed the average wholesale price (AWP) of ingredients plus a usual and customary fee. There has clearly been a tendency for compounded drug prices to bear little relation to the cost of making them, and to unnecessarily increase the overall cost of health care.</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 recommends striking following language: <i>Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.</i> 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>Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment</p>	<p>Disagree. Commenter strikes the specific language apparently on the basis that if his recommendation on keeping the individual treatment guideline on “Topical analgesics, compounded” is accepted, the language in the individual treatment guideline on the topic of “Topical Analgesics” is inconsistent. Disagree for the reasons set forth in the response to the comment submitted by Ralph Kendall, Vice President, Clinical Services, Healthsystems, dated February 20, 2009, on Section</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 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, Topical Analgesics, compounded, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Topical Analgesics	<p>Commenter recommends the following revision:</p> <p><i>Lidocaine Indication: Neuropathic pain</i> <i>Lidocaine patch (Lidoderm®):</i> Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). 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 local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post herpetic neuralgia.</p> <p>Other topical lidocaine preparations: Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics.</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The commenter does not offer substantive reasons for the proposed edits to the text of the guideline relating to “Lidocaine.”	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Topical Analgesics	<p>Commenter suggests the following revision:</p> <p><i>Capsaicin:</i> Recommended only as an option in patients who have not responded or are intolerant to other treatments. <i>Formulations:</i> Capsaicin is <u>commercially generally</u> available as a 0.025% formulation (as a treatment for osteoarthritis), and a 0.075%, and 0.1% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. Commenter does not offer a justification for the recommended edits to the text of the guideline relating to “Capsaicin.” ODG conducted its own evidence-based review on this topic and the studies supported use of only the two strengths set forth in the guideline.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	mastectomy pain).			
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics</i>	<p>Commenter suggests the following revision:</p> <p>Baclofen: Not recommended <u>as a topical preparation</u>. 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.</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The commenter does not offer substantive reasons for the proposed edits to the text of the guideline relating to “Baclofen.”	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics</i>	<p>Commenter suggests the following revision:</p> <p>Gabapentin: Not recommended <u>as a topical preparation</u>. There is no peer-reviewed literature to support use.</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The commenter does not offer substantive reasons for the proposed edits to the text of the guideline relating to “Gabapentin.”	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter continues to endorse comments submitted previously by the American College of Occupational and Environmental Medicine (ACOEM), particularly those expressing concern about sanctioning treatments supported only by uncontrolled trials, case series and other lower-graded forms of published data.</p> <p>Commenter states that it is of interest that the average monthly amount Liberty Mutual alone has paid for physician dispensed compounds has <i>increased 568%</i> since the March, 2007 modification to CCR OMFS Pharmaceuticals Section 9789.40 (b). Based on commenter’s experience, he estimates that the entire California workers’ compensation system is now paying in excess of \$20 million annually for medications that are unregulated and of unproven efficacy. Commenter offers the following recommendations to help ensure that this increased expenditure of resources is optimally benefiting injured workers and that their treatments are effective.</p>	David C. Deitz, M.D., PhD, Vice President National Medical Director, Commercial Professional Services Liberty Mutual Group February 20, 2009 Written Comment	<p>Disagree. With regard to the comment relating to ODG’s rating methodology, the comment does not address the substantive changes made to the proposed regulations during the 2nd 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>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</p>	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter continues to have concerns regarding the proposed changes that deal with compounded pharmaceuticals, and makes suggestions concerning issues in the following 4 areas:</p> <p>1. Under the subtitle, <u>“There is no evidence of the value of adding extra components that have unproven efficacy to a compounded medication,”</u> commenter notes that the Work Loss Data Institute’s prior comment that the previous MTUS proposal to ban an entire class of topical compound medication was unfair, and that the ingredients, not the delivery method, should be addressed in the guidelines. Commenter agrees with ODG’s comment that, “Many agents are compounded as monotherapy or in combination for pain control [...and...] There is little to no research to support the use of many of these agents.”</p> <p>Commenter also agrees with the ODG comment with clarifying language indicating that, “...there is no evidence for use of any other muscle relaxant as a topical product, and that there is no evidence for use of any other anti-epilepsy drug as a topical product.”</p> <p>Commenter states there needs to be consideration of situations where insufficient care is being taken by the prescribing physician to describe when compounded balms and salves, creams and ointments, unguents and perfumes are appropriate. For example, commenter is not opposed to capsaicin cream, which is manufactured and has a record of efficacy. However, commenter indicates that Liberty Mutual data for the last 12 months show far fewer requests for that medication for pain as they have had for Wasabi cream, which has no efficacy record.</p>		<p>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>Agree in part regarding Item No. 1. Agree with the comment stating that only active ingredients that have demonstrated efficacy should be combined in a compounded topical mixture. Disagree with the proposed additional language to the guideline. The suggested edit is duplicative as it merely repeats what is already contained in the guidelines.</p> <p>Agree in part regarding Item No. 2. Agree that the reasonable practice of medicine dictates that once some therapy is applied, documentation of the specific benefit of that intervention should be evident for any drug to be continued. Disagree with commenter’s edits specifying the time frame in which efficacy is demonstrated with using a compounded topical analgesic agent. DWC believes that efficacy should be addressed for every treatment, not only topical analgesics. This subject is addressed in Part 1, Introduction</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter agrees that the ingredients should provide significant clinical benefit and that all should be of proven worth. Commenter states that the current provision that any medication not proven to be effective should invalidate the appropriateness of the compounded medication is reasonable, based on the studies demonstrating that transdermal absorption is dependent on multiple factors like lipid solubility, dermal metabolism, part of the body used, etc. Commenter adds that the addition of extraneous compounds ‘believed to help’ where no proof exists raises the possibility of interfering with the absorption and/or metabolism of the compounds known to be effective. For this reason commenter strongly urges the Division to adopt the provision below. Thus, commenter also supports the ODG provision that <i>“Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.”</i></p> <p>Commenter recommends that the individual treatment guideline on the topic of “Topical Analgesics” be amended as follows:</p> <p>“Only topical preparations with proven transdermal penetration and efficacy for any substance identified as an active ingredient in the compounded medication are allowed. Use of compounded topical medications should be limited to those instances where adequate proof of efficacy exists for the specific preparation used, whether it is a single-drug or multiple component compound.”</p> <p>2. Under the subtitle, <u>“There does not appear to be adequate expectation or requirement for provider documentation that a compounded and/or topical medication is effective,”</u> commenter notes that the use of compound medications often continues in the</p>		<p>to the chronic pain medical treatment guidelines at page 8-9, wherein it is stated: “The physician should periodically review the course of treatment of the patient and any new information about the etiology of the pain or the patient's state of health. 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.medbd.ca.gov/pain_guidelines.html).”</p> <p>Disagree regarding Item No. 3. Commenter appears to argue that the individual treatment guideline on the topic of “Topical Analgesic” does not properly address usage. ODG conducted its own evidence-based review, and prepared its guideline based on the evidence. The guideline provides that the use of these compounded agents requires knowledge of the</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>absence of demonstration of efficacy. Commenter states that while research-quality evidence is not, nor will be, available for the majority of possible compounds, the reasonable practice of medicine dictates that once some therapy is applied, documentation of the specific benefit of that intervention should be evident for any drug to be continued. Commenter states that it is good practice to have long-term use of medications normally indicated for short term use (such as opioids, cyclooxygenase-2 inhibitors and benzodiazepines) reviewed frequently for continued effectiveness with attention to issues of tapering and discontinuation. Commenter indicates that given the lack of evidence of efficacy for most compounded medication ingredients, he believes that a requirement for periodic review and documentation of initial and ongoing efficacy is necessary and is consistent with good medical practice. Commenter opines that this is in the best interests of the injured worker and has the ancillary benefit that medications not explicitly documented to be effective will be discontinued.</p> <p>Commenter recommends that the individual treatment guideline on the topic of “Topical Analgesics” be amended as follows:</p> <p>“For any compound medication we recommend that initial (within 1-3 weeks) and on-going (every 4-6 weeks) efficacy and effectiveness be documented. Whenever possible, this documentation should contain quantitative measures of effectiveness (e.g., specific quantification of functional improvements).”</p> <p>3. Under the subtitle, <u>“Topical preparations, particularly compounded ones, are typically at the margins of effective care, though there is some evidence for efficacy of topical NSAIDs (which are</u></p>		<p>specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. In order for a physician to recommend treatment with a compounded agent, he or she must specify the specific treatment goal for the patient, such as why the patient is unable to use other proven therapies.</p> <p>Disagree regarding Item No. 4. The MTUS regulations are not intended to regulate medical providers networks and who provides services, such as dispensing compounded drugs.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>available in standard formulations which do not require compounding). Commenter suggests that such unproven formulations should be used last (i.e., after established therapies have been tried and failed, or otherwise shown to be contraindicated or not fully effective) and with specific measurable goals.” commenter notes that there are no randomized controlled trials evaluating the use of many topical compounded medications. Commenter opines that unless specific indications exist, use of compounded medications without evidence of efficacy should be allowed only as an option in patients who have not responded or are intolerant to other treatments. Commenter indicates that such allowed use should be required to show some tangible gain (e.g., specific and defined functional improvement, lowering of overall oral pain medication use, etc.). Commenter adds that as the use of these drugs is often initiated to minimize the use of oral medications such as opioids, and to minimize overall side effects of chronic medication (by lowering overall dose), a reasonable time should pass to allow determination as to whether other therapies, with more proof of efficacy, might be all that is needed. Commenter alleges that there are no long-term studies of the effectiveness or safety for the vast majority of compounded medications; thus, their use in chronic conditions should be sparing and done with concern for chronic side effects.</p> <p>Commenter states that medication should have a documented record of efficacy. For example, commenter notes transdermal tricyclic antidepressants (TCAs) would only be appropriate where there is documented need for a TCA and the claimant is unable to swallow or absorb an oral preparation.) Commenter notes this is consistent with WHO recommended guidelines on the use of opiates for acute and chronic pain, where the oral form of the</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>medication is the preferred route in all instances, except when there is an obvious and proven contraindication to the oral route.</p> <p>Commenter recommends that the individual treatment guideline on the topic of “Topical Analgesics” be amended as follows:</p> <p>“Except in extraordinary circumstances, compounded medications should not be an initial therapeutic choice for industrial injuries, particularly common problems for which effective branded or generic formulations already exist. Treating physicians who utilized compounded medications should be required to articulate a clear rationale as to why their patient is unable to use other proven therapies and requires a compound medication.”</p> <p><i>-and-</i></p> <p>“Specifically, for topical preparations (e.g., for a "balm or salve") the DWC guideline should limit the situation where topical medications are allowed to be prescribed for work-related injuries to circumstances in which there is a documented justification for the medication, where the medication has a proven record of efficacy, and the injured worker is unable to use standard oral preparations for medically documented and appropriate reasons.”</p> <p>4. Under the subtitle, <u>“To control quality of preparations and to allow utilization of network/MPN efficiencies, it seems reasonable to allow all licensed compounding pharmacists to dispense.”</u> commenter notes that the state of Florida has a provision as follows - 465.0276 (2), (c): “Prior to dispensing, give patient a prescription and advise that they can have it filled by practitioners' office or any pharmacy.”</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that this allows the use of network compounding pharmacists, who have as a core competency in the preparation of appropriately compounded pharmaceuticals. Commenter believes that this affords a degree of resource management consistent with the California MPN.</p> <p>Commenter recommends that the individual treatment guideline on the topic of “Topical Analgesics” be amended as follows:</p> <p>“Prior to dispensing a compounded medication, the patient should receive a prescription and be advised that he or she can have this prescription filled by the practitioners’ office or at any licensed compounding pharmacy”</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 notes that the first two sentences of this section provide:</p> <p>“Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety.”</p> <p>If, as the guideline states, the use is largely experimental and there is little evidence to the treatment’s efficacy or safety, commenter questions why it is “recommended.”</p> <p>Commenter states that compounding of these ointments has filled the niche previously held by re-packaging drugs. Commenter opines that this is likely to become a bigger problem with this permissive language as it will be difficult, if not impossible, to deny the use of these questionable substances.</p> <p>Commenter objects to the guideline in its entirety because of the lack of levels of evidence being stated.</p>	<p>Steven Suchil Assistant Vice President American Insurance Association February 20, 2009 Written Comment</p>	<p>Disagree. Commenter objects to language in the introductory paragraph of the individual treatment guideline on the topic of “Topical Analgesics,” wherein it is stated that topical analgesics are “[l]argely experimental in use with few randomized controlled trials to determine efficacy or safety.” Although the introductory language states that topical analgesics are “[l]argely experimental in use with few randomized controlled trials to determine efficacy or safety,” the guideline recommends the use of topical analgesics as an option as indicated in the specific sections of the guideline. The specific sections of the guideline details review of the individual agents, and sets forth</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>In Topical Analgesics, as in many other topic areas, commenter notes a lack of evidence yet it is “recommended.”</p> <p>Commenter notes that the guideline contains the following language:</p> <p>“Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.”</p> <p>Commenter opines that this proviso will only lead to reformulating to allow for prescribing these very questionable and expensive prescriptions.”</p> <p>Commenter states that if the guideline is to be retained he suggests the following clarification:</p> <p>“Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended shall result in a not recommended citation for the compounded substance.”</p>		<p>the evidence-base for each agent.</p> <p>Disagree with the comment that it will be “impossible to deny the use of these questionable substances,” based on the guideline language because the guideline provides that “[a]ny compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.” Moreover, the remaining text of the guideline clearly states what agents are not recommended. In this regard, disagree with commenter’s edit on this language, as his edits make the guideline confusing.</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 state that according to members of CWCI, compounded prescriptions, and particularly compounded topical analgesics, is an area of considerable and growing abuse in the workers’ compensation system in California. Commenters state that compounded products are reasonable and necessary only in exceptional medical circumstances that should always be documented and pre-authorized. Commenters opine that if the regulations are adopted as currently written, the DWC will appear to sanction the abuse, claims administrators will be powerless to prevent it, inadequate, substandard, or injurious medical care will be imposed on injured employees, and medical costs will rise unnecessarily. Commenters indicate that the FDA regards compounded drugs as unapproved new drugs for</p>	<p>Brenda Ramirez Claims and Medical Director California Workers’ Compensation Institute (CWCI)</p> <p>Michael McClain General Counsel & Vice President California Workers’ Compensation Institute (CWCI)</p> <p>February 20, 2009 Written Comment</p>	<p>Disagree. See response to comment submitted by Ralph Kendall, Vice President, Clinical Services, Healthsystems, dated February 20, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics, compounded, above. Moreover, see response to comment submitted by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>which safety and efficacy have not been demonstrated and it is difficult to understand why the Division has chosen to ignore, and has deleted, the specific FDA warnings about the potential dangers of compounding topical medications containing local anesthetics. Commenters add that if no change is made to this section, an additional increase in medical costs will result, which needs to be addressed in statements of economic impact.</p> <p>Commenters opine that the regulation is internally inconsistent as it recommends topical analgesics when the regulation also states that topical analgesics are “largely experimental in use with few randomized controlled trials to determine efficacy or safety.”</p> <p>Commenters endorse the comments on compounded and topical medications submitted by Dr. David Deitz on behalf of Liberty Mutual Insurance Group.</p> <p>Commenters recommend that DWC remove the references to compounding in the topic guideline for topical analgesics and restore the topic guideline on compounded topical analgesics as originally written. Commenters further recommend that DWC change the “recommended” status for topical analgesics to “not recommended.”</p>		Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i>	<p>Commenter points out that the Chronic Pain Medical Treatment Guidelines (pg. 116) indicate that topical analgesics are “largely experimental in use with few randomized controlled trials to determine efficacy or safety.” The Guidelines also point out that many agents are often combined to create a compounded product and propose that “any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.”</p> <p>Commenter provides the following recommendations</p>	Marie W. Wardell Claims Operations Manager State Compensation Insurance Fund February 20, 2009 Written Comment	Disagree. See response to comment submitted by Ralph Kendall, Vice President, Clinical Services, Healthsystems, dated February 20, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics, compounded, above. Moreover, see response to comment submitted	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>related to Topical Analgesics:</p> <ul style="list-style-type: none"> • While compounded dermal products may be “largely experimental,” the fundamental drugs involved in the compounded dermal products must continue to meet the requirement of evidence-based, peer-reviewed, nationally recognized standards of care. State Fund recommends that the Chronic Pain Guidelines specify this requirement in order to clarify any uncertainty. • Commenter recommends that any compounded dermal product must demonstrate safety and efficacy in well designed studies in order to be ‘recommended.’ Dermal medications should not be combined in a compound unless there are clinical trials demonstrating that the combination dermal compound is safe, efficacious and has no unintended consequences. • Commenter recommends specifying that compounded analgesics are for dermal use only and are not intended to be administered orally or in any other form. Medications with evidence of efficacy by one route are not equally effective via another route. By clarifying this language in the Guidelines, commenter can prevent unnecessary utilization review disputes which could lead to potential delays in treatment for injured employees. <p>Commenter offers the following language:</p> <p>“Each individual drug that is used to create a compounded topical analgesic product must be supported by evidence-based, peer-reviewed, nationally recognized standards of care. Any compounded topical analgesic product that has not been demonstrated as safe and efficacious in well designed studies is not recommended.”</p>		<p>by Robert Nickell, Pharmacist, dated February 14, 2009, and Scott Goldman, M.D., dated February 12, 2009, on Section 9792.24.2(a), Chronic Pain Medical Treatment Guidelines, Part 2. Pain Intervention and Treatments, Topical Analgesics – compounded, above.</p>	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Lastly, commenter has concerns regarding the lack of a fee schedule for compounded topical analgesics. If any compounded dermal product is recommended in the Guidelines, commenter believes that a corresponding fee schedule must be developed in order to determine reasonable reimbursement rates for approved drugs and prevent costly litigation.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Compounding Pharmacy</p>	<p>Commenter suggests the following:</p> <p>1. Recommend ADDITION of a section entitled "Compounded Drugs," as follows:</p> <p>Compounded Drugs: Specially compounded drugs are permissible in the acute hospital setting.</p> <p>Pharmacist-compounded formulations are generally not recommended.</p> <p>Conditions for Which Pharmacist-Compounded Formulations Are Recommended:</p> <p>* Documented patient allergy to the inactive ingredient(s) in commercially available formulation(s). Medical records must document the allergy(ies), and prior written approval must be obtained from the payor.</p> <p>* No commercially available formulation exists that meets the patient's particular medical needs.</p> <p>Exception: Use of a pharmacist-compounded formulation containing concentration(s) of active ingredient(s) that differ from those in commercially available formulation(s) is not recommended unless there is evidence-based research to show that the pharmacist-compounded formulation is more efficacious than that which is commercially available</p>	<p>Denise Niber-Montoya, Sr. Claims Adjuster Contra Costa County Risk Management February 19, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>(in either OTC or prescription form).</p> <p>* Patient, under the care of a pain management specialist, requires specially-compounded capsules to facilitate weaning from narcotics.</p> <p>* Documented inability to swallow necessitating specially compounded formulation(s). Prior written approval must be obtained from the payor.</p> <p>2. Recommend CHANGE to the section "Topical analgesics, compounded" as follows:</p> <p>See "Topical Analgesics" and "Compounded Drugs."</p> <p>3. Recommend CHANGE to all references of "See Topical analgesics, compounded" to:</p> <p>See "Topical Analgesics, compounded" and "Compounded Drugs."</p> <p>4. Commenter recommends that the chronic pain medical treatment guidelines include an additional section entitled "Co-Packaged Drugs and Medical Foods: Not recommended," as follows:</p> <p>“Co-Packaged Drugs and Medical Foods: Not recommended Theramine (tm) is not recommended. GABAdone (tm) is not recommended.</p> <p>OR ALTERNATIVE Recommended Language (addressing Theramine (tm) and GABAdone (tm) Ingredients), as follows:</p> <p>Co-Packaged Drugs and Medical Foods: Not recommended</p>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p> δ-aminobutyric acid (GABA): Not recommended choline bitartrate: Not recommended L-arginine: Not recommended Whey protein hydrolysate: Not recommended L-histidine: Not recommended L-glutamine: Not recommended metabromine: Not recommended 5-hydroxytryptophan: Not recommended grape seed extract: Not recommended L-serine: Not recommended cinnamon bark: Not recommended cocoa / cocoa powder: Not recommended Glutamic Acid: Not recommended Griffonia Extract: Not recommended Whey Protein: Not recommended Valerian Extract: Not recommended Ginkgo Biloba: Not recommended </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 recommends that the chronic pain medical treatment guidelines include information about medical food/nutraceuticals in the guidelines. (Recommend to include the following information) Medical Foods: According to the FDA a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." The designation as a "medical food" allows manufacturers to make medical claims about a product. It should be noted that these agents do NOT undergo FDA review and may not be safe and effective like an FDA approved medication. The manufacturers are responsible for ensuring safety and efficacy. There are no human studies documents or reviews of drug interactions, side effects, or hepatic, renal, and gastrointestinal effects. It is recommended that traditional agents be selected for the treatment of</p>	<p>Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice.</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>the conditions these products claim to treat. Products include but are not limited to the following:</p> <p>GABAdone™, Hypertensa™, Limbrel®, Theramine™, Sentra AM™, Sentra PM™, Prazolamine™, Senophylline™, Lytensopril™, Strazepam™, Trazamine™, Theraproxen™.</p>			
<p>9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Topical Analgesics - compounded</i></p>	<p>As a health care practitioner, I feel it highly inappropriate to categorically limit the prescribing habits of physicians who are evaluating the health, wellbeing and healing process of patients.</p>	<p>Robin Johnson, RPh King's Compounding Pharmacy February 17, 2009 Written Comment</p>	<p>Disagree. 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 it is not the intention of the MTUS to interfere with the doctor-patient relationship. However, because the primary 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</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			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).)	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Vioxx	Commenter finds it comical that reference is made to Vioxx since it was pulled from the market in 2004, and aside from any manufacturer samples still hiding deep in someone's drug closet, commenter doubts it would become an issue. Commenter states that the act of prescribing it or dispensing it would be a <i>de facto</i> violation of medical and pharmacy regulation.	Mike Pavlovich, PharM.D. RPM Pharmaceuticals February 11, 2009 Written Comment	Disagree. Commenter objects to the mention of the individual treatment guideline on the topic of "Vioxx" in the chronic pain medical treatment guidelines on the basis that the drug "was pulled from the market in 2004." Disagree with the comment. The guideline indicates that the drug was "pulled from market 10/5/05." The information is left in the guideline on an informational basis for the benefit of the regulated public.	None.
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments Ziconotide (Prialt®) And Intrathecal drug delivery systems, medications And Chronic Pain	Commenter appreciates the consideration that the Division has provided in reviewing his 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 Chronic Pain Treatment Guidelines and the language now indicates that PRIALT (ziconotide, intrathecal infusion) is "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." Commenter notes that under the section titled, "Implantable Drug Delivery Systems Medications" on pages 56 – 57 of the Chronic Pain Treatment	Nick Poulious, Ph.D. Vice President, Pricing & Reimbursement Elan Pharmaceuticals, Inc. February 12, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Implantable drug-delivery systems Medications</i></p>	<p>Guidelines, PRIALT is recommended 3rd stage after documentation of a trial of intrathecal morphine AND hydromorphone (Dilaudid). Commenter would like to inform the Division of the inconsistencies between the “Implantable 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 believes that this minor modification, in addition to the language changes that he has previously recommended, will further eliminate the inconsistencies between the language contained within these two sections.</p> <p>In summary, commenter agrees with the modifications to the “Ziconotide” section of the Chronic Pain Treatment Guidelines; however, he recommends that these changes also be incorporated into the “Implantable Drug Delivery Systems Medications Section.” Specifically, he respectfully recommends that the word “AND” in the “Implantable 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>			

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	[Note: Commenter has enclosed the detailed drug information for PRIALT (ziconotide). This information is part of the rulemaking file and is available upon request.]			
9792.24.2 Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments- (General Comment)	<p>Commenter suggests including information regarding medications for constipation prophylaxis, including but not limited to, saline laxatives (glycerin, lactulose, sorbitol), bulk-forming laxatives (psyllium, methylcellulose, and polycarbophil), stimulant laxatives (bisacodyl, phenolphthalein, castor oil, cascara sagrad, senna), and osmotic agent (polyethylene glycol). Commenter suggests the following language:</p> <p>“Patients taking opioid analgesics frequently encounter constipation as a side effect of their therapy. While taking chronic opioid therapy, an osmotic laxative plus a stimulant is advised, especially for those who are bedbound. Bulking agents plus adequate fluid intake (eight 8ounce glasses of fluid per day) may be tried, but there is evidence that inadequate fluid intake can result in an impaction. Initiation of a daily prophylactic bowel regimen is recommended to avoid GI complications such as impaction and paralytic ileus when daily use of opioids is anticipated. This should consist of a stimulant (e.g., Senna, up to two tablets four times daily), an osmotic laxative (e.g., lactulose, 15 to 30 mL daily), and ample water intake for the period of time the patient remains on regular, scheduled doses of opioids.</p> <p>“Such a program will provide predictable and effective elimination, and reduce evacuation problems and GI complaints. Enemas and suppositories may be necessary to clear the rectum prior to commencement of the bowel management program.”</p>	Ralph Kendall Vice President, Clinical Services Healthsystems February 20, 2009 Written Comment	Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	None.
9792.24.2	Commenter would like to point out that the proposed	Richard Martin,	Disagree. The comment does not	None.

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chronic Pain Medical Treatment Guidelines (General Comment)	<p>MTUS for chronic pain has omitted any mention of spinal facet joint blocks, injections or facet rhizotomies. Commenter states that the ODG Guidelines do mention this topic briefly in their chronic pain guidelines. Commenter indicates that the ODG chronic pain section has a few sentences on this topic and basically sends you back to extensive discussion of these procedures in the neck and low back sections of ODG. Commenter indicates that these procedures are used for chronic spinal pain and the ACOEM initial back chapter's glosses over them very briefly.</p> <p>Commenter states that these procedures have become more popular than epidural injections and there are frequent incidences when administration of the procedures does not follow guideline standards in ODG. Commenter believes that it will be a frequent point of unnecessary contention if this issue is not addressed in some detail in the MTUS chronic pain guidelines.</p> <p>Commenter has worked as a Peer Reviewer for SCIF for many years. Commenter believes that this subject will come up over and over and it would be best to address it now rather than in a future revision. If not, commenter believes there will be a significant amount of unnecessary med-legal evaluations and unnecessary court hearings if this topic is not addressed in the pending MTUS updates.</p>	M.D., MPH February 6, 2009 Written Comment	address the substantive changes made to the proposed regulations during the 2 nd 15-day notice.	
9792.24.2 Chronic Pain Medical Treatment Guidelines (General Comment)	Commenter states that she did not understand some of the proposed changes. Commenter states that, for example, on page 15 of the proposed changes pertaining to chronic pain, section 4 indicates that: "Deletion of an ODG individual treatment topic or relevant portions of a topic when the treatment	Roberta Valdez February 17, 2009 Written Comment	Disagree. Insomnia treatment drugs were removed from the ODG's Chapter on Pain, and not adapted into the chronic pain medical treatment guidelines. DWC believes that this topic	

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommendation does not relate to chronic pain.” Commenter notes that various medications are then listed one of which is Ambien (zolpidem). Commenter states that one of the medications that she is currently taking for chronic pain is Ambien as she has difficulty sleeping directly as a result of chronic pain. (Commenter’s condition is permanent and stable but she still suffers from chronic pain as a result of herniated discs with a subsequent 3 level discectomy and fusion).</p> <p>Commenter inquires about whether this change means that she will have difficulty continuing with her medication, Ambien. Commenter strongly protests as sleeping difficulties often exist with chronic pain.</p>		<p>belongs to a sleep disorders special topic area. DWC intends to develop guidelines addressing this additional special topic in the future. In the interim, Section 9792.23(b) applies to provide treatment for sleep disorders. (See, MTUS, 1st 15 Day Notice, Appendix A1, dated November 2008, at pp. 15-16.)</p>	
<p>9792.24.3 Postsurgical Treatment Guidelines (General Comment)</p>	<p>Commenters state that the explanation provided in the Notice of Modification for using the terms “therapist” and “therapy” instead of “physical therapist” and “physical therapy” is to clarify that physical medicine is intended to encompass both physical therapy and occupational therapy and may be performed by either a physical therapist or an occupational therapist. Commenters state that the Institute agrees with that intent but urges the Division to specify “physical or occupational therapist” and “physical or occupational therapy” because the terms “therapist” and “therapy” are open to wide interpretation that will trigger disputes. Commenters indicate that if the Administrative Director decides to retain the terms “therapist” and “therapy,” it will be necessary to add definitions of these terms to these regulations. Commenters recommend that DWC replace the term “therapist” with “physical or occupational therapist” and the term “therapy” with “physical or occupational therapy” wherever the terms “physical therapist” and “physical therapy” were modified during this rulemaking.</p>	<p>Brenda Ramirez Claims and Medical Director California Workers’ Compensation Institute (CWCI)</p> <p>Michael McClain General Counsel & Vice President California Workers’ Compensation Institute (CWCI)</p> <p>February 20, 2009 Written Comment</p>	<p>Disagree. The regulations are clear that the use of the terms “therapy” and “therapist” refers to “physical therapy or therapist” and “occupational therapy or therapist” consistent with Labor Code section 4604.5(d).</p>	<p>None.</p>
<p>9792.24.3</p>	<p>Commenter continues to object to the addition of the</p>	<p>Steven Suchil</p>	<p>Disagree. The comment does not</p>	<p>None.</p>

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<p>Postsurgical Treatment Guidelines (General Comment)</p>	<p>postsurgical treatment guidelines because, in his opinion, these guidelines are not evidence-based, as required by the statutory authority. Commenter's rationale has been submitted with earlier comments and will not be repeated. Commenter hopes his comments as to those guidelines will receive attention before the rulemaking is completed.</p> <p>Commenter's greatest concern is that the postsurgical treatment guidelines speak in terms of number of visits but is silent as to the treatment to be provided. Commenter states that without specificity, disputes will be rampant, unnecessary treatment to some is assured, and medical costs will rise.</p> <p>Commenter indicates in the case of the proposed postsurgical treatment guidelines, they clearly state there are no studies to support the allocation of services. Commenter notes the MTUS requires evidence and clinically based, peer-reviewed, nationally recognized guidelines. Commenter believes that this clearly does not meet any of the statutory requirements.</p> <p>Commenter states that continued addition of guidelines that do not clearly state the level of evidence is not consistent with the goals of improved patient care and reduced expenses related to unnecessary treatments and litigation. Commenter is already seeing the cost for medical care beginning to rise. Commenter believes that in the absence of fee schedule increase this indicates increased utilization.</p>	<p>Assistant Vice President American Insurance Association February 20, 2009 Written Comment</p>	<p>address the substantive changes made to the proposed regulations during the 2nd 15-day notice. Commenter raised the same arguments during the 45-day comment period, and the 1st 15-day comment period. His comments were appropriately addressed in the 45-day comment period chart.</p>	
<p>9792.26 Medical Evidence Evaluation Advisory Committee (General</p>	<p>Commenter states that the Medical Evidence Evaluation Advisory Committee is responsible for providing recommendations to the Medical Director on matters concerning the MTUS. Commenter indicates that members of the committee represent various medical specialties including, but not limited</p>	<p>Marie W. Wardell Claims Operations Manager State Compensation Insurance Fund February 20, 2009</p>	<p>Disagree. The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day notice. However, DWC does acknowledge the comment and is in process of</p>	<p>None.</p>

MEDICAL TREATMENT UTILIZATION SCHEDULE	RULEMAKING WRITTEN COMMENTS 2 nd 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Comment)	to, the orthopedic field, chiropractic field, and psychology field. Commenter recommends that the committee include a specialist from the Clinical Pharmacology field, unless one has already been appointed as a subject matter expert.		adding to the MEEAC a specialist from the clinical pharmacology field.	
9792.24.2(a) Chronic Pain Medical Treatment Guidelines Part 2. Pain Intervention and Treatments <i>Salicylate topicals</i>	Commenter states that he is concerned that the MTUS is overlooking references to many other agents. Commenter states that for example, no mention is made to methylsalicylate as a topical agent. Commenter questions whether one is to assume that if an agent is not listed, it is therefore “recommended” or “not recommended”?	Robert Nickell, Pharmacist February 14, 2009 Scott Goldman, M.D. February 12, 2009 Written Comment	Disagree. The use of methylsalicylate is recommended in the chronic pain medical treatment guidelines. The <i>Salicylate topical</i> guideline provides: “Salicylate topicals Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004) See also Topical analgesics; & Topical analgesics, compounded.”	None.