

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.24 – General Comment	<p>Commenter states that he has been informed that workers compensation is trying to change by getting rid of pain medication. Commenter opines that pain management should be between the doctor and patient, not determined by some person looking at a piece of paper and making assumptions as to what is better. Commenter questions for whom this is better for – the insurance company’s bottom line or for the patient. Commenter states that he was injured in 2004 and that his doctor requested physical therapy to treat him and was denied many times and that his requested surgery was denied as well. Commenter alleges that these regulations will only help the insurance company and not the injured worker. Commenter requests that the Division stop this from happening.</p>	John Esmeyer July 31, 2015 Written Comment	<p>Disagree: The proposed guidelines still allows physicians to prescribe pain medication. Pursuant to Labor Code § 4600(b), “...medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment based upon the guidelines adopted by the administrative director...” DWC is required to evaluate evidence-based guidelines and studies to be adopted for medical treatment in the workers’ compensation system. The recommended guidelines in the MTUS are selected because they provide an evidenced-based framework for the most effective treatment for work-related injuries or conditions, not because of some financial component. There are serious risks with some treatments, such as surgery, so careful case selection is important. If a patient’s clinical condition</p>	None.

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			changes, requests for treatment that was previously denied on the basis of medical necessity can always be reconsidered.	
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	Commenter would like the Division to consider the inclusion of their company's high frequency spinal cord stimulator in the Chronic Pain Treatment Guidelines. Commenter provided information regarding The SENZA-RCT Randomized Controlled Trail study [copy available upon request].	Tamara Rook Vice President Nevro Corporation August 6, 2015 Written Comment	Disagree: The DWC is in the process of incorporating by reference the "Official Disability Guidelines (ODG) Treatment in Workers' Compensation – Pain (Chronic)" published on April 6, 2015. This guideline addresses treatment when a patient has chronic pain and is not limited to indications of chronic pain in the low back and leg. The ODG guideline does not include any reference to the SENZA-RCT Randomized Controlled Trial Study that was published on October 2015 after the publication date of the ODG guideline that is being incorporated. The DWC will not delay this rulemaking because a new study is published that may or may not affect its proposed recommendations. There is a	None.

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			regulatory process already in place that must be followed to evaluate whether a recommendation found outside the MTUS is warranted in the limited situation when a medical treatment or procedure is not addressed by the MTUS or if one is attempting to rebut the MTUS' presumption of correctness.	
Chronic Pain Medical Treatment Guidelines – Part 2 References for Procedure Summary	<p>Commenter notes that within the Guides, spinal cord stimulation is listed under the Procedure Summary. Within this reference it states: “For use in failed back surgery syndrome (FBSS), see MTUS Low Back Complaints.”</p> <p>Commenter states that the MTUS related to Low Back Complaints refers to the ACOEM Practice Guidelines (2004) Chapter 12.</p> <p>Commenter would like to know if the DWC intends to keep this reference to the ACOEM Practice Guidelines for low back complaints and not instead utilize the Official Disability Guidelines (ODG) which are more</p>	Jennifer Snyder Capitol Advocacy, LLC for Boston Scientific and Medtronic August 11, 2015 Written Comment	Disagree: Yes, the DWC intends to keep this reference to the ACOEM Practice Guidelines for this rulemaking. This rulemaking pertains to the Chronic Pain Medical Treatment Guidelines set forth in §9792.24.2 and the Opioids Medical Treatment Guidelines set forth in §9792.24.4 and will not be amending the Low Back Complaints guideline set forth in §9792.23.5. Currently, section 9792.23.5 incorporates by reference the ACOEM Practice Guidelines, 2 nd Edition (2004) into the MTUS. The DWC has plans to update the current Low Back	None.

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	<p>up-to-date or other Guidelines that might reflect more current practice. Commenter notes that the MTUS does generally intend to incorporate the ODG in its proposed rulemaking. Commenter would like to know if a clarifying change is needed or if this is appropriately referenced in the general MTUS proposed regulations.</p> <p>Commenter states that since the ACOEM is outdated and could create confusion among practicing physicians and payers, she recommends incorporating the ODG low back chapter on spinal cord stimulation directly into the Chronic Pain Treatment Guidelines as a way to avoid delegation and additional regulatory change, to provide greater clarification to those physicians in California that utilize spinal cord stimulation to treat chronic pain, and to provide clearer direction to the Workers Compensation Payers so as to reduce the possibility of inappropriate denials and delays.</p>		<p>Complaints guideline in the near future but any amendments to the Low Back Complaints guideline must also go through the formal rulemaking process. There is a regulatory process already in place that must be followed to evaluate whether a recommendation found outside the MTUS is warranted in the limited situation when a medical treatment or procedure is not addressed by the MTUS or if one is attempting to rebut the MTUS' presumption of correctness.</p> <p>Disagree: If a practicing physician or payer believes a recommendation in the current MTUS Low Back Complaints guideline is outdated and challenges the MTUS' presumption of correctness or if he or she believes the MTUS does not address a medical treatment or procedure perhaps because it is new, then there is a regulatory process already in</p>	None.

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			place that must be followed to evaluate whether the recommendation found outside the MTUS is warranted.	
Chronic Pain and Opioid Medical Treatment Guidelines – Chiropractic Care	<p>Commenter is pleased that the Department acknowledges the need for non-opioid alternative therapies for pain treatment. Commenter is puzzled by the omission of chiropractic care as one of the alternatives listed, especially since seemingly every alternative to opioids is listed from yoga to massage. Commenter opines that this is an oversight and requests that chiropractic care be listed as well. Commenter provides the following argument for inclusion of chiropractic care in the list of alternative treatments.</p> <p>Commenter states that the conditions doctors of chiropractic treat are among the most prevalent for which injured workers seek care. Consider these facts:</p> <ul style="list-style-type: none"> • Back pain is the second leading cause for physician visits. 	<p>Moses Jacob, MD Chairman California Chiropractic Association August 14, 2014 Written Comment</p> <p>September 1, 2015 Oral Comment</p>	Disagree: Omitting chiropractic care as one of the alternative therapies to opioid treatment does not preclude consideration of chiropractic care for chronic pain. In fact, because chiropractic care is, as stated by the commentator, among the most prevalent treatments sought by injured workers, it is fully addressed in the Manual therapy & manipulation sections of the MTUS Chronic Pain Medical Treatment guidelines as well as in most of the MTUS’ clinical topics guidelines and is recommended when incorporated in the plan of care with associated improvement in function.	None.

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	<ul style="list-style-type: none"> • Back pain is second only to childbirth for hospitalizations. • Back pain is the most prevalent chronic medical condition. • Back pain is the number one cause of long-term disability. <p>Commenter states that this year the Joint Commission, an independent, not-for-profit organization which accredits and certifies more than 20,500 health care organizations and programs in the United States, including every major hospital, revised its pain management standard to include chiropractic services. Commenter notes that Joint Commission accreditation and certification are recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards.</p> <p>Commenter states that clinical experts in pain management who provide input into the commission's standards affirmed that treatment strategies may consider both</p>		<p>Disagree: The DWC intends that chiropractic treatment be available to injured workers when medically necessary and that the omission of specific listing of this non-pharmacologic approach to opioids (that includes self-care strategies) should not impede appropriate use of chiropractic treatment (see above response). In addition, the DWC carefully selected ODG's Chronic Pain Medical Treatment Guidelines because its recommendations are evidenced-based. The DWC does not alter the content of ODG's clinical summaries.</p> <p>Disagree: Again, the section on non-opioid treatments is not meant to be an exhaustive list, but examples of types of</p>	<p>None.</p> <p>None.</p>

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	<p>pharmacologic and nonpharmacologic approaches. Previously nonpharmacologic approaches were not included. Services provided by doctors of chiropractic (who were recognized in 2009 as physicians by the commission) and acupuncture are now included in the standard of care for pain management, effective January 2015.</p> <p>Commenter opines that this new standard allows the chiropractic profession to help more patients who might not previously have been informed by their health care system or doctor of non-drug approaches to pain management.</p> <p>Commenter states that starting next year the Oregon Health Plan (OHP) will prioritize chiropractic and other complementary therapies over painkillers or surgery for patients with back pain. Commenter states that this reflects a huge shift from the previous policy, which heavily favored narcotics as the first line of defense against pain.</p>		<p>therapy. In addition, even the listed therapies are subject to review for medical necessity using the appropriate section of the MTUS.</p> <p>Disagree: The proposed Chronic Pain Medical Treatment Guidelines incorporate both pharmacologic and non-pharmacologic treatment including chiropractic care and acupuncture. Pursuant to Labor Code section 5307.27 the medical treatment utilization schedule's authorizing statute and Labor Code section 4604.5, the MTUS shall incorporate scientific, evidenced-based, peer reviewed, nationally recognized standards of care. Recommendations in the MTUS must be evidence-based. Commenter references the Joint Commission and the Oregon Health Plan (OHP) but the words used (e.g. "clinical experts in pain management</p>	None.

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	<p>Commenter opines that there is ample research to back up the Oregon Health Plan’s decision. A 2003 study found that spinal manipulation offers greater short-term back pain relief than a variety of medications, and in 2004 researchers found chiropractic care more effective than medical care for treating chronic lower back pain.</p> <p>Commenter states that chiropractic coverage is included by cost-conscious programs such as Medicare, workers’ compensation, Healthy Families and the Veterans Administration system, as well as most group health plans.</p> <p>Independent, peer-reviewed studies have shown that health plans that include chiropractic care have lower overall costs than those that do not. Commenter notes that research has found that adding chiropractic care to a health plan in California does not result in an increase in cost. Rather, patients use chiropractic care as a direct, typically less expensive, substitute for care provided by a medical doctor.</p>		<p>who provide input into the commission’s standards affirmed...” and “...next year the Oregon Health Plan (OHP) will prioritize...” suggests a policy directive rather than a recommendation supported by scientific medical evidence as mandated by the MTUS’ authorizing statutes. In addition, if there are relevant studies to support these policy directives then they would have been evaluated by ODG when drafting the relevant chiropractic recommendations. Finally, the statutory standard for inclusion of a guideline into the MTUS does not mention the need for a cost evaluation.</p>	

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	<p>Commenter would like to emphasize that doctors of chiropractic are trained and licensed to serve as primary care doctors and provide care to patients without the use of potentially dangerous drugs or expensive surgeries. Doctors of chiropractic are trained in a holistic approach that focuses on prevention, wellness care, dietary and nutritional counseling, exercise, rehabilitation and ergonomics.</p> <p>Commenter looks forward to the inclusion of chiropractic care in the list of alternative treatments for chronic pain and chronic opioid treatment.</p>		<p>Disagree in part: Technical disagreement, doctors of chiropractic may serve as primary treating physicians not “primary care doctors” in the workers’ compensation system.</p> <p>Disagree: See first response above.</p>	<p>None.</p> <p>None.</p>
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	<p>Commenter would like to commend the Division of Workers' Compensation (DWC) for its recently proposed update to the Chronic Pain Medical Treatment Guidelines, which includes Spinal Cord Stimulation (SCS) therapy for Failed Back Surgery Syndrome (FBSS) patients. Commenter represents on the state's leading labor organizations, and it's</p>	<p>Michael A. Bolden, J.D. Government Relations Advocate SEIU California August 17, 2015 Written Comment</p>	<p>Disagree in part: Although the proposed Chronic Pain Medical Treatment Guidelines’ recommendation on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for Failed Back Surgery Syndrome (FBSS), instead it references the MTUS Low Back Complaints guideline which incorporates</p>	<p>None.</p>

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	<p>his responsibility to advocate for the safety, health and well-being of California's hard-working men and women - including in the unfortunate situation when an employee is injured on the job. Commenter opines that these workers must have access to all safe, clinically proven, cost-effective therapies to recover from their injuries as soon as possible. Commenter states that this requires that injured workers suffering from FBSS have access to SCS as a treatment option.</p> <p>Commenter states that many workers serving in critical capacities in California are at risk for back injury and therefore FBSS. Commenter notes that multiple studies have shown that SCS is an effective treatment for FESS that can reduce pain and improve workers' quality of life, giving these patients a shot at resuming their normal lives and possibly returning to work. Commenter notes that SCS is widely covered by Medicare, workers' compensation plans in 48 other states, and most commercial health insurers.</p>		<p>by reference the ACOEM Practice Guidelines, 2nd Edition (2004) and states, "Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the standard nonoperative or operative interventions." FBSS as an indication for SCS is covered but in the current MTUS Low Back Chapter.</p> <p>Disagree in part: The DWC disagrees in part with commenter's general statement "that any effort to remove treatment options for workers compensation patients in the state would only set California back and cause further harm to workers." The MTUS is based on the principals of evidence-based medicine. New scientific studies and guidelines are constantly being published. If the evolving evidence shows that the efficacy of a treatment</p>	None.

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	<p>Commenter opines that California's workers should have access to treatment options available to other patients and workers in the state and across the country. For these reasons, commenter is encouraged by DWC's move to amend its December proposal so that the guidelines now include SCS for FBSS patients.</p> <p>Commenter opines that any effort to remove treatment options for workers' compensation patients in the state would only set California back and cause further harm to workers.</p>		<p>option is lacking or the harm that it causes is actually greater than its value, then removal of that treatment option would be beneficial to California's workers.</p>	
Opioids Treatment Guideline	<p>Commenter thanks the Division for taking on the important task of revising the opioid treatment guidelines. Commenter opines that everyone should be aware of the preventable deaths which have occurred from overdoses of prescription drugs, prescribed in the mistaken belief the opioids were non-addicting.</p> <p>Commenter states that there is a fine line between over and under prescribing. Commenter notes that there have been suicides due to the</p>	Sandiford Helm, II, M.D., QME August 14, 2015 Written Comment	<p>Agree: The DWC agrees with the Commenter's statement about being aware of the preventable deaths which have occurred from overdoses of prescription drugs prescribed in the mistaken belief that opioids are non-addicting but there is a fine line between over and under prescribing.</p>	None.

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	<p>under-treatment of pain.</p> <p>Commenter opines that the proposed Guidelines cover all the issues which should be considered regarding opioid treatment and that there is no specific item which is not appropriate.</p> <p>Commenter opines, however, that the proposed Guidelines create a documentation burden on the provider which will be very difficult to meet. Commenter has submitted a chart comparing the requirements of the Medical Board of California (MBC) and the proposed DWC guidelines [available upon request]. Commenter opines that the MBC has been very effective in investigating physicians providing opioids.</p>		<p>Agree: The DWC in its proposed guidelines has attempted to cover all the issues which should be considered.</p> <p>Disagree: That the proposed guidelines create a documentation burden on providers which will be very difficult to meet and will result in harm to injured workers by denying opioids. The proposed Opioids Treatment Guidelines is based on a variety of established guidelines, including the Medical Board of California (MBC) opioid guideline, “Guidelines for Prescribing Controlled Substances for Pain”. The MBC guideline applied to a wide variety of patient populations and the MTUS Opioids Treatment Guideline is specific to the population of injured workers with non-cancer pain. Regardless, the</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter states that the regulatory burden placed by the proposed DWC Guidelines far surpasses that placed by the MBC's effective Guidelines. Commenter states that Utilization Review physicians in California are very vigilant and any deviation from the requirements of the Guidelines will be deemed a failure to comply with them. Commenter states that this is particularly true in the request to document why opioids are being provided in the presence of, for example, depression or anxiety, where there are no clear cut standards.</p> <p>Commenter opines that these</p>		<p>DWC's analysis shows high agreement with the MBC guideline, including the daily morphine equivalent dose (MED) of 80 mg. /day. The MTUS guideline is meant to be instructive and to give treating physicians the tools and criteria needed to ensure safe and appropriate prescribing of opioids.</p> <p>Disagree: Commenter specifically mentions the documentary burdens when opioids are being provided in the presence of depression or anxiety. The proposed guidelines recommend the use of the Patient Health Questionnaire and other validated tools such as Screener and Opioid Assessment for Patients with Pain – Revised (SOAP-R) or Opioids Risk Tool (ORT). Use of these tools and screening for mental health disorders (e.g. depression and anxiety) are a</p>	None.

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	<p>proposed Guidelines will make it very difficult to provide opioids to injured workers.</p> <p>Commenter states that if it is the goal to make opioid unavailable for treatment in workers' compensation injuries, that it would be cheaper and less frustrating to simply ban them. If this is not the goal, commenter recommends that the Division alter or clarify the documentation requirements so that it will be possible for diligent, well-meaning and well-trained physicians in California to comply with them.</p> <p>Commenter opines that the majority of UR physicians will focus on the boxes, Pages 6-9 of Part 1; therefore, this is the area that requires the closest attention.</p>		<p>strong risk factor for both misuse/abuse and opioid overdose events. Several guidelines provide strong recommendations to screen for these conditions prior to initiating chronic opioid treatment.</p> <p>Disagree: It is NOT the DWC's goal to make opioids unavailable for treatment in workers' compensation injuries. It is the DWC's goal in the proposed Opioids Treatment Guidelines to provide a balance between appropriate treatment of pain among injured workers and safety in the use of opioids for that purpose.</p> <p>Disagree: Pages 6-9 of Part 1 provide Summary Recommendations. A bold disclaimer already states, “Reviewers and health care providers <u>should not rely exclusively on the summary recommendations.</u>”</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter is also concerned that the level of documentation exceeds that demanded by existing Evaluation and Management codes. Commenter is unaware of any vehicle to reimburse physicians for this required high level of documentation.</p> <p>Commenter opines that there is duplication and a lack of coordination in the various efforts to deal with the problem of deaths from opioid prescribing. Commenter notes that overlap of requirements between the MBC and DWC. Commenter states that AB 1124 may contain language discussing tapering of opioids.</p>		<p>Disagree: The level of documentation required by the treating physician does not need to be performed in a single visit. Urine drug testing, for example is billed separately from the E&M visit. The guideline discusses a wide variety of circumstances, but only a portion is applicable to the patient at any given time. The initial evaluation prior to initiation of opioids is likely the most labor intensive, but the medical evidence supports careful evaluation and documentation to ensure patient safety from opioid dependence and overdose.</p> <p>Disagree: The MBC guideline applies to a wide variety of patient populations and the MTUS Opioids Medical Treatment Guidelines is specific to the population of injured workers with non-cancer pain. DWC's analysis shows high agreement with the</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter opines that multiple differing requirements from various government agencies will make compliance difficult.</p>		<p>MBC guideline, including the daily morphine equivalent dose (MED) of 80 mg./day. Physicians treating injured workers are required to follow the MTUS, which is based upon the medical evidence. The establishment of a workers' compensation formulary pursuant to AB 1124 consistent with EBM and the MTUS should not create any conflicts but should instead enhance the MTUS. However, the formulary is not part of the proposed regulations at this time.</p>	
Opioids Treatment Guideline	<p>Commenter is concerned that obtaining access to appropriate treatments for pain will become increasingly difficult. Commenter opines that it is important for physicians to have the tools that they need to treat their patients and help them return to work.</p> <p>When treating pain, physicians consider multiple approaches in determining how to best reduce a</p>	<p>Annamalai Ashokan, M.D. August 20, 2015 Written Comment</p>	<p>Disagree in part; Agree in part: Disagree: that obtaining access to appropriate treatment for pain will become increasingly difficult. Agree: Physicians need tools to treat patients and help them return to work.</p> <p>Agree in part; Disagree in part: Agree: Opioid medications are not generally the first line of</p>	<p>None.</p> <p>None.</p>

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	<p>patient’s pain while mitigating abuse risk. It’s understood that opioids may not be the best first option for treating pain and given that, these guidelines must provide broad access to other treatments. For example, access to non-addictive agents and topical treatments. Commenter states that by not recommending these options as first line treatments, the physician will be significantly limited in their ability to appropriately treat the patient. Commenter opines that covering a broad range of treatments will expedite a patient’s recovery and reduce the costs associated with abuse.</p> <p>Commenter states that if it is determined that an opioid is an appropriate treatment; she opines that access to abuse deterrent opioids must be provided. Commenter acknowledges that opioid substance abuse is a large public health problem but in order to appropriately address the issue, physicians must be able to access additional tools like abuse deterrent formulated opioids.</p>		<p>treatment, especially for mild to moderate acute pain and that other therapies, such as non-opioid medication, appropriate physical activity and complementary/alternative modalities should be considered.</p> <p>Disagree: This guideline does recommend a broad range of other non-opioid treatments. However, this is an opioids treatment guideline and the details of the other non-opioid treatments are covered in the MTUS in the relevant Clinical Topics or Special Topics guidelines.</p> <p>Disagree: that access to abuse deterrent formulations is limited by the proposed guideline. The technology for developing abuse-resistant opioids is an emerging field and is not currently incorporated in nationally-recognized clinical guidelines; therefore, the evidence-based Opioids Treatment Guidelines</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter opines that only allowing access to cheap, generic opioid treatments will not help the abuse issue and further complicate the patient’s case by increasing the risk of abuse.</p> <p>Commenter would like to see these recommendations included if the Department of Workers Compensation implements a prescription drug formulary. Commenter states that access to appropriate treatments must be provided and creating a formulary system that focuses solely on controlling costs through access restrictions will not help the patient return to work.</p>		<p>do not specify formulation of the opioid to be used and leaves it to the physician to consider the appropriate formulation for the patient and clinical situation. There is not restrictive language in the proposed guideline and no recommendations on using generic medications.</p> <p>Agree in part; Disagree in part: Agree: If the proposed regulations for the Opioids Treatment Guidelines are approved by the Office of Administrative Law, then any subsequent regulations pertaining to the Prescription Drug Formulary will be consistent with these recommendations. Disagree: Commenter’s statement about “controlling costs” is directed towards the proposed workers’ compensation prescription medication formulary, and does not apply to the MTUS guidelines under consideration.</p>	None.

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Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	<p>Commenter opines that it is imperative that injured California workers suffering from failed back surgery syndrome (FBSS) have access to Spinal Cord Stimulation (SCS) therapy and intrathecal drug delivery (IDDS). Commenter states that the inclusion of these types of therapy for FBSS patients is an important step in the right direction. Commenter opines that the DWC must update the guideline to include peer-reviewed clinical evidence and specific treatment criteria on FBSS that includes SCS and intrathecal drug delivery (IDD).</p> <p>Commenter states that SCS for FBSS is supported by randomized controlled trials (RCTs) 1, 2 and several large post market SCS registries reporting positive outcomes for over 1,000 patients. SCS is a widely accepted and recommended treatment among doctors serving a broad spectrum of FBSS patients across the U.S. and around the world. Organizations like the American Pain Society, the Food & Drug</p>	Al Liceaga, MD August 20, 2015 Written Comment	<p>Disagree: Commenter recommends that language in ODG’s Low Back chapter containing a literature review of FBSS for SCS and IDDS be included in the proposed MTUS Chronic Pain Chapter section on SCS. However, doing this would be an attempt to amend the current MTUS recommendations in the Low Back Chapter via this rulemaking. The DWC is unable to amend the MTUS’ Low Back Chapter without going through the formal rulemaking process to amend that regulatory section. However, the DWC is in the process of evaluating and updating the treatment guidelines for the Low Back.</p> <p>Disagree: If a physician believes there is evidence to rebut any recommendation in the MTUS, then the requesting physician may attempt to rebut the MTUS’s presumption of</p>	<p>None.</p> <p>None.</p>

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	Administration, and the American Society of Interventional Pain Physicians all support SCS as a treatment option for FBSS. SCS is covered by Medicare, workers' compensation plans in 49 other states and most commercial health insurers. The <i>Official Disability Guidelines</i> low back chapter contains a literature review of FBSS for SCS. Commenter strongly encourages the DWC to include ODG's literature review of FBSS for SCS in their Low Back Chapter into the proposed MTUS Chronic Pain Chapter section on SCS.		correctness. Rebutting the MTUS requires submitting additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated using the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1, where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine. Also, see above response.	
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	Commenter states that he is a board certified Pain Medicine specialist who treats a variety of chronic pain patients in both the workers comp and private sectors. Commenter states that while he is not in agreement with many guideline recommendations in general, he does understand their importance in ensuring uniform quality care and reducing un-	Gary L. Baker, MD August 26, 2015 Written Comment	Disagree in part: Although the proposed Chronic Pain Medical Treatment Guidelines' recommendation on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for failed back surgery syndrome (FBSS) patients, instead it references the MTUS Low Back Complaints	None.

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	<p>necessary treatments. Commenter is concerned about the omission of Failed Back Surgery Syndrome (FBSS) as an indication for trial Spinal Cord Stimulation (SCS). Commenter states that SCS is a well establish treatment for conditions including FBSS. It is supported by nationally recognized guidelines and the preponderance of current scientifically based medical evidence. Commenter states that he has implanted these devices in his patients and has observed the "life changing" improvements they have provided to patients. Commenter opines that there will always be some naysayers pointing to a few medical articles questioning the utility of SCS; and that this is true of virtually all of medicine. Commenter opines that if the Division is going to base the Chronic Pain Medical Treatment Guidelines on the majority of medical evidence to exclude certain treatments, then it must use that same medical evidence to include valid treatments, such as SCS. Commenter opines that to do otherwise would render the guidelines as arbitrary and</p>		<p>guideline which incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004) and states, "Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the standard nonoperative or operative interventions." FBSS as an indication for SCS has not been omitted.</p> <p>In addition, if a physician believes there is evidence to rebut any recommendation in the MTUS, then the requesting physician may attempt to rebut the MTUS's presumption of correctness. Rebutting the MTUS requires submitting additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated using the MTUS Methodology for Evaluating Medical</p>	

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	lacking of credibility.		Evidence set forth in section 9792.25.1, where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine.	
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	<p>Commenter commends the Division of Workers' Compensation (DWC) for its recently proposed update to the Chronic Pain Medical Treatment Guidelines, which includes Spinal Cord Stimulation (SCS) therapy for Failed Back Surgery Syndrome (FBSS) patients.</p> <p>Commenter states that injured firefighters must have access to all safe, clinically-proven, cost-effective therapies to recover from their injuries as soon as possible. Commenter opines that this requires that the DWC ensure injured workers suffering from FBSS have access to SCS as a treatment option.</p> <p>Commenter states that unfortunately, many workers -- not just firefighters -</p>	Christy Bouma Governmental Advocate California Professional Firefighters August 27, 2015 Written Comment	Disagree in part: Although the proposed Chronic Pain Medical Treatment Guidelines' recommendation on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for failed back surgery syndrome (FBSS) patients, instead it references the MTUS Low Back Complaints guideline which incorporates by reference the ACOEM Practice Guidelines, 2 nd Edition (2004) and states, "Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the standard nonoperative or operative interventions." FBSS	None.

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	<p>- serving in critical capacities in California are at risk for back injury and therefore FBSS. Multiple studies have shown that SCS is an effective treatment for FBSS that can reduce pain and improve workers' quality of life, thereby giving these patients a shot at resuming their normal lives and possibly returning to work. Commenter states that SCS is widely covered by Medicare, workers' compensation plans in 48 other states and most commercial health insurers. Commenter opines that California workers should have access to treatment options available to other patients, as well as other workers in the state and across the country. For these reasons, commenter is encouraged by DWC's move to amend its December proposal so that the guidelines now include SCS for FBSS patients. Commenter opines that any effort to remove treatment options for workers' compensation patients in the state would only set California back and hurt its workers.</p>		<p>as an indication for SCS is covered but in the current MTUS Low Back Chapter.</p> <p>Disagree in part: The DWC disagrees in part with commenter's general statement "that any effort to remove treatment options for workers compensation patients in the state would only set California back and cause further harm to workers." The MTUS is based on the principals of evidence-based medicine. New scientific studies and guidelines are constantly being published. If the evolving evidence shows that the efficacy of a treatment option is lacking or the harm that it causes is actually greater than its value, then removal of that treatment option would be beneficial to California's workers.</p>	None.
Chronic Pain Medical Treatment Guidelines	Commenter states that in many instances the word "should" is used. Commenter opines that this term	Karen L. Sims Claims Operations Manager	Disagree: The MTUS constitutes the standard for the provision of medical	None.

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Opioid Treatment Guidelines – General Comment	<p>gives the impression that a recommendation is being given instead of a requirement and that this can cause confusion.</p> <p>Commenter recommends that the DWC replace “should” with “shall” when applicable.</p>	State Compensation Insurance Fund September 1, 2015 Written Comment	care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.	
Opioid Treatment Guidelines	<p>Commenter notes that the Opioids Treatment Guidelines state, “If opioids are prescribed, the Controlled Substance Utilization Review and Evaluation System (CURES), California’s Prescription Drug Monitoring Program should be accessed”.</p> <p>Commenter recommends that if CURES is going to be mandated, office dispensing of opioids should not be allowed since other physicians will not be aware of the medications dispensed from other physicians’ offices</p>	Karen L. Sims Claims Operations Manager State Compensation Insurance Fund September 1, 2015 Written Comment	Disagree: The DWC does not have the authority to prohibit physician prescribing in the office setting. The proposed Opioid Treatment Guidelines clearly endorses the use of CURES throughout the document and encourages registration to CURES through hyperlinks. However, it is beyond the scope of the MTUS to limit physician prescription authority, which is governed by the Medical and Pharmacy Boards of California.	None.

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Opioid Treatment Guidelines	<p>Commenter notes that ACOEM has published a more recent version of their Opioid Treatment Guidelines in March 2014.</p> <p>Commenter recommends that the DWC review the more recent version of ACOEM’s Opioid Treatment Guidelines to incorporate into MTUS.</p>	<p>Karen L. Sims Claims Operations Manager State Compensation Insurance Fund September 1, 2015 Written Comment</p>	<p>Disagree: The MTUS goes through a rigorous review process in conjunction with the Medical Evidence Evaluation Advisory Committee (MEEAC). The ACOEM Opioid Treatment Guidelines were reviewed as part of the MTUS Opioid Treatment Guidelines. The MEEAC advised that the DWC create their own guideline, incorporating the best evidence from a variety of guidelines. The ACOEM Opioid Treatment Guideline came into existence much later in this process, though the content of the two is very similar as both are evidence-based.</p>	None.
Opioid Treatment Guidelines	<p>Commenter notes that the Opioids Treatment Guidelines recommend that driving and operation of heavy equipment should be discouraged while on these medications.</p> <p>Commenter recommends that the DWC take a stronger stance on driving and operation of heavy equipment while on opioids such as,</p>	<p>Karen L. Sims Claims Operations Manager State Compensation Insurance Fund September 1, 2015 Written Comment</p>	<p>Disagree: Commenter’s suggested language “injured workers shall not be allowed to perform...” is too proscriptive. The proposed recommendation that driving and operation of heavy equipment should be discouraged is sufficient warning because each patient should be evaluated on a case-</p>	None.

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	<p>“injured workers shall not be allowed to perform safety sensitive tasks while taking opioids or at a minimum get clearance from their PTP”.</p>		<p>by-case basis and medical evidence on this topic continues to evolve.</p>	
<p>Chronic Pain Medical Treatment Guidelines – Home Health Care – Page 88-89</p>	<p>Commenter opines that the placement of the OR/AND in the statement “The individual has trouble leaving the home without help (e.g., using a cane, wheelchair, walker, or crutches; special transportation; or help from another person) because of the occupational illness or injury OR</p> <ul style="list-style-type: none"> • Leaving the home isn't recommended because of the occupational illness or injury AND • The individual is normally unable to leave home and leaving home is a major effort (CMS, 2014).” can be misleading. <p>Commenter states that according to CMS, the first two should be grouped together such that it should read as:</p> <p>Criteria 1: The individual has trouble leaving the home without help (e.g., using a cane, wheelchair, walker, or crutches; special transportation; or help from</p>	<p>Joyce Ho, M.D. Medical Director CompPartners, Inc. August 27, 2015 Written Comment</p>	<p>Agree: Formatting needs to be revised to show the meaning of the phrase “To be homebound” is broken up into the criteria groups/bullet points suggested by commenter instead of just two groups/bullet points to comport with CMS 2014.</p>	<p>The definition has been amended to the following: “To be homebound means:</p> <ul style="list-style-type: none"> • The individual has trouble leaving the home without help...because of the occupational illness or injury <p>OR</p> <ul style="list-style-type: none"> • Leaving the home isn’t recommended because of the occupational illness or injury <p>AND</p> <ul style="list-style-type: none"> • The individual is normally unable to leave home and leaving home is a major effort.”

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	<p>another person) because of the occupational illness or injury OR Leaving the home isn't recommended because of the occupational illness or injury AND Criteria 2: The individual is normally unable to leave home and leaving home is a major effort (CMS, 2014).</p> <p>Commenter states that this guideline does not provide specific guidance on the duration and frequency and she opines that this can be especially problematic for non-medical services due to a lack of consensus in the general medical community.</p>		<p>Disagree: The DWC does not believe the criteria for frequency and duration of services; especially non-medical services should be more specific. Given the wide variety of possible home health and home care scenarios, it is imperative that the need for medical treatment and supportive home care be clearly established by the treating physician. A professional assessment in the home (e.g. R.N.) is then needed to more clearly assess the home situation and establish the home care plan, including levels of care and frequency. This guideline</p>	<p>None.</p>

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			allows for the flexibility needed to ensure appropriate delivery of home care services for injured workers.	
Chronic Pain Medical Treatment Guidelines – Ziconotide (Prialt) – Page 182 Intrathecal Drug Delivery System (IDDS) – Page 94-98	<p>Commenter opines that these sections contain information that is incomplete regarding the indication, efficacy, and safety of Prialt and is inconsistent with the most recent (2012) Polyanalgesic Consensus Conference (PACC) recommendations for the use of intrathecal drug delivery systems (IDDS) in the treatment of chronic pain. Commenter provides updated information regarding the use of Prialt in the management of severe chronic pain [Complete listing of references is available upon request].</p> <p>Commenter states that page 183 of the MTUS Chronic Pain Guidelines document describes Prialt as a “non-opioid intrathecal therapy for the treatment of chronic pain” and that the IDDS section on pages 94-98 appears to focus on intrathecal opioids. Commenter states that the evidence for the use of intrathecal morphine is generally based on</p>	Michael Romanowicz Head of Pricing, Healthcare Policy & Strategy Jazz Pharmaceuticals August 27, 2015 Written Comment	Disagree: The proposed MTUS Opioid Treatment clinical topics on Spinal Cord Stimulators (SCS) and Ziconotide (Prialt) are evidence-based, not consensus-based. The Polyanalgesic Consensus Conference-2012 (PACC) recommendations are primarily consensus-based. Furthermore, the majority of panel members disclosed in the article have a conflict of interest, although not Jazz Pharmaceuticals. The article cited by the commentator also includes a number of other risks and complications for Prialt not mentioned by the commentator. Furthermore, not all implantable devices are capable of using Prialt. Review of the article shows that Ziconotide/Prialt is only recommended as a first line intervention in cases of venous	None.

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	<p>nonrandomized studies that lack a placebo control group; however, the efficacy and safety of Prialt for the treatment of chronic pain was studied in three double-blind, placebo-controlled, multicenter studies in a total of 457 patients (268 Prialt, 189 placebo) using two different titration schedules. The two initial short-term studies utilized a fast titration schedule involving daily dose increases up to a maximum dose of 57.6 mcg/day in 5 to 6 days. While the fast titration studies demonstrated efficacy, there were high rates of serious adverse events and discontinuations. As a result, the third study was conducted using a slower titration schedule (starting dose \leq2.4 mcg/day titrated upward at intervals of \leq2-3 times per week, up to a recommended maximum dose of 19.2 mcg/day), which improved the safety and tolerability of Prialt, and is the basis for the dose initiation and dose titration information in the Prialt prescribing information. The primary efficacy variable in the slow titration study was the mean percent change in the VASPI score from baseline to day</p>		<p>stasis, cardiac failure renal disease and/or peripheral neuropathy. Our proposed guideline recommends the use of Prialt for IDDS after evidence of trial and failure of intrathecal morphine or hydromorphone. When a medical procedure is not addressed by the MTUS, the requesting physician may submit additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated using the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1 where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine and allows additional evidence-based research to be considered when determining if a recommendation found outside</p>	

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	<p>21. In the intent-to-treat efficacy analysis, there was a statistically significant difference between groups in the mean percent change in VASPI score (the primary efficacy variable) from baseline with the Prialt group having a 12% mean improvement at Week 3 compared to a 5% mean improvement in the placebo group. The 95% confidence interval for the treatment difference (Prialt–placebo) was 0.4%, 13%. Most of the Prialt group had nonmalignant pain 108/112 (96%).⁵ A subsequent open-label study showed that the efficacy of Prialt was maintained during long-term treatment.</p> <p>Commenter states that the safety of Prialt has been evaluated in 1,254 patients with severe chronic pain, with a mean treatment duration of 193 days. Commenter states that when evaluating the safety of IDDS it is important to distinguish among pharmacologic agents, because the safety profile of Prialt is substantially different from the safety profiles of opioids. Commenter notes that unlike opioid medications, Prialt is not</p>		<p>the MTUS is warranted. However, the use of Prialt in IDDS is a treatment option under the guideline as written.</p> <p>Disagree: See above. In addition, as mentioned, Prialt can be used as a first-line intervention when medically justified by the clinical condition of the patient.</p> <p>Disagree: The proposed MTUS guideline, procedure topic Zoconotide (Prialt) describes the differences between intrathecal opioids and Prialt,</p>	<p>None.</p> <p>None.</p>

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	<p>associated with tolerance or withdrawal, respiratory depression, and catheter tip granulomas. Commenter states that, as noted on page 130 of the MTUS Guidelines, Prialt is associated with neuropsychiatric adverse events. Commenter opines that a history of psychosis is a contraindication to Prialt use; however, a history of depression is not a contraindication.</p> <p>Commenter states that the use of Prialt as first-line intrathecal therapy is supported by the 2012 PACC Guidelines. Commenter states that the PACC panel of experts in the field of intrathecal therapy has convened at regular intervals since 2000 to review the research literature and provide updated recommendations regarding best practices for intrathecal therapies in pain management. The 2012 PACC Guidelines recommend that intrathecal drug delivery be considered as an option for patients requiring long-term management of refractory chronic pain. Commenter notes that morphine and Prialt are the</p>		<p>including information that Prialt is a non-opioid option with the advantage of being non-addictive as commentator states. Proposed guideline includes a review of the medical evidence, including the FDA black box warning regarding neurological effects and evidence of reversible cognitive impairment in 30% of patients in clinical trials. Evidence of myalgia and muscle cramping are described and cited, and concerns with abrupt discontinuation of opioids when switching to Prialt (case studies) are also described. The guidelines recommend Prialt for specific patients for whom the benefits outweigh the risks and specific dosage guidelines are included for initiating treatment.</p>	

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	<p>only 2 FDA-approved intrathecal therapies for pain management. The PACC Guidelines recommend Prialt as first-line intrathecal therapy for both nociceptive pain and neuropathic pain. Commenter notes that other first-line intrathecal therapies recommended by PACC are morphine, hydromorphone, or fentanyl for nociceptive pain, and morphine or morphine + bupivacaine for neuropathic pain. Commenter states that the use of other intrathecal agents (non-FDA approved) such as hydromorphone (for neuropathic pain), clonidine, mepivacaine, bupivacaine, fentanyl, baclofen, sufentanil (alone or in combination) are not recommended by PACC as first-line therapies but rather as second, third, fourth and/or fifth-line approaches for either nociceptive or neuropathic pain.</p>		<p>Disagree: As mentioned, Prialt can be used as a first-line intervention when medically justified by the clinical condition of the patient. See above regarding 2012 PACC Guidelines.</p>	<p>None.</p>
<p>Chronic Pain Medical Treatment Guidelines – Intrathecal Drug Delivery System (IDDS) – Page 94-98</p>	<p>Commenter states that on page 96 it appears there remains a typographical error in the content in the following section:</p> <p>a. Section-Indications for Implantable drug-delivery systems;</p>	<p>Michael Romanowicz Head of Pricing, Healthcare Policy & Strategy Jazz Pharmaceuticals August 27, 2015 Written Comment</p>	<p>Disagree: that the meaning of the ODG content is unclear without a formatting edit, there does not appear to be an error that requires correction. The recommendation allows for a temporary trial AND that</p>	<p>None.</p>

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	<p>b. Subsection: Permanently implanted intrathecal (intraspinal) infusion pumps for the administration of opioids or non-opioid analgesics, in the treatment of chronic intractable pain, are considered medically necessary</p> <p>Commenter notes the content as written:</p> <ul style="list-style-type: none"> • “A temporary trial of spinal (epidural or intrathecal) opioids has been successful prior to permanent implantation as defined by a 50% reduction in pain. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met. Used for the treatment of <u>non-malignant (non-cancerous) pain</u> with a duration of greater than 6 months and all of the following criteria are met and documented by treating providers in the medical record:” <p>Commenter recommends the following formatting change on page 96 which provides clarity with identifying when permanently implanted intrathecal (intraspinal) infusion pumps for the administration of opioids or non-opioid analgesics, in the treatment of chronic intractable pain, are considered</p>		<p>patients meet all of the numbered criteria. Adding another bullet point as commenter recommends is confusing because it suggests that the temporary trial is separated from the numbered criteria.</p>	

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	<p>medically necessary. Proposed Formatting Change:</p> <ul style="list-style-type: none"> • A temporary trial of spinal (epidural or intrathecal) opioids has been successful prior to permanent implantation as defined by a 50% reduction in pain. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met. • Used for the treatment of non-malignant (non-cancerous) pain with a duration of greater than 6 months and all of the following criteria are met and documented by treating providers in the medical record: 			
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	Commenter is in complete agreement to support recent draft regulations urging the DWC to continue including SCS for FBSS.	P. Jeffrey Smith, D.O. Desert Orthopedic Center August 18, 2015 Written Comment	Disagree in part: Although the proposed Chronic Pain Medical Treatment Guidelines' recommendation on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for failed back surgery syndrome (FBSS) patients, instead it references the MTUS Low Back Complaints guideline which incorporates by reference the ACOEM Practice Guidelines, 2 nd	None.

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			Edition (2004) and states, “Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the standard nonoperative or operative interventions.” FBSS as an indication for SCS is covered but in the current MTUS Low Back Chapter.	
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	<p>Commenter has been made aware that the California Department of Workers Compensation is considering dropping spinal cord stimulation for the indication of failed back surgery syndrome. Commenter notes that the guidelines that have been used by workers compensation have allowed this indication for many years. This indication is substantiated by multiple scientific studies. [Note that no list was provided.]</p> <p>Commenter states that spinal cord stimulation in the Richard North Study from Journal of Neurosurgery</p>	<p>Nathan Miller, M.D. Yogesh Patel, M.D. Michael Sebaheer, M.D. Gordon Iwasaki, PA-C Andrew Saurin, PA-C Coastal Pain & Spinal Diagnostics Medical Group August 26, 2015 Written Comment</p>	<p>Disagree: It is has not been dropped. The DWC is in the process of incorporating by reference the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” published on April 6, 2015. The proposed guideline does not address the routine of SCS for failed back surgery syndrome (FBSS) patients. Currently, the proposed Chronic Pain Medical Treatment Guidelines references the MTUS Low Back Complaints guideline</p>	None.

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	<p>on August 2007 showed improved results and therefore lower cost for spinal cord stimulation vs. reoperation for failed back surgery syndrome.</p> <p>Commenter states that nearly all commercial carriers and the Center for Medical Services (Medicare) allows for this therapy for the treatment of failed back surgery syndrome.</p> <p>Commenter states that patients will suffer if this modality is taken away from them. Commenter opines that there is no good clinical or scientific reason to remove this indication for use of spinal cord stimulation as a modality to treat failed back surgery syndrome.</p>		<p>which states, ““Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the standard nonoperative or operative interventions.” FBSS as an indication for SCS is covered but in the current MTUS Low Back Chapter. The DWC is in the process of evaluating and updating the treatment guidelines for the Low Back. The DWC is unable to amend the MTUS’ Low Back Chapter without going through the formal rulemaking process. If a physician feels that there is evidence to rebut any recommendation in the MTUS, then the requesting physician may attempt to rebut the MTUS. Rebutting the MTUS requires submitting additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is</p>	

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			then evaluated using the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1, where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine.	
9792.24.2(b) and (c)	<p>Commenter recommends the following revised language:</p> <p>(b) The eChronic pPain mMedical tTreatment gGuidelines apply when the patient has chronic pain as determined by following the clinical topics, as defined in Section 9792.20</p> <p>Commenter states that the MTUS currently contains at least 3 inconsistent operational definitions of chronic pain. One of these resides in the current language and the draft proposal of 9792.24.2, and the current revision cycle is an opportunity to achieve consistency.</p>	Robert Ward Clinical Director CID Management August 28, 2015	Agree: Commenter points out the MTUS currently contain inconsistent operational definitions of chronic pain. The definition for chronic pain should be consistent according to definition of chronic pain set forth in section 9792.20.	Section 9792.24.2(b) is amended by deleting the phrase “as determined by following the clinical topics” and adding the phrase “as defined in section 9792.20.”

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	<p>(c) When a patient is diagnosed with has chronic pain and the treatment for the condition is covered in the clinical topics sections but is not addressed in the eChronic pPain mMedical tTreatment gGuidelines, the clinical topics section applies to that treatment.</p> <p>Commenter opines that the language "is diagnosed with" in 9792.24.2 (c) indicates that the Chronic Pain Medical Treatment Guidelines are only to be used if the treating physician has rendered a diagnosis of chronic pain; and not otherwise, even if the patient clearly has chronic pain. It is doubtful that this was the DWC's intent.</p>		<p>Agree. The phrase “is diagnosed with” suggests this guideline only applies if the treating physician has rendered a diagnosis of chronic pain. This is not the DWC’s intent.</p> <p>The DWC has also made grammatical revisions on its own for clarity.</p>	<p>Section 9792.24.2(c) is amended by deleting the phrase “is diagnosed with” and replaces it with the word “has”. In addition, the DWC is making grammatical revisions changing lower case “c” and “t” to capital letters “C” and “T” and adding the phrase “of the MTUS” for clarity.</p>
<p>9792.23(b)(1) and 9792.24.2(b) and (c)</p>	<p>Commenter recommends that the language of 9792.23(b)(1) be amended, as it is presently inconsistent with 9792.20(b) as well as the intent of proposed 9792.24.2.</p> <p>9792.20(b) has been very recently amended to define chronic pain as "pain lasting three or more months</p>	<p>Robert Ward Clinical Director CID Management August 28, 2015</p>	<p>Agree: The definition for chronic pain should be consistent according to definition of chronic pain set forth in section 9792.20 that is defined as “pain lasting three or more months from the initial onset of pain.”</p>	<p>Section 9792.23(b)(1) is amended by deleting the phrase “that persists beyond the anticipated time of healing” and replaced with the phrase “lasting three or more</p>

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	<p>from the initial onset of pain."</p> <p>9792.23(b)(1) continues to define chronic pain as "pain that persists beyond the anticipated time of healing". 9792.23(b)(1) also explicitly states that this is the definition of chronic pain which is to be used to determine when and if the Chronic Pain Medical Treatment Guidelines in 9792.24.2 shall apply.</p> <p>9792.24.2(b), both current and proposed versions, provides an operational definition of chronic pain as "chronic pain as determined by the following clinical topics." As all clinical topics in the MTUS precede 9792.24.2 (e.g., 9792.23 through 9792.24.1), there are no "following clinical topics" within the regulatory framework; and there are none within the language of 9792.24.2.</p> <p>9792.24.2(c), both current and proposed, states that decisions as to when the Chronic Pain Medical Treatment Guidelines should be used is to be based on whether the "patient is diagnosed with chronic pain". Commenter opines that this is</p>		<p>Agree: The definition for chronic pain should be consistent according to definition of chronic pain set forth in section 9792.20 that is defined as "pain lasting three or more months from the initial onset of pain."</p> <p>Agree: This provision is vague and ambiguous and will be revised to clarify that the Chronic Pain Medical Treatment Guidelines apply when the patient has chronic pain as defined in section 9792.20.</p> <p>Agree. The phrase "is diagnosed with" suggests this guideline only applies if the treating physician has rendered a diagnosis of chronic pain. This is not the DWC's intent.</p>	<p>months from the initial onset of pain."</p> <p>See above.</p> <p>Section 9792.24.2(b) is amended by deleting the phrase "as determined by following the clinical topics" and adding the phrase "as defined in section 9792.20."</p> <p>Section 9792.24.2(c) is amended by deleting the phrase "is diagnosed with" and replaces it with the word "has". In addition, the DWC is making grammatical revisions changing lower case "c" and "t" to capital letters "C" and "T" and adding the phrase "of</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	inconsistent with the understood DWC intent based on the recent revision of 9792.20(b). This also effectively gives the treating physician complete control over when the Chronic Pain Medical Treatment Guidelines will be used, as they can trigger this by adding of excluding a diagnosis of chronic pain.		The DWC has also made grammatical revisions on its own for clarity.	the MTUS” for clarity.
9792.24.4(b)	<p>Commenter recommends the following revised language:</p> <p><u>(b) The Opioids Treatment Guidelines describe the appropriate use of opioid medications as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain. These guidelines apply when alternative therapies do not provide adequate pain relief and the use of opioid medications is being considered as part of the treatment regimen.</u></p> <p>Commenter opines that this description of when the guidelines apply creates a significant unintended</p>	Robert Ward Clinical Director CID Management August 28, 2015	Agree: The inclusion of the phrase that these guidelines apply when “alternative therapies do not provide adequate pain relief and...” is confusing and needs to be deleted. The Opioids Treatment Guidelines allow the option to go straight to opioids without first having to demonstrate that the alternative therapies do not provide adequate pain relief. The DWC also agrees that this phrase creates unintended consequences such as the potential inconsistencies in the recommendations found in the guidelines with respect to	Section 9792.24.4(b) is amended to delete the phrase “alternative therapies do not provide adequate pain relief and...”

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>consequence.</p> <p>Commenter states that this language effectively excludes the use of the Opioids Treatment Guidelines until it has been demonstrated that "alternative therapies do not provide adequate pain relief". In turn, the regulatory language that describes when the Opioids Treatment Guidelines are to be used becomes inconsistent with the recommendations within those guidelines with respect to acute and post-operative care.</p> <p>Commenter opines that unless the suggested redaction is made, use of these guidelines for determining the medical necessity of opioids would not be available for acute and post-operative care, as these phases of recovery would have effectively lapsed by the time that the clinical history could include substantial evidence of failure of alternative therapies.</p>		acute and post-operative care.	
Opioid Medical Treatment Guidelines – 1.3	Commenter notes that the guideline draft recommends that for <u>severe acute injuries</u> , that opioids not be	Robert Ward Clinical Director CID Management	Disagree: The proposed Opioids Treatment Guidelines allow the option to go straight	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Severe Acute Injuries – Page 24	<p>used unless the following forms of treatment have been attempted and have failed, or are contraindicated:</p> <p>Acetaminophen and NSAIDs Physical activity/physical therapy with graded exercise Alternative therapy such as acupuncture, massage and yoga</p> <p>Commenter opines that this recommendation may represent an inadvertent copy/paste from recommendations for milder injuries. Commenter states that this recommendation is essentially one that delays the use of opioids until after the acute phase of injury has lapsed, as a trial of such care typically requires several weeks. Opioids are often used immediately after injuries of this severity.</p> <p>Commenter states that physical activity/therapy and exercise, massage and yoga are generally inappropriate for severe injuries in the acute phase.</p> <p>Commenter recommends that the</p>	August 28, 2015	to opioids if "there are reasonable expectations that only opioids will produce immediate pain relief and sleep immediately following the injury". The conjunction "and/or" is before each of the options and it appears the commenter has missed option "(c)" which is stated above.	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	requirement for failed conservative care prior to the use of opioids for severe acute injury be removed.			
Opioid Medical Treatment Guidelines – 3 Opioids for Chronic Pain and Chronic Opioid Treatment – Page 32	<p>Commenter states that the term “chronic pain” is defined in this guideline as pain lasting longer than three (3) months from the initial onset of injury pain (i.e., over 12 weeks).</p> <p>Commenter recommends that this definition be removed, and that the guideline instead refer to 8CCR9792.20 for the definition of chronic pain.</p> <p>Commenter opines that the establishment of a separate definition within the guideline will create inconsistency, or the need to undertake coordinated revision of the guideline and 9792.20, in the event that the regulatory definition is again amended in the future.</p>	Robert Ward Clinical Director CID Management August 28, 2015	<p>Agree in part; Disagree in part: Agree: That the current language is inconsistent with the definition of Chronic Pain in section 9792.20 and needs to be revised.</p> <p>Disagree: Disagree with commenter’s suggestion that “the guideline instead refer to 8CCR9792.20 for the definition of chronic pain” or that there may be the potential of revising the regulatory definition of chronic pain in the future.</p>	Section B.3. Opioids for Chronic Pain and Chronic Opioid Treatment section is amended to amend the phrase “longer than three (3) months” and replace it with “three (3) or more months.”
Opioid Medical Treatment Guidelines – 3 Opioids for Chronic Pain and Chronic Opioid Treatment – Page	<p>Commenter quotes the following:</p> <p>7. Make regular efforts to taper opioids.</p> <p>Commenter recommends that this section be amended to include a</p>	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: This section is an overview of recommendations, and specifically instructs readers to “See Section 4, Tapering Opioids” for details.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
34	specific recommendation of the maximum interval between tapering efforts, as has been elsewhere in the guideline draft (e.g., at least 6 months).			
Opioid Medical Treatment Guidelines – 3.3.7.1 Tracking Pain and Function to Monitor Effectiveness of Chronic Opioid Treatment – Page 46	<p>Commenter quotes the following:</p> <p>The most valid and consistent method for tracking function is to routinely measure physical function by documenting actual physical performance, including exertional capacity, degree of flexibility, and improved strength.</p> <p>Commenter opines that it is likely that a subset of providers will view this recommendation as supportive of frequent and routine functional capacity evaluations (FCE). Commenter states that this practice is not only resource intensive; it is not supported by EBM guidelines for FCE, which recommend against the use of this type of assessment as an outcome measure. Commenter state that if the DWC does not intend to support the use of FCE as a routine clinical outcome measure, he recommends that a statement to that</p>	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: This section should not be interpreted as a reference to Functional Capacity Evaluations (FCEs) and does not imply any recommendation for frequent and routine FCEs. FCE’s are used to assess the current objective functional capacity of the injured worker, usually in the context of return to work with restrictions. FCEs are subject to medical necessity and their routine use as described by the commentator would be medically inappropriate. The current language specifies routine testing of physical function at the office visit that would be incorporated into the physician’s progress report, and would not require any	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	effect be added to this section. It may also be useful from a provider education perspective to refer the provider to appropriate methods for tracking function.		special studies, equipment, or reports.	
Opioid Medical Treatment Guidelines – 3.3.7.2 Clinically Meaningful Improvement in Pain and Function – Page 48	<p>Commenter quotes the following:</p> <p>1. Document clinically meaningful (30% or more) improvement in pain and function or pain interference with function during the acute/subacute pain trial periods as well as during the trial of chronic opioid treatment, prior to initiating chronic opioid treatment. Continuing opioid treatment in the absence of this level of functional improvement is not medically necessary care. [61, 112, 113]</p> <p>Commenter opines that the recommendation of threshold of efficacy of 30% is an oversimplification of the recommendations in the peer-reviewed literature. While there was a published recommendation to consider a 30% improvement from baseline to be clinically meaningful improvement, there is also a</p>	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: The level of detail on this topic is felt to be appropriate for the purpose and is similar to other opioid guidelines. Improvements in pain and function as measured by instruments should be factored into the assessment of the patient and this can be done without using “minimal important change (MIC)” terminology. No change needed.	None.

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	<p>recommendation to couple this with the minimal important change (MIC) for specific instruments.</p> <p>For example, assessment of pain on a 10-point scale has a MIC of 2 points. A patient who has a baseline pain scale value of 3 without medication who then reports improvement to 2 with medication has a 33% improvement from baseline. However, they have not had clinically meaningful improvement, as they have not demonstrated the MIC for this outcome measure.</p> <p>Commenter recommends that this section be revised to require <u>both</u> clinically meaningful improvement and minimal important change on the assessment instrument being used.</p>			
Opioid Medical Treatment Guidelines – 4.1 Indications For Tapering Opioids – Page 53	Commenter opines that the guideline is fairly clear about which patients should receive tapering, with respect to duration of opioid use. However, there is no consideration as to whether there is a daily dosage that is sufficiently low that tapering is not required	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: DWC is not aware of any evidence basis for making this recommendation. The need for tapering should be made on a case by case basis rather than provide a daily dosage that is sufficiently low that tapering is not required.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter recommends that the guideline also consider recommending a daily dosage in MED that represents the minimum daily dosage requiring tapering.</p>		<p>Disagree: the guideline already lists 80 MED and is a suggested daily dosage that indicates consideration of tapering but it is not a dosage “requiring tapering.”</p>	<p>None.</p>
<p>Opioid Medical Treatment Guidelines – 4.2 Methods for Tapering Opioids – Page 55</p>	<p>Commenter notes that subsection 3.b. recommends inpatient detox and a pain management program.</p> <p>Commenter recommends that the DWC should consider offering meaningful recommendations regarding the duration of inpatient detox (length of inpatient stay). This is required for technical compliance with LC5307.27.</p> <p>Commenter opines that the DWC should consider offering meaningful recommendations as to what types of services should be included in a pain management program. The draft recommendation of "20 full days of 160 hours" is an amount of service, without any recommendations regarding the nature of the service.</p> <p>Commenter states that a pain</p>	<p>Robert Ward Clinical Director CID Management August 28, 2015</p>	<p>Disagree: There is technical compliance with Labor Code section 5307.27 throughout this section the duration for the various methods of tapering are mentioned. However, the duration of inpatient stay can only be determined on a case-by-case basis dependent on the patient’s clinical needs.</p> <p>Disagree: Here, commenter is referring to the Pain Management Programs which could be a part of an inpatients detox treatment. See responses to Chronic Pain Medical Treatment Guideline – Chronic Pain Programs (Functional restorations programs [FPRs]) below.</p> <p>Agreed: Yes, it is a collection.</p>	<p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>management program is not a specific form of treatment, but is a collection of different medical treatment services. LC4610(g)(4) requires that every authorization "specify the specific medical treatment service approved". A request for a program that merely describes the duration of the program cannot be authorized in a manner that is consistent with the requirements of LC4610(g)(4).</p> <p>Commenter recommends that the DWC consider adding language to communicate the need for such specificity when requesting authorization of any type of program.</p> <p>Commenter opines that the inclusion of such language can serve to greatly reduce the frequency and duration of delays in authorization.</p>		<p>However, when making a treatment request the details of the specific treatment services that comprise of the program can be provided. If a request for a program contains the details of the specific treatment services, not just a description of the duration of the program, then it can be approved consistent with the requirements of LC4610(g)(4).</p> <p>Disagree: Treating physicians should always provide specific documentation to establish the medical necessity of the treatment plan, not just in this instance, but for any request.</p> <p>Commenter's recommendation will not be incorporated because it is unnecessary, otherwise, this language should be incorporated after any and all recommendations in the MTUS.</p>	<p>None.</p> <p>None.</p>
Opioid Medical Treatment Guidelines – 9	Commenter notes that the guideline draft asks the treating physician to provide "documentation to justify	Robert Ward Clinical Director CID Management	Disagree: Factors to consider would include those noted in B. Recommendations, Sections	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Managing Peri-operative Pain in Workers on Chronic Opioid Treatment Undergoing Elective Surgery – Section 3.f – Page 61	<p>continued use of opioids at doses higher than pre-operative levels for up to 12 weeks." However, there is no indication as to what potential factors might justify such continuation for longer than 6 weeks.</p> <p>Commenter recommends that the DWC include some discussion or indication as to what factors might warrant such continuation.</p>	August 28, 2015	2 and 3. Management of pain and improving function are always considerations for continuation of treatment.	
Chronic Pain Medical Treatment Guideline – General Comment	<p>Commenter opines that this guide represents a needed improvement, as the current version is outdated. Commenter states there are revisions required for the following reasons:</p> <ul style="list-style-type: none"> • The creation of inconsistencies with other portions of the MTUS; • Lack of technical compliance with Labor Code 5307.27 (“shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases.”) • Opportunities for the DWC to 	Robert Ward Clinical Director CID Management August 28, 2015	<p>Disagree: The DWC and MEEAC carefully coordinate the component guidelines that together comprise the MTUS. There should not be conflicting recommendations from the guidelines in the MTUS.</p> <p>Disagree: There is compliance with Labor Code section 5307.27 because the proposed recommendations for the Chronic Pain Programs/Functional Restoration Programs’ addresses the frequency, duration, intensity, and appropriateness by stating, “While these programs are</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	clarify its intent.		recommended (see criteria below), the research remains ongoing as to (1) what is considered the “gold-standard” content for treatment; (2) the group of patients that benefit most from this treatment; (3) the ideal timing of when to initiate treatment; (4) the intensity necessary for effective treatment; and (5) cost-effectiveness. It has been suggested that interdisciplinary/multidisciplinary care models for treatment of chronic pain may be the most effective way to treat this condition.” Labor Code sections 5307.27 and 4604.5 also mandates that the recommendations in the MTUS be evidence and scientifically based, peer-reviewed, and nationally recognized. The proposed recommendations for the Chronic Pain Programs/Functional Restoration Programs’ are as specific and detailed as the	

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			<p>scientific medical evidence can support. Finally, Chronic Pain Programs/Functional Restoration Programs is covered in the current MTUS Chronic Pain Medical Treatment Guidelines which incorporates by reference an earlier version of ODG's guideline from May 2009 and previously approved by the Office of Administrative Law.</p> <p>Disagree: The DWC believes its intent is clear and would welcome specific suggestions where there is ambiguity in our intent.</p>	None.
Chronic Pain Medical Treatment Guideline – Chronic Pain Programs (Functional restorations programs[FPRs] – Page 45	<p>Commenter recommends that the draft be revised to inform treating physicians that the specific treatment services, and the quantity of each, to be provided within such a program be specified within the request for authorization.</p> <p>Commenter states that a program is</p>	Robert Ward Clinical Director CID Management August 28, 2015	<p>Disagree: Research remains ongoing. The recommendations in the Chronic Pain Programs/Functional Restoration Programs' are as specific and detailed as the scientific medical evidence can support.</p> <p>Agree: Yes, it is a collection.</p>	None. None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>not a specific form of treatment, but is a collection of different medical treatment services.</p> <p>Commenter states that while the draft does make it clear that "what is considered 'gold standard' content for treatment" has not been established, LC4610(g)(4) requires that every authorization "specify the specific medical treatment service approved". A request for a program that merely describes the duration of the program cannot be authorized in a manner that is consistent with the requirements of LC4610(g)(4).</p> <p>Alternatively, commenter recommends that the DWC consider adding a separate topic entry of "Programs" to communicate the need for such specificity when requesting authorization of any type of program (chronic pain program, functional restoration program, multidisciplinary pain program, pain management program, progressive</p>		<p>However, when making a treatment request the details of the specific treatment services that comprise of the program can be provided.</p> <p>Disagree: If a request for a program contains the details of the specific treatment services, not just a description of the duration of the program, then it can be approved consistent with the requirements of LC4610(g)(4).</p> <p>Disagree: Commenter's suggestion to add a separate topic entry of "Programs" will not be incorporated. Characteristics of the various programs are already delineated in the guideline and the requesting physician must always provide specific documentation to establish the</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>goal attainment program, detoxification program).</p> <p>Commenter opines that inclusion of such language can serve to greatly reduce the frequency and duration of delays in authorization.</p>		<p>medical necessity when requesting the service as part of the pre-authorization process.</p>	
<p>Chronic Pain Medical Treatment Guideline – Detoxification – Page 72</p>	<p>Commenter recommends that the draft be revised to inform treating physicians that the specific treatment services, and the quantity of each, to be provided within such a program be specified within the request for authorization.</p> <p>Commenter states that a program is not a specific form of treatment, but is a collection of different medical treatment services.</p> <p>Commenter states that while the draft does make it clear that "what is considered 'gold standard' content for treatment" has not been established, LC4610(g)(4) requires that every authorization "specify the specific medical treatment service approved". A request for a program that merely describes the duration of the program cannot be authorized in a manner that</p>	<p>Robert Ward Clinical Director CID Management August 28, 2015</p>	<p>Disagree: Here commenter addresses “Chronic Pain Programs” instead of Detoxification on Page 72. He states, “See Comment above with regards to chronic pain programs.” Therefore, see responses to Chronic Pain Medical Treatment Guideline – Chronic Pain Programs (Functional restorations programs[FPRs]) in pages 49 - 53 above.</p>	<p>None.</p>

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	<p>is consistent with the requirements of LC4610(g)(4).</p> <p>Alternatively, commenter recommends that the DWC consider adding a separate topic entry of "Programs" to communicate the need for such specificity when requesting authorization of any type of program (chronic pain program, functional restoration program, multidisciplinary pain program, pain management program, progressive goal attainment program, detoxification program).</p> <p>Commenter opines that inclusion of such language can serve to greatly reduce the frequency and duration of delays in authorization.</p>			
<p>Chronic Pain Medical Treatment Guideline – Functional Restoration Programs – Page 86</p>	<p>Commenter recommends that the draft be revised to inform treating physicians that the specific treatment services, and the quantity of each, to be provided within such a program be specified within the request for authorization.</p> <p>Commenter states that a program is not a specific form of treatment, but</p>	<p>Robert Ward Clinical Director CID Management August 28, 2015</p>	<p>Disagree: See responses to Chronic Pain Medical Treatment Guideline – Chronic Pain Programs (Functional restorations programs[FPRs]) in pages 49 -53 above.</p>	<p>None.</p>

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	<p>is a collections of different medical treatment services.</p> <p>Commenter states that while the draft does make it clear that "what is considered 'gold standard' content for treatment" has not been established, LC4610(g)(4) requires that every authorization "specify the specific medical treatment service approved". A request for a program that merely describes the duration of the program cannot be authorized in a manner that is consistent with the requirements of LC4610(g)(4).</p> <p>Alternatively, commenter recommends that the DWC consider adding a separate topic entry of "Programs" to communicate the need for such specificity when requesting authorization of any type of program (chronic pain program, functional restoration program, multidisciplinary pain program, pain management program, progressive goal attainment program, detoxification program).</p> <p>Commenter opines that inclusion of</p>			

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	such language can serve to greatly reduce the frequency and duration of delays in authorization.			
Chronic Pain Medical Treatment Guideline – Gabapentin (Neurontin) and Gralise (gabapentin enacarbil ER) – Page 87 - 88	<p>Commenter opines that these two related entries appear to be inconsistent.</p> <p>Commenter states that these are essentially equivalent medications. However, the entry for gabapentin recommends the medication for some conditions, whereas the entry for Gralise recommends against use of the medication.</p> <p>Commenter notes that the entry for Gralise refers the reader to the MTUS Knee complaints chapter. There is no mention of this specific medication or the class of medications to which it belongs anywhere in the MTUS Knee Complaints chapter.</p>	Robert Ward Clinical Director CID Management August 28, 2015	<p>Disagree: The extended-release nature of Gralise makes it different from generic gabapentin regular release which is the recommended first-line agent for treatment of the listed conditions.</p> <p>Disagree: The MTUS Knee complaints chapter is cited because this medication typically prescribed for the treatment of restless legs syndrome. If a specific injury or condition is not found in the MTUS’s guidelines, then a medical literature search can be conducted to find a recommendation outside of the MTUS.</p>	<p>None.</p> <p>None.</p>
Chronic Pain Medical Treatment Guideline – Home	Commenter notes that the DWC has been in the process of developing its own guidelines for home health	Robert Ward Clinical Director CID Management	Disagree: the proposed MTUS Chronic Pain Medical Treatment guideline section on	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Health Care Services – Page 88 - 89</p>	<p>services. Commenter opines that adoption of the language in the proposed chronic pain treatment guidelines may be inconsistent with the planned home health care guidelines.</p> <p>Commenter requests that the DWC consider either making this entry consistent with its intended home health care guidelines/regulations; or it should indicate that this section will be superseded once such are adopted.</p> <p>Commenter opines that this guideline entry should also include, by reference, the limitations on this type of service imposed by Labor Code 5307.8. As "No fees shall be provided for any services, including any services provided by a member of the employee's household, to the extent the services had been regularly performed in the same manner and to the same degree prior to the date of injury.", it likewise follows that no authorizations for such service can be made.</p>	<p>August 28, 2015</p>	<p>home health care describes the criteria for establishing medical necessity, whereas reimbursement for services will be address in the proposed Home Health Care fee schedule, including limitations on reimbursement to family members for certain services imposed by Labor Code 5307.8.</p> <p>Disagree: Commenter’s suggested language will not be incorporated because it’s unnecessary. See above response.</p> <p>Disagree: See above response.</p>	<p>None.</p> <p>None.</p>
<p>Chronic Pain Medical Treatment</p>	<p>Commenter states that the recommendations in the draft are</p>	<p>Robert Ward Clinical Director</p>	<p>Disagree: that the proposed timeframes are internally</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Guideline – Manual Therapy & Manipulation – Page 109 and 110</p>	<p>internally inconsistent with regard to the requirements for re-evaluation for outcomes of treatment. The guideline first instructs us that re-evaluation should take place after 8 weeks of treatment; then instructs us that re-evaluation should take place monthly; and then finally instructs us that re-evaluation should take place at each treatment session. Commenter recommends that the DWC amend this section such that the recommended interval for re-evaluation is consistent.</p> <p>Commenter opines that the recommendation represents a major departure from current norms of care, as it supports maintenance care at a frequency of once every other week indefinitely: "treatment may be continued at 1 treatment every other week until the patient has reached MMI and maintenance treatments have been determined".</p> <p>Commenter states that there is no known source of scientific evidence that supports this specific recommendation for ongoing maintenance care. Additionally, in</p>	<p>CID Management August 28, 2015</p>	<p>inconsistent, the recommended intervals for re-evaluation address four separate clinical patient categories in the rehabilitation process, including (1) general recommendations, (2) certain conditions of chronic pain, and (3) cases of re-injury, interrupted continuity of care, exacerbation of symptoms and patients with co-morbidities. Finally (4) palliative care should be documented at each session.</p> <p>Disagree. Recommendations are evidence-based. Treatment is not recommended after the patient has reached maximum medical improvement (MMI). The hard California cap of 24 visits set forth in Labor Code section 4604.5(c)(1) is not considered part of the medical evidence.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>the event that a provider of such care is also the primary treating physician, there will be a strong financial incentive on the part of that provider to delay a P&S finding as long as possible.</p> <p>Commenter states that this recommendation is inconsistent with the treatment cap that is established by Labor Code 4604.5(c)(1).</p> <p>Commenter strongly recommends that the DWC redact this recommendation for perpetual maintenance care.</p>		<p>Disagree: See above.</p> <p>Disagree: that this sections needs redaction or recommends perpetual care. See above.</p>	<p>None.</p> <p>None.</p>
<p>Chronic Pain Medical Treatment Guideline – Opioid Topics – Page 138 - 140</p>	<p>Commenter notes that the recommendations in the draft each start with a reference to the MTUS Opioids Treatment Guidelines; and many then continue with extensive additional language.</p> <p>To minimize confusion, commenter recommends that guideline topics "Opioids, criteria for use" through "Opioids, state medical board's</p>	<p>Robert Ward Clinical Director CID Management August 28, 2015</p>	<p>Disagree: Current format in the Chronic Pain Medical Treatment Guideline provides more clarity as to the range of topics included in the MTUS Opioid Medical Treatment Guidelines. Some of the mentioned opioid entries provide helpful content and do not simply refer to the Opioid guideline, and current topic</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	guidelines" should be redacted from the guidelines. This will leave in place a single entry: "Opioids"; which will refer users to the MTUS Opioids Treatment Guidelines.		indexing is consistent with ODG formatting	
Chronic Pain Medical Treatment Guideline – Physical Medicine Treatment – Page 143	<p>Commenter notes that at the end of the recommendation, immediately following a reference to the MTUS Postsurgical Treatment Guidelines, the following appears:</p> <p>"Patients should be formally assessed after a "six-visit clinical trial" to evaluate whether PT has resulted in positive impact, no impact, or negative impact prior to continuing with or modifying the physical therapy."</p> <p>Commenter recommends that this language be moved to precede the reference to the MTUS Postsurgical Treatment Guidelines. The reason for this recommendation is that the suggestion to assess the outcomes of therapy after 6 visits is inconsistent with the requirements of the MTUS Postsurgical Treatment Guidelines for all forms of surgery with a recommended general course of care</p>	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: Post-surgical guidelines include this qualifier: ‘Patients should be formally assessed after a “six-visit clinical trial” to evaluate whether PT has resulted in positive impact, no impact, or negative impact prior to continuing or modifying the physical therapy.’	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>that is different from 12 sessions. The MTUS Postsurgical Treatment Guidelines specify that such assessment is to be based on the initial course of care, which is 1/2 of the general course of care.</p> <p>Commenter opines that the current placement of the recommendation to assess after 6 visits may result in confusion and/or misapplication of the MTUS Postsurgical Treatment Guidelines.</p>			
Chronic Pain Medical Treatment Guideline – Physician-dispensed drugs – Page 144	Commenter notes that this entry makes no recommendations regarding the practice, nor is it useful in determining the medical necessity of any medication. Commenter recommends that the DWC consider amending this section to include an actual recommendation, or the DWC should consider redacting the entry.	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: This entry provides an important definition for “physician dispensed drugs” that will assist treating physicians and reviewing physicians and also provides important links to other parts of the proposed guidelines that contain recommendations. There is no mandate that every section of the MTUS contain a recommendation.	None.
Chronic Pain Medical Treatment Guideline – Progressive goal	Commenter recommends that the draft be revised to inform treating physicians that the specific treatment services, and the quantity of each, to	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: The proposed guidelines provide criteria for progressive goal attainment programs. However,	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
attainment program (PGAP) – Page 146	<p>be provided within such a program be specified within the request for authorization.</p> <p>Commenter states that a program is not a specific form of treatment, but is a collections of different medical treatment services.</p> <p>Commenter states that while the draft does make it clear that "what is considered 'gold standard' content for treatment" has not been established, LC4610(g)(4) requires that every authorization "specify the specific</p>		<p>commenter recommends that further details be provided regarding specific treatment services and quantity of each to be provided within such a program. Progressive goal attainment programs is evaluated on a case by case basis and providing details regarding the specific treatment services may not fit the clinical needs of each unique patient. Treating physicians should always provide documentation to establish the medical necessity of the treatment plan.</p> <p>Agree: that a progressive goal attainment programs (by definition) offers a variety of specific services within a variety of different specialties.</p> <p>Disagree: Here, commenter is categorizing the proposed PGAP recommendations with the proposed Chronic Pain Programs/Functional Restoration Programs</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>medical treatment service approved". A request for a program that merely describes the duration of the program cannot be authorized in a manner that is consistent with the requirements of LC4610(g)(4).</p>		<p>discussed above. If a request for a program contains the details of the specific treatment services, not just a description of the duration of the program, then it can be approved consistent with the requirements of LC4610(g)(4). See responses to Chronic Pain Medical Treatment Guideline – Chronic Pain Programs (Functional restorations programs[FPRs]) in pages 49-53.</p>	
<p>Chronic Pain Medical Treatment Guideline – Psychological evaluations – Page 148-149</p>	<p>Commenter opines that the recommendations for use of the various psychological instruments should also include recommendations for determining under what circumstances these assessments should be considered as integral to E/M services; and when such assessments should be considered as necessary as a separate and distinct medical service.</p> <p>Commenter states that the practice of "unbundling" appears to be very common with psychological survey</p>	<p>Robert Ward Clinical Director CID Management August 28, 2015</p>	<p>Disagree: This rulemaking pertains to the Chronic Pain Medical Treatment Guidelines set forth in §9792.24.2 Billing and reimbursement rules are not included in the MTUS and are not part of the proposed Chronic Pain Medical Treatment Guideline but are addressed in the Official Medical Fee Schedule.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	instruments.			
Chronic Pain Medical Treatment Guideline – Psychological treatment – Page 149-150	<p>Commenter notes that the recommendations include a number of sessions "if progress is being made".</p> <p>Commenter recommends that the DWC include an indication of what constitutes sufficient progress to warrant continuation of care; as well as indicating at what point(s) assessment of progress should be made. Otherwise, the recommendation has no objective meaning.</p>	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: The proposed guideline states, "The provider should evaluate symptom improvement during the process..." The progress being made depends upon the individual patient factors that must be assessed on a case by case basis and a physician's clinical judgment will be used.	None.
Chronic Pain Medical Treatment Guideline – Repackaged Drugs – Page 151	<p>Commenter notes that the draft does not actually make a recommendation for or against repackaged drugs.</p> <p>Commenter recommends that the DWC consider inclusion of an explicit recommendation against the practice; or alternatively to provide criteria for when the practice should be considered necessary.</p>	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: This entry provides an important definition for "repackaged drugs" that will assist treating physicians and reviewing physicians and also provides important links to other parts of the proposed guidelines that contain recommendations. There is no mandate that every section of the MTUS contain a recommendation.	None.
Chronic Pain Medical Treatment	Commenter notes that the draft states, "See specific body-part chapters in	Robert Ward Clinical Director	Disagree: The hyperlink is active and operational.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guideline – Restless Legs Syndrome – Page 151	<p>the MTUS", formatted as a hyperlink to a dead DIR web page.</p> <p>Commenter recommends that the DWC indicate which specific body-part chapter(s) one should look to for recommendations for this condition. If there are no recommendations for this condition in any of the specific body-part chapter(s), then commenter recommends that the DWC consider redacting this entry, as it contains no recommendations for or against any form of treatment.</p>	CID Management August 28, 2015	Disagree: Link refers to current MTUS body part chapters and readers are taken to the MTUS Knee Complaints chapter. The MTUS body part chapters are in the process of being updated, in the interim, if an MTUS body part chapter does not address a particular treatment, then a medical literature search can be conducted to find a recommendation outside of the MTUS.	None.
Chronic Pain Medical Treatment Guideline – RS-4i Sequential Stimulator – Page 151	<p>Commenter notes that the draft states, "See Interferential current stimulation (ICS)."</p> <p>Commenter opines that this is a potentially misleading reference, as it implies that the RS-4i is a form of ICS; and it is not. It is an experimental combination of ICS and EMS. Additionally, the support for the device in the ICS discussion on page 103 is based entirely on a single study that was produced by the device manufacturer (e.g., a biased</p>	Robert Ward Clinical Director CID Management August 28, 2015	Agree in part; Disagree in part: Agree: that the RS-4i Sequential Stimulator contains both ICS and EMS features. Disagree: that an evidence appraisal based on cost vs. benefit compared to other forms of electrical therapy should be included. The MTUS does not assess medical evidence on the basis of cost.	None.

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	<p>study within the terms of the MTUS hierarchy of evidence).</p> <p>Commenter notes that the cost of a standard ICS unit ranges from \$200 to \$800. The cost of the RS-4i is \$3200. Because this specific device is not supportable on an evidence-based appraisal of the cost vs. benefit as compared to other forms of electrical therapy, commenter recommends that the DWC consider amending the recommendation for the RS-4i sequential stimulator.</p>			
Chronic Pain Medical Treatment Guideline – Weaning, carisoprodol (Soma) – Page 176	<p>Commenter notes that the recommendation in the draft is for a tapering rate of "30 mg/day". Commenter states that this is effectively impossible, as the medication is available only as a 350mg tablet.</p> <p>Commenter recommends that the DWC consider an alternative tapering schedule that utilizes the 350mg tablets only. One such tapering schedule was developed by the Department of Veterans Affairs Medical Center, Portland, Oregon; and was published in the Oregon</p>	Robert Ward Clinical Director CID Management August 28, 2015	Disagree: The 30 mg/day cited does not apply to carisoprodol it applies to phenobarbital: “A maximum suggested dose of phenobarbital is 500mg/day and the taper is 30 mg/day with slower taper in an outpatient setting.	None.

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	<p>DUR Board Newsletter 2002; 4:1. 28 Dec 2005. Commenter provided a graphic image of that tapering schedule has been attached to these comments [copy available upon request].</p>			
<p>Chronic Pain Medical Treatment Guideline – Yoga – Page 182</p>	<p>Commenter opines that the recommendation in the draft fails to offer any meaningful guidance for patient selection for this service (no patient selection criteria for either initial or continuing treatment); and fails to offer any recommendations for frequency or duration.</p> <p>Commenter states that the language in the draft is internally inconsistent: "recommend approval where requested by a specific patient, but not adoption for use by any patient."</p>	<p>Robert Ward Clinical Director CID Management August 28, 2015Chr</p>	<p>Disagree: This section refers to Behavioral Interventions/Cognitive Behavioral Therapy (CBT) which explains that further information on psychosocial variables can be found in the introduction.</p> <p>Disagree: The proposed language is not internally inconsistent. This section begins with “Recommended as an option for motivated patients” and goes on to explain “since outcomes from this therapy are very dependent on a motivated patient, we recommend approval where requested by a specific patient, but not adoption for use by any patient.” The recommendation for approval is for patients who are motivated to do yoga.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter notes that the draft also states, "Also see relevant MTUS body chapters". However, there are no mentions of this form of treatment in any of the MTUS body chapters.</p> <p>Commenter recommends that the DWC revise this guideline entry to remedy its shortcomings; or redact it. Commenter opines that as written, it is non-compliant with LC 5307.27.</p>		<p>Disagree: Yoga is a form of exercise which is extensively covered throughout the MTUS body chapters. The MTUS body part chapters are in the process of being updated, in the interim, if an MTUS body part chapter does not address a particular treatment, then a medical literature search can be conducted to find a recommendation outside of the MTUS.</p> <p>Disagree: This section is complaint with Labor Code section 5307.27. The efficacy of yoga is supported by ample medical evidence as cited in this section. In addition, yoga is covered in the current MTUS Chronic Pain Medical Treatment Guidelines which incorporates by reference an earlier version of ODG's guideline from May 2009 and previously approved by the Office of Administrative Law.</p>	<p>None.</p> <p>None.</p>

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Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	<p>In April of this year, the commenter joined in association with numerous colleagues who treat chronic pain in presenting a letter and supporting evidence asking that spinal cord stimulation (SCS) for failed back surgery syndrome (FBSS), and intrathecal therapy for specific pain problems continue to be covered in California [copy available upon request]. Commenter appreciates the changes that were made to preserve this effective treatment, which were endorsed by the following organizations:</p> <p>The American Society of Anesthesiologists, The American Society of Interventional Pain Physicians, The North American Neuromodulation Society, The California Society of Anesthesiologists, The California Society of Interventional Pain Physicians, The California Society of Industrial Medicine, and the administrators of <i>every</i> academic pain program in the State of California.</p>	<p>Joshua P. Prager, MD August 28, 2015 Written Comments September 1, 2015 Oral Comment</p>	<p>Disagree in part: To be clear, the proposed Chronic Pain Medical Treatment Guidelines’ recommendations on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for failed back surgery syndrome (FBSS) patients, instead it references the MTUS Low Back Complaints guideline which incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004) which states, “Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the standard nonoperative or operative interventions.” FBSS as an indication for SCS is covered but in the current MTUS Low Back Chapter.</p>	<p>None.</p>

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	<p>Commenter states that coverage of SCS for FBSS allows workers in California to join those in the 48 other states in being eligible for effective treatment of their chronic back pain. In addition, SCS for FBSS is covered by Medicare and most commercial health insurers.</p> <p>Commenter opines that while the MTUS changes are gratifying, they continue to cite 2004 recommendations made by the American College of Occupational and Environmental Medicine (ACOEM) and that this may lead to ambiguities. The ACOEM <i>Practice Guidelines, 2nd ed.</i>, which are cited by MTUS in the Low Back Complaints section (regulations 9792.23.5), state: “Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the standard non-operative or operative interventions. (Chap. 12, p. 307).” Commenter notes that this statement is false in</p>		<p>Agree in part; Disagree in part: Agree: The proposed Chronic Pain Medical Treatment Guidelines on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for failed back surgery syndrome (FBSS) patients, instead, as indicated by commenter, it references the MTUS Low Back Complaints guideline which incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004). Disagree: Commenter recommends that the SCS literature summary presented to the DWC in April 2015 be included in the proposed</p>	<p>None.</p> <p>None.</p>

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	<p>light of the past 10 years of evidence and clinical practice.</p> <p>Commenter notes that the 2004 ACOEM source predates more than a decade of subsequent clinical studies of SCS in the management of chronic pain associated with FBSS. Most importantly, it overlooks the recent, landmark SENZA study of high-frequency SCS (HF10) therapy that provides a scientifically rigorous, pivotal, Level 1 comparison of HF10 and SCS. More than two-thirds of the HF10 patients achieved back and leg pain remission over 12 months. Commenter states that this result is remarkable, given that 86.6% of the patients had undergone previous failed back surgery, and patients averaged 13.6 years since their pain diagnosis. Follow-up now extends to 18 months and demonstrates that the benefits of HF10-SCS therapy are durable.</p> <p>With this new evidence in mind, commenter opines that it is difficult to justify not including the April literature summary of SCS for FBSS</p>		<p>MTUS Chronic Pain Chapter section on SCS. However, doing this would be an attempt to amend the current MTUS recommendations in the Low Back Chapter via this rulemaking. The DWC is unable to amend the MTUS' Low Back Chapter without going through the formal rulemaking process to amend that regulatory section. However, the DWC is in the process of evaluating and updating the treatment guidelines for the Low Back.</p> <p>In addition, if a physician believes there is evidence to rebut any recommendation in the MTUS, then the requesting physician may attempt to rebut the MTUS's presumption of correctness. Rebutting the MTUS requires submitting additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated</p>	

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	<p>presented to the DWC in regard to the proposed guidelines. Commenter opines that the summary includes numerous clinical trials of SCS conducted since 2004, and would give the public, insurers, and physicians an opportunity to evaluate what is known <i>today</i> about SCS for FBSS.</p> <p>Commenter notes that the new proposed guideline includes coverage for intrathecal therapy; however, it is important to note that there is a reference in the ODG that is negative about the merits of intrathecal therapy. This reference cites guidelines from the State of Washington. Washington is the only state that denies this coverage and did so in contradiction to the findings of a highly respected independent body (ECRI Institute) it had commissioned to evaluate the evidence.</p> <p>Commenter provided several PDF documents to the DWC [documents available upon request]. These PDFs represent work product that was</p>		<p>using the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1, where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine.</p> <p>Disagree: Despite the fact the Washington study “is negative about the merits of intrathecal therapy” it will remain because it is an important study to be considered. This reference was included by the original source ODG guideline and was vetted and evaluated by their research team. In addition, the DWC does not and cannot unilaterally amend the recommendations found in the Procedure Summaries and references because we are incorporating by reference ODG’s April 6, 2015 guideline. Any amendments or edits to the Procedure</p>	None.

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	<p>presented to the DWC earlier this year. Commenter acknowledges that the cover letter addresses some issues that are no longer of concern; however, the letter describes the layout of the work product that follows. An executive summary was provided that discusses the issues in general and subsequently explains the layout of the succeeding documents. These documents include an executive summary, a summary of the evidence, and finally an evidence table and bibliography that supports the summary of the evidence.</p> <p>Commenter opines that chronic pain patients deserve the best care that clinical science and medicine <i>currently</i> offers.</p>		<p>Summaries and references must be reviewed and approved by the Work Loss Data Institute (ODG) because it is their copyrighted materials.</p> <p>Agree: The DWC agrees with commenter's summary of the documents provided to the DWC in an earlier meeting.</p> <p>Agree: Chronic pain patients should be able to receive the best care that is supported by the best available medical evidence.</p>	<p>None.</p> <p>None.</p>
Chronic Pain Medical Treatment Guidelines – General Comment	Commenter is generally supportive of the DWC's efforts in relation to this rulemaking. Commenter states that the choice to use the Official Disability Guidelines is a positive step; however, commenter objects to the adoption of a specific addition instead of incorporating the most	Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment September 1, 2015	Disagree: In order to properly incorporate the ODG guidelines by reference into our regulations, subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the	None

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	<p>current version.</p> <p>Commenter would also like the Division to anticipate the incorporation of a Prescription Drug Formulary as part of this rulemaking process.</p> <p>Commenter would like to address the lack clarity in the guidelines. Commenter notes that there are several instances that need to be corrected from the Utilization Review standpoint, in order to ensure that there are consistent Utilization Review Determinations and to avoid a situation where we have injured worker "A" and "B" receiving -- having different determinations from the Utilization Review referencing the exact same section of the guidelines or the exact same clinical criteria. Commenter notes that there are several sections in the guidelines that reference lists of things that the providers need to do prior to initiating an opioid trial in post-operative opioid prescribing and in chronic pain opioid prescribing. Commenter states that those lists are not clear as to what is required, what</p>	Oral Comment	<p>document by title and date of publication or issuance.” Therefore, incorporating the “most current version” without stating the date of publication or issuance is not allowed.</p> <p>Agree: Although the Prescription Drug Formulary is not part of this rulemaking, the DWC will certainly keep the upcoming formulary regulations in mind when completing this rulemaking.</p> <p>Disagree: The proposed MTUS provide evidence-based guidelines for a wide variety of clinical situations so the medically necessary treatment for two different patients with a given diagnosis may not always be exactly the same, and that is not a flaw of the guideline. The primary intent of the guideline is to provide the best evidence-based care.</p> <p>Disagree: Consistent application of the guidelines</p>	<p>None.</p> <p>None.</p> <p>None.</p>

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	<p>is required to be documented, what must be in the medical record. Commenter opines that from a Utilization Review perspective, this creates a situation where requests for additional information, delays occur because it is unclear as to what is required and what needs to -- and what is recommended or perhaps a best practice.</p>		<p>by providers and utilization review is desirable, but the guidelines are not intended to apply a rigid set of rules. Medical evidence is weaker for some types of treatment, a limitation of any clinical guideline, and is clearly stated when present.</p> <p>Disagree: that the recommendations and requirements for clinical documentation are unclear. Principles of management of chronic pain and opioid therapy, including documentation requirements are clearly explained and often repeated throughout the guidelines. Both guidelines include numerous cross references, detailed explanations, and references in addition to summary information.</p>	None.
9792.24.2(a)	<p>Commenter notes that the text of the proposed regulation, § 9792.24.2(a) states in part:</p>	<p>Ben Roberts Executive Vice President</p>	<p>Disagree: In order to properly incorporate the ODG guidelines by reference into</p>	None.

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	<p><i>Part 2 is entitled the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” consisting of an edited version from the Official Disability Guidelines published on April 6, 2015, which the Division of Workers’ Compensation has adapted with permission from the publisher.</i></p> <p>Commenter opines that by including a specific version of the Official Disability Guidelines, this rule effectively hinders providers and reviewers from applying current medical evidence in the formulation and review of treatment plans. Commenter states that the information in those Guidelines may become outdated and not reflective of new evidence based medicine, new peer-review studies, and new treatment and medication. Commenter notes that one of the main benefits of the use of third-party guidelines such as the Official Disability Guidelines or ACOEM, is that they are regularly updated to reflect new clinical information. This</p>	<p>PRIUM August 30, 2015 Written Comment</p> <p>September 1, 2015 Oral Comment</p>	<p>our regulations, subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the document by title and date of publication or issuance." Therefore, incorporating the “most current version” without stating the date of publication or issuance is not allowed. Also, allowing the MTUS to be automatically updated whenever ODG updates their guidelines is an unlawful delegation of the DWC’s regulatory authority and will not be permitted by the Office of Administrative Law.</p>	

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	<p>helps to avoid the time and expense of having a group or committee perform this task and enables the standard of care for injured workers' to adapt to changes in evidence based medicine sooner.</p> <p>Commenter recommends that the reference to a specific edition of the Official Disability Guidelines should be removed and replaced with language indicating that the current or most recent version of the Official Disability Guidelines should be referenced.</p>		Disagree: See above.	None.
9792.24.2(b)	<p>Commenter notes that the text of the proposed regulation, § 9792.24.2(b) states:</p> <p><i>The Chronic Pain Medical Treatment Guidelines apply when the patient has chronic pain as determined by following the clinical topics.</i></p> <p>Commenter notes that the text of this proposed regulation references clinical topics but fails to reference where the clinical topics are located.</p> <p>Commenter recommends that this</p>	<p>Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree: A clarification should be made to the “clinical topics reference. Disagree: The DWC will not adopt commenter’s suggested language to use the phrase “section of the MTUS” but rather will use the phrase “as defined in section 9792.20” for even greater specificity.</p>	<p>Section 9792.24.2(b) is amended by deleting the phrase “as determined by following the clinical topics” and adding the phrase “as defined in section 9792.20” for clarification.</p>

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	<p>regulation be updated to include the appropriate reference, as follows:</p> <p><i>The Chronic Pain Medical Treatment Guidelines apply when the patient has chronic pain as determined by following the clinical topics <u>section of the MTUS.</u></i></p>			
9792.24.2(c)	<p>Commenter notes that the text of the proposed regulation, § 9792.24.2(c) states:</p> <p><i>When a patient is diagnosed with chronic pain and the treatment for the condition is covered in the clinical topics sections but is not addressed in the Chronic Pain Medical Treatment Guidelines, the clinical topics section applies to that treatment.</i></p> <p>Commenter states that the text of this proposed regulation references clinical topics but fails to reference where the clinical topics are located.</p> <p>Commenter recommends that this regulation be updated to include the appropriate reference as follows:</p>	<p>Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment</p>	<p>Agree: Language regarding the location of the Clinical Topics section of the MTUS is lacking.</p>	<p>Section 9792.24.2(c) is amended by deleting the phrase “is diagnosed with” and replaces it with the word “has”. In addition, the phrase “of the MTUS” is added for clarity. The DWC is also making grammatical revisions on its own changing lower case “c” and “t” to capital letters “C” and “T” and adding the phrase “of the MTUS” for clarity.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>When a patient is diagnosed with chronic pain and the treatment for the condition is covered in the clinical topics sections of the MTUS but is not addressed in the Chronic Pain Medical Treatment Guidelines, the clinical topics section of the MTUS applies to that treatment.</i></p>			
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 1.1</p>	<p>Commenter opines that paragraphs and sections need to be more clearly identified and that a consistent pattern should be used. Commenter states that throughout the Guidelines there are inconsistencies in the labeling and numbering of paragraphs. For example; Section 1.1 paragraph 1 would be an accurate citation for both of the following paragraphs:</p> <p><i>Document moderate to severe soft tissue injury. (Section 1.1, paragraph 1)</i></p> <p><i>Prescribe weaker opioids and the lowest effective dose. Stronger opioids may be considered only if weaker ones are ineffective or not tolerated. The FDA categorizes drugs into five Schedules (from I to V). [83]</i></p>	<p>Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment</p>	<p>Agree: Formatting corrections were made so that paragraphs and sections are clearly identified and a consistent pattern is followed.</p>	<p>Formatting throughout the proposed Opioids Treatment Guidelines was amended to follow a consistent pattern broken up into two sections “A. Summary Information” and “B. Recommendations”. In each of the two sections, a consistent numbering system is followed. See Table of Contents for the pattern followed.</p>

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	<p><i>Schedule V drugs (weakest) have the lowest potential for abuse and Schedule I drugs (strongest) are considered to have the highest potential for abuse. [84] (Section 1.1, paragraph 1)</i></p> <p>Commenter references another example in Section 1.2, where the first five paragraphs are marked by bullet points, rather than numbers. It is unclear how to cite to one of these paragraphs. Commenter states that keeping a consistent “outline” format would facilitate citation for utilization review and discussion purposes.</p>			
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 1.1 – page 20</p>	<p>Commenter notes the that the text in Section 1.1, page 20, of the proposed guideline states:</p> <p><i>A brief course of short-acting opioids is an option to provide analgesia for moderate to acute severe pain due to acute soft tissue injuries when pain is uncontrolled by other measures and/or accompanied by functional deficits. [7] The provider should ensure that the following conditions are met prior to prescribing opioids for moderate to severe soft tissue</i></p>	<p>Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment</p>	<p>Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>injuries:</i></p> <p>Commenter opines that by using the term “should” in the second sentence rather than the term “shall,” ambiguity and potential confusion is created. Commenter states that in order for the Guidelines to be useful, they must be clear and not ambiguous.</p> <p>It is indicated that “[t]he target audiences for the Guidelines are primary care and medical and surgical specialty physicians, including pain specialists, caring for injured workers in the State of California and <i>medical providers who perform utilization review and independent medical review.</i>” (emphasis added) Opioid Treatment Guidelines, Part 1 section A3.6</p> <p>Commenter states that in order for the Guidelines to be useful for the aforementioned audiences, the Guidelines must clearly define what is required in order to be in compliance.</p>		<p>mandate that precludes physicians from considering specific clinical situations.</p> <p>Disagree: Emphasis is not required because the proposed guidelines target audience is equally weighted among those listed.</p> <p>Agree in part; Disagree in part: Agree: The MTUS should be referenced when requesting or reviewing medical treatment. Disagree: that inclusion of qualifying language in the guidelines creates confusion and undermines the ability of</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Specifically for utilization review and independent medical review to be performed, commenters opines that the medical provider performing the review must reference a clear set of criteria outlined in the Guidelines in order to certify requested treatment. Commenter states that ambiguity introduced by terms such as may, should, might, prefer, etc., undermine the ability of the medical providers performing utilization review and independent medical review.</p> <p>Commenter recommends the following revised language:</p> <p><i>A brief course of short-acting opioids is an option to provide analgesia for moderate to acute severe pain due to acute soft tissue injuries when pain is uncontrolled by other measures and/or accompanied by functional deficits. [7] The provider should shall ensure that the following conditions are met prior to prescribing opioids for moderate to severe soft tissue injuries:</i></p> <p>Commenter opines that throughout</p>		<p>physicians to provide medical treatment or review medical necessity of medical treatment. Licensed providers are expected to use professional judgement in the application of clinical guidelines depending upon the characteristics of the patient.</p> <p>Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS' recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>the proposed Guidelines there are numerous places where the use of the term “shall” rather than “should” would be appropriate. Rather than noting each specific incident, commenter recommends that the Division review the Guidelines and make the necessary adjustments. Specifically, any time the guidelines reference an item, or list of items, that the provider needs to comply with or document, the language should be changed to be stricter so as to avoid unnecessary confusion and delay in the utilization review and independent medical review processes.</p>			
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 1.1 – Paragraph 5 - page 21</p>	<p>Commenter notes that the text in Section 1.1, paragraph 5, page 21, of the proposed guideline states:</p> <p><i>Do not introduce sedative-hypnotics, including anti-histamines (H1-blockers) and benzodiazepines, if considering prescribing opioids. Attempt to discontinue these medications in patients receiving them if prescribing opioids. [33, 80] (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative</i></p>	<p>Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment</p>	<p>Disagree: The language is not conflicting, but rather addressing two separate situations. One where sedative-hypnotics have not been started and one where they have previously been prescribed.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>Hypnotics)</i></p> <ul style="list-style-type: none"> <i>• If sedative hypnotics such as anti-histamines or benzodiazepines are being prescribed by a different treating physician (for example, for a non-industrial condition), it is important to communicate the risk to the other provider to facilitate coordinated patient care.</i> <p>Commenter states that the language in this paragraph indicates that it is inappropriate to introduce sedative-hypnotics if the provider is considering prescribing opioids. The second sentence uses the softer term “attempt to discontinue” when referring to sedative-hypnotics. Commenter opines that when medical providers perform utilization review and independent medical review, conflicting terms and statements such as this make it very difficult for the medical provider to certify a requested treatment if the treatment involves sedative-hypnotics.</p> <p>Commenter recommends that the DWC clarify the language to indicate</p>		<p>Disagree: The use of the term “attempt to discontinue” clearly states that the weaning or discontinuation process should be started before considering opioids.</p> <p>Disagree: Page 22, bullet #5 clearly states “Do not</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	whether or not the introduction of opioids is appropriate when the injured worker is already receiving sedative-hypnotics, including anti-histamines (H1-blockers) and benzodiazepines.		introduce sedative-hypnotics, including anti-histamines (H ₁ blockers) if considering prescribing opioids. Attempt to discontinue these medications in patients receiving them if prescribing opioids.”	
Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 1.1 – Paragraph 1 - page 21	<p>Commenter notes that the text in Section 1.1, paragraph 1, page 21, of the proposed guideline states:</p> <p><i>Prescribe only one opioid at a time. The lowest dose capable of providing analgesia should be used. [85-87]</i></p> <p><i>a. Doses for opioid-naïve patients should not exceed 80 mg/day morphine equivalent dosage (MED).</i></p> <p>Commenter states that the inclusion of the term “opioid naïve” in the language indicates that morphine equivalent doses in excess of 80 mg/day would be appropriate for injured workers who are opioid “experienced”. Commenter opines that if it is the intention of the Guideline to show 80 mg/day as the threshold, that qualifying language needs to be removed.</p>	<p>Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment</p> <p>September 1, 2015 Oral Comment</p>	Disagree: This section addresses initiation of opioids in patients with mild acute injury, who will generally be opioid naïve. The recommendation for caution for patients taking over 80 MED is addressed in subsequent sections of the guideline.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter notes that the referenced guidelines and underlying studies indicate that dosages above 50 mg/day of morphine equivalents are when the risk of serious adverse effects increases. Reference to a threshold of 80 mg/day is inconsistent with the guidelines and studies incorporated by these rules.</p> <p>Commenter recommends the following revised language:</p> <p><i>Prescribe only one opioid at a time. The lowest dose capable of providing analgesia should be used. [85-87]</i></p> <p><i>a. Doses for opioid naïve patients should not exceed 80 50 mg/day morphine equivalent dosage (MED).</i></p>		<p>Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution.</p> <p>The MED is only one of a series of controls to ensure the</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.	
Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 1.3 – Paragraph 1 - page 24	<p>Commenter notes that the text in Section 1.3, first paragraph, page 24, of the proposed guidelines states:</p> <p><i>Opioids are recommended for the treatment of acute, severe pain uncontrolled by other modalities and/or with functional deficits. A brief course may also be indicated for pain following severe injuries. [7, 20] Providers should ensure that the following conditions are met when prescribing opioids for severe acute</i></p>	Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment	Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>injuries:</i></p> <p>Commenter states that there is ambiguity in the text due to the use of the word “should.” Commenter recommends that the requirement to document the items listed be included in the language as this is often the only way that medical providers performing utilization review and independent medical review are able verify that the required listed items have taken place. Commenter opines that by using the term “document,” or “document in the medical records” under the individual items listed, a presumption is created that any item that does not have that term does not need to be documented.</p> <p>Commenter recommends the following modified language:</p> <p><i>Opioids are recommended for the treatment of acute, severe pain uncontrolled by other modalities and/or with functional deficits. A brief course may also be indicated for pain following severe injuries. [7, 20] Providers shouldshall ensure that</i></p>		<p>mandate that precludes physicians from considering specific clinical situations.</p> <p>Disagree: See above.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>the following conditions are met <u>and documented in the medical record</u> when prescribing opioids for severe acute injuries:</i></p>			
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 2 – Paragraph 2 - page 30</p>	<p>Commenter notes that the text in Section 2, second paragraph, page 30, of the proposed guidelines states:</p> <p><i>If opioids are being considered beyond the acute phase, these clinical practices should be followed:</i></p> <p>Commenter notes that there is ambiguity in the text due to the use of the word “should.”</p> <p>Commenter recommends including the requirement to document the items listed be included in the language as this is often the only way that medical providers performing utilization review and independent medical review are able verify that the required listed items have taken place. Commenter opines that by using the term “document,” or” document in the medical records” under the individual items listed, a presumption is created that any item that does not have that term does not</p>	<p>Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment</p>	<p>Disagree. The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>need to be documented.</p> <p>Commenter recommends the following revised language:</p> <p><i>If opioids are being considered beyond the acute phase, these clinical practices should shall be followed and documented in the medical record:</i></p>			
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 5 – Paragraph 1 - page 56</p> <p>Effecting Section 1.1; Section 1.2; Section 1.3; Section 1.4; Section 2; Section 3; Section 3.3.3</p>	<p>Commenter notes that the text in Section 5, first paragraph, page 56, of the proposed guidelines states:</p> <p><i>The total opioid dose should be documented as morphine equivalent dose (MED) in mg/day at every patient visit. [6] Online dosing calculators may be used for this purpose.</i></p> <p>Commenter opines that the requirement that morphine equivalent dose be documented at each office visit is an important requirement. This requirement is not mentioned in any other section and may be missed by providers because of its location.</p> <p>Commenter recommends that the</p>	<p>Ben Roberts Executive Vice President PRIUM August 30, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree: The DWC agrees that the total opioid dose should be documented as (MED) in mg/day at every patient visit. Disagree: Commenter’s suggestion to revise multiple sections to add this phrase will not be incorporated because we believe that this recommendation is already adequately reinforced in the document.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>following sections be revised to reflect this change:</p> <p>Section 1.1, page 21 <i>If the decision is made to prescribe opioids, clinical practice should include all of the following:</i></p> <p>...</p> <p><u>3. Document in the medical record the total opioid dose as morphine equivalent dose (MED) mg/day at every patient visit.</u></p> <p>3. <u>4. Prescribe opioids at night or when the patient is not at work.</u></p> <p>Section 1.2, page 23 <i>If the provider decides to prescribe opioids, clinical practice should include the following:</i></p> <p>...</p> <p><u>6. Document in the medical record the total opioid dose as morphine equivalent dose (MED) mg/day at every patient visit.</u></p>		<p>Disagree: This topic is adequately addressed in its own section</p> <p>5. Documentation of Morphine Equivalents page 56, and is reinforced in the Summary Recommendations charts as well.</p> <p>Disagree: See above.</p> <p>Disagree: See above.</p>	<p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>The following clinical best practices should be followed:</i></p> <p><i>1. Consult CURES prior to the opioid trial. CURES may also be consulted during the trial period, based on provider’s assessment of need. (See Section 3.3.4, Use of CURES to Ensure Safe and Effective Opioid Use)</i></p> <p><i>2. Document in the medical record the total opioid dose as morphine equivalent dose (MED) mg/day at every patient visit.</i></p> <p><i>23. Conduct urine drug screening prior to the trial. Urine drug screening may be repeated during the trial period, based on the provider’s assessment of need. (See Section 3.3.6, Use of Urine Drug Testing, and Appendix C, Guidance on Conducting and Interpreting Urine Drug Testing)</i></p>			
Opioid Medical Treatment Guidelines – Part 1: Executive Summary,	<p>Commenter notes that the text in Section 3.3.3 of the proposed guidelines states:</p> <p><i>Initiation of opioids for the treatment</i></p>	Ben Roberts Executive Vice President PRIUM August 30, 2015	Agree in part; Disagree in part: Agree: Two separate lists are not needed and will be combined into one list. Disagree: that ‘shall’ be used	Section 3.3.3 Initiation of Chronic Opioid Treatment is amended by deleting bullet points and

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Introduction, and Recommendations – Section 3.3.3</p>	<p><i>of chronic pain should be considered a trial to assess efficacy (degree and duration of pain reduction, improvements in function, quality of life) and side effects. [7, 54, 57, 59] The trial of opioid treatment for a period up to several weeks, and not more than three (3) months, should not be considered a commitment to long-term therapy.</i></p> <p><i>The following clinical practices are recommended for initiating chronic opioid therapy [97]:</i></p> <ul style="list-style-type: none"> <i>• Describe initiation of opioids as a therapeutic trial for a limited period of time (typically no more than 60 days).</i> <i>• Explain that progress will be carefully monitored for both benefit and harm, considering both the efficacy (pain reduction, improvement in function and quality of life) and adverse effects of opioid treatment.</i> <i>• Prescribe the lowest possible dose initially and titrate to effect.</i> <i>• Begin chronic opioid therapy with a short-acting opioid. Consider longer-acting only if the shorter-acting medications are not effective.</i> 	<p>Written Comment</p>	<p>instead of “should”. The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.</p>	<p>replacing them with number “1., 2., 3., and 4.” because they denote clinical practices that should be followed for the initiation of chronic opioid therapy. The sentence “The following clinical practices should be followed:” is deleted because the previously bulleted points are combined with the numbered items that follow this sentence. The clinical practices previously numbered “1. – 4.” are renumbered from (5. – 9.” to combine these items with items 1 through 4 which were previously bulleted points. The two lists are combined into one list with a total of 9 items.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>reduction, improvements in function, quality of life) and side effects. [7, 54, 57, 59] The trial of opioid treatment for a period up to several weeks, and not more than three (3) months, should shall not be considered a commitment to long-term therapy.</i></p> <p><i>The following clinical practices are recommended shall be followed and documented in the medical record when for initiating chronic opioid therapy [97]:</i></p> <ul style="list-style-type: none"> <i>• 1. Describe initiation of opioids as a therapeutic trial for a limited period of time (typically no more than 60 days).</i> <i>• 2. Explain that progress will be carefully monitored for both benefit and harm, considering both the efficacy (pain reduction, improvement in function and quality of life) and adverse effects of opioid treatment.</i> <i>• 3. Prescribe the lowest possible dose initially and titrate to effect.</i> <i>• 4. Begin chronic opioid therapy with a short-acting opioid. Consider longer-acting only if the shorter-acting medications are not effective.</i> 		<p>related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.</p> <p>Disagree: Commenter’s recommendation to delete the phrase “are recommended” and replace it with “shall be followed and documented in the medical record when” will not be adopted because of the same reason stated above.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>The following clinical best practices should be followed:</i></p> <p>4. <u>5.</u> Consult CURES prior to the opioid trial. CURES may also . . .</p>			
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	<p>Commenter states that spinal cord stimulation (SCS) has been shown to be a very effective treatment for back and leg pain due to failed spinal surgery. Commenter notes that at the present time, there is level one evidence that the current spinal cord stimulator systems successfully treat at least 50% of these patients. Newly (2015) developed spinal cord stimulator systems have level one evidence to show that these systems will successfully treat upwards of 85% of failed low back syndrome patients. Often patients treated with spinal cord stimulation are able to decrease their dependence on opioid pain medications and many are able to return to work. Commenter opines that this will result in significant long term cost savings to the California workers compensation system as there will be fewer visits to</p>	<p>James A. Willis MD Medical Director Summit Pain Management Institute August 31, 2015 Written Comment</p>	<p>Disagree: Spinal Cord Stimulation (SCS) has not been dropped as a covered service. Although the proposed Chronic Pain Medical Treatment Guidelines' recommendation on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for Failed Back Surgery Syndrome (FBSS) patients, instead it references the MTUS Low Back Complaints guideline which incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004) and states, "Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the</p>	<p>None.</p>

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	<p>physicians and lower pharmaceutical expenses. Commenter states that these savings will be lost if spinal cord stimulation for failed low back syndrome is no longer covered. Commenter opines that eliminating spinal cord stimulation as a covered service in the light of recent significant advances in SCS technology would not be in the long term best interest of either injured workers or the worker's compensation system.</p>		<p>standard nonoperative or operative interventions." FBSS as an indication for SCS is covered but in the current MTUS Low Back Chapter.</p>	
<p>Chronic Pain Medical Treatment Guidelines - H-Wave</p>	<p>Commenter notes that the Department of Industrial Relations ("DIR") proposes to adopt the April 2015 version of the Official Disability Guidelines ("ODG") for chronic pain, written by Work Loss Data Institute ("WLDI"). Commenter objects to the adoption of that version's H-wave entry, and for the following reasons recommends that the H-wave entry currently found in the MTUS remain unchanged until such time as WLDI addresses some major scientific and legal problems infecting its proposed H-Wave guidelines.</p>	<p>Nicholas P. Roxborough, Esq. For Electronic Waveform Lab, Inc. (H-Wave ®) August 25, 2015 Written Comment</p>	<p>Disagree: Commenter requests that the H-wave entry in the proposed Chronic Pain Medical Treatment Guidelines remain unchanged from the H-wave entry currently found in the MTUS which incorporated by reference an adapted version of ODG's Treatment in Workers' Comp – Chapter on Pain (Chronic) from October 31, 2007. However, a comparison of each H-wave stimulation (EWT) entry shows that they both begin with "Not recommended as an isolated intervention..." for</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter opines that the April, 2015 ODG entry for H-Wave is replete with inaccurate statements and unreasonable requirements, most of which are the subject matter of a pending federal law suit in California's Central District Court [commenter provided a copy and it is available upon request].</p> <p>Commenter states the following:</p> <p>(1) The proposed Guideline is based upon three McDowell studies that are 15 to 20 years old, and were conducted on something other than an H-Wave® device, outside of the United States. That this device is unrelated to the real H-Wave® and is not even approved or available in the United States is without dispute;</p>		<p>chronic pain. In fact, a line-by-line comparison shows that the proposed recommendations in the 2015 version of ODG is entirely consistent with the recommendations in the 2009 version that is currently incorporated by reference into the MTUS. If anything the proposed 2015 version of ODG is more favorable to H-Wave® because it clarifies EWL’s ownership of the H-Wave® trademark.</p> <p>Disagree: The proposed 2015 version of ODG’s H-wave stimulation (EWT) entry is based upon every study in the 2009 entry, including the studies that Commenter prefers, (Blum, Smith, and Kumar) plus another 4 additional studies. The H-Wave® device has received only FDA 510(k) approvals, meaning this device was approved for marketing by the FDA because it is “substantially equivalent” to</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>(2) The three McDowell studies carry a lower quality rating than the studies approving HWave ® treatment;</p> <p>(3) These McDowell studies concern "ischemic" pain, which is uncommon in the field of occupation medicine;</p> <p>(4) The proposed H-Wave entry is one sided and biased in that it omits the majority of the studies that are highly rated and relevant to chronic pain and recovery;</p>		<p>other devices already on the market. This type of FDA approval does not require high quality studies showing the device is safe and effective.</p> <p>Disagree: The McDowell Studies are important and cannot be ignored. However, the studies supporting H-Wave used patient criteria of unresponsiveness to conventional therapy including physical therapy, medications and TENS and also cannot be ignored. In either case, there is insufficient evidence to recommend the use of H-wave stimulation (HWT) for the treatment of chronic pain because there are no high quality studies on this topic.</p> <p>Disagree: The proposed 2015 version of ODG's H-wave stimulation (EWT) entry is based upon every study in the 2009 entry, including the studies that Commenter prefers, (e.g. Blum, Smith, and</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>(5) And, finally, the proposed H-Wave entry would make it impractical for doctors to comply with the requirements given the heavy amount of paperwork that already overwhelms most medical professionals in the industry. Collectively, if not individually, these are some of the reasons why the ODG's April 2015 H-Wave entry should not be adopted at this time, if at all.</p> <p>Commenter states that the McDowell Study was not based on his client's product but a knock-off version in England.</p> <p><u>Commenter asks, "please advise us of what new medical evidence" to suggest these modifications.</u></p> <p>Commenter alleges a conspiracy</p>		<p>Kumar) plus another 4 additional studies.</p> <p>Disagree: Except for some formatting changes to make it easier to use, a line-by-line comparison shows that the proposed recommendations in the 2015 version of ODG is entirely consistent with the recommendations in the 2009 version that is currently incorporated by reference into the MTUS. There are no additional documentation requirements as commenter suggests.</p> <p>Agree: The McDowell Studies were not based on commenter's clients' product H Wave® but that was clearly indicated in the proposed guideline.</p> <p><u>Disagree: The four additional contributions to the Medical Literature on HWT as well as a critical re-evaluation of the previous studies include:</u></p>	<p>None.</p> <p>None.</p> <p><u>None.</u></p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>between members of DIR, State Compensation Insurance Fund, the MEEAC committee and ODG to restrict H-Wave Treatment to injured workers.</p> <p><u>The ODG entry violates EWL's Trademark.</u></p>		<p><u>Blume, 2009; Thiese, 2013; Smith, 2009; and Smith 2011)</u></p> <p>Disagree: The DWC denies commenter's allegations of a conspiracy to restrict H-Wave Treatment to injured workers.</p> <p><u>The proposed recommendation regarding H-Wave (the term is commonly used as a reference to Hertz wave, used in this form of electrotherapy) is essentially the same that appears in the 2009 ODG H-Wave entry adopted into the current MTUS; a trademark objection was not made at the time the 2009 guideline was adopted. Regardless, the proposed recommendation for H-Wave stimulation concerns a treatment modality, not a device, and therefore does not address a specific product or its individual, associated use. The Executive Medical Director has found that there are several products providing this form of electrotherapy</u></p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<u>treatment and, in fact, distinguishes them in the proposed recommendation. This would serve to, rather than confuse or mislead the public, clarify the trademark of the comment's client.</u>	
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	<p>The company that Commenter represents manufactures spinal cord stimulators (SCS) and the implantable drug pump (or intrathecal drug delivery, IDD) for the treatment of chronic, intractable pain. Commenter states that for this patient population with inadequate pain relief or intolerable side effects from medication, SCS and IDD are important options.</p> <p>Commenter notes that when the DWC posted draft MTUS chronic pain guidelines in a December 2014 forum, California physicians, manufacturers and other stakeholders submitted comments on SCS and IDD. Commenter's organization recommends that the DWC 1) include Failed Back Surgery Syndrome (FBSS) as an SCS indication and 2) clearly state that IDD therapy is</p>	<p>Mary E. Ryan Senior Program Manager State Government Affairs</p> <p>Mark Telles Senior Manager Health Economics</p> <p>Kirsten Hedstrom</p> <p>Medtronic Neuromodulation September 1, 2015 Written and Oral Comment</p>	<p>Agree: As long as the scientific medical evidence supports the use of SCS and IDD, they will remain options for patients.</p> <p>Agree: We agree with commenter's summary of the timing of the DWC's postings and the versions that were posted by the DWC.</p>	<p>None.</p> <p>None.</p>

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	<p>recommended for certain chronic pain patients under specific conditions. Commenter appreciates that, in the proposed rulemaking posted on July 17, the DWC took IDD and SCS procedure and evidence summaries, verbatim, from the April 6, 2015 version of the Official Disability Guidelines (ODG).</p> <p>Commenter notes that the proposed MTUS SCS chronic pain guidelines contain a literature review of SCS for Complex Regional Pain Syndrome (CRPS) and clear criteria for use of the SCS therapy. But for Failed Back Surgery Syndrome, the proposed guidelines state: “For use in failed back surgery syndrome (FBSS), see MTUS Low Back Complaints”. The MTUS low back complaints section on SCS references the American College of Occupational and Environmental Medicine (ACOEM) low back complaint guideline, 2004:</p> <p>C. Implantable Spinal Cord Stimulators Implantable spinal cord stimulators are rarely used and should be</p>		<p>Agree: The DWC agrees with commenter’s summary that the proposed Chronic Pain Medical Treatment Guidelines’ recommendation on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for Failed Back Surgery Syndrome (FBSS) patients, instead it references the MTUS Low Back Complaints guideline which incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004).</p>	<p>None.</p>

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	<p>reserved for patients with low back pain for more than six months duration who have not responded to the standard non-operative or operative interventions.</p> <p>Commenter states that this is an outdated and inappropriate reference. Unlike the April 6, 2015 ODG low back chapter, the ACOEM reference does not contain a literature summary of SCS for FBSS. Commenter opines that this omission will likely result in denials and treatment delays for patients with FBSS whose physicians have recommended SCS. Commenter recommends that the DWC use this opportunity to be clear about its intent to provide coverage to injured workers who have been diagnosed with FBSS. Commenter states that an efficient way to accomplish this is to include the appropriate ODG clinical literature and coverage criteria for FBSS in the MTUS Chronic Pain Chapter.</p> <p>Commenter recommends that following revised language:</p>		<p>Disagree: Commenter recommends that language in ODG’s Low Back chapter containing a literature review of FBSS for SCS be included in the proposed MTUS Chronic Pain Chapter section on SCS and proposes language to include this literature review. The DWC will not adopt commenter’s suggested language. Adopting commenter’s suggested language would be an attempt to amend the current MTUS recommendations in the Low Back Chapter via this rulemaking. The DWC is unable to amend the MTUS’ Low Back Chapter without going through the formal rulemaking process to amend that regulatory section. However, the DWC is in the process of evaluating and</p>	<p>None.</p>

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	<p><i>For use in failed back surgery syndrome (FBSS); see the MTUS Low Back Complaints, <u>see below</u>.</i></p> <p>Commenter recommends the following additional language:</p> <p><u>For Failed Back Surgery Syndrome: Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See also the Pain Chapter for Indications for stimulator implantation. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions. Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in recent years has it met with widespread acceptance and recognition by the medical community. In the first decade after its introduction, SCS was extensively practiced and applied to a wide spectrum of pain diagnoses, probably indiscriminately. The results at</u></p>		<p>updating the treatment guidelines for the Low Back.</p> <p>Disagree: Commenter’s recommended language will not be incorporated. Including the ODG clinical review for FBSS in the proposed MTUS Chronic Pain guidelines cannot be done because of the reasons stated above. In addition, not including this literature review will not result in denials and treatment delays for patients with FBSS as commenter suggests. A regulatory process is already in place so that medical evidence can be cited if an injury or condition is not addressed by the MTUS or if the MTUS’ presumption of correctness is being challenged. Physician’s may submit additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated using the MTUS Methodology for</p>	<p>None.</p>

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	<p><u>follow-up were poor and the method soon fell in disrepute. In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy. There are several reasons for this development, the principal one being that the indications have been more clearly identified. The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient, SCS may lead to cost-saving and</u></p>		<p>Evaluating Medical Evidence set forth in section 9792.25.1, where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine.</p>	

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	<p><u>more health gain relative to CMM for FBSS.</u></p> <p><u>Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery according to the joint American College of Physicians/ American Pain Society guideline recommendations on surgery and interventional treatments. (Chou, 2008) The National Institute for Health and Clinical Excellence (NICE) of the UK completed their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluding that SCS is recommended as a treatment option for adults with failed back surgery syndrome lasting at least 6 months despite appropriate conventional medical management. (NICE, 2008)</u></p> <p><u>These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient,</u></p>			

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	<p><u>SCS may lead to cost-saving and more health gain relative to CMM for FBSS and CRPS. (Taylor, 2005) (Taylor, 2006). SCS for treatment of chronic nonmalignant pain, including FBSS, has demonstrated a 74% long-term success rate (Kumar, 2006). SCS for treatment of failed back surgery syndrome (FBSS) reported better effectiveness compared to reoperation. (North, 2005) A cost utility analysis of SCS versus reoperation for FBSS based on this RCT concluded that SCS was less expensive and more effective than reoperation, and should be the initial therapy of choice. Should SCS fail, reoperation is unlikely to succeed. (North, 2007)</u></p> <p><u>Neuromodulation may be successfully applied in the treatment of visceral pain, a common form of pain when internal organs are damaged or injured, if more traditional analgesic treatments have been unsuccessful. (Kapural, 2006) (Prager, 2007) A recent RCT of 100</u></p>			

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	<p><u>failed back surgery syndrome (FBSS) patients randomized to receive spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group), found that 48% of SCS patients versus 9% of CMM patients achieved the primary outcome of 50% or more pain relief at 6 months. This study, funded by Medtronic, suggested that FBSS patients randomized to spinal cord stimulation had 9 times the odds of achieving the primary end point. (Kumar, 2007) According to the European Federation of Neurological Societies (EFNS), spinal cord stimulation (SCS) is efficacious in failed back surgery syndrome (FBSS). (Cruccu, 2007) See also Psychological evaluations (SCS) in the Stress & Other Mental Conditions Chapter. Recent research: New 24-month data is available from a study randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical</u></p>			

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	<p><u>management (CMM) or CMM alone. At 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. All 100 patients in the study had undergone at least one previous anatomically successful spine surgery for a herniated disk but continued to experience moderate to severe pain in one or both legs, and to a lesser degree in the back, at least six months later. Conventional medical therapies included oral medications, nerve blocks, steroid injections, physical and psychological therapy and/or chiropractic care. (Kumar, 2008) (Frey, 2009) There is fair evidence that spinal cord stimulation is moderately effective for failed back surgery syndrome with persistent radiculopathy, though device-related complications are common. (Chou3, 2009) A nonrandomized, prospective cohort study in workers comp patients with</u></p>			

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	<p><u>chronic back and leg pain after spine surgery, i.e. failed back surgery syndrome (FBSS), found no significant difference in pain, disability, or opioid use between patients that received (at least a trial of) SCS, care at a pain clinic, or neither (usual care) at 12 and 24 months. Only 25% of SCS patients in this study received psychological screening prior to the trial, whereas ODG recommends psychological screening prior to all SCS implantations. Because few patients in any group in this study achieved success at any follow-up, the authors suggested that no treatment has a substantial impact on average in this patient group. (Turner, 2010) In this sample of workers' compensation recipients, the high procedure cost of SCS was not counterbalanced by lower costs of subsequent care, and SCS was not cost-effective. The benefits and potential cost savings reported in RCTs may not be replicated in workers' comp patients. (Hollingworth, 2011)</u></p>			

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	<p>(LOS).</p> <p>Commenter provided references to more recent clinical studies, not included in the ODG that supports SCS for chronic back and leg pain (CBLP) in individuals who have undergone previous back surgery, or failed back surgery syndrome (FBSS).</p>		reasons already stated above.	
Chronic Pain Medical Treatment Guidelines - Implantable drug-delivery systems/ Intrathecal drug delivery systems	<p>Commenter states that intrathecal drug delivery is a clinically and economically effective treatment option for patients with chronic intractable pain that is refractory to conventional medical management. During the pre-rulemaking comment period, commenter’s organization urged the DWC to reference the entire ODG commentary for IDD. In the December pre-rulemaking draft, this sentence is present in ODG yet was absent in the draft of the MTUS guideline: “Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated in the blue criteria below, after failure of at least 6 months of less invasive methods,</p>	<p>Mary E. Ryan Senior Program Manager State Government Affairs</p> <p>Mark Telles Senior Manager Health Economics</p> <p>Kirsten Hedstrom Medtronic Neuromodulation September 1, 2015 Written and Oral Comment</p>	<p>Agree: That the inclusion of this sentence “Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated in the blue criteria below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial” was needed in this proposed MTUS guideline and was already included in the 45-Day Comment version.</p>	None.

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	<p>and following a successful temporary trial”. Commenter opines that the inclusion of this sentence is vitally important and supports the use of IDD for select patients. Commenter supports that the division included this sentence in currently proposed MTUS guideline.</p> <p>Commenter references the Washington State Health Care Authority (HCA) report (2008) cited by ODG and, by extension, the MTUS. Commenter disagrees with ODG’s characterization of the IDD technology assessment conducted by that HCA, and recommends that this sentence be removed in MTUS IDD procedure summary. Commenter states that the underlying technology assessment submitted to HCA by an independent center, the ECRI Institute Health Technology Assessment Information Service, concluded:</p> <ul style="list-style-type: none"> • “Implantable infusion pumps are reserved for individuals for whom conservative treatments and in some cases, surgery, have failed and 		<p>Disagree: Despite the fact the Washington study “is negative about the merits of intrathecal therapy” it will remain because it is an important study to be considered. This reference was included by the original source ODG guideline and was vetted and evaluated by their research team. The DWC does not and cannot unilaterally amend the recommendations found in the Procedure Summaries and references because we are incorporating by reference ODG’s April 6, 2015 guideline. Any amendments or edits to the Procedure Summaries and references must be reviewed and approved by the Work Loss</p>	<p>None.</p>

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	<p>surgical correction of cause(s) of pain is not an option.”</p> <ul style="list-style-type: none"> • “Drug infusion with an implantable pump leads to clinically significant pain relief in patients with chronic non-cancer pain.” • “Intrathecal administration of opioids by implantable pump was associated with an overall decrease in the quantity of other drugs taken or a decrease in the proportion of patients taking other drugs.” <p>Commenter notes that the MTUS draft procedure summary for IDD contains this sentence: See also MTUS Low Back Complaints. Commenter states that there is no mention of IDD in this MTUS section and recommends that this sentence be removed.</p>		<p>Data Institute (ODG) because it is their copyrighted materials.</p> <p>Disagree: Commenter’s recommendation to remove the MTUS Low Back Complaints reference will not be removed because it contains other important recommendations pertaining to the Low Back. The IDDS recommendation is already contained in the proposed Chronic Pain Guideline.</p>	None.
Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations	<p>Commenter references the third bullet from the bottom. It currently states:</p> <p><i>Opioid-naïve patients (those who have not previously been treated with opioids) with acute pain treatment receiving medically necessary</i></p>	Kimberly Kirchmeyer Executive Director Medical Board of California August 31, 2015 Written Comment	Agree: The word “treatment” is a typographical error and will be deleted.	Executive Summary, second page, third from the last bullet point is amended to delete the word “treatment” because it is a typographical

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<p>– Page 2</p>	<p><i>treatment with opioid medication should not receive doses above 80mg/day morphine equivalent dose (MED).</i></p> <p>Commenter opines that there appears to be an error. Commenter recommends revising this statement to read:</p> <p>Opioid-naive patients (those who have not previously been treated with opioids) with acute pain treatment receiving medically necessary treatment with opioid medication should not receive doses above 80mg/day morphine equivalent dose (MED).</p>			<p>error, now states “Opioid-naive patients (those who have not previously been treated with opioids) with acute pain treatment receiving medically necessary treatment with opioid medication should not receive doses above 80mg/day morphine equivalent dose (MED).”</p>
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 3.3.1.1 - page 37</p>	<p>Commenter notes that Item Number 3 states:</p> <p><i>Initiate chronic opioid treatment only if the screening tools identify a predicted increase risk for substance misuse/abuse and other alternatives are not viable; in this case, provide documentation in the medical records that attempts are being made to address the identified risks.</i></p>	<p>Kimberly Kirchmeyer Executive Director Medical Board of California August 31, 2015 Written Comment</p>	<p>Agree: Changes will be made to correct these grammatical errors.</p>	<p>Section 3.3.1.1 Screening for Drug Misuse/Abuse item #3 is amended to delete the words “only” and the word “and” and adding the phrase “only if” to correct grammatical errors.</p>

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	<p>Commenter notes that there appears to be an error. Commenter recommends revising this statement to read:</p> <p>Initiate chronic opioid treatment only if the screening tools identify a predicted increase risk for substance misuse/abuse and <u>only if</u> other alternatives are not viable; in this case, provide documentation in the medical records that attempts are being made to address the identified risks.</p>			
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 3.3.8 – Opioid Titration and Dosing Threshold - page 51</p>	<p>On page 51 of the Executive Commenter references the following paragraph:</p> <p><i>Due to lack of sufficient evidence to guide outpatient care, the routine prescription of naloxone to patients on chronic opioid treatment is not recommended. Naloxone is recommended in hospital-based and emergency department settings for the treatment of opioid overdose. Refer to the MTUS Chronic Pain Guidelines for more information.</i></p> <p>Commenter opines that this statement</p>	<p>Kimberly Kirchmeyer Executive Director Medical Board of California August 31, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree: First sentence will be deleted. Outpatient use may be warranted. Disagree: Commenter’s suggested language, “<u>Naloxone is also recommended on a case-by-case basis for outpatient, pre-hospital use, to treat opioid overdoses for patients who are prescribed opioids for acute and chronic pain</u>” will not be adopted because it is sufficiently covered in the MTUS proposed Chronic Pain</p>	<p>Section 3.3.8 – Opioid Titration and Dosing Threshold is amended to delete the first sentence: “Due to lack of sufficient evidence to guide outpatient care, the routine prescription of naloxone to patients on chronic opioid treatment is not recommended. Naloxone is recommended in</p>

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	<p>may discourage providers from prescribing naloxone for outpatient use, even when it is warranted.</p> <p>Commenter recommends the following revised language:</p> <p>Due to lack of sufficient evidence to guide outpatient care, the routine prescription of naloxone to patients on chronic opioid treatment is not recommended. Naloxone is recommended in hospital-based and emergency department settings for the treatment of opioid overdose. <u>Naloxone is also recommended on a case-by-case basis for outpatient, pre-hospital use, to treat opioid overdoses for patients who are prescribed opioids for acute and chronic pain.</u> Refer to the MTUS Chronic Pain Guidelines for more information.</p>		Medical Treatment Guidelines which this section references.	hospital-based and emergency department settings for the treatment of opioid overdose. Refer to the MTUS Chronic Pain Guidelines for more information.”
Opioid Medical Treatment Guidelines – Part 1: Executive Summary, Introduction, and Recommendations – Section 4.1 –	Commenter notes that there is no mention of pregnancy as a criteria for tapering. Commenter requests that the Division add pregnancy to this list.	Kimberly Kirchmeyer Executive Director Medical Board of California August 31, 2015 Written Comment	Agree: The DWC agrees with commenter that “pregnancy” should be monitored as a criteria for tapering and will be included.	Section 4.1 Indications for Tapering Opioids is amended to add “pregnancy”: “Pregnancy (refer to the Medical Board of

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Indications for Tapering Opioids - page 54				California Guidelines for Prescribing Controlled Substances for Pain for additional information).”
Chronic Pain Medical Treatment Guidelines - Pain Outcomes and Endpoints – Page 10	<p>Commenter refers to the second paragraph, as follows:</p> <p><i>Complicating the measurement of pain is that there is often a wide variability in how much pain a given stimulus or injury will cause. This variability is influenced by genetics, mood, beliefs, sex, ethnicity, and other factors such as early-life pain experiences with pain.</i></p> <p>Commenter notes that there appears to be an error.</p> <p>Commenter recommends the following revised language:</p> <p>Complicating the measurement of pain is that there is often a wide variability in how much pain a given stimulus or injury will cause. This variability is influenced by genetics, mood, beliefs, sex, ethnicity, and</p>	<p>Kimberly Kirchmeyer Executive Director Medical Board of California August 31, 2015 Written Comment</p>	<p>Agree: The inclusion of the word “pain” in the last sentence is a typographical error that will be deleted.</p>	<p>Part 1: Introduction, under the heading Pain Outcomes and Endpoints, last sentence second paragraph, is amended to delete the word “pain” to correct a typographical error, so that it reads “This variability is influenced by genetics, mood, beliefs, sex, ethnicity, and other factors such as early-life experiences with pain.”</p>

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	other factors such as early-life pain experiences with pain.			
Opioid Medical Treatment Guidelines – Utilization Review	<p>Commenter notes there is a common theme regarding an adversarial relationship with Utilization Review, based upon the interpretation of different guidelines. Commenter has a Functional Restoration Program and spends a fair amount of time dealing with the same exact wording, and the wording is really that negative predictors of success need to be addressed in the guidelines. Commenter states that it's the actual ODG Guidelines, and the negative predictors can be anything from depression, how depressed, it's not real clear, smoking cigarettes, being on too much pain medication, and some of these are reasons to put people into functional restoration. Commenter opines that the problem is that the Utilization Review physician is looking at that and saying, "No. This person has a negative predictor. They can't go into an FRP." Commenter states that the Division must address those negative predictors. Commenter states that we need to look at them and explain, for</p>	Jacob Rosenberg, MD September 1, 2015 Oral Comment	Disagree: That the proposed Procedure topic on functional restoration programs and chronic pain programs should provide more specific guidance and recommendations on negative predictors. The proposed guideline cites the available evidence for opioid use, comorbid psychiatric illness, and disability, and other factors. The section on "Predictors of success and failure" cites the lack of appropriate screening tools and further cites available evidence but without any recommendations. The reader is directed to the detailed section "Criteria for the general use of multidisciplinary pain management programs" that includes the recommendation "(8) Negative predictors of success (as outlined above) should be identified, and if present, the pre-program goals	None.

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	<p>example how to address their depression or their cigarette smoking or whatever it is. Commenter opines that perhaps there's some extra scrutiny that's given before the entire Functional Restoration Program is carried out, so that progress is measured to determine that the treatment's working. Commenter opines that this is applicable to the opiates.</p>		<p>should indicate how these will be addressed.” At this point in time, more specificity would not constitute an evidence-based recommendation due to the current state of the medical literature, the wide variety of patient clinical conditions and the wide variation in the types of functional restoration/chronic pain programs.</p> <p>This is a complex topic and medical evidence on a variety of factors is reviewed in in the proposed MTUS Chronic Pain Medical Treatment Guidelines.</p> <p>The lack of an evidence-based screening tool to predict program success is noted. One important negative predictor for success is opioid dependence disorder (ODD) is discussed extensively in the clinical topic “Chronic pain programs, opioids” in the proposed MTUS Chronic Pain Medical Treatment Guidelines.</p>	

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			However, a spectrum of options, including programs that include detox or even use of opioids are all discussed. The guideline is intended to assist physicians in better understanding the various factors that need to be considered when prescribing or evaluating the medical necessity of these types of programs.	
Opioid Medical Treatment Guidelines – General Comment	Commenter opines that while considering opiate guidelines, it is essential to remember why guidelines are currently necessary. Commenter states that until the mid-1990s very few patients with Chronic Non-Cancer Pain (CNCP) received Chronic Opioid Analgesic Therapy (COAT). Starting in the 1990s and continuing through 2004, physicians prescribed COAT with increasing frequency but with minimal monitoring or risk assessment. Commenter states that a fundamental reason for physicians being so willing to initiate COAT was that many clinicians and patients perceived a substantial improvement in quality of	Jacob Rosenberg, MD August 31, 2015 Written Comment September 1, 2015 Oral Comment	Agree in part; Disagree in part: Agree: that chronic opioid therapy was uncommon until the mid-1990s. Disagree: that prescription chronic opioid therapy for non-cancer pain is safe, did not have adverse outcomes, and universally resulted in an improved quality of life for patients. The facts of the opioid overdose epidemic are well outlined by the Centers for Disease Control (CDC). The data on adverse effects and are well-established. The DWC has not published data on the prevalence or effects of	None.

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	<p>life (QOL) in CNCP who were prescribed long acting opiates. Commenter notes that some patients seemed to require high doses, but responded with significant functional improvement. Severe adverse events were rare.</p> <p>Commenter states that while clinicians responded to their anecdotal experience by increasing utilization of COAT there was a simultaneous epidemic of drug overdoses primarily related to illicit use of prescription medication. Commenter states that most overdoses were not related to medications prescribed directly by a physician. In fact, commenter states that even in high risk patients, the incidence of overdose is less than 0.5% (studies cited by DWC). Commenter notes that there has not been comparison to similar high risk patients, who have uncontrolled chronic pain, and did not receive COAT.</p> <p>Commenter notes that many clinicians and patients have found</p>		<p>opioid prescriptions.</p> <p>Disagree: Overdoses from prescription medications, including opioids are being tracked by state public health departments as well as the Centers for Disease Control (CDC) separately from illicit use of prescription medication. The proposed guideline also includes evidence-based methods to reduce illicit use of prescription medications, such as urine drug testing and safe drug disposal.</p> <p>Agree: that COAT can be useful in improving quality of life and it is the intention of the</p>	<p>None.</p> <p>None.</p>

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	<p>COAT useful for improving QOL, and opines that the real issue is how to provide the highest quality care so that the risk/benefit ratio is as low as possible.</p> <p>Commenter states that the proposed guidelines from DWC are vague and non-specific. They quote and misquote from a variety of sources without specifying appropriate care. Commenter opines that this may be a result of concern because the DWC does not want to limit treatment options; however, he opines that the effect will be that UR physicians can find a reason to deny opiate trials in every patient and deny continuing opiates in every patient (regardless of benefit) currently receiving COAT.</p> <p>Commenter is concerned with what the speaker representing Prium stated, he quotes "...is it 80 milligrams is the maximum dose for everybody?" Commenter does not believe that's taken from the literature anywhere. Commenter provides an example of how the State of Washington has been</p>		<p>proposed guideline to provide a balance between appropriate treatment of pain and safety in the use of opioids for that purpose in the non-cancer pain population of injured workers.</p> <p>Disagree: The proposed guidelines are very detailed and specific, however they are meant to be guidelines. These recommendations provide users with guidance but are not a prescriptive mandate that precludes a physician from considering specific clinical situations. Licensed providers are expected to use professional judgement in the application of clinical guidelines depending upon the characteristics of the patient.</p> <p>Agree: The proposed MTUS recommendation of 80 MED is NOT the maximum does for everyone, but rather, it is the trigger for pain consultation and additional caution as commenter points out.</p>	<p>None.</p> <p>None.</p>

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	<p>misinterpreted as limiting COAT to a maximum dose of 120mg MED. He states that is the dose that warrants consultation with a pain management physician, not the maximum dose for everyone. He thinks this is an important distinction to make. Commenter also opines that quoting the ACOEM guideline of 100mg MED/day as a maximum dose is inappropriate because ACOEM offers no basis for this dose other than the consensus opinion of physicians who have never treated patients with COAT. Commenter expects there will be bias in such a consensus opinion. Commenter opines that because an absolute limit is stated without regard to functional benefit demonstrates ACOEM bias. Commenter notes that the claim to evaluate the literature yet despite inadequate literature support recommendations are made on the appropriate monitoring in COAT with a high degree of confidence despite the acknowledged lack of evidence to support the recommendation. Commenter opines that such claims may be reasonable</p>		<p>There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 -120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution.</p>	

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	<p>on a common sense basis, but that such a claim of confidence without evidence is hypocrisy from a group that claims to base recommendations only on high quality studies.</p> <p>Commenter is not stating that there should not be limits on initiating and maintaining COAT, rather he opines that the statements in the DWC guidelines will not promote better care, but rather provide for increasingly adversarial positions between UR physicians and PTPs (particularly pain management physicians). Commenter states that if the DWC’s purpose is to absolutely prevent greater than 100mg MED (despite a lack of evidence for or against such a limit) then he recommends that the guidelines state so unequivocally. Commenter opines that the current statements will only lead to utilization review companies instituting denials based on whatever fragments from the DWC guideline discussions that are most restrictive. Commenter would like to emphasize that the guidelines, as currently written, allow a utilization review</p>		<p>Disagree: DWC recommends 80 mg MED as the recommended upper limit that triggers consultation with a pain management specialist and to exhibit extra caution. It is NOT the DWC’s purpose to “absolutely prevent greater than 100mg MED”. Again, these recommendations provide users with guidance but are not a prescriptive mandate that precludes a physician from considering specific clinical situations. Licensed providers are expected to use professional judgement in the application of clinical guidelines depending upon the characteristics of the patient.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>physician to deny a trial of COAT because in their opinion (having never seen the patient) the treating doctor has not adequately considered any number of factors. A physician who has never interviewed the patient will be assessing risk/benefit.</p> <p>Commenter opines that a more useful set of guidelines, from both the UR perspective and PTP perspective, would be significantly more specific in delineating requirements for initiating and maintaining COAT. That way all parties can focus on the real goal of improvement in QOL (which includes increased function). Commenter acknowledges that all physicians need to recognize that COAT carries significant risk of adverse consequences, but also the risk of failure to improve QOL. The risk of failure to improve QOL is considerably higher than the risk of an adverse event. Commenter opines that there is also the general risk to society that has to be considered. Commenter states that more intensive evaluation along with detailed follow up will improve all outcomes</p>		<p>Disagree: The proposed guideline emphasizes that assessment of improvements in pain and in function, two important aspects of quality of life, are clearly described in all stages of opioid therapy, including COAT.</p> <p>Disagree: It is not the intention of the DWC that patients are left with a poor quality of life, there are many approaches to chronic pain that can be prescribed when the risk/benefit of COAT cannot be justified by improvements in pain, function, and other factors.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	(increasing successful outcomes and limiting adverse outcomes).			
Opioid Medical Treatment Guidelines – Proposed Opiate Guidelines	<p>Commenter submits the following guidelines for initiating and maintaining COAT.</p> <p>Commenter notes that the guidelines are very restrictive, but opines that they will actually result in more appropriate care. Commenter states that while some primary treatment physicians (PTPs) may be unhappy meeting specific initiation requirements he opines that they will be hard pressed to argue that any step is unnecessary. Commenter states that listing clear criteria that have to be met means that UR physicians are responsible only for making sure the PTP has performed a complete evaluation. Commenter states that the UR physician cannot adequately assess risk/benefit since they have not seen the patient. Clear and specific guidelines will reduce UR physicians’ ability to deny medications based on their interpretations, and at the same time, will encourage PTPs to perform a detailed and thorough assessment</p>	Jacob Rosenberg, MD August 31, 2015 Written Comment	Disagree: The DWC is statutorily mandated to adopt evidence-based clinical guidelines. The DWC with advisory recommendations from the Medical Evidence Evaluation Committee (MEEAC), reviews and evaluates numerous medical guidelines and scientific studies. Commentator’s suggested language includes recommendations found in the proposed regulation, but does not provide any citations, guidance on dosage, and requires exhaustive documentation. The proposed Opioids treatment guidelines already discusses areas of documentation with further explanation and supportive evidence and contains summary tables for ease of use. The proposed MTUS guideline purposefully does not include a preformed documentation “template” that	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>(which is quite time consuming).</p> <p>Commenter recommends that in order to initiate opiate therapy, all of the following steps must be performed:</p> <ol style="list-style-type: none"> 1) Identify pathology responsible for pain with an appropriate history, physical exam and review of essential medical records. 2) Document conservative care that has failed. 3) Document why more invasive treatment has not been trialed (injection/surgery/SCS/FRP). 4) Document how the pain has interfered with physical and social function. 5) Document that the patient has received an appropriate risk assessment with at least 2 standardized tools; one assessing psychological status (e.g. PHQ9 or CES depression inventory) and one addressing risk of aberrant behaviors (e.g. ORT or SOAPP). The physician should decide whether a psychiatric 		<p>applies to every patient as suggested by commenter. The MTUS guideline is intended to educate and promote evidence-based care while allowing physician flexibility in appropriate documentation for each patient.</p> <p>Disagree: See above.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>evaluation is necessary at this point.</p> <p>6) If a psychiatric/psychology evaluation is appropriate (based on test results), before initiating COAT, then it should be authorized regardless of whether psych is an included body part. The implication is that psychiatric factors may be delaying recovery and need to be identified. The request for psychiatric evaluation should not be denied and then COAT denied because there is no psychiatric exam.</p> <p>7) Document discussion and evaluation of any risk factors (i.e. prior sexual abuse history, depression, or prior drug or alcohol use). The decision of whether it is appropriate to proceed with a trial of COAT is between the physician and the patient. Only documentation that risk factors have been considered is appropriate. The UR physician is not able to make</p>			

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	<p>an appropriate decision on whether risk/benefit is reasonable since they have never seen the patient. Please remember the PTP is assuming substantial risk in initiating treatment. If they meet all of the required steps (1-12) they have performed an extensive evaluation. If they are on the MPN their judgment must be respected in the context of the complete evaluation performed.</p> <p>8) Provide an informed consent explaining the risks (side effects, respiratory arrest, hormonal suppression, sleep apnea) and benefits (30% reduction in pain and improvement in function).</p> <p>9) Discuss with the patient their responsibilities (providing a signed contract) detailing how to take medication (no crushing, chewing, no use of heat with transdermal medications, no alcohol use, no use of machinery until doses are stabilized, proper</p>			

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	<p>storage and proper disposal, a list of aberrant behaviors including self-escalating doses, taking medications from friends, not taking medication exactly as prescribed)</p> <p>10) Provide a set of functional goals and a current mini-functional assessment as a base line. Document that the patient was advised that if functional goals are not met then the medication will be discontinued.</p> <p>11) Obtain a baseline UDT.</p> <p>12) Obtain a baseline CURES report.</p> <p>Commenter opines that the above guidelines are clear, promote superior patient care, and allow for adequate assessment to see if COAT can reasonably be initiated. Further, if a PTP meets all of these requirements they will have adequately assessed the patient and be prepared to follow up with the care essential to promote good outcomes. Commenter states that this will give UR physicians</p>		<p>Disagree: Commenter is parroting what is already required in our guideline, but just making the documentation a mandatory template. Documentation alone does not establish medical necessity, there are criteria within the above listed categories not summarized in commenter's suggested language that are</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>clear objective data that they can use to determine if a trial of COAT is acceptable. Commenter opines that they will not be able to deny a trial because ORT is too high or surgery has not been performed, or function is not impaired enough. Commenter opines that those issues should be discussed by the PTP with the patient, but such clinical decisions that are primarily risk/benefit related cannot be appropriately made by a physician reviewing a chart, who has never seen the patient.</p>		<p>described in detail in the proposed MTUS guideline. Agree that not all details regarding interactions and discussion of risk benefit would be available in the documentation, but significant factors and considerations should be documented and available for review.</p>	
<p>Opioid Medical Treatment Guidelines – Proposed Opiate Guidelines</p>	<p>Commenter recommends the following trial and long-term use of COAT guidelines:</p> <ol style="list-style-type: none"> 1) Initial prescriptions should be for 2 weeks maximum with a scheduled follow up appointment to assess for adverse side effects. Initial dose must be based on conversion of current opiate MED or starting at 30 mg MED equivalent or less if opiate naïve. 2) A 2 week trial is too early to consider treatment failure, but any 	<p>Jacob Rosenberg, MD August 31, 2015 Written Comment</p>	<p>Disagree: Commenter’s proposed COAT guidelines will not be incorporated because it provides a good description of an individual treatment plan, it is NOT a guideline. It does include the concepts and principles already included in the proposed MTUS Opioids Treatment Guidelines, however, it lacks flexibility and details, such as use of assessment tools, agreements and monitoring , e.g. use of CURES, frequency</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>improvement or adverse response should be documented.</p> <p>3) Dose increase can be considered if there are no adverse effects and there is inadequate pain relief /improvement function.</p> <p>4) Reassess in additional 2 weeks with the same documentation again considering a dose increase if marginal improvement.</p> <p>5) If 100 mg MED is reached without any functional improvement then COAT can be considered a failure and medication tapered over 2 weeks. Alternatively, there can be consideration of a single 2 week trial of opiate rotation to see if there is improved function.</p> <p>6) If there is 20% documented functional improvement then a dose increase can be considered with re-evaluation at 2 week to 4 week intervals. If there is no further functional improvement then the dose should be titrated back to lowest possible level to maintain functional</p>		<p>of urine drug testing and many other details. Also, commenter's guideline proposes a 100 mg MED without effect before tapering is to be considered which is too high in most cases.</p>	

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	<p>gains.</p> <p>7) Functional gains can be documented as RTW, ability to return to modified work, decrease in Oswestry (or comparable functional index) score of 25% (noting decrease of 5 points is considered clinically meaningful) or 25% or greater ability for shuttle/continuous walking, enhanced HEP performed daily, 25% increase ability for continuous weight bearing. QOL validated instruments can be used in place of specific functional gains</p> <p>8) At conclusion of 12 weeks the optimal dose should have been reached. Stable function (30% improvement from baseline) should have been documented. Doses should remain stable.</p> <p>New complaints of increased pain not explained by increasing pathology should raise the suspicion of tolerance and a possible failure of COAT. Consideration of one trial of 25% dose increase can be considered, but if there is failure to document</p>			

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	<p>functional improvement then weaning to lowest level that stabilizes functional gains (if any) should be performed.</p> <p>9) At one year a trial wean should be performed to see if doses can be decreased and function maintained.</p> <p>10) There is no expectation of further additional functional gains with maintenance therapy, but stability of function and absence of side effects should be documented on every visit. Increased doses do require additional increases in function.</p> <p>11) UDT and random pill counts should be performed at intervals based on risk assessment. High risk patients 3 to4 UDTs and checks per year and moderate risk patients 2 to 3 times per year. Cures report documented a minimum of every 4 months.</p> <p>12) Abnormal results on UDT/CURES or aberrant behavior warrant discussion. Repeat aberrant behavior (greater than 3 incidents)</p>			

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	<p>mandates a wean. Any variation from expected results mandates discussion of why variation occurred and reassessment of risk/benefit ratio.</p> <p>13) Positive marijuana warrants detailed discussion of use pattern and re-evaluation of risk benefit, but does not necessarily mandate cessation of COAT. That decision is left to the provider as long as there is no other aberrant behavior (e.g. unexplained results on UDT/CURES, run out of medication early, missing appointments, or failure to comply with request for UDT or pill count).</p>			
General Comments	<p>Commenter stresses the importance of the principle that patient safety and quality of care should be the foremost concern as we consider the adoption of these proposed guidelines. Commenter opines that injured workers should have access to appropriate, safe and effective pain management.</p> <p>Commenter states that treatment options and flexibility is needed in the treatment of injured workers.</p>	<p>Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment September 1, 2015 Oral Comment</p>	<p>Agree: The DWC agrees that injured workers should have access to appropriate, safe and effective pain management.</p> <p>Agree: The DWC agrees that treatment options and flexibility is needed in the treatment of injured workers.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter’s organization has actively promoted the science and art of medicine, the care and well-being of patients, the protection of the public health and the betterment of the medical profession. Within the workers’ compensation system, physicians are the stakeholders primarily responsible for managing the care of the injured worker. It falls on the physician to provide medical treatment that may “cure or relieve” the injured worker from their work-related injury. Commenter opines that limiting a physician’s access to treatment options that have been clinically proven successful and FDA-approved will only hinder the timely and cost-effective recovery of the injured worker.</p> <p>Commenter opines that these proposed guidelines are much more prescriptive than existing Medical Board guidelines.</p> <p>Commenter is concerned that the proposed guidelines do not fully appreciate the extraordinary complexity in treating injured</p>		<p>Agree in part; Disagree in part: Agree: CMA has actively promoted the science and art of medicine, the care and well-being of patients, the protection of the public health and the betterment of the medical profession. Disagree: Labor Code section 4600(b) requires “medical treatment that <u>is reasonably required</u> to cure or relieve” failing to include the phrase “is reasonably required” and use of the word “may” before the phrase “cure or relieve” incorrectly implies fewer limitations to treatment than the specific labor code language.</p> <p>Disagree: The proposed Opioids Treatment Guidelines is based on a variety of established guidelines, including the Medical Board of California (MBC) opioid guideline “Guidelines for Prescribing Controlled</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>workers with chronic pain. Commenter’s organization has long advocated that long-term opioid therapies should only be conducted in practice settings where careful evaluation, regular follow-up, and close supervision are ensured. Commenter’s organization is also aware, and its physician members recognize, that opioids are one of many options to mitigate pain, and that in some instances, alternative modalities may be appropriate in order to cure or relieve an injured worker’s chronic pain. Commenter opines that it is not the jurisdiction of the DWC to mandate a standard of care when dealing with chronic pain patients. Commenter is concerned that the proposed guidelines create a two-tiered system when prescribing opiates to patients experiencing chronic pain-one standard as provided by the Medical Board and another by the DWC.</p> <p>Commenter states that the diagnosis and treatment of pain is integral to the practice of medicine. Physicians must carefully structure a treatment</p>		<p>Substances for Pain.” The MBC guideline applies to a wide variety of patient populations while the MTUS Opioids Treatment Guideline is specific to the population of injured workers with non-cancer pain. Nevertheless, the proposed guideline shows a high agreement with the MBC guideline, including the daily morphine equivalent dose (MED) of 80 mg./day and does not create a two-tiered system when prescribing opiates. The MTUS guideline is meant to provide guidance and to give treating physicians the tools and criteria needed to ensure safe and appropriate prescribing of opioids. The treatments covered in the proposed guidelines cover complex patient issues and alternative treatments alike.</p> <p>Agree: The DWC agrees with the MBC’s policy statement that “medicine is practiced one patient and a time and</p>	<p>None.</p>

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	<p>plan that uniquely reflects the benefits and risks of opioid use for each individual injured worker. In 2014, the Medical Board of California (MBC) adopted a policy statement titled, “Prescribing Controlled Substances for Pain.” These guidelines are intended to help physicians improve outcomes for patient care. In particular, these guidelines address the use of opioids in the long-term treatment of chronic pain. Commenter states that the MBC correctly stated, “[m]edicine is practiced one patient at a time and each patient has individual needs and vulnerabilities.”</p> <p>Commenter is concerned that the proposed guidelines create a rigid, one-size-fits all standard of care when prescribing opiates to patients experiencing chronic pain. Commenter recommends that the DWC recognize that deviations from these guidelines will occur and may be appropriate depending on the unique needs of the injured worker.</p> <p>Commenter states that the proposed</p>		<p>each patient has individual needs and vulnerabilities.”</p> <p>Disagree: The proposed guidelines do not create a rigid one-size-fits all standard of care when prescribing opiates to patients experiencing chronic pain. The DWC does recognize that deviations from these guidelines will occur and may be appropriate depending on the unique clinical needs of the injured worker.</p> <p>Disagree: The proposed guidelines provide strong evidence for the appropriate level of evaluation and</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>guidelines burden physicians with excessive documentation requirements.</p> <p>Commenter opines that the excessive documentation requirements within the proposed guidelines problematic and troubling, greatly impacting the cost to provide care to injured workers and further limiting the time providers have to treat their patients. For example, on page 21, number 4, the guidelines require a provider to document in the medical record that over a dozen contraindications are <u>not</u> present. Commenter states that depending on the injured worker and the particular injuries, it will be ineffective to document that over a dozen contraindications are <u>not</u> present. Commenter is concerned that in order to meet the burdensome documentation requirements within the guidelines a provider will spend the majority of their time filling out paperwork instead of treating injured workers.</p> <p>Commenter opines that although the guidelines state that they are in line</p>		<p>documentation when treating non-cancer pain with opioids.</p> <p>Disagree: The contraindications listed should be considered by any physician prescribing opioids because opioids carry a significant risk. After a physician has considered the contraindications listed, then the documentation requirement can be fulfilled with a simple indication that the contraindications are not present. However, if any of these conditions are present, then written documentation must be provided to justify the use of opioids.</p> <p>Disagree: The MBC guideline applies to a wide variety of</p>	<p>None.</p> <p>None.</p>

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	<p>with the MBC’s guidelines, in fact, the proposed guidelines are much more prescriptive and rigid. For example, the requirement found on page 20 of the guidelines requires a provider to document that certain modalities, such as acupuncture, massage and yoga, have been initiated and failed. As drafted, an employer or claims adjuster could require a physician to send an injured worker to obtain acupuncture, have them return with their pain undiminished, then send the injured worker to a massage therapist, have them return with their pain undiminished, then recommend they go to a few yoga classes, have them return with their pain undiminished all before allowing a provider to prescribe an opioid which in all likelihood would cure or relieve their pain.</p> <p>Commenter opines that the DWC has created an avenue for employers and claims adjusters to unjustly deny requested medical treatment based solely on the lack of documentation, which will lead to delays in care for</p>		<p>patient populations while the MTUS Opioids Treatment Guideline is specific to the population of injured workers with non-cancer pain. Nevertheless, the proposed guideline shows a high agreement with the MBC guideline, including the daily morphine equivalent dose (MED) of 80 mg./day. The example provided by commenter of the rigidity and prescriptive component of the proposed guidelines is inaccurate. The proposed guidelines allow the option to go straight to opioids if "there are reasonable expectations that only opioids will produce immediate pain relief and sleep immediately following the injury". The conjunction “and/or” is before each of the options and it appears the commenter has missed option “(c)” which is quoted above.</p> <p>Disagree: See above.</p>	<p>None.</p>

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	<p>injured workers.</p> <p>Commenter opines that by requiring physicians to direct injured workers towards treatments that are unlikely to be helpful will result in a failed DWC mission of “minimizing the adverse impact of work-related injuries on California employees and employers.” Commenter opines that the onerous burden on physicians to document that different modalities were tried and failed will only increase the adverse impact on both injured workers and employers by delaying timely and effective treatment.</p> <p>Commenter states that the proposed guidelines should take into consideration protections afforded to patients under California’s Intractable Pain Act.</p> <p>Commenter recommends that the DWC to revisit the proposed guidelines in light of current law, specifically, Business and Professions Code §2241.5, which states:</p>		<p>Disagree: If multiple modalities have been initiated and failed, these should indeed be documented to substantiate medical necessity to ensure safety and efficacy. It is also important that alternative therapies be tried before using chronic opioid therapy, as the evidence shows that these alternative treatments may be very effective in some patients and the safety profile is excellent. However, as already stated, the proposed guidelines allow the option to go straight to opioids if "there are reasonable expectations that only opioids will produce immediate pain relief and sleep immediately following the injury".</p> <p>Disagree: Commenter implies that the proposed guidelines somehow fail to take into consideration protections afforded to patient under the</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>(a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.</i></p> <p><i>(b) No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section.</i></p> <p>Commenter states that California's</p>		<p>California Intractable Pain Act. The proposed Opioids Treatment Guidelines allows physicians to prescribe or dispense or administer to a person under his or her treatment "dangerous or prescription controlled substances for the treatment of pain or a condition causing pain, including but not limited to, intractable pain" consistent with Business and Professions Code §2241.5(a). In addition, these proposed guidelines do not subject physicians and surgeons to disciplinary actions for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances consistent with Business and Professions Code §2241.5(b).</p> <p>Disagree: The proposed</p>	<p>None.</p>

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	<p>Intractable Pain Act, alongside clinical research and practice, find value in prescribing opiate drugs to persons suffering from severe chronic intractable pain. For some patients, pain management is the single most important treatment a physician can provide.</p> <p>Commenter states that physicians should assess accuracy of all aberrant CURES results.</p> <p>Commenter recommends that the DWC amend the proposed guidelines to clarify how a physician should handle an “aberrant” Controlled Substance Utilization Review and Evaluation System (CURES) response. The proposed guidelines require a physician to consult CURES to determine whether prescription of an opioid might be contraindicated. However,</p>		<p>guideline has been through a rigorous process of evaluation to ensure that physicians have the most up to date guidance on the use of opioid therapy and is intended to avoid the adverse outcomes so prevalent currently. The efficacy of opioids is clearly overstated in this comment and the risks seem to be ignored completely. This is out of step with the current Medical Board of California guidelines.</p> <p>Agree: Physicians need to use their clinical judgment in assessing CURES results.</p> <p>Disagree: The best evidence suggests use of a pharmacy drug monitoring program such as CURES. The CURES program is in evolution and is continuously improving. The treating physician should use clinical judgment in assessing CURES results, but this does not need to be incorporated into the guideline language.</p>	<p>None.</p> <p>None.</p>

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	<p>commenter is aware of many instances where the CURES database report has been inaccurate. Therefore, commenter urges the DWC to amend the proposed guidelines by inserting language that would require a physician to assess the accuracy of any aberrant CURES results before determining an appropriate response.</p> <p>Commenter is concerned that the abbreviated treatment protocols charts may cause confusion on the appropriate treatment requirements.</p> <p>Commenter opines that the “Abbreviated Treatment Protocols” (summary chart) chart will generate confusion. Commenter opines that there will be instances where a physician will rely on the summary chart for considerations or monitoring details and then receive a denial of the requested treatment due to a more detailed requirement in the guidelines.</p> <p>Commenter refers to the MTUS Opioids Treatment Guidelines, Part 1, A2, page 9 of the summary chart, and</p>		<p>Disagree: The Abbreviated Treatment Protocols are intended as a quick reference and do not take the place of the detailed recommendations that follow.</p> <p>Disagree: It is not the intent of the guideline that the summary chart information be used alone, the charts are reference tools for the more detailed descriptions in the guideline. UR and IMR reviewers should never rely on the summary charts alone and this is clearly stated in A2. Abbreviated Treatment Protocols, Important Note About the Abbreviated Protocols: “Reviewers and health care providers should <u>not rely exclusively on the summary recommendations</u>, since summary recommendations are necessarily incomplete. In order to provide medically appropriate care based on guideline recommendations, it</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>that it indicates under the column titled “Considerations” that urine drug testing (UDT) should be considered <i>and documented</i> at every visit. Further on in the document, under section “3.3.6. Use of Urine Drug Testing (UDT)” it states, “[p]eriodic drug testing is useful...” (Emphasis added.) Commenter opines that if a physician has initially considered and documented the consideration of a UDT and made a medical determination that UDT is not useful for a particular injured worker then the proposed guidelines seem to allow for the denial of the primary treating physician’s requested medical treatment merely because the physician did not document at every subsequent visit that a UDT was considered and determined to be not useful.</p> <p>Commenter is concerned that employers or utilization review organizations (UROs) will use a physician’s reliance on the summary chart as an excuse to deny requested treatments. Commenter is concerned about the increasing number of</p>		<p>is important to consult the main body of the guideline itself.”</p> <p>Disagree: The proposed guidelines present the medical evidence and suggested practices. Not all practices need to be rigidly adopted, however the nature of opioids is such that dependency can develop over time, sometimes rapidly, so it is prudent to periodically assess the need for urine drug testing, even if not indicated initially. It is not the intent of the guideline to provide opportunities for UR or IMR denial of treatment requests, the intent is to provide the evidence for practices that ensure patient safety when prescribing opioid therapy. If the provider does not think that urine drug testing is warranted, the rationale should be documented on an appropriate basis. The documentation need not be lengthy, but is should be</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>denials of treatment based on lack of documentation and other non-medically based reasons. Commenter opines that the addition of this chart into the guidelines could prove to be used as a basis for an increase in denials or delays of medically appropriate treatment.</p> <p>Commenter recommends that the DWC consider either removing the summary chart entirely or moving the chart to the end of the document so that a physician understands that the written guidelines are the basis through which they will receive approval or denial of requested medical treatments.</p>		<p>clear.</p> <p>Disagree: It is not the intent of the guideline that the summary chart information be used alone, the charts are reference tools for the more detailed descriptions in the guideline. UR and IMR reviewers should never rely on the summary charts alone and this is clearly stated in A2. Abbreviated Treatment Protocols, Important Note About the Abbreviated Protocols: “Reviewers and health care providers should <u>not rely exclusively</u> on the summary recommendations, since summary recommendations are necessarily incomplete. In order to provide medically appropriate care based on guideline recommendations, it is important to consult the main body of the guideline itself.</p>	None.
Opioid Medical Treatment Guidelines –	Commenter recommends the following amended language to the first bullet on page 1:	Michelle Rubalcava Legal Counsel California Medical	Disagree: Commenter is suggesting changes to the Executive Summary and is not	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part A, A1	<p>Opioid medications are not the first line of treatment <i>for mild injuries</i> and should not in general be used for mild injuries.</p> <p>Commenter opines that without this proposed amendment, the proposed regulations would seem to state that there is absolutely no circumstance where opioids would be the first line of treatment.</p>	<p>Association (CMA) August 31, 2015 Written Comment</p>	<p>intended to be considered a recommendation but rather a general policy statement. Detailed recommendations follow for a variety of clinical situations, including severe acute injuries. The Executive Summary is not intended to take precedence over detailed recommendations in the guideline.</p>	
Opioid Medical Treatment Guidelines – Part A, A1	<p>Commenter recommends the following amended language to the fourth bullet on page 2:</p> <p><i>At the time of initial prescription, and at every visit when opioid use is discussed at subsequent visits,</i> patients should be advised regarding responsible storage and disposal of opioid medications.</p> <p>Commenter opines that the requirement to have a physician engage a patient on responsible storage and disposal of opioid medications at every visit is excessive. Mandating the physician engage the patient on every visit will</p>	<p>Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment</p>	<p>Disagree: Commenter is suggesting changes to the Executive Summary and is not intended to be considered a recommendation but rather a general policy statement. Reinforcement of safe storage and disposal may be delegated to other clinical staff at the patient encounter. A quick reminder may be all that is necessary for some patients, others may require more coaching. Behavior change usually requires more than a single instruction, the physician reminders convey the importance of safe</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	further dilute the time a physician spends discussing a patients' overall health status. Commenter states that this requirement seems unnecessary especially if the physician has already properly instructed the patient in this regard.		practices to the patient and family members. The Executive Summary is not intended to take precedence over detailed recommendations in the guideline.	
Opioid Medical Treatment Guidelines – Part A, A1	<p>Commenter recommends the following amended language to the ninth bullet on page 2:</p> <p>Patients with chronic pain may be candidates for treatment with opioids if pain management and functional improvement have not been achieved with other treatment methods, including complimentary modalities, <i>or if other treatment methods are determined at the outset to be medically inappropriate</i> and the following conditions are met:</p> <p>Commenter states that this bullet seems to interfere with the Intractable Pain Act and the California Pain Patient's Bill of Rights. Commenter opposes any interference with a physician's professional judgment in determining what is and what is not medically necessary.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	<p>Disagree: The proposed guideline does not interfere with the rights of patients or of physicians to practice. It systematically contains recommendations supported by the best medical evidence for the safe and effective use of opioid therapy.</p> <p>Disagree: Added language “or if other treatment methods are determined at the outset to be medically inappropriate” does not have to be included in the guideline language. Patient characteristics may preclude a treatment option, if so the rationale for guideline exception should be documented. The proposed guidelines allow for this flexibility.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Opioid Medical Treatment Guidelines – Part A, A1	<p>Commenter recommends the following amended language to the sixth sub-bullet on page 3:</p> <p>CURES is queried and the results documents; aberrant results are a contraindication to chronic opioid treatment. <i>Treating physician shall assess the accuracy of aberrant response before determining appropriate response.</i></p> <p>Commenter states that there are enough instances where the CURES database results have been inaccurate so as to require that any aberrant results should be assessed for accuracy. Commenter opposes any language that does not include further guidance from the DWC on how to handle aberrant CURES responses.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: Commenter has consistently suggested that the proposed guidelines are too prescriptive and too rigid. Here, she is advocating the exact opposite. However, as the DWC has consistently stated throughout our responses to these comments, the MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations or using their professional judgment..	None.
Opioid Medical Treatment	Commenter recommends striking the third bullet on page 3:	Michelle Rubalcava Legal Counsel	Disagree: Section 10. Opioid use in Catastrophic Injures	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Guidelines – Part A, A1</p>	<p>Clinicians should conduct semiannual attempts to wean patients whose has been 80 mg/day MED or higher for at least six months to lower than 80 mg/day MED.</p> <p>CMA opposes the assertion and belief that it is medically appropriate for all injured workers to be weaned off their medications based solely on the fact that the injured worker’s dose has been 80/mg/day or higher for at least six months.</p> <p>Commenter acknowledges that in the majority of situations it would be medically appropriate to attempt to wean or taper injured workers off their medications; however, commenter opines that the DWC’s mandate that it be attempted semiannually for all injured workers is far too prescriptive.</p> <p>The MBC statement that “[m]edicine is practiced one patient at a time and each patient has individual needs and vulnerabilities.” highlights</p>	<p>California Medical Association (CMA) August 31, 2015 Written Comment</p>	<p>addresses use of chronic opioid treatment in the population of patients where significant recovery of physical function is not expected, such as severe burns, crush, or spinal cord injury “are exempt from many of the recommendations in this guideline.” The requirement for routine attempts at weaning are not included, although other recommendations are made to ensure patient safety, e.g., consultation with a pain specialist prior to dose escalation above 80 mg/day MED.</p> <p>The intention of the guideline is to provide guidance, however, the best evidence to date does suggest that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative. The Medical Board of California also chose 80 MED for its</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>commenter’s position that medicine is not a “one size fits all” equation. There will be cases where an injured worker has developed tolerance for a certain medication. As stated in the MBC guidelines, “[p]hysical tolerance develops for some effects of opioids, but not others.” In addition, in the case of a catastrophic injury, the pain associated with the injury will likely be a life-long pain.</p> <p>Commenter notes that the guidelines state in A3. Background, page 10, “It is not the intention of the Opioids Treatment Guidelines to restrict proper medical use of opioids.” In catastrophic cases, the proper medical use of opioids may be necessary for a lifetime.</p>		<p>Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution.</p> <p>Agree: Recommendations of the guideline do not preclude consideration of individual patient factors such as catastrophic injury.</p>	None.
Opioid Medical Treatment Guidelines – Part A, A1	<p>Commenter is not offering any specific amendment language to this section; however, she seeks clarification of the fourth bullet on page 3.</p> <p>Commenter states that she supports the conceptual idea but seeks clarification regarding how it would practically be implemented? Would the referral need to be vetted through</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	<p>To clarify--The 4th bullet on page 3 states: “Clinicians may consult with or refer to a pain specialist based on clinical need.”</p> <p>Yes, this falls under § 9792.6 and 9792.6.1 Utilization Review Standards’ to assure reimbursement, the referral to</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	UR?		the pain specialist requires authorization through the utilization review process.	
Opioid Medical Treatment Guidelines – Part A, A2	<p>Commenter recommends the following change to the box titled “Non-opioid Treatments” on page 6:</p> <p>In order to reduce any confusion the commenter suggests moving the column titled “Non-opioid Treatments” to the right hand of the page, perhaps after the column titled “Discontinuing.”</p> <p>Commenter opines that the current placement of the “Non-opioid Treatments” column is likely to cause some confusion as it sits right next to a column titled “Indication” wherein it states that in some cases “Opioids MAY BE indicated.”</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: The reader is directed “to consult the main body of the guideline itself” The main body of the guideline describes in detail the appropriate use of non-opioid treatments. When read as it is intended, this quick Summary Recommendations table is clear and not confusing.	None.
Opioid Medical Treatment Guidelines – Part A, A2	<p>Commenter recommends striking the third bullet, under “Prescribe Only” in the column titled “Best Practices if Opioids Used” on page 6:</p> <p>One opioid at a time</p> <p>Commenter states that their members who specialize in the treatment of chronic pain have long believed that</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: There may be such circumstances but the medical evidence strongly suggests that the effects of each opioid be assessed before prescribing an additional opioid. Furthermore, doses greater than 80 mg morphine equivalent dose (MED) and combination opioid therapy may	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>combination therapy that involves different kinds of opioids may be medically appropriate and medically necessary, depending on the injured worker and the specific work-related injury.</p> <p>Commenter’s organization has done some outside research on this question and has found the results to be varied. Research supports the theory that opioid combination therapy may have greater advantages in improving opioid response.</p> <p>One example would include the U.S. National Library of Medicine, National Institutes of Health, “Efficacy and safety of dual-opioid therapy in acute pain.” The author studied the results on the co-administration of two or more opioids and found in some instances a dual-opioid combination lead to synergistic analgesia.¹</p>		<p>significantly increase risks of adverse effects.</p> <p>The proposed guideline criteria for opioid use in acute pain encourage consultation or management by a pain specialist for high risk or medically complex cases.</p> <p>The intent of the guideline is not to be prescriptive but to provide the medical evidence on safety and efficacy of opioid therapy, including careful monitoring of the effects of the medication and use of non-opioid therapies to enhance pain control.</p>	
Opioid Medical Treatment Guidelines –	CMA recommends the following amended language to the column titled “Best Practices if Opioids	Michelle Rubalcava Legal Counsel California Medical	Disagree: The DWC will not incorporate commenter’s suggestion to add the word	None.

¹ <http://www.ncbi.nlm.nih.gov/pubmed/22420602>

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Part A, A2	<p>Used” on page 6:</p> <p>Lowest effective dose, No higher than 80mg/day MED <i>initially</i>.</p> <p>Commenter states that there will be some unique instances where an initial dose of more than 80mg/day may be medically necessary in order to cure or relieve the injured worker.</p> <p>Commenter requests that the DWC point to the evidence-based literature on which it relied to propose that an 80/mg/day threshold is the appropriate limitation for daily opioid use.</p>	<p>Association (CMA) August 31, 2015 Written Comment</p>	<p>“initially” to the “Best Practices if Opioids Used” on page 6 because The Opioid Medical Treatment Guidelines do not prohibit the appropriate use of opioids at any dose, the guidelines only ensure that evidence-based practices be used to ensure patient safety and efficacy. The 80 mg/day MED is not a hard upper limit.</p> <p>See Part Opioids Treatment Guidelines—Supplementary Materials (Part 2), Dosing Threshold, p. 64 for a summary of recommendations by each evidence-based opioid guideline used in developing the proposed MTUS Opioid Medical Guidelines. In addition, CMA, the organization commenter represents, also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution.</p>	

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Opioid Medical Treatment Guidelines – Part A, A2	<p>Commenter references the column titled “Discontinuing” on page 9.</p> <p>Commenter agrees that the requirement to “attempt to wean” is appropriate in situations where “tapering” has failed. However, commenter remains opposed to a blanket requirement to “wean and taper” all injured workers merely because they are on a current treatment that prescribes them more than 80mg/day.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: This is a summary of the full recommendations found in section 4. <i>Tapering Opioids</i> . Weaning to 80 mg/day should be attempted and results documented as doses above that level carry considerable risks to patient safety. These tapering recommendations are evidence-based and do allow continuation where benefit is established.	None.
Opioid Medical Treatment Guidelines – Part A3.2	<p>Commenter references the last paragraph of A3.2, page 11.</p> <p>Commenter opines that generally speaking, the statement that the Opioids Treatment Guidelines are consistent with the MBC guidelines is accurate; however, commenter states that the Opioids Treatment Guidelines are overly prescriptive in comparison to the MBC guidelines. Commenter opines that this creates a two-tiered system when prescribing opioids to patients with chronic pain.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: The MBC guideline applies to a wide variety of patient populations while the MTUS Opioids Treatment Guideline is specific to the population of injured workers with non-cancer pain. Nevertheless, the proposed guideline shows a high agreement with the MBC guideline, including the daily morphine equivalent dose (MED) of 80 mg./day. The perceived creation of a two-tiered system is a criticism of the language that DWC choose to use but an analysis by the	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			DWC and as admitted by commenter, indicates there is consistency between the two guidelines.	
Opioid Medical Treatment Guidelines – Part A3.4	<p>Commenter agrees with the assessment that the answer to the question regarding the long-term effectiveness and safety of opioids for the treatment of chronic non-cancer pain remains unanswered. As a result, the commenter opposes closing the door to a potentially safe and effective form of curing or relieving chronic pain.</p> <p>In fact, commenter would argue that especially because the question remains unanswered that it would behoove the DWC to allow for more flexibility within the guidelines as opposed to the overly rigid path that is being proposed.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	<p>Disagree: The Opioid Medical Treatment Guidelines provide the best available evidence on the safe and effective use of opioids to cure and relieve from the effects of the injury.</p> <p>The guidelines are not overly proscriptive and do allow for medically necessary use of opioids. However, due to the safety profile of opioids, the evidence strongly demonstrates that every patient requires diligent assessment when on opioid therapy, whether for a short course or for long-term treatment.</p>	None.
Opioid Medical Treatment Guidelines – Part 1, B1-B1.3 Severe Acute Injuries	<p>Commenter referenced pages 20-24.</p> <p>Commenter opines that there is an odd sequence of sections starting with page 20. The recommendations begin with “moderate to severe acute” to “mild acute” to “severe</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Agree: The sequencing is odd and commenter’s suggestion to move “mild acute” to the section before “moderate to severe” will be incorporated.	The sequencing of Section 1. Opioids for Acute Pain (up to four weeks after injury or pain onset) is amended to begin with 1.1. Mild Acute,

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	acute”. Commenter recommends moving “mild acute” to the section before “moderate to severe.”			then 1.2 Moderate to Severe Acute, and then to 1.3 Severe Acute Injuries.
Opioid Medical Treatment Guidelines – Part 1, B.1.3 Severe Acute Injuries	<p>Commenter references Part 1, B.1.3, Severe Acute Injuries, #2, pg. 24.</p> <p>Commenter states that the proposed recommendation requires the provider to ensure that there are “reasonable expectations” that only opioids will produce immediate pain relief...” Commenter agrees that it should be within the provider’s discretion to prescribe opioids if the provider believes it medically necessary. Commenter opines that the way in which the language is drafted leaves open the question, whose reasonable expectations must be met? The provider’s reasonable expectation? The employer’s reasonable expectation? The claim adjuster’s reasonable expectation? Commenter states that when subjective terms such as “reasonable” are used in guidelines, it opens the door for inconsistent actions and results.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: Every scenario that could indicate a reasonable expectation of the treating physician cannot be described here, the treating physician should substantiate the need for an opioid by documenting the nature and extent of the severe acute injury, patient symptoms and response to treatment and other clinical factors so that the rationale is clear. The guidelines are intended for the use by treating and reviewing physicians.	None.
Opioid Medical	Commenter recommends adding	Michelle Rubalcava	Disagree: The use of CURES	None.

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Treatment Guidelines – Part 1, B.1.3 Severe Acute Injuries	<p>language which requires the provider to question the patient regarding any aberrant CURES response to any section that requires the physician to access the CURES database.</p> <p>Commenter recommends that the exact same wording be used in each section instead of allowing for variations in the language, no matter how slight.</p> <p>Commenter references Part 1, B.1.3, Severe Acute Injuries, #3, pg. 25.</p> <p>Commenter agrees with the last bullet in #3, wherein it states, “[i]f the search indicates that other opioids are being used, the patient should be questioned about the additional medications.”</p> <p>Commenter opines that any time there is an aberrant CURES response there should be some investigation as to the nature of the aberrant response.</p>	Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	<p>is well emphasized throughout the guideline and in the clinical summary. Once aware of the usefulness of CURES, physicians may check as often as necessary based on clinical judgment.</p> <p>Disagree: Exact same wording is not necessary to convey the information.</p> <p>Agree: The word “should” will remain and the DWC agrees with commenter’s response. However, we point out that commenter’s use of the word “should” is consistent with the wording in the proposed guidelines. This is inconsistent with commenter’s earlier suggestion to “require” the physician to question the patient which is too prescriptive and does not allow room for clinical judgment.</p>	<p>None.</p> <p>None.</p>
Opioid Medical Treatment Guidelines –	Commenter recommends the following amended language to Part 1, B1.3, page 26, #7(d):	Michelle Rubalcava Legal Counsel California Medical	Disagree: The guideline only proposes monitoring for discontinuation of opioids, not	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Part 1, B.1.3 Severe Acute Injuries	<p><i>Unjustified</i> noncompliance...</p> <p>Commenter also recommends applying this qualifier anytime the term of noncompliance is mentioned in regard to possibly discontinuing an injured worker’s opioid treatment regime due to “noncompliance.”</p>	Association (CMA) August 31, 2015 Written Comment	a hard recommendation to discontinue in the event of noncompliance. Physicians are always encouraged to explore the root causes of noncompliance to determine if there is a valid reason.	
Opioid Medical Treatment Guidelines – Part 1, B3.2 Consideration of Alternative Treatments For Chronic Pain and Chronic Opioid Treatment	<p>Commenter recommends the following amended language to the first paragraph in Part 1, B3.2, page 35:</p> <p>Non-opioid alternative therapies for pain treatment should be tried whenever possible <i>appropriate</i> before resorting <i>initiating</i> to chronic opioid therapy.</p> <p>Commenter opines that the term “whenever possible” is too broad of a term to be used within this context. Commenter opines that the overly prescriptive nature of the proposed guidelines is creating a two-tiered system when prescribing opiates for chronic pain patients.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: The current language conveys the level of caution substantiated by the medical evidence when initiating chronic opioid therapy for chronic pain. The additional level of caution used in the language does not render the guideline overly prescriptive.	None.
Opioid Medical Treatment	Commenter recommends the following amended language to the	Michelle Rubalcava Legal Counsel	Agree: Use of the word “only” is not placed properly in the	Opioid Medical Treatment Guidelines

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Guidelines – Part 1, B3.3.1.1 Screening for Drug Misuse/Abuse	<p>first paragraph in Part 1, B3.3.1.1, page 37, #3:</p> <p><i>If the screening tools identify a predicted increased risk for substance misuse/abuse, initiate chronic opioid treatment only if the screening tools identify a predicted increased risk for substance misuse/abuse and other alternatives are not viable; in this case, provide documentation in the medical record that attempts are being made to address the identified risks.</i></p> <p>Commenter opines that as currently drafted the language is confusing and may lead physicians to believe that the prescription of opioids is never allowed if there is a predicted increased risk for substance misuse/abuse.</p>	California Medical Association (CMA) August 31, 2015 Written Comment	sentence and may make interpretation more restrictive.	Part 1, B3.3.1.1 Screening for Drug Misuse/Abuse, #3 is amended as follows: “Initiate chronic opioid treatment only if the screening tools identify a predicted increased risk for substance misuse/abuse and <u>only</u> if other alternatives are not viable;”
Opioid Medical Treatment Guidelines – Part 1, B3.3.1.1 Screening for Drug Misuse/Abuse	<p>Commenter recommends adding the following language after #4 in Part 1, B3.3.1.1, page 39:</p> <p><i>5. It is prudent to share the signed agreement with other health care providers treating the patient.</i></p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: The suggested addition is included in the next section 3.3.3 Initiation of Chronic Opioid Treatment found on the following and does not need reiteration for clarity.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that this language is used in the following section and should also be added to section B3.3.1.1.</p>			
<p>Opioid Medical Treatment Guidelines – Part 1, B3.3.6 Use of Urine Drug Testing (UDT)</p>	<p>Commenter references Part 1, B3.3.6, Use of Urine Drug Testing (UDT).</p> <p>Commenter notes that the proposed guidelines require an extraordinary amount of UDT. Commenter references, that as MBC guidelines state, “physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately.”</p>	<p>Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment</p>	<p>Disagree: The value of urine drug screening is supported by the medical evidence. Minimum recommendations include a urine drug screen prior to an opioid trial (subacute or chronic pain) and randomly 2 times per year for most patients. Urine drug screening is a convenient and cost-effective tool to detect diversion and use of non-prescribed substances, important safety issues in the population of patients on opioid therapy.</p>	<p>None.</p>
<p>Opioid Medical Treatment Guidelines – Part 1, B3.3.8 Opioid Titration and Dosing Threshold</p>	<p>Commenter recommends consistency throughout the proposed guidelines. Commenter recommends that the guidelines use the term “office visit” instead of the term “evaluation.”</p> <p>Commenter references Part 1, B3.3.8, #4, page 51.</p> <p>Commenter notes that the proposed guidelines require the provider to</p>	<p>Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment</p>	<p>Disagree: The proposed guideline is intended to describe best evidence-based clinical practices and does not replace fee schedule rules. Office visits are part of evaluation and management and are not intended to be interpreted as specialty consultations.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>advise patients at each “evaluation”, however, throughout most of the document the term “visit” is used.</p> <p>Commenter opines that consistency is critical especially since the codes of consult have been eliminated.</p>			
<p>Opioid Medical Treatment Guidelines – Part 1, B3.3.8 Opioid Titration and Dosing Threshold</p>	<p>Commenter references Part 1, B3.3.8, #6, page 51.</p> <p>Commenter states that the California Department of Public Health encourages “routine provision of take-home Naloxone to patients prescribed long-term/high dose opioids and patients known to use opiates non-medically.”² The Department of Health Care Services issued a similar letter.³</p> <p>Commenter recommends that the DWC consider expanding Naloxone availability.</p>	<p>Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree: First sentence will be deleted. Outpatient use may be warranted. Disagree: Commenter’s suggested language, “<u>Naloxone is also recommended on a case-by-case basis for outpatient, pre-hospital use, to treat opioid overdoses for patients who are prescribed opioids for acute and chronic pain</u>” will not be adopted because it is sufficiently covered in the MTUS proposed Chronic Pain Medical Treatment Guidelines.</p>	<p>Section 3.3.8 – Opioid Titration and Dosing Threshold is amended to delete the first sentence: “Due to lack of sufficient evidence to guide outpatient care, the routine prescription of naloxone to patients on chronic opioid treatment is not recommended. Naloxone is recommended in hospital-based and emergency department settings</p>

² <http://www.calhospital.org/sites/main/files/file-attachments/lnc-afl-14-19.pdf>

³ http://files.medi-cal.ca.gov/pubdoco/BULLETINS/docs/Letter_22470.1.pdf

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				for the treatment of opioid overdose. Refer to the MTUS Chronic Pain Guidelines for more information.”
Opioid Medical Treatment Guidelines – Part 1, B4.1 Indications for Tapering Opioids	<p>Commenter references the first paragraph of Part 1, B4.1, pg. 54.</p> <p>Commenter opines that the decision to implement “weaning and tapering” attempts for patients taking over 80mg/day MED for over six (6) months seems extraordinarily arbitrary, especially given the different individual factors of each injured worker, such as, weight, height, tolerance, etc.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: This is a guideline not a prescriptive mandate that does not allow physicians to use judgment. Specific individual patient factors should always be considered and documented in the treatment plan. Medical evidence strongly indicates that caution needs to be exercised above 80 mg MED and if a patient falls outside of that recommendation the reasons should be documented to substantiate medical necessity. The intent is to consider tapering on a periodic basis to assess the need for continuation of opioid therapy at the lowest effective dose.	None.
Opioid Medical Treatment Guidelines – Part 1, B4.2	Commenter recommends the following amended language on Part 1, B4.2, pg. 55, #5:	Michelle Rubalcava Legal Counsel California Medical Association (CMA)	Disagree: The language as written by the American Medical Association states only to “never abandon” when	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Methods for Tapering Opioids	<p>Never abandon <i>Avoid abandoning a patient for whom tapering is indicated <u>until the patient has had a reasonable time to find an alternative source of care, and ensure that the patient has adequate medications, if appropriate, to avoid unnecessary risk from withdrawal symptoms.</u></i></p> <p>Commenter vigorously opposes a blanket prohibition on patient abandonment. There may be instances, such as a violent patient, which necessitates a provider abandoning his patient. Commenter states that the MBC guidelines are more in line with the commenter's views that in the rarest of circumstances, patient abandonment may be a necessity.</p>	August 31, 2015 Written Comment	reasonable and does not conflict with the stated example of intentional injury. The DWC's intention is not to define professional conduct but to ensure patient safety in the context of an evidence based clinical guideline.	
Opioid Medical Treatment Guidelines – Part 1, B6 Consultation with Specialists	<p>Commenter references Part 1, B6, page 56.</p> <p>Commenter agrees that primary treating physicians (PTPs) should consult with specialist in the care of injured workers experiencing chronic pain, however, the commenter would like to take this opportunity to recognize that without adequate provider networks access is merely</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: This comment goes beyond the scope of this comment period because it provides a commenter but no specific recommendations for the proposed Opioids Treatment Guidelines.	None.

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Chronic Pain Medical Treatment Guidelines – Pain (Chronic), Part 1, Intro	<p>an illusion.</p> <p>Commenter notes that the opening paragraph states that “physician should provide conservative management.” Commenter is always concerned when subjective terms like this are used which can then lead to inconsistent decisions on what is considered medically appropriate treatment. Commenter asks if there a definition for conservative management.</p>	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Agree: For clarification, a definition of conservative management is added.	PART 1: Introduction is revised to define “conservative management” by adding, “that is, a treatment approach designed to avoid surgical and other medical and therapeutic measures with higher risk of harm compared to benefit. (Singh, 2013)”
Chronic Pain Medical Treatment Guidelines – Part 1, Intro, Def. of “Types of Pain (Acute vs Chronic)	Commenter notes that when defining “types of pain” the ODG guidelines states, “Although acute and chronic pain is considered separately below, an individual can experience them simultaneously.” Commenter opines that this statement is confusing and seems contrary to the concept of pain continuum.	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: Current research and thinking is that pain exists on a continuum. Definitions of Acute and Chronic Pain are accordingly less rigid, however for the purpose of the guidelines, these concepts were simplified to make them more usable.	None.
Chronic Pain Medical Treatment Guidelines – Part 1, Intro, Page 4 “Models”	Commenter takes issue with the assertion that “models” establish “acceptable standards of care.” Commenter argues that, in fact, it is physicians who establish “acceptable standards of care.”	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Agree: DWC is applying the term broadly but for clarity will change.	Part 1: Introduction, under Models is amended to delete the word “standard” and replace it so that it now states

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Chronic Pain Medical Treatment Guidelines – Part 1, Intro, Page 5, “Illness Behavior Model”	Commenter would like the DWC to understand that “pain” is a symptom, as well as being a disease and an illness. Commenter states that as an illness, pain has a host epiphenomena. Psychosocial factors are common to many chronic illnesses and are not unique to pain.	Michelle Rubalcava Legal Counsel California Medical Association (CMA) August 31, 2015 Written Comment	Disagree: The comment does not substantively address the proposed changes to the current medical treatment utilization schedule regulations that address chronic pain. The reason for including biopsychosocial factors in the chronic pain guideline is that it changes the paradigm from a biomedical model that focuses on pathology of the injury to a multidimensional approach that is more effective at controlling pain once it becomes chronic.	“acceptable guidance” for care. None.
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	Commenter appreciates the Division for retaining Spinal Cord Stimulation as a treatment option for Failed Back Surgery Syndrome (FBSS) in the proposed MTUS Chronic Pain Medical Treatment guideline. Commenter strongly believes this is an essential step in the right direction for California injured workers to maintain access to this important treatment option. Commenter opines that further clarity is needed in the	Barbara Marcanti Global Director, HealthCare Economics and Health Policy St. Jude Medical, Inc. August 31, 2015 Written Comment	Disagree: The DWC is in the process of incorporating by reference the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” published on April 6, 2015. The proposed guideline does not address the routine of SCS for failed back surgery syndrome (FBSS) patients. Currently, it	None.

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	<p>new guideline related to SCS as a treatment for FBSS. The Official Disability Guideline (ODG), in its low back chapter, has a literature summary which clearly supports FBSS. A review of the proposed MTUS chronic pain guideline doesn't; in fact it references the 2004 ACOEM low back chapter and does not include nearly eleven years' worth of additional evidence. Commenter opines that if the Division leaves the reference as stated, it may result in injured workers' being denied SCS treatment for FBSS or result in significant additional administrative burdens causing unnecessary delays to access the procedure; all, potentially impacting the injured worker reaching maximum medical improvement and return to work. Commenter states that it is important to have more current FBSS literature included in the chronic pain section. [Note that commenter provides a long list of references which is available upon request.]</p> <p>Commenter states that spinal cord</p>		<p>references the MTUS Low Back Complaints guideline which incorporates by reference the 2004 ACOEM low back chapter. Commenter recommends that language in ODG's Low Back chapter containing a literature review of FBSS for SCS be included in the proposed MTUS Chronic Pain Chapter section on SCS. However, doing this is an attempt to amend the current MTUS recommendations in the Low Back Chapter via this rulemaking. The DWC is unable to amend the MTUS' Low Back Chapter without going through the formal rulemaking process to amend that regulatory section. However, the DWC is in the process of evaluating and updating the treatment guidelines for the Low Back.</p> <p>If a physician feels that there is evidence to rebut any recommendation in the MTUS,</p>	<p>None.</p>

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	<p>stimulation (SCS) (also called neurostimulation or Dorsal Column Stimulation (DCS) is a proven therapy recommended by doctors to manage their patient’s chronic pain and improve quality of life. Neurostimulation systems are approved or cleared by the U.S. Food and Drug Administration (FDA) for the management of chronic pain in the back, neck, arms, or legs. Benefits of neurostimulation may include:</p> <ul style="list-style-type: none"> • A reduction in pain by 50 percent or greater • A reduction or elimination in the use of pain medications⁴ • Increased activity levels and an improved overall quality of life <p>Commenter notes that neurostimulation is not a cure for what is causing the pain and does not treat specific diseases. Instead, it is a therapy that's designed to mask pain by blocking pain signals before they reach the brain. It has been used to manage pain that comes from failed back surgery syndrome (FBSS) or</p>		<p>then the requesting physician may attempt to rebut the MTUS. Rebutting the MTUS requires submitting additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated using the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1, where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine.</p> <p>Disagree: This rulemaking pertains to the Chronic Pain Medical Treatment Guidelines set forth in §9792.24.2 and the Opioids Medical Treatment Guidelines set forth in §9792.24.4 and will not be amending the Low Back Complaints guideline set forth in §9792.23.5. Currently,</p>	None.

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	<p>post-laminectomy syndrome and other neuropathies.</p> <p>Commenter states that Spinal Cord Stimulation is a widely accepted standard-of-care treatment option among physicians when treating a broad spectrum of FBSS patients across the US. Organizations like American Society of Interventional Pain Physicians (ASIPP) and American Pain Society (APS) support SCS as a treatment option for SCS. SCS is also covered by many major health insurance plans, Medicare, and workers' compensation programs in 48 states.</p> <p>Commenter states that SCS is also supported by numerous rigorous clinical studies; such as, randomized controlled trials (RCT) which show SCS is a clinically effective treatment, even more so than reoperation or conventional medical management (CMM) that reduces pain among patient with FBSS. There are large post-market registries which report positive outcomes for more than 1,000 SCS patients. Commenter</p>		<p>section 9792.23.5 incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004) into the MTUS. The DWC has plans to update the current Low Back Complaints guideline in the near future but any amendments to the Low Back Complaints guideline must also go through the formal rulemaking process. There is a regulatory process already in place that must be followed to evaluate whether a recommendation found outside the MTUS is warranted in the limited situation when a medical treatment or procedure is not addressed by the MTUS or if one is attempting to rebut the MTUS' presumption of correctness.</p>	

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	<p>states that multiple studies demonstrate more cost-effective – combined with the pain relief and quality of life improvement it offers – puts therapy below the commonly accepted willingness-to-pay threshold in the U.S.</p> <p>Commenter opines that SCS used in the carefully selected patient may lead to cost-savings and more health gain relative to conventional medical management for FBSS and CRPS. Commenter notes that additional research published as recently as 2015 suggest that in a clinical practice, SCS+CMM treatment of FBSS patient’s refractory to CMM provides good value for the money.</p> <p>Commenter requests that the Division clarify the MTUS guideline to better reflect a more robust literature summary reflective of FBSS clinical evidence published since 2004 and that it be included in the chronic pain section of the guideline.</p>		<p>Disagree: See above. Proposed section on spinal cord stimulation is based on ODG and is current. Content does not cover SCS for failed back surgery syndrome but refers the user to the MTUS low back chapter, which is currently not included in this rulemaking.</p>	<p>None.</p>
Chronic Pain Medical Treatment Guidelines -	<p>Commenter states that the California Labor Code requires the Division of Worker’s Compensation to adopt a</p>	<p>Kristen V. Hedstrom, MPH – Director Health, Economics &</p>	<p>Disagree: This rulemaking pertains to the Chronic Pain Medical Treatment Guidelines</p>	<p>None.</p>

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Spinal Cord Stimulators	<p>Medical Treatment Utilization Schedule (MTUS) that incorporates “evidenced-based, peer-reviewed, and nationally recognized standards of care.” Commenter notes that since the last revisions of the MTUS guideline for chronic in 2009, published studies support SCS as a clinically and cost effective treatment of intractable pain in FBSS patients. For example, in 2014, an independent review evaluated retrospective insurance claims data from 2000-2009 and associated SCS with lower complication rates and shorter hospital lengths of stay compared with spinal reoperation, both of which were statistically significant.⁴ Commenter states that a 2010 study by Taylor et al found that in the UK, the incremental cost-effectiveness of SCS when compared with conventional medical management was £5,624 per quality-adjusted life</p>	<p>Reimbursement, Neuromodulation Boston Scientific September 1, 2015 Written Comment</p>	<p>set forth in §9792.24.2 and the Opioids Medical Treatment Guidelines set forth in §9792.24.4 and will not be amending the Low Back Complaints guideline set forth in §9792.23.5. Currently, section 9792.23.5 incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004) into the MTUS. The DWC has plans to update the current Low Back Complaints guideline in the near future but any amendments to the Low Back Complaints guideline must also go through the formal rulemaking process. There is a regulatory process already in place that must be followed to evaluate whether a recommendation found outside the MTUS is warranted in the</p>	

⁴ Lad S, Babu R, Hagley J, et al. Utilization of Spinal Cord Stimulation in Patients With Failed Back Surgery Syndrome. Spine 2014.

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	<p>year (QALY) and £6,392 per QALY when compared with reoperation.⁵ Commenter notes that a 2013 study by Kumar et al used Markov models to identify an incremental cost-effectiveness ratio (ICER) of CAN\$9,293 for FBSS when compared with conventional medical management (CMM) over a 20-year time horizon.⁶ Commenter opines that these publications show that SCS yields a long term cost savings with improved quality of life compared with surgery and CMM.</p> <p>Commenter notes that the Food and Drug Administration’s (FDA) recognizes SCS as an “aid in the management of chronic intractable pain of the trunk or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome.” Commenter states that both the public and private sectors recognize SCS as a treatment option for patients and widely cover the procedure for FBSS, including</p>		<p>limited situation when a medical treatment or procedure is not addressed by the MTUS or if one is attempting to rebut the MTUS’ presumption of correctness.</p>	

⁵ Taylor R, Ryan, J, et al. The Cost-effectiveness of Spinal Cord Stimulation in the Treatment of Failed Back Surgery Syndrome. Pain 2010.

⁶ Kumar K, Rizvi S. Cost-Effectiveness of Spinal Cord Stimulation Therapy in Management of Chronic Pain-Pain Medicine 2013.

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	<p>Medicare (Noridian Local Coverage Determination L33489, Spinal Cord Stimulators for Chronic Pain) and the majority of private insurers.</p> <p>Commenter states that the patients who are appropriate candidates for SCS have failed many, if not all possible conservative medical treatments, such as back surgery, injections, physical therapy and medications, including opioids. In some cases, SCS is the only treatment that provides the pain relief necessary to allow a sick or injured worker to return to the workforce. Commenter opines that the revised guidelines, as written, are an important first step in ensuring that injured workers have access to SCS.</p>		<p>Disagree: Patients who require spinal cord stimulation do have access when medically necessary, there is no prohibition on the use of spinal cord stimulators. The proposed guidelines are intended to guide treatment based on the strength and quality of medical evidence and are not intended to be proscriptive.</p>	<p>None.</p>
<p>Chronic Pain Medical Treatment Guidelines – Complex Regional Pain Syndrome (CRPS)</p>	<p>Commenter is recommending that the California Department of Industrial Relations include the use of IV Ketamine to treat the pain and disability associated with Complex Regional Pain Syndrome (CRPS) in its new Chronic Pain Medical Treatment Guidelines.</p> <p>Commenter states that CRPS is rated</p>	<p>James W. Broatch, MSW, Executive Vice President RSDSA September 1, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree that pain from CRPS is a serious concern. Disagree: that IV Ketamine should be recommended for treatment of CRPS. The medical evidence is well summarized in the clinical topic Ketamine in the proposed chronic pain medical treatment</p>	<p>None.</p>

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	<p>as the most painful chronic pain syndrome by the McGill Pain Index and people with CRPS are two-and-a half times at risk of suicide as those suffering with other chronic pain syndromes. Commenter notes that in 2004, his organization funded an Internet survey of 888 adults diagnosed with CRPS. The 75 question survey, conducted by the Johns Hopkins School of Medicine, found that "although initial injury was related to work in many patients, their compensatory benefits were often inadequate and insufficient medical insurance coupled with poor financial benefits could potentially prevent many of these patients from accessing optimal therapeutic choices." Commenter states that CRPS remains a poorly understood and frequently hard-to-treat neuro-inflammatory syndrome. Commenter states that early quality treatment has the best chance of resulting in the best outcome. Commenter notes that, initially, for individuals who develop CRPS, a diagnosis can be elusive as there is no</p>		<p>guidelines. Serious toxicity and safety concerns, including neurotoxicity and hepatic dysfunction and other significant adverse effects do not offset the limited evidence of benefit.</p> <p>Agree: Early recognition and treatment of CRPS is important and that there is no</p>	<p>None.</p>

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	<p>gold diagnostic standard. It is a diagnosis by exclusion. CRPS is acutely more painful because of NMDA activity and hyper-responsiveness to NMDA. NMDA is a neurotransmitter present in the dorsal horns and spinothalamic tracts, and is the number one initiator of 'wind-up' in acutely painful conditions. Commenter states that <i>Ketamine</i> a NMDA antagonist has proven efficacious in treating refractory CRPS, although continued research is needed! Commenter states that intravenous Ketamine by reducing the hyper-responsiveness to NMDA can reduce the pain of CRPS and help restore functioning of individuals and facilitate <i>return to work</i>.</p>		<p>established evidence-based diagnostic test.</p> <p>Disagree: There is no evidence that early infusion with ketamine will prevent progression or course of CRPS.</p>	None.
Chronic Pain Medical Treatment Guidelines - Spinal Cord Stimulators	<p>Commenter is a physician who states that he is passionate about offering his patients the most effective therapies for pain control. Commenter is concerned that if the proposed guide is implemented as drafted, that it will significantly limit his ability to effectively treat Worker's Compensation patients with established and well-studied effective</p>	<p>Kasra Amirdelfan Pain Management Physician IPM Medical Group September 1, 2015 Written and Oral Comment</p>	<p>Disagree: Use of spinal cord stimulators for failed back surgery syndrome are addressed in the MTUS Low Back Complaints guideline This rulemaking pertains to the Chronic Pain Medical Treatment Guidelines set forth in §9792.24.2 and the Opioids Medical Treatment Guidelines</p>	None.

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	<p>therapies such as Spinal Cord Stimulation (SCS.)</p> <p>Commenter states that there have been significant advances in the SCS field in the recent past. Commenter is one of ten U.S. investigators in a recently published study for a new spinal cord stimulator, called Senza, which is capable of a unique therapy called HF10. This research project, which was called the SENZA-RCT (Randomized Controlled Trial), provided us with level 1 evidence on Spinal Cord Stimulation and was recently published in the Journal of Anesthesiology. It also led to the recent FDA approval of this groundbreaking technology. Commenter states that this new spinal cord stimulator was shown to be superior to traditional spinal cord stimulation capable of compelling, long term back and leg pain control. Commenter continues to witness more efficacious technologies from all companies in this field.</p> <p>As an investigator in the SENZA-RCT, commenter has witnessed the</p>		<p>set forth in §9792.24.4 and will not be amending the Low Back Complaints guideline set forth in §9792.23.5. Currently, section 9792.23.5 incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004) into the MTUS. The DWC has plans to update the current Low Back Complaints guideline in the near future but any amendments to the Low Back Complaints guideline must also go through the formal rulemaking process. There is a regulatory process already in place that must be followed to evaluate whether a recommendation found outside the MTUS is warranted in the limited situation when a medical treatment or procedure is not addressed by the MTUS or if one is attempting to rebut the MTUS' presumption of correctness.</p> <p>Disagree: The ODG guideline that the DWC is incorporating</p>	<p>None.</p>

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	<p>efficacy of this device in a number of his low back and leg pain patients. Commenter states that each of these patients would be willing to testify to the effectiveness of their therapy if the opportunity ever presented itself. Commenter states that he is a physician who is intimately familiar with this patient population and the available treatment options. Commenter opines that SCS is an extremely effective therapy for appropriately selected patients. Commenter states that access to this therapy should not be eliminated as an option for the chronic pain patients.</p> <p>Commenter opines that a better guideline and criteria to choose the most appropriate patients for spinal cord stimulation, in order to mitigate waste and over-utilization, is necessary. Commenter would like to be involved in developing this guideline. Based on his years of experience of treating worker's compensation patients, his deep knowledge of SCS and his involvement in research with this</p>		<p>by reference does not include any reference to the SENZA-RCT Randomized Controlled Trial Study that was published on October 2015 after the publication date of the ODG guideline that is being incorporated. The DWC will not delay this rulemaking because a new study is published that may or may not affect its proposed recommendations. There is a regulatory process already in place that must be followed to evaluate whether a recommendation found outside the MTUS is warranted in the limited situation when a medical treatment or procedure is not addressed by the MTUS or if one is attempting to rebut the MTUS' presumption of correctness.</p> <p>Disagree: The ODG Chronic pain guideline was recommended by the Medical Evidence Evaluation Advisory Committee (MEEAC) for the</p>	None.

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	<p>technology, commenter opines that he is uniquely positioned to be able to assist in developing the criterion for a more responsible utilization of these devices.</p> <p>Commenter is specifically concerned about patients with chronic low back and leg complaints, especially since the DWC has proposed adopting the ACOEM Practice Guidelines from 2004. Commenter states that these guidelines do not include the most recently published evidence for SCS. Commenter has submitted copies of the two recently published studies regarding Senza for consideration and reference [copies available upon request]. Commenter often sees patients with chronic low back and leg complaints with the diagnosis of Failed Back Surgery Syndrome or chronic radiculopathy that can effectively be treated with SCS. Commenter notes that most, if not all, private insurance companies, Medicare, as well as worker's compensation carriers, based on existing and emerging new evidence, commonly cover this therapy.</p>		<p>workers' compensation population.</p> <p>Disagree: Commenter is already involved in developing the DWC's guidelines by submitting his comments. The DWC considers and responds to every comment and greatly values his and the input from other members of the public.</p> <p>Disagree: The DWC is not proposing to adopt the ACOEM Practice Guidelines from 2004, it is proposing to adopt ODG's April 2015 version of the Chronic Pain Medical Treatment Guidelines. Any references in the Chronic Pain Medical Treatment Guidelines for treatments to the Low Back cite the <u>current</u> MTUS regulations which incorporate by reference ACOEM's 2nd Edition 2004. Again, the DWC cannot make changes to those regulations unless we go through the formal rulemaking process.</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter opines that the SENZA-RCT study provides Level 1 clinical evidence available for HF10 therapy that should be specifically considered by the DWC prior to finalizing the Practice Guidelines. This study included 241 participants from 10 centers around the country. Over 70% of the study subjects presented with the diagnosis of FBSS. The Senza-EU study, which was published in 2013, also had a large proportion of patients with FBSS at 81%. Each of these studies reported significant and compelling reductions in patient’s back and leg pain for a prolonged period of time.</p> <p>Commenter recommends that the DWC consider the clinical evidence that has been recently published, and reconsider the proposed SCS coverage guidance for patients with FBSS and chronic lower extremity radiculopathy. Commenter states that this is the era of evidence-based medicine and we now have level 1 evidence to support this type of therapy. The ACOEM guidelines</p>		<p>The DWC has plans to update the Low Back Chapter after we complete this rulemaking.</p> <p>Disagree: The SENZA RCT study recommended by commenter was published after the publication date of the ODG guideline the DWC is incorporating by reference into our regulations. Commenter’s suggestion would require the DWC to delay this rulemaking and wait for the SENZA RCT to be reviewed and included in ODG’s subsequently published guideline. The DWC will not delay this rulemaking because it contains many more recommendations that will be used to guide medical care of California’s injured workers. Again, a physician may cite the SENZA RCT study in his or her request for authorization to rebut the MTUS’ presumption of correctness. Again, there is already a regulatory process in place that will be followed to evaluate</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>state that SCS should be “rarely used” for FBSS, or for patients with chronic low back complaints. Commenter disagrees with this statement, as it is no longer current, based on the available, high quality evidence, which warrants broader coverage for the appropriately selected patients with FBSS and chronic radiculopathy.</p> <p>Commenter states that it is noteworthy that the 18-month data from the Senza-RCT was also recently presented at a peer attended scientific meeting. The 18-month outcomes data is very similar, if not identical, to the published 12 month results underscoring the long-term efficacy of this device. The 18-month data is also being submitted for publication. The 24-month data to establish further longevity of this breakthrough therapy will be presented in December, at the North American Neuromodulation Society meeting. Commenter will share those outcomes with the Division when they become available. For reference, commenter has provided a copy of</p>		<p>whether a recommendation found outside the MTUS is warranted in the limited situation when a medical treatment or procedure is not addressed by the MTUS or if one is attempting to rebut the MTUS’ presumption of correctness.</p>	

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	<p>the 18-month abstract as well as the two clinical publications, the Senza-RCT and the Senza-EU study [copies available upon request].</p> <p>Commenter opines that it is in the best interest of everyone, especially the patients, to consider the most current high quality, published peer-reviewed, evidence available before limiting the state’s injured workers’ treatment options for chronic low back pain. Commenter states that the Division should not eliminate this option; but rather, devise a criterion such that the most appropriate patients are the ones who gain access to this effective therapy.</p>		Disagree: See above. Patients do have access to medical treatment that is supported by high quality evidence.	None.
Chronic Pain Medical Treatment Guidelines – Omissions from ODG	<p>Commenter notes that the MTUS Chronic Pain Medical Treatment Guidelines state that they are “adapted from” and “edited from” the ODG Chronic Pain guidelines.</p> <p>Commenter provides a list referencing the edited and adapted guides from ODG that were not used in the development of the MTUS Chronic Pain Medical Treatment</p>	Robert A. McLaughlin, ESQ, APC September 1, 2015 Written Comment	Agree: Yes, that is correct. Adaptations/edits/deletions were made because the MTUS is composed of guidelines from ODG, ACOEM, the State of Colorado and internally created by the DWC. The source ODG Chronic Pain document in this rulemaking, occasionally cited other ODG chapters that are already	None.

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	<p>Guidelines.</p> <p>Commenter has the following questions regarding each ODG guide noted that was not incorporated into the MTUS Chronic Pain Management Guidelines:</p> <p>1) Why were these sections of ODG edited and adapted out of the proposed MTUS Chronic Pain Management Guidelines?</p> <p>2) What was the EBM standard used to justify the editing and adapting out the ODG guides noted in the attached document?</p>		<p>covered in the current MTUS. This rulemaking is for Chronic Pain. Amendments to any other MTUS guideline must be done in a separate rulemaking. Therefore, the DWC adapted/edited/deleted those portions and instead referred readers to the current or proposed MTUS guideline to maintain internal consistency.</p> <p>Response to Commenter’s question #1: Deletions from the source ODG document were made to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Response to Commenter’s question #2: Principle of EBM were neither used nor required in order to make deletions from the source ODG document. The deletions were made to maintain internal consistency within the treatment guidelines that form</p>	<p>None.</p> <p>None.</p>

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	<p>The following references the page number that is used for the treatment guide in the MTUS Chronic Pain Medical Treatment Guidelines, the title of the treatment modality at issue and a verbatim citing of the material in the ODG guides not incorporated into the MTUS:</p> <p>PSYCHOLOGICAL TREATMENTS</p> <p>p. 17 Antidepressants:</p> <p><u>Specifically studied underlying pain etiologies:</u> (also see below for specific drugs)</p> <p><u>Neuropathic pain:</u> Recommended both tricyclic antidepressants and SNRIs (i.e. duloxetine and venlafaxine) as first line options. (Dworkin, 2007) (Finnerup, 2007) Other recent reviews recommended tricyclic antidepressants as a first-line option, especially if pain is accompanied by insomnia, anxiety, or</p>		<p>the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #1: No substantive changes were made. The only change made between the version in the source ODG document and the proposed Chronic Pain section is the order of the first two sentences. The flipping of the order was made because SNRI's are less toxic than TCA's</p> <p>Question #2: Nothing was deleted, just a flipping of the order.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>depression. (Saarto-Cochrane, 2007) (ICSI, 2007) All first-line treatment options for neuropathic pain had an NNT of 9 or less, with the lowest NNT reported for tricyclic antidepressants, which was 4. Serotonin-noradrenaline reuptake inhibitors had an NNT of 7, but this drug class was also associated with the highest discontinuation rate of first-line drugs with a NNH of 11. Pregabalin, gabapentin, and gabapentin extended release had NNTs of 8, 7, and 9 respectively, though gabapentins had the lowest NNHs of all drugs reported (25-32). Second-line drugs tramadol and capsaicin 8% patches had moderate to low effect sizes, but only low quality evidence was available for lidocaine patches and the NNT could not be calculated. (Finnerup, 2015)</p> <p>p. 17 Antidepressants:</p> <p><i>Low Back Pain: Chronic:</i> A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain</p>		<p>Question #1: Body part specific recommendations were removed, instead readers are instructed to “Refer to MTUS Low Back Complaints” to maintain</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>(short-term pain relief), but the effect on function is unclear. This effect appeared to be based on inhibition of norepinephrine reuptake. SSRIs have not been shown to be effective for low back pain (there was not a significant difference between SSRIs and placebo) and SNRIs have not been evaluated for this condition. (Chou, 2007) Reviews that have studied the treatment of low back pain with tricyclic antidepressants found them to be slightly more effective than placebo for the relief of pain. A non-statistically significant improvement was also noted in improvement of functioning. SSRIs do not appear to be beneficial. (Perrot, 2006) <i>Acute</i>: Not routinely recommended. (Chou, 2007)</p> <p><i>Radiculopathy</i>: Antidepressants are an option, but there are no specific medications that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. (Dworkin, 2007)</p>		<p>internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See Above response.</p> <p>Question #1: Body part specific recommendations were removed, instead readers are instructed to “Refer to MTUS Low Back Complaints” to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>p. 18 Antidepressants Weaning of medications (antidepressants) in the Mental Chapter for more information and references.</p> <p>p. 35 Behavioral interventions/CBT Recommend screen for patients with risk factors for delayed recovery, including fear avoidance beliefs. See Fear-avoidance beliefs questionnaire (FABQ) in the Low Back Chapter. Initial therapy for these “at risk” patients should be physical therapy for exercise instruction, using a cognitive motivational approach to PT. Consider separate psychotherapy</p>		<p>topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: The current MTUS incorporates by reference ACOEM’s Stress Chapter not ODG’s Mental Chapter. This reference was removed to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was removed because it references ODG guidelines (Low Back Chapter, Stress/Mental Chapter, and Multi-disciplinary pain programs of ODG) that are NOT currently part of the MTUS. Instead, readers are referred to the proposed MTUS Opioids</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>CBT referral after 4 weeks if lack of progress from PT alone.</p> <p>Please refer to the ODG Psychotherapy Guidelines for further recommendations.</p> <p>Also see the Low Back Chapter, “Behavioral treatment”, and the Stress/Mental Chapter. See also Multi-disciplinary pain programs.</p> <p>p. 36 Benzodiazepines <i>Polypharmacy, sedatives & stimulants</i>: The potential for adverse outcomes increases with concurrent prescribing of medications with sedative properties; thus, concomitant prescribing of opioids, tramadol, benzodiazepenes, and other sedating medications (such as H1 blocker antihistamines) is not recommended. The prescribing of psychostimulants to combat the sedating side effects of other medications is discouraged. If a pharmacologic intervention produces side effects significant enough to warrant their own treatment, the pharmacologic intervention itself</p>		<p>Treatment Guidelines, and to the current MTUS Low Back Complaints and Stress-Related Conditions to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: The was removed because this section is extensively covered in the proposed Opioids Medical Treatment Guideline (See “Concurrent Use of Benzodiazepines and Other Sedative Hypnotics” and the DWC wanted to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p>	<p>None.</p> <p>None.</p> <p>None</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>should be considered ineffective secondary to intolerable side effects. (Atluri, 2012)</p> <p>p. 37 Biopsychosocial model of chronic pain</p> <p>See Chronic pain programs (functional restoration programs), which are recommended where there is access to programs with proven successful outcomes, for patients with conditions that put them at risk of delayed recovery, including the detailed "Criteria for use of multidisciplinary pain management programs" highlighted in blue.</p> <p><i>Definition:</i> The biopsychosocial model, first proposed by George Engel, MD, acknowledges the important interplay between the biological, psychological, and social systems in illness. While disease is defined as the objective effect of pathology, illness includes the patient's perception of lack of health. An exclusively biomedical focus on objective pathology and disease is of limited usefulness in conditions like chronic pain. A focus on the patient's</p>		<p>Question #1: This was removed because it references ODG's Mental Illness & Stress Chapter which is NOT currently part of the MTUS. Instead, readers are referred to the Introduction to the MTUS Chronic Pain Guidelines for a definition and detailed description and to the Chronic pain programs which are both a part of this rulemaking to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>illness, which includes his or her psychological reactions and social function, may lead to more effective involvement in treatment, with diminished disability, improved function, and diminished co-morbidity. The model focuses on disease and illness, with illness being viewed as an interaction of biological (physiological), psychological and social factors. Disease is defined as the objective event that involves the actual pathology. Pain is experience as a unique experience, and a range of psychological and socioeconomic factors can modulate physical pathology to affect symptoms and subsequent disability. The model is utilized in interdisciplinary pain clinics as patients with chronic pain are at increased risk for emotional disorders, maladaptive cognitions, functional deficits, nociceptive dysregulation, and physical deconditioning. See also Psychosocial adjunctive methods in the Mental Illness & Stress Chapter.</p> <p>p. 47 Chronic pain programs/FRPs</p>		<p>Question #1: This was removed because they are body part specific (Shoulder, Knee, and Neck), instead</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>Outcomes (in terms of body parts)</i></p> <p><i>Shoulder (and other upper extremity disorders):</i> This large cohort study concluded that an interdisciplinary functional restoration program (FRP) is equally effective for patients with chronic upper extremity disorders, including the elbow, shoulder and wrist/hand, as for patients with lumbar spine disorders, regardless of the injury type, site in the upper extremity, or the disparity in injury-specific and psychosocial factors identified before treatment. (Howard, 2012)</p> <p><i>Knee (and other lower extremity disorders):</i> This cohort study demonstrated that FRP was equally efficacious for patients with chronic lower extremity (LE) injuries (involving the hip, knee, ankle, and foot) and low back pain (LBP) injuries. Both patient groups significantly improved on measures of pain, disability, and depression after the FRP, and patients in both groups displayed similarly high</p>		<p>readers are referred to the corresponding MTUS Clinical Topic guideline for that body part, in addition, a reference to see the proposed MTUS Opioids Treatment Guidelines for recommendations on the use of opioids was added, to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p>	<p>None.</p>

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	<p>return-to-work and work-retention rates one year later. (Mayer, 2013)</p> <p><i>Neck (and cervical spine):</i> There are limited studies about the efficacy of chronic pain programs for neck disorders. (Karjalainen, 2003) This may be because rates of cervical claims are only 20-25% of the rates of lumbar claims. In addition, little is known as to chronicity of outcomes. Researchers using PRIDE Program (Progressive Rehabilitation Institute of Dallas for Ergonomics) data compared a cohort of patients with cervical spine disorders to those with lumbar spine disorders from 1990-1995 and found that they had similar outcomes. Cervical patients were statistically less likely to have undergone pre-rehabilitative surgery. (Wright, 1999) Interdisciplinary functional restoration programs (FRPs) are equally efficacious for treating both chronic occupational cervical and lumbar disorders, and FRPs are equally effective, irrespective of the compensable body part(s). (Hartzell, 2014)</p>		<p>Question #1: The current MTUS incorporates by reference the Low Back</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>p. 46 Chronic pain programs/FRPs dimension (psychological, social, or occupational). Back schools were not included unless they included the above criteria. There was strong evidence that intensive multidisciplinary biopsychosocial rehabilitation with functional restoration improved function when compared to inpatient or outpatient nonmultidisciplinary rehabilitation. Intensive (> 100 hours), daily interdisciplinary rehabilitation was moderately superior to noninterdisciplinary rehabilitation or usual care for short- and long-term functional status (standardized mean differences, -0.40 to -0.90 at 3 to 4 months, and -0.56 to -1.07 at 60 months). There was moderate evidence of pain reduction. There was contradictory evidence regarding vocational outcome. Less intensive programs did not show improvements in pain, function, or vocational outcomes. It was suggested that patients should not be referred to multidisciplinary biopsychosocial rehabilitation without knowing the</p>		<p>Complaints Chapter from ACOEM and has recommendations specific to that body part. The deleted section also contains recommendations for low back pain and was removed to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>actual content of the program. (Guzman, 2001) (Guzman-Cochrane, 2002) (van Geen, 2007) (Bendix, 1997) (Bendix, 1998) (Bendix2, 1998) (Bendix, 2000) (Frost, 1998) (Harkapaa, 1990) (Skouen, 2002) (Mellin, 1990) (Haldorsen, 2002)</p> <p><i>Multidisciplinary biopsychosocial rehabilitation for subacute low back pain among working age adults:</i> The programs described had to include a physical component plus ether a psychological, social and/or vocational intervention. There was moderate evidence of positive effectiveness for multidisciplinary rehabilitation for subacute low back pain and that a workplace visit increases effectiveness. The trials included had methodological shortcomings, and further research was suggested. (Karjalainen, 2003)</p> <p>p. 99 Insomnia treatment</p> <p>For more detail on Insomnia treatment, see the Mental Chapter.</p>		<p>Question #1: The current MTUS incorporates by reference the Low Back Complaints Chapter from ACOEM and has recommendations specific to that body part. The deleted section also contains recommendations for low back pain and was removed to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: To maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS, this was removed because it</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>p. 116 Muscle relaxants (for pain) Recommend non-sedating muscle relaxants with caution as a second-line option for short-term (less than two weeks) treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) See the Low Back Chapter.</p>		<p>references ODG’s Mental Illness & Stress Chapter which is NOT currently part of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was removed because it references ODG’s Low Back Chapter which is NOT currently part of the MTUS. Instead readers are instructed to “Refer to the relevant Clinical Topics section of the MTUS for recommendations” to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was removed because it contains an opioid recommendation.</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>p. 138 Opioids psychological intervention</p> <p>Recommended as an option to improve effectiveness of opioids for chronic pain.</p> <p>p. 149 Psychological evaluations See also the Stress/Mental Chapter.</p> <p>p. 155 Spinal cord stimulators See also Psychological evaluations (SCS) in the Stress & Other Mental Conditions Chapter.</p>		<p>Instead, readers are referred to the proposed MTUS Opioids Treatment Guideline to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was deleted because it references ODG's Mental Illness & Stress Guideline which is NOT currently part of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: To maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS, Stress and Other Mental Conditions Chapter is removed because it references ODG's Mental Illness & Stress</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>should be covered only when (1) is justified. An employer or their insurer shall not be liable for household tasks the injured worker’s spouse or other member of the injured worker’s household performed prior to the injury free of charge. (CMS, 2015)</p> <p>(AND)</p> <p>Personal care services and domestic care services should not be covered when there are no skilled (licensed nurse or therapist) home health services being provided.</p> <p>p. 127 NSAIDs</p> <p><i>Back Pain - Acute low back pain & acute exacerbations of chronic pain:</i> Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a</p>		<p>Non-clinical services that are medically necessary and reasonable may be provided even when there are no skilled home health services being provided.</p> <p>Question #2: This section was removed because it is contrary to the case law interpretation of Labor Code section 4600. EBM standards were not used to delete this section.</p> <p>Question #1: The current MTUS incorporates by reference the Low Back Complaints Chapter from ACOEM and has recommendations specific to that body part. The deleted section also contains recommendations for low back pain and was removed and replaced with a reference to the current MTUS Low Back Complaints to maintain</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007)</p> <p><i>Back Pain - Chronic low back pain:</i> Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and</p>		<p>internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was deleted because it references ODG's Low Back Chapter which is NOT currently part of the MTUS.</p> <p>Question #2: See above response.</p>	<p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications.</p> <p>p. 149 Psychological evaluation/treatment</p> <p>See above p. 149</p> <p>p. 179 Work conditioning, work hardening</p> <p>(10) <i>Drug problems</i>: There should be documentation that the claimant’s medication regimen will not prohibit them from returning to work (either at their previous job or new employment). If this is the case, other treatment options may be required, for example a program focused on</p>		<p>Question #1: This was deleted because it references ODG’s Mental Illness & Stress Guideline which is NOT currently part of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was deleted because it is not relevant to work hardening and is addressed in the proposed MTUS Opioids Medical Treatment Guidelines.</p> <p>Question #2: See above response.</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>detoxification.</p> <p>DIAGNOSTIC TESTS</p> <p>p. 81 Facet blocks</p> <p>See the Low Back Chapter and the Neck Chapter for criteria for diagnosis and treatment.</p> <p>p. 149 Psychological evaluations See above</p> <p>FUNCTIONAL RESTORATION</p> <p>p. 46 Chronic pain programs (2 places) See above</p>		<p>Question #1: This was deleted because it references ODG’s Low Back Chapter and Neck Chapter which is not currently part of the MTUS. Instead, readers are referred to the “MTUS Low Back Complaints and Neck and Upper Back Complaints” to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was deleted because it references ODG’s Mental Illness & Stress Guideline which is NOT currently part of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was deleted because it references ODG’s</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>p. 142 Percutaneous electrical nerve stimulation</p> <p>This RCT concluded that both PENS and therapeutic exercise for older adults with chronic low back pain significantly reduced pain. (Weiner, 2008) See also TENS.</p>		<p>Low Back Chapter which is NOT currently part of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: The current MTUS incorporates by reference the Low Back Complaints Chapter from ACOEM and has recommendations specific to that body part. The deleted section also contains recommendations for low back pain and was removed to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p>	<p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>p. 158 TENS, chronic pain</p> <p><u>Recommendations for specific body parts</u> (See specific body-part chapters below):</p> <p><u>Low back</u>: Not recommended as an isolated intervention</p> <p><u>Knee</u>: Recommended as an option for osteoarthritis as adjunct treatment to a therapeutic exercise program</p> <p><u>Neck</u>: Not recommended as a primary treatment modality for use in whiplash-associated disorders, acute mechanical neck disease or chronic neck disorders with radicular findings</p> <p><u>Ankle and foot</u>: Not recommended</p> <p><u>Elbow</u>: Not recommended</p> <p><u>Forearm, Wrist and Hand</u>: Not recommended</p> <p><u>Shoulder</u>: Recommended for post-</p>		<p>Question #1: The current MTUS incorporates by reference the Low Back Complaints Chapter from ACOEM and has recommendations specific to that body part. The deleted section also contains recommendations for low back pain and was removed and replaced with a reference to the MTUS Low Back Complaints to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was removed because they are body part specific (Low back, Knee, Neck, Ankle and foot, Elbow, Forearm, Wrist and Hand, and Shoulder), instead</p>	<p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>stroke rehabilitation</p> <p>p. 159 TENS, chronic pain</p> <p><u>Current Treatment Coverage Guidelines:</u></p> <p>- <i>BlueCross BlueShield</i>: TENS is considered investigational for treatment of chronic back pain, chronic pain and post-surgical pain, but is covered for certain members based on CMS rules. (BlueCross BlueShield, 2007)</p> <p>- <i>CMS</i>: The use of TENS for the relief of acute post-operative pain is covered for 30 days or less (as an adjunct and/or alternative to pharmaceutical treatment). TENS is also covered as treatment for chronic intractable pain. Medicare requires a month-long trial period in order to determine if there is a significant</p>		<p>readers are referred to the corresponding “MTUS chapters on specific body parts” to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This was removed to reduce confusion to the reader because they contain recommendations regarding medical necessity that are supported by documents expressing policy positions. For example, Jaques, 2012 makes a blanket prohibition against the use of TENS and DWC does not intend any blanket prohibitions. Policy position documents, although at best, may be considered very low-level evidence, are not even</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>therapeutic effect. (Medicare, 2006) On June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) issued an updated decision memo concluding that TENS is not reasonable and necessary for the treatment of chronic low back pain based on a lack of quality evidence for its effectiveness. Coverage is available only if the beneficiary is enrolled in an approved clinical study. (Jacques, 2012)</p> <p>- <i>Aetna & Humana</i>: consistent with the CMS Guidelines (Aetna, 2005) (Humana, 2004)</p> <p>- VA: TENS is considered equivocal when compared to other modalities. (US Dept. VA, 2001)</p> <p>- <i>European Federation of Neurological Societies (EFNS)</i>: TENS may be better than placebo (level C) although worse than electroacupuncture (level B); TENS is non-invasive and suitable as a preliminary or add-on therapy. (Cruccu, 2007)</p> <p>Criteria for the use of TENS:</p>		<p>included in the MTUS' EBM standard set forth in 8 CCR section 9792.25.1. The recommendations supported with higher-level evidence pertaining to the use of TENS, in Chronic Pain, however, were left in place.</p> <p>Question #2: The EBM standard is set forth in 8 CCR section 9792.25.1 and policy position documents published by BlueCross, BlueShield, CMS, Aetna & Humana, US Veterans Administration, and the European Federation of Neurological Societies are not included in the MTUS' EBM standard set forth in 8 CCR section 9792.25.1. Policy position documents may, at best, be considered very low-level evidence. <i>Note: not all policy position documents contain recommendations pertaining to medical necessity, some policy position document citations were left in the proposed</i></p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>Chronic intractable pain</i> (for the conditions noted above):</p> <p>(1) Documentation of pain of at least three months duration</p> <p>(2) There is evidence that other appropriate pain modalities have been tried (including medication) and failed</p> <p>(3) A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial</p> <p>(4) Other ongoing pain treatment should also be documented during the trial period including medication usage</p> <p>(5) A treatment plan including the specific short- and long-term goals of treatment with the TENS unit should</p>		<p><i>guideline because they are only informational in nature.(See pages 261-262)</i></p>	

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	<p>be submitted</p> <p>(6) After a successful 1-month trial, continued TENS treatment may be recommended if the physician documents that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. At this point purchase would be preferred over rental.</p> <p>(7) Use for acute pain (less than three months duration) other than post-operative pain is not recommended.</p> <p>(8) A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessary</p> <p><i>Form-fitting TENS device:</i> This is only considered medically necessary when there is documentation that there is such a large area that requires stimulation that a conventional system cannot accommodate the treatment, that the patient has medical conditions (such as skin pathology)</p>			

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>that prevents the use of the traditional system, or the TENS unit is to be used under a cast (as in treatment for disuse atrophy)</p> <p>p. 179 & 180 Work conditioning, work hardening</p> <p>See above p. 179</p> <p>FUNCTIONAL RESTORATION TREATMENTS</p> <p>p. 81 Physical Therapy</p> <p>An educational technique known as the Alexander technique, along with exercise, is effective for long-term relief of chronic low back pain, according to the results of a randomized trial reported in the BMJ. (Little, 2008)</p>		<p>Question #1: See Above.</p> <p>Question #2: See above response.</p> <p>Question #1: This phrase was removed “is effective for long-term relief of chronic low back pain, according to the results of a randomized trial reported in the BMJ. Lessons in the Alexander technique...” was removed because it contains recommendations for low back pain and was removed to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: This is removed</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>p. 109 Manual therapy & manipulation (2 separate categories in ODG combined for MTUS)</p> <p>Recommended for chronic pain if caused by musculoskeletal conditions, only when manipulation is specifically recommended by the provider in the plan of care, if also recommended as an option in the Low Back Chapter and the Neck Chapter. (For more information and references, see those chapters.) Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. Manipulation under anesthesia is not recommended. See also specific body-part chapters below:</p> <p>Low back: Recommended as an option. <i>Therapeutic care</i> – Trial of 6 visits over 2 weeks, with evidence of objective functional improvement, total of up to 18 visits over 6-8 weeks. <i>Elective/maintenance care</i> –</p>		<p>because it references ODG’s Low Back Chapter and Neck Chapter neither of which are in the current MTUS. In addition, it provides recommendations to other specific body parts (Head, Hip, Elbow, Shoulder, Ankle & Foot, Forearm, Wrist, & Hand, and Knee) and for Carpal tunnel syndrome all of which are currently covered in the specific body-part chapters in the MTUS. Readers are instructed to “See also specific body-part chapter in the MTUS” to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Not medically necessary. <i>Recurrences/flare-ups</i> – Need to re-evaluate treatment success, if RTW achieved then 1-2 visits every 4-6 months.</p> <p><u>Neck and upper back:</u> Recommended as an option. See chapter for specific recommendations according to condition.</p> <p><u>Head:</u> Recommended for the prophylactic treatment of headaches (not a chronic pain treatment).</p> <p><u>Hip:</u> Recommended as an option. See chapter for specific recommendations according to condition.</p> <p><u>Elbow:</u> Recommended only on a short-term limited basis. See chapter for specific recommendations according to condition.</p> <p><u>Shoulder:</u> Recommended as an option. See chapter for specific recommendations according to condition.</p> <p><u>Ankle & Foot:</u> Not recommended.</p>			

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><u>Carpal tunnel syndrome:</u> Not recommended.</p> <p><u>Forearm, Wrist, & Hand:</u> Not recommended.</p> <p><u>Knee:</u> Not recommended. (AND)</p> <p>More information from the Low Back Chapter (see that chapter for more references):</p> <p><i>Number of Visits:</i> Several studies of manipulation have looked at duration of treatment, and they generally showed measured improvement within the first few weeks or 3-6 visits of chiropractic treatment, although improvement tapered off after the initial sessions. If chiropractic treatment is going to be effective, there should be some outward sign of subjective or objective improvement within the first 6 visits.</p> <p><i>Active Treatment versus Passive Modalities:</i> Manipulation is a passive treatment, but many chiropractors also perform active treatments, and these recommendations are covered</p>		<p>Question #1: This is removed because it provides recommendations to the low back all of which are currently covered in the specific body-part chapters in the MTUS. Readers are instructed to “See also specific body-part chapter in the MTUS” to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>under Physical therapy (PT), as well as Education and Exercise. The use of active treatment modalities instead of passive treatments is associated with substantially better clinical outcomes. (Fritz, 2007) Active treatments also allow for fading of treatment frequency along with active self-directed home PT, so that less visits would be required in uncomplicated cases.</p> <p><i>Current Research:</i> A recent comprehensive meta-analysis of all clinical trials of manipulation for low back conditions has concluded that there was good evidence for its use in acute, sub-acute, and chronic low back pain, while the evidence for use in radiculopathy was not as strong, but still positive. (Lawrence, 2008) A Delphi consensus study based on this meta-analysis has made some recommendations regarding chiropractic treatment frequency and duration for low back conditions. They recommend an initial trial of 6-12 visits over a 2-4 week period, and, at the midway point as well as at the end of the trial, there should be a</p>		<p>Question #1: This is removed because it provides recommendations to the low back all of which are currently covered in the specific body-part chapters in the MTUS. Readers are instructed to “See also specific body-part chapter in the MTUS” to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>formal assessment whether the treatment is continuing to produce satisfactory clinical gains. If the criteria to support continuing chiropractic care (substantive, measurable functional gains with remaining functional deficits) have been achieved, a follow-up course of treatment may be indicated consisting of another 4-12 visits over a 2-4 week period. According to the study, “One of the goals of any treatment plan should be to reduce the frequency of treatments to the point where maximum therapeutic benefit continues to be achieved while encouraging more active self-therapy, such as independent strengthening and range of motion exercises, and rehabilitative exercises. Patients also need to be encouraged to return to usual activity levels despite residual pain, as well as to avoid catastrophizing and overdependence on physicians, including doctors of chiropractic.” These recommendations are consistent with the recommendations in ODG, which suggest a trial of 6 visits, and then 12 more visits (for a total of 18) based</p>			

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>on the results of the trial, except that the Delphi recommendations in effect incorporate two trials, with a total of up to 12 trial visits with a re-evaluation in the middle, before also continuing up to 12 more visits (for a total of up to 24). Payers may want to consider this option for patients showing continuing improvement, based on documentation at two points during the course of therapy, allowing 24 visits in total, especially if the documentation of improvement has shown that the patient has achieved or maintained RTW. (Globe, 2008) The latest project completed by the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) addresses chiropractic management of the chronic pain patient. The CCGPP guideline provides clear case management suggestions and dosing recommendations when confronted with the patient suffering ongoing chronic pain after treatments that exceed ODG recommendations. Chiropractic management may be more beneficial, safer, and rendered at much lower costs, compared to</p>			

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	<p>narcotics or invasive medical procedures to control chronic pain. (Farabaugh, 2010) The CCGPP guideline includes specific chronic care dosing recommendations: (1) Mild exacerbation: 1-6 visits per episode, with re-evaluation at beginning of each episode; (2) Scheduled ongoing care: 1-4 visits per month, with re-evaluation at minimum every 12 visits, or as necessary to document condition changes; (3) Moderate or severe exacerbation should follow acute care guidelines [in Low Back Chapter], with re-evaluation every 2-4 weeks, as outlined in acute care guidelines. (Farabaugh2, 2010) This Cochrane review concluded that chiropractic manipulation appears to be as effective as other commonly used approaches for treating chronic low back pain. (Rubinstein, 2011) This RCT found that maintenance spinal manipulation, every 2 weeks for the following 9 months after the initial intensive manipulative therapy, was the best option to improve pain and disability scores at the 10-month evaluation. (Senna, 2011) In this</p>			

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	<p>study the use of ‘health maintenance care’ for work-related low back pain (i.e., continued provider visits to prevent recurrences after resolution and return to work), the disability recurrence rate was higher for physical therapists (16.9%) or physicians (12.5%), than for chiropractors (6.5%) or no treatment (5.5%), suggesting that there may be value in ongoing chiropractic care beyond the initial period of treatment, at least compared to other types of providers. (Cifuentes, 2011) This updated Cochrane review, which used the latest methodology for determining the quality of the evidence of effectiveness, demonstrates that spinal manipulative therapy has a small advantage compared with other recommended therapies like exercise, standard medical care and physical therapy for the management of chronic low back pain. (Bronfort, 2012) An RCT to determine the optimal number of visits for spinal manipulation for chronic LBP found that either 12 or 18 are best, depending on time frame, with 18 best after a year. (Haas,</p>		<p>Question #1: This is removed because it provides</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>2013)</p> <p>p. 109 Manual therapy & manipulation (from ODG Manual therapy)</p> <p>See Physical medicine treatment. The use of active treatment instead of passive modalities is associated with substantially better clinical outcomes. The most commonly used active treatment modality is Therapeutic exercises (97110), but other active therapies may be recommended as well, including</p> <p>Neuromuscular reeducation (97112), Manual therapy (97140), and Therapeutic activities/exercises (97530).</p> <p>p. 179 Work conditioning, work hardening</p> <p>See p. 179 above</p>		<p>recommendations to the low back all of which are currently covered in the specific body-part chapters in the MTUS. Readers are instructed to “See also specific body-part chapter in the MTUS” to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Question #2: See above response.</p> <p>Question #1: See above response.</p> <p>Question #2: See above response</p>	<p>None.</p> <p>None.</p> <p>None.</p>
Chronic Pain Medical Treatment Guidelines - Acupuncture	Commenter opines that the Administrative Director will receive a great deal of testimony regarding the dangers of pain medications and	Matthew Bauer, President The Acupuncture Now Foundation	Agree in part; Disagree in part: Agree: Acupuncture is already approved for use within the MTUS.	None.

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	<p>compelling testimony regarding the relief from suffering these medications can bring. Commenter requests that the Division consider that there is a completely drug-free alternative form of therapy – acupuncture – that is already approved for use within the MTUS and opines that this should be greatly expanded.</p> <p>Commenter states that there have been two landmark studies, one conducted in Germany⁷ and paid for by their insurance industry the second in the U.S.⁸ and funded by a grant from the National Institutes of Health, that both found acupuncture to be roughly twice as effective as “conventional care” for the treatment of chronic low back pain. The “conventional care” these studies</p>	<p>September 1, 2015 Written Comment</p>	<p>Disagree: The DWC disagrees with commenter’s suggestion that recommendations for the use of acupuncture should be greatly expanded. Content for acupuncture is found in the current MTUS Acupuncture Guidelines. Content pertaining to opioids in the MTUS Chronic Pain guideline were largely removed and are now addressed in the new MTUS Opioids Treatment guideline. Acupuncture is addressed in Section 3.2 ”Consideration of Alternative Treatments for Chronic Pain and Chronic Opioid Treatment” where it states: “Non-opioid alternative therapies for pain treatment should be tried whenever possible before resorting to</p>	

⁷ *Haake M, Müller HH, Schade-Brittinger C, et al. German acupuncture trials (GERAC) for chronic low back pain.* Arch Intern Med. 2007;167(17):1892-1898. At 6 months, positive response rate was 47.6% in the real acupuncture group, 44.2% in the sham acupuncture group, and 27.4% in the conventional therapy group.

⁸ *Cherkin D, Sherman K, Avins A, et al. A randomized trial comparing acupuncture, simulated acupuncture, and usual care for chronic low back pain.* Arch Intern Med. 2009;169(9):858-866 At eight weeks, mean dysfunction scores for the first three groups (individualized acupuncture, standardized acupuncture, simulated acupuncture) were 4.5, 4.5, and 4.4 points compared to 2.1 points for conventional care. Symptoms improved by 1.6 to 1.9 points in the first three groups and 0.7 in the conventional care group.

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	<p>referred to include the use of pain medications, especially opioid medications, and chronic low back pain is the leading condition for which those medications are prescribed.</p> <p>Commenter states that taken together, these studies should be seen as a major breakthrough in addressing the policies under consideration by your agency: Two high quality studies showing a safe, drug-free alternative to be twice as effective as the drugs that have health experts so alarmed in the treatment of the most common condition for which those drugs are prescribed. Commenter states that none of our public health officials have seemed aware of this good news as expanding the role acupuncture can play in combating this drug epidemic is virtually never mentioned⁹ Commenter notes that the current MTUS has the following guideline for the use of acupuncture:</p> <p><i>§ 9792.24.1. Acupuncture Medical</i></p>		<p>chronic opioid therapy (references cited) and, “in addition these treatment modalities should be continued even if opioids are used for relieving chronic pain: Complementary/alternative modalities, such as acupuncture, massage, and yoga. (references cited)”</p> <p>In addition, this rulemaking is to updated the Chronic Pain Medical Treatment Guidelines and add the Opioids Treatment Guidelines to the MTUS. As already stated, the MTUS currently has an Acupuncture Guidelines but any change to that guideline needs to be done in a separate rulemaking.</p>	

⁹ *CDC Publication Prescription Drug Overdose-Understanding the Epidemic*

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	<p><i>Treatment Guidelines.</i></p> <p><i>(a) As used in this section, the following definitions apply:</i></p> <p><i>(1) “Acupuncture” is used as an option when pain medication is reduced or not tolerated...</i></p> <p>Commenter questions why a safer, drug-free therapy shown to be twice as effective as conventional care only be used as an “option” when “pain medication is reduced or not tolerated”? Commenter requests that the MTUS guidelines be changed to allow acupuncture to be used as a first-line therapy before opioids or other pain medications are prescribed. Commenter opines that it makes no sense for the twice as effective drug-free therapy to be relegated to an “option” after drugs.</p> <p>Commenter cites the following from a recent study published in the British Journal of Medicine¹⁰:</p> <p><i>“In the United States, opioid</i></p>			

¹⁰ BMJ 2015; 350 doi: <http://dx.doi.org/10.1136/bmj.g6380> (Published 05 January 2015)
Cite this as: BMJ 2015;350:g6380

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	<p><i>prescription for low back pain has increased, and opioids are now the most commonly prescribed drug class. More than half of regular opioid users report back pain.”</i></p> <p>Commenter cites that following from a 2007 Cochrane Database systematic review on opioid studies¹¹:</p> <p><i>“Based on our results, the benefits of opioids in clinical practice for the long-term management of chronic LBP remain questionable.”</i></p> <p>Commenter cites that following quote from a CDC publication “Prescription Drug Overdose-Understanding the Epidemic”:</p> <p><i>“In recent years, there has been a dramatic increase in the acceptance and use of prescription opioids for the treatment of chronic, non-cancer pain, such as back pain or osteoarthritis.” “People who take prescription painkillers can become</i></p>			

¹¹ *Cochrane Database Syst Rev. 2007 Jul 18;(3):CD004959.Opioids for chronic low-back pain.*
Deshpande A1, Furlan A, Mailis-Gagnon A, Atlas S, Turk D.

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	<p><i>addicted with just one prescription. Once addicted, it can be hard to stop.”</i></p> <p>Commenter states that the current MTUS guidelines only allow for the option of acupuncture after the use of these dangerous medications and is encouraging the use of a therapy found to be only half as effective as acupuncture which can lead to addiction after just one round of prescription! Commenter opines that perhaps the Administrative Director or others within the Division of Workers’ Compensation or the Department of Industrial Relations are unaware of the research on acupuncture presented here or there may be confusion over exactly how acupuncture works¹². Commenter</p>		<p>Disagree: Acupuncture is already approved for use within the MTUS and may be approved before the use “of these dangerous medications”. See above response.</p>	<p>None.</p>

¹² While the so-called “real” (verum) acupuncture did not significantly outperform the so-called “sham” acupuncture in the German and U.S. chronic low back pain studies, we believe this was due to under-treating with acupuncture, i.e. an inadequate “dosage”. Several recent studies have found the frequency and duration of acupuncture plays a major role in its effectiveness. We believe if the acupuncture done in those studies had been done at the appropriate dosage, the “real” acupuncture would have been THREE times more effective than conventional care as that is what experienced Acupuncturists see in practice. A large randomized controlled trial published in The Lancet found that acetaminophen, the most frequently used pain medication in the world, is no more effective than a placebo for managing acute lower back pain and it is known to cause serious side-effects. Given the seriousness of the opioid epidemic, the fact that the world’s most popular pain medication does not outperform placebo, and the call for exploring safer

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	requests that now that this compelling evidence of a safer and more effective therapy has been brought to your attention that the DWC modifies the treatment guidelines to encourage the use of acupuncture in fighting the epidemic of opiate abuse by enhancing the application of acupuncture to ease the suffering of injured workers.			
Opioid Medical Treatment Guidelines –	Commenter supports the value of setting reasonable limits on opioid use, and of encouraging prescribers to	Robert Blink, MD Occupational & Environmental	Agree: We appreciate the support.	None.

alternatives, we see no reason to hold back on acupuncture; the safer and more effective alternative, just because some questions remain about its exact mode of action.

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General Comment	<p>use validated tools to manage pain and to attempt decrease and cessation of opioids, as well as to document function. Commenter appreciates the comprehensive research overview and opines that the DWC should be complimented on this work.</p> <p>Commenter requests that the DWC attend to the realities of the effects of these proposed Guidelines on real-life clinical practice, including the resource requirements of time and systems revisions. Commenter recommends that the DWC work to minimize negative impacts on such areas as emergency departments and busy clinics by ensuring that the guidelines are clear, unambiguous, practical to use, and available for implementation without significant cost to providers.</p> <p>Commenter opines that before the guidelines are implemented, CURES should be verified as quickly accessible in actual practice, and there should be reasonable methods to allow smooth provision of needed care in the unusual circumstance where CURES is not functioning or</p>	Medicine Physicians September 1, 2015 Written Comment	<p>Agree: The DWC strives to make the proposed Chronic Pain Medical Treatment Guidelines and Opioids Treatment Guidelines clear, unambiguous, practical to use and available for implementation without significant costs. In fact, both of these guidelines, once effective, will be available for public viewing in the DWC's website free of charge.</p> <p>Disagree: California's Department of Justice has plans on upgrading CURES. It's our understanding that the upgrade will launch in January of 2016 and will be completed by July 2016.</p>	<p>None.</p> <p>None.</p>

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	<p>temporarily unavailable to a clinician.</p> <p>Commenter states that attention is needed to ensure that providers, including those who seldom provide care in the Workers' Compensation system, but are vital to occasional cases (such as dentists, ENT, OB-GYN, etc.) are not needlessly discouraged from participating in the system. This may require some sort of ad hoc assistance system. Commenter supports and implementation that will not harm patients or make the functioning of the system significantly more complex than it already is.</p>		<p>Agree: The DWC strives to make the proposed Chronic Pain Medical Treatment Guidelines and Opioids Treatment Guidelines clear, unambiguous, practical to use and available for implementation without significant costs. In fact, both of these guidelines, once effective, will be available for public viewing in the DWC's website free of charge. In addition, the DWC will be providing on-line physician training that will be launched Summer of 2016.</p>	<p>None.</p>
<p>Opioid Medical Treatment Guidelines – Executive Summary – Part 1</p>	<p>Commenter cites the following sentence from Page 1, Paragraph 2:</p> <p><i>“A key difference between occupational and non-occupational guidelines is that a main goal of the former is the restoration of function to ensure early return to work.”</i></p> <p>Commenter notes that this statement appears to endorse some sort of basic</p>	<p>Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree: Agree that function should be considered in any pain guideline, whether for occupational or non-occupational patients. Disagree: That there is no difference. The clinical guidelines used in the development of the proposed Opioids Medical Treatment</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>difference in optimal treatment between occupational and non-occupational guidelines. Commenter opines that this distinction may historically have been followed, but lacks scientific or practical validity. Commenter states that any pain guidelines should pay attention to function, whether work-related or otherwise.</p>		<p>Guidelines is based and derived from clinical guidelines developed for working age adults. The statement is also intended to emphasize the importance of function and return to work as clinical endpoints. In addition, definitions of function beyond activities of daily living may differ in other populations, e.g. pediatric or geriatric.</p>	
<p>Opioid Medical Treatment Guidelines – Executive Summary – Part 1</p>	<p>Commenter cites the following sentence from Page 2, Paragraph 2: <i>Central nervous system depressants, including anti-histamines, benzodiazepines, and alcohol, should not be used simultaneously with opioids and should be discontinued before prescribing opioid medication.</i></p> <p>Commenter states that antihistamine and benzodiazepine use should be markedly limited with opioids but there should be some leeway in certain situations, including patients who require such other medications for other reasons (e.g. allergies, neurologic conditions, psychiatric</p>	<p>Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree: Use should be limited but there should be some leeway in certain situations. Disagree: The DWC disagrees with commenter’s implication that there is an absolute restriction. The intention is to provide a strong warning against the concomitant use of antihistamine and benzodiazepines as the risks of overdose are significant.</p> <p>MTUS guidelines are not intended to provide a blanket prohibition, but the patient characteristics and reasoning</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>conditions). While uncommon, commenter states that clinical judgment must be employed. Commenter opines that an absolute restriction risks patient harm.</p>		<p>for prescribing CNS depressants and opioids should be carefully documented.</p>	
<p>Opioid Medical Treatment Guidelines – Executive Summary – Part 1</p>	<p>Commenter cites the following sentence from Page 2, Paragraph 3:</p> <p><i>Patients should be cautioned about the potential adverse effects of opioids, including impacts on alertness. Driving and operation of heavy equipment should be discouraged while on these medication</i></p> <p>Commenter opines that while driving should be discouraged while taking opioids in many situations, there are some patients on stable doses without side effects who can drive without increased risk. Commenter recommends using modifiers in this paragraph to make this less than an absolute proscription, subject to careful expert clinical assessment on a case-by-case basis.</p>	<p>Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment</p>	<p>Disagree: The proposed MTUS Opioids Treatment Guideline is not meant to be proscriptive, as reflected in the use of the word “should” instead of “shall not”. If the DWC meant this to be an absolute proscription, it would have used the language “shall not” drive.</p>	<p>None.</p>
<p>Opioid Medical Treatment Guidelines –</p>	<p>Commenter cites the following sentence from Page 2, Paragraph 7:</p>	<p>Robert Blink, MD Occupational & Environmental</p>	<p>Disagree: The text defines opioid-naïve as “those who have not previously been</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Executive Summary – Part 1	<p><i>Opioid-naïve patients (those who have not previously been treated with opioids) with acute pain treatment receiving medically necessary treatment with opioid medication should not receive doses above 80 mg/day morphine equivalent dose (MED).</i></p> <p>Commenter opines this sentence is confusing as the truly opioid naive patient (even with a past history of opioid use, should be started at a low dose with a slow increase (“start low, go slow”). Commenter states that the opioid naive patient should never be started on 80 mg/day MED. Commenter recommends defining “opioid naïve” patients more clearly – he questions if this refer to those who have never taken opioids, those who have never taken high-dose opioids, or those who have not taken opioid in the past six weeks, or some other definition.</p>	Medicine Physicians September 1, 2015 Written Comment	treated with opioids” and is part of the Executive Summary intended to be a summary which does not contain details included in the “Recommendations” portion of this proposed guideline. In addition, taken in context of the Executive Summary, it is clear that the intention is to start low and 80 mg/day MED mg/day MED would not be the recommended initial dose in an opioid-naïve patient.	
Opioid Medical Treatment Guidelines – Executive Summary – Part 1	<p>Commenter cites the following sentence from Page 3, Paragraph 9:</p> <p><i>Results of periodic urine drug testing (at point of care initially and verified</i></p>	Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015	Disagree: Commenter states “that this limits drug screening to four times yearly in all situations” and suggests language to remove this	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>by a federally certified laboratory) performed on a random basis two to four times a year during chronic treatment, and if the provider is concerned about misuse, abuse, or diversion.</i></p> <p>Commenter notes that this limits drug screening to four times yearly in all situations, but he opines that there are some circumstances where additional testing is in fact needed, as reflected on pages 44 and 45, including Table 2l.</p> <p>Commenter recommends the following revised language:</p> <p><i>“Results of periodic urine drug testing (at point of care initially and verified by a federally certified laboratory) performed on a random basis two to four times a year during chronic treatment, and <u>more frequently if the provider is concerned</u> has justified concerns about misuse, abuse, or diversion.”</i></p>	Written Comment	limitation. Commenter’s suggested language is unnecessary because the phrase “and if the provider is concerned about misuse, abuse, or diversion” already makes clear that a physician may conduct additional drug screening under these circumstances.	
Opioid Medical Treatment Guidelines –	Commenter cites the following sentence from Page 4, Paragraph 3:	Robert Blink, MD Occupational & Environmental	Agree in part; Disagree in part: Agree: Methadone needs to be prescribed by a specialist.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Executive Summary – Part 1	<p><i>Methadone may be indicated for specific types of patients and should be initiated, titrated, and monitored cautiously by providers who have substantial experience with its use and risks.</i></p> <p>Commenter opines that this statement should be accompanied by a warning that methadone, more than any other of the prescribed opioids, has been associated with overdose deaths.</p>	Medicine Physicians September 1, 2015 Written Comment	Disagree: that additional safety language needs to be included in the Executive Summary because it is only a summary. There is a clear, bold warning in the Recommendations sections that discusses methadone and also references Appendix D which is a Black Box Warning, Methadone. This section, bolded, provides a strong warning, here in part: “Deaths, cardiac and respiratory have been reported during ignition and conversion of pain patients to methadone treatment from treatment with other opioid agonists. It is critical to understand the pharmacokinetics of methadone when converting patients from other opioids...” .	
Opioid Medical Treatment Guidelines – Executive	<u>Commenter cites Column 1, “Injury Type”</u> , top box: (e.g., strains, tendonitis, repetitive strain injuries)	Robert Blink, MD Occupational & Environmental Medicine Physicians	Disagree: This Summary separates the severity of the acute pain from Mild, Moderate to Severe, to Severe	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Summary – Part 1 – Summary Recommendations – Opioids for Acute Pain	Commenter notes that the term “repetitive strain” is not defined. Commenter notes that this refers to a supposed etiology, not physiology; and includes spine disorders that may be Moderate to Severe. In addition, some extremity disorders that would fit this category would include shoulder tendinitis e.g., that could require opioids for sleep in some situations. Commenter recommends not using this term as an example.	September 1, 2015 Written Comment	and is not meant to refer to the physiology of the injury so the use of the phrase “repetitive strain” is appropriate. In addition, this is a Summary chart intended to provide a quick, general overview not the details commenter is suggesting.	
Opioid Medical Treatment Guidelines – Executive Summary – Part 1 – Summary Recommendations – Opioids for Acute Pain	<u>Commenter cites Column 5, #3 Bullet 5 (under “Best Practices If Opioids Used”):</u> <i>Lowest effective dose, No higher than 80mg/day MED.</i> Commenter opines that 80 mg/day is much too high to start in most cases.	Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment	Disagree: When this is read in context, the sentence would read, “Prescribe only lowest effective dose, no higher than 80 mg/day MED” which means start with the lowest effective. 80 mg/day MED would not be the recommended initial dose for a patient in most cases.	None.
Opioid Medical Treatment Guidelines – Executive Summary – Part 1 – Summary	Commenter states that this page should be split into two separate pages for the two separate charts that are displayed here as if they are one table. Commenter opines that this is very confusing and will mislead	Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment	Disagree: Both sections apply to Opioids for Acute Pain and are posted on one page for ease of use. Rows are sufficiently offset to distinguish the two portions of the table.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Recommendations – Opioids for Acute Pain	many reviewers into believing that there was some continuity between the two halves of the “Table” when there is not.			
Opioid Medical Treatment Guidelines – Executive Summary – Part 1 – Summary Recommendations – Opioids for Post-Operative Pain	<p><u>Commenter cites Col 1, Bullet 2:</u> <i>Wean patient off benzodiazepines and other sedative-hypnotics</i></p> <p>Commenter opines that while this is usually correct, this should be modified to reflect that such measures must be medically appropriate based on careful clinical judgment. Commenter states that making this a blanket statement is unwise.</p>	Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment	Disagree: The intention is to provide a strong warning against the concomitant use of antihistamine and benzodiazepines as the risks of overdose are significant. Again, this is a Summary chart intended to provide a quick, general overview not to replace the Recommendations section which contains clear language that careful consideration must be taken when making this clinical decision.	None.
Opioid Medical Treatment Guidelines – Executive Summary – Part 1 – Summary Recommendations – Opioids for Subacute Pain	<p><u>Commenter cites all four footnotes below the “Table”</u></p> <p>Commenter opines that this makes it look like the intent is to require usage of these specific instruments and nullify the utility of any other instruments. Commenter states that while there is a clear need to use only tools that fulfill the purpose and have</p>	Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment	Disagree: The tools described in the Summary tables are only examples, as is explained in chapter 3.3.5 Use of Tools. The intent is to describe the characteristics and use of evidence-based tools. Use of any specific assessment tool is not mandatory.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>good literature to support such use, forcing the use of these instruments even in the face of equivalent or superior assessment measures (e.g. complex psychological evaluation) is unnecessary and potentially counterproductive. Commenter recommends a revision recommending these tools, or similar measures that have been validated in peer-reviewed studies, but may not be required if more exhaustive assessment has been done appropriately such as more thorough psychological testing that includes assessment of the relevant issues.</p>		<p>Section 2. Opioids for Subacute Pain (1-3 Months) states: “Screen for risk using validated tools if medically indicated, if this has not already been done in the acute pain phase. (See Section 3.3.5, Use of Tools to Monitor Patients on Chronic Opioid Treatment). During the subacute pain phase, a consult with a pain specialist may be obtained for complex management and/or if warranted based on clinical evaluation. (See Section 6. Consultation with Specialists).” Section 6. includes consultation with psychiatry/behavioral medicine, and addiction medicine as well as pain specialists.</p>	
<p>Opioid Medical Treatment Guidelines – Executive Summary – Part 1 – Summary</p>	<p><u>Commenter cites all four footnotes below the “Table”</u></p> <p>Commenter opines that this makes it look like the intent is to require usage of these specific instruments and</p>	<p>Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment</p>	<p>Agree in part; Disagree in part Agree: that duplication is not required. Disagree: that the proposed guideline states that it is required. The Summary table</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Recommendations – Opioids for Chronic Pain	nullify the utility of any other instruments. Commenter states that while there is a clear need to use only tools that fulfill the purpose and have good literature to support such use, forcing the use of these instruments even in the face of equivalent or superior assessment measures (e.g. complex psychological evaluation) is unnecessary and potentially counterproductive. Commenter recommends a revision recommending these tools, or similar measures that have been validated in peer-reviewed studies, but may not be required if more exhaustive assessment has been done appropriately such as more thorough psychological testing that includes assessment of the relevant issues.		is designed to give a quick overview; it is not intended to replace the more detailed sections that follow. It is not necessary to duplicate assessment already provided by a psychologist or psychiatrist. See response above.	
Opioid Medical Treatment Guidelines – Executive Summary – Part 1	<p>Commenter cites the following sentence from Page 10, Paragraph 2:</p> <p><i>Some injured workers may require opioids for the management of their acute or chronic pain. It is not the intention of the Opioids Treatment Guidelines to restrict proper medical use of opioids. However safe and responsible prescribing is necessary</i></p>	Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment	<p>Agree in part; Disagree in part:</p> <p>Agree: this is an important concept.</p> <p>Disagree: This is sufficiently emphasized in the guideline and the commenter’s recommendation to bold this sentence is unnecessary.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>to avoid unintended consequences, including prolonged disability and iatrogenic morbidity and mortality.</i></p> <p>Commenter strongly agrees with this statement. Recommends that this should be in BOLD type.</p>			
Opioid Medical Treatment Guidelines – Executive Summary – Part 1	<p><u>Commenter cites the following sentence from Page 21 Section 2. A.</u></p> <p><i>a. Doses for opioid-naïve patients should not exceed 80 mg/day morphine equivalent dosage (MED). [77, 88, 89] (See Section 3.3.8, Opioid Titration and Dosing Threshold)</i></p> <p>Commenter recommends that the opioid naive patient should not be started on anywhere near 80 MED.</p>	Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment	Disagree: When read in context, it is clear that opioid naïve patients should not be started on 80 mg/day MED. The sentence directly above the sentence commenter quotes states, “Prescribe weaker opioids and the lowest effective dose. Stronger opioids may be considered only if weaker ones are ineffective or not tolerated.” The intent is to start low and 80 mg/day MED would not be the recommended initial dose in an opioid-naïve patient. However, this section addresses acute pain treatment, and a fairly rapid escalation of dose may initially be required to control pain.	None.
Opioid Medical	<u>Commenter cites the following</u>	Robert Blink, MD	Disagree: This is an evidence-	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatment Guidelines – Executive Summary – Part 1	<p><u>sentence from Page 21 Section 3.</u></p> <p><i>3. Prescribe opioids at night or when the patient is not at work. [89]</i></p> <p>Commenter stats that there is a need to be careful with driving and at work but might not be an issue if no side-effects.</p>	Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment	based recommendation. The full impact of opioid treatment on reaction time of reflexes, concentration, and other factors involved in driving and working may be difficult to accurately assess, so caution should be used. This recommendation needs to be evaluated on a case by case basis, as with any other recommendation in this proposed guideline.	
Opioid Medical Treatment Guidelines – Executive Summary – Part 1	<p><u>Commenter cites the following sentence from Page 34 Section 5 Bullet 3.</u></p> <p><i>Use of current medications that might negatively interact with other medications used for pain treatment. Particular attention should be given to identifying use of benzodiazepines or other sedative-hypnotics, which should not be prescribed simultaneously with opioids. Do not introduce these medications if considering prescribing opioids. Attempt to discontinue these medications in patients receiving them if prescribing opioids. (See</i></p>	Robert Blink, MD Occupational & Environmental Medicine Physicians September 1, 2015 Written Comment	<p>Agree in part; Disagree in part:</p> <p>Agree: The DWC agrees with commenter’s recommendation that there be allowance for exceptions based on the physician’s careful clinical judgment. This is an evidence-based recommendation. There is always consideration for exceptions based on evaluation and documentation of patient characteristics.</p> <p>Disagree: The medical evidence strongly suggests use of caution in prescribing these medications together and exceptions should be rare.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics) Coordinate care with other providers who may be prescribing these medications.</i></p> <p>Commenter recommends that there be an allowance for exceptions based on the physician’s careful clinical judgment.</p>		<p>Commenter implies that this section does not allow room for this exception which is incorrect. Use of the word “should not” allows room for an exception, if this was meant to be a prohibition then the words “shall not” would have been used.</p>	
<p>Chronic Pain Medical Treatment Guidelines - Acupuncture</p>	<p>Commenter recommends that use of acupuncture as a first line of treatment for work related injuries for both mild and moderate acute, subacute and chronic pain as an alternative to opioids.</p> <p>Commenter notes that there is no mention of acupuncture for post-operative pain after discharge. Commenter states that acupuncture for post-operative pain is considered an effective protocol and there are numerous studies that can be accessed that attest to the efficacy of acupuncture in this situation. Commenter cites that following four studies:</p>	<p>Karen Bostock, President California Acupuncture Association September 1, 2015 Written Comment</p>	<p>Disagree: The primary intention of this section is to address prescribing opioids post-operatively.</p> <p>However, section 1.4. Opioids for Post-operative Pain, second bullet states:</p> <ul style="list-style-type: none"> • “Considerations for prescribing opioids for post-operative pain include all of the following”, <p>1. “...(See Section 3.2. “Consideration of Alternative Treatments for Chronic Pain and Chronic Opioid Treatment”</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter questions whether all stakeholders to the MTUS implementation have the same focus.</p> <p>Commenter opines that if all parties to the MTUS focus on excellent practices and outstanding execution of patient care, then corollary issues of drug safety and cost control will take care of themselves. Commenter states that when competing views of stakeholder groups are pulling the project in different directions, inadequate results will be obtained.</p> <p>Commenter questions that if workers' suffering (from "inadequately treated" or "improperly managed" opioid medications) is the primary concern, why does the MTUS document on Opioids open with the following sentence:</p> <p><i>'Opioid misuse remains a national concern due to adverse health impacts and other unintended consequences. '</i></p>		<p>Agree: Not all MTUS stakeholders will have the same focus.</p> <p>Disagree: Although stakeholder groups may have competing views and or interests, it is the DWC who decides the content of the MTUS. We follow the mandates set out in Labor Code section 5307.27 that the MTUS incorporate evidence-based, peer-reviewed, nationally recognized standards of care.</p> <p>Disagree: Those are DWC's concerns, but the sentence quoted by commenter is absolutely true as evidenced by our national opioids epidemic and will remain in our proposed guideline. The sentence quoted does NOT contradict DWC's concerns of inadequate or improperly managed use of opioids for the treatment of pain among some injured workers.</p>	<p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Opioid Medical Treatment Guidelines – Executive Summary	<p>Commenter references the following statement from the section, “Key Recommended Practices”:</p> <p><i>"Clinicians should conduct semiannual attempts to wean patients whose dose has been 80 mg/ day MED or higher far at least six months to lower than 80 mg/ day MED.(p.3)"</i></p> <p>Commenter states that in the detailed section on Maintenance of Opioid Therapy, it is recommended that [physicians]:</p> <p><i>"3. Conduct semiannual attempts to wean to lower than 80 mg/ day MED in patients whose dose is above 80 mg/ day MED, and who have been on that dose or higher far at least 180 days (i.e., six [6] months). [77,88,89]</i></p> <ul style="list-style-type: none"> <i>• Opioid medication should never be abrupt/y discontinued in any patient who has been treated far longer than two (2) weeks. In these patients, opioid doses should be reduced gradually as tolerated, while</i> 	Beverly Powell Patient September 1, 2015 Written Comment	Disagree: The quote highlighted by commenter from the Executive Summary is consistent with the recommendations found within the proposed guideline. The Executive Summary only contains a general summary. Readers need to go to the Recommendations section in order to get the complete recommendation. Although the recommendations section contains the quote highlighted by commenter, it goes into greater detail about the precautions a physician must take when weaning patients from opioids.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p><i>monitoring/or symptoms of withdrawal or other adverse impact, including increase in pain, or decrease in function. (See Section 4.2, Methods far Tapering Opioids)</i></p> <ul style="list-style-type: none"> • <i>Referral to a pain specialist may be considered." (p.52)</i> <p>Commenter states that this section of the Opioid Treatment Guidelines is inconsistent with other guidelines given for tapering opioids, elsewhere in this same document (see Indications for Tapering Opioids, section 4.1, and Methods for Tapering Opioids, section 4.2.) (p.55)</p> <p>Commenter opines that, as currently drafted, these policies would disrupt the life of a person with pain every six months with a medical experiment changing their drug dose, because some studies show that high dosages of opioids are dangerous.</p> <p>Commenter states that there are counter arguments by other studies, such as the one commissioned by the DIR in 2012 by Nuckols and</p>		<p>Disagree: Medical evidence strongly supports periodic attempts to wean for a variety of reasons, especially patient safety. However, each case must be assessed individually to determine the appropriate use of opioid therapy, including attempts to wean.</p> <p>Disagree: The guidelines are based on an assessment of all the evidence and are</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Diamant, that indicate that there are serious dangers in the techniques made necessary by an arbitrary, calendar approach to tapering medications not related to patient and clinical indicators. Commenter states that this is switching one opioid for another, also called rotation, which is considered very dangerous.</p> <p>Commenter questions if it is the intention of the DWC to taper California workers' compensation claimants with chronic pain diagnoses off their medications twice per year (and theoretically, back on, assuming the tapering trial is a failure). Commenter would like to know if this will occur regardless of the medication and/ or its efficacy, disrupting patient lives every six months. Commenter questions the necessity of doing this to order to address "a national concern due to adverse health impacts and other unintended consequences" (from opioid misuse in general, not by these patients specifically).</p> <p>Commenter opines that a particular</p>		<p>incorporated as such. It is normal that scientific studies have varying results, these must be weighed by evaluating the strength of evidence using accepted processes and standards.</p> <p>Disagree: Medical evidence strongly supports periodic attempts to wean for a variety of reasons, especially patient safety. However, each case must be assessed individually to determine the appropriate use of opioid therapy, including attempts to wean. In addition, this recommendation is made because medical evidence has shown that the known risk of adverse events increases while the evidence for increased benefits remains weak. This recommendation, supported by medical evidence, is for the patient's safety, not just to address a national policy concern.</p> <p>Disagree: Medical evidence</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>worker on a high-dose drug has his/her appropriate medication and changing it around every six months is not going to help anyway, but will harm the patient’s pain prognosis.</p> <p>Commenter state that the policy document states that the tapered patient should be monitored for “adverse impacts . . . including increase in pain, or decrease in function.” Commenter questions that Division’s concern over "workers who suffer when chronic pain is inadequately treated or when opioid medications are improperly managed" in that directive to "treatment.”</p> <p>Commenter opines that the stated objectives for the treatment of chronic pain patients do not jibe with this part of the Opioid Treatment Guidelines. Commenter requests that the Division return some humanity back into this section with some judicious editing.</p>		<p>strongly supports periodic attempts to wean for a variety of reasons, especially patient safety. However, each case must be assessed individually to determine the appropriate use of opioid therapy, including attempts to wean.</p> <p>Disagree: The DWC is concerned about "workers who suffer when chronic pain is inadequately treated or when opioid medications are improperly managed". However, we need to provide a balance between appropriate treatment of pain among injured workers and safety in the use of opioids for that purpose. The concern for workers’ safety in the use of opioids is extremely humane.</p>	None.
Opioid Medical Treatment Guidelines –	Commenter states that there is a serious administrative issue that she would like to address. Commenter	Beverly Powell Patient September 1, 2015	Disagree: Treatments consistent with the MTUS or those that are supported by the	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Alternative Treatments	<p>states that workers' compensation insurance companies' consistently deny most doctor-recommended treatments aside from medications or a short list of invasive surgeries and injections.</p> <p>Commenter state that she has never, while dealing with private insurers for other treatment outside the workers' compensation system, has she had to deal with the intense interference of insurers in medical treatments, like she has had to deal with regularly in the California Workers' Compensation system.</p> <p>Commenter notes that the draft MTUS on Opioids Treatment Guidelines calls for an "extensive list of non-opioid treatments tried and found ineffective" be utilized before opioid therapy is started. Commenter would like to know how are physicians to get approvals for such things as adequate physical therapy visits, behavioral therapy, and palliatives like trigger point therapy, etc. in this type of insurance environment. Commenter opines</p>	Written Comment	<p>best available medical evidence found outside the MTUS should be approved by the insurer with UR and IMR serving a review function to determine what is reasonable and necessary treatment.</p> <p>Agree: We assume she is accurately stating her personal experience.</p> <p>Disagree: A recommendation contained in this proposed guideline states, "Non-opioid alternative therapies for pain treatment should be tried whenever possible before resorting to chronic opioid therapy" It then goes on to list the various non-opioid alternative therapies (e.g. acupuncture, massage, and yoga). This specific recommendation should fulfill</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>that it is easier for a doctor to get a course of opioid medications approved than to get physical therapy or acupuncture, or something new and innovative approved by an insurer.</p> <p>Commenter opines that there needs to be a mechanism by which doctors can get these alternatives through "the insurance system" in a timely fashion. Commenter opines that otherwise, if patients continue to have to wait for long and involved procedures to force the insurers to approve, the patients' condition will continue to worsen and conservative and alternative therapies will be of no use.</p>		<p>the commenter's hope in appropriate patients for easier, timely approval.</p>	
<p>Chronic Pain Medical Treatment Guidelines – General Comment</p>	<p>Commenter notes that a few months ago, the Department of Health and Human Services sponsored a discussion around a "National Pain Strategy." They also had a discussion in their documentation about Pain Models.</p> <p>As a patient, commenter does not like the simple categorization of patients and the many assumptions made</p>	<p>Beverly Powell Patient September 1, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree: Certainly, the DWC empathizes with commenter's statement that "until you have given up a job you loved, and hobbies and sports you cherished, due to chronic pain, you don't know what most patients are going through." Disagree: Commenter dislikes the simple categorization and</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>about their motivations related to pain, work, and maintaining functionality. Commenter opines that until you have given up a job you loved, and hobbies and sports you cherished, due to chronic pain, you don't know what most patients are going through.</p> <p>Commenter opines that much can be learned by shining a light back on the medical profession and the allied businesses such as insurance that sometimes create obstacles to health for chronic pain patients.</p> <p>Commenter gives the following example:</p> <p>How is Pain Medicine practiced? In a discussion in a local chronic pain support group, patients listed known</p>		<p>the assumptions made about a patients motivations related to pain, work, and maintaining functionality. She is referring to the discussion she attended with the Department of Health and Human Services and their documentation about Pain Models. The DWC incorporated recommendations that are supported by the best available medical evidence and any categorization that may have been made is supported by the scientific data.</p> <p>Agree in part; Disagree in part: Agree: Much can be learned by analyzing the relationships suggested by commenter. Disagree: No changes will be made as a result of this comment because it is a general policy suggestion that does not reference the proposed regulations.</p>	<p>None.</p>

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	<p>specialty medical practices that serve pain patients. Commenter states that they came up with the following list: rehabilitation medicine, neurology, anesthesiology, rheumatology, orthopedics, sports medicine and board certified pain medicine practitioners. Examining this list, commenter has the following question that relates to the frequency with which chronic pain sufferers have significant problems with muscle pain, strength and function.</p> <p>"Is there a medical specialty that is dedicated to dealing with pain/disease/illness associated with the muscular system?"</p> <p>Commenter wonders about this due to an injury in 1996 which resulted in back and leg pain. Her diagnosis was lumbar disc problems which resulted in her getting (multiple) injections and having two surgeries, to little effect. Commenter states that despite her treatment (invasive procedures) she still experiences muscle spasm, pain, stiffness, etc. Commenter has only just recently</p>		<p>Disagree: No changes will be made as a result of this comment because it is a rhetorical question that does not suggest any specific changes to the proposed regulations. Commenter then describes her medical situation which the DWC certainly empathizes with, but again, no changes will be made as a result of this comment because it does not suggest any changes nor does it reference the proposed regulations.</p>	<p>None.</p>

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	<p>heard of specialized MRI systems that have good imagining of soft tissue, and stresses that they are not available to everyone, due to cost (over \$5000 per image).</p> <p>Commenter states that the pioneering work of Drs. Travell and Simons on muscle pain, trigger points, referred pain patterns, etc., seems a well-kept secret. Commenter states that for her and for many others, it is a powerful tool for pain relief (C. Davies. The Trigger Point Therapy Workbook. New Harbinger Publications, 2004). Commenter notes that this is not mentioned at all in the directory of treatments to be considered in the California Workers' Compensation MTUS-Chronic Pain guideline.</p> <p>Commenter recommends a different kind of model entirely. As a patient, one whose chronic pain developed over time from an acute injury, commenter sees a distinction between idiopathic chronic pain that develops in usually unknown ways, and long-term chronic pain that accompanies chronic illness (such as arthritis).</p>		<p>Disagree: The Trigger Points Therapy Workbook (C. Davies. The Trigger Point Therapy Workbook. New Harbinger Publications, 2004) referenced by commenter is neither a medical treatment guideline nor a scientific study. Labor Code section 5307.27 requires that the MTUS be evidence-based, peer-reviewed and nationally recognized standards of care.</p> <p>Disagree: Commenter recommends a different kind of model entirely. She points out that the current research is inadequate and should redirect its inquiries from pain that is “normal” to pain that develops in usually unknown ways. Commenter’s policy suggestion will not prompt any changes to the proposed</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter opines that this difference is important because no one seems to know the genesis of some kinds of chronic pain. Commenter wonders why not? Why are we not finding out? Commenter opines that distinguishing it from pain that is "normal" for a given chronic disease or condition could lead to better research inquiries, and even perhaps, to prevention and cures.</p> <p>Commenter hopes for a day when people are able to have more "personalized medicine" in the treatment of people with pain.</p> <p>As an example, commenter states that such hope is now being extended to the patient who is battling obesity: experts are identifying specific "versions" of the obese patient, and calling for greater specificity in diagnoses of obesity:</p> <p>http://www.newswise.com/articles/expert-alert-precision-medicine-and-obesity).</p>		<p>guidelines. Again, Labor Code section 5307.27 requires that the MTUS be evidence-based, peer-reviewed and nationally recognized standards of care. Unless and until there is scientific data that supports Commenter's new model, then her suggestions cannot be incorporated into the MTUS.</p> <p>Disagree: Commenter makes interesting policy suggestions about personalized medicine and using the example of patients battling obesity and her hope that this type of thinking can be applied in the chronic pain arena. She surmises that this could lead to better research, treatment and outcomes for patients. She strongly advocates medical education. However, she questions the education provided to nurses, nurse-practitioners, physicians-assistants, pharmacists and other medical professionals</p>	None.

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	<p>Commenter opines that this is an area of medicine where, like chronic pain, there has been stigma attached to the patient, and often, poor communication between patients and doctors. Commenter opines that there has even been a tendency to blame and negatively label patients in these disease categories.</p> <p>Commenter notes that progress is being made for obese individuals by rational analysis, resulting in more appropriate categorization of obese populations.</p> <p>Commenter opines that if we could apply this same sort of rational thinking in the chronic pain arena, specificity could lead to more and better research, treatment and outcomes for patients.</p> <p>Commenter states that medical education is one of the very important areas that can impact delivery of appropriate care and that it is great to know that California requires a certain amount of medical education</p>		<p>who come in contact with pain patients including surgeons and states, “there is no reason in this day and age patients should have neuromas created from poor surgical practices leading to nerves sewn up in wounds.” Commenter’s policy suggestion will not prompt any changes to the proposed guidelines. Again, Labor Code section 5307.27 requires that the MTUS be evidence-based, peer-reviewed and nationally recognized standards of care. Unless and until there is scientific data that supports Commenter’s new model, then her suggestions cannot be incorporated into the MTUS.</p>	

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	<p>on pain for California-practicing physicians. Commenter asks if this also applies to nurses, nurse-practitioners, physicians-assistants, pharmacists and other medical professionals who come in contact with pain patients. Commenter would like to know how specific that the education is related to the work these professionals do. Commenter would like to know if surgeons are now trained not to involve the nervous system in scar tissue (as is what happened when her back surgery was sewn up).</p> <p>Commenter opines that there is no reason in this age that patients should have neuromas created from poor surgical practices leading to nerves sewn up in wounds. Commenter state that this type of high-impact medical event and others like it could and should be eliminated.</p> <p>Commenter recommends that the Division add more patients, of different injury classes, to research and discovery efforts. Commenter states that the policies that the</p>		<p>Disagree: Currently, the public, including any and all patients, are invited to comment on proposed rulemaking which is an integral part of the rulemaking process. In addition, the DWC does not conduct primary research and discovery, but</p>	<p>None.</p>

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	Division explores and proposes have a terrific impact on injured workers and that injured workers deserve a say in how policies and regulations are shaped.		rather, carefully selects from existing published guidelines or published medical studies that are then incorporated by reference into the MTUS.	
General Comment	<p>Commenter notes that the key principle underlying these guidelines is that clinical decisions are to be based on Evidence Based Medicine (EBM). Commenter would like to emphasize that these guidelines must allow the physician to use their clinical judgment in evaluating the patient to be consistent with the accepted definition of Evidence Based Medicine.</p> <p>Commenter strongly supports the provision of the highest quality and most effective medical treatment for injured workers. Commenter opines that the practice of medicine is an art, and determining the proper treatment for every patient and condition is not simply a matter of finding the treatment option supported by the highest level of medical evidence. Evidence Based Medicine (EBM) has been defined to include a systematic approach to making clinical decisions</p>	Diane Worley California Applicants' Attorneys Association (CAAA) September 1, 2015	<p>Agree: Yes, the DWC agrees with commenter's statement that these guidelines are evidence-based and allows physicians to use their clinical judgment in evaluating the patient.</p> <p>Disagree: The DWC disagrees that the practice of medicine is just an art. Rather, the practice of medicine is both an art and science.</p> <p>Agree: EBM is a systematic approach to making clinical decision which allows the integration of the best available research evidence with clinical expertise and patient values this is</p>	<p>None.</p> <p>None.</p> <p>None.</p>

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	<p>which allows the integration of the best available research evidence with clinical expertise and patient values.</p> <p>Commenter states that this definition is consistent with the explanation of EBM as set forth in the article "Evidence based medicine: what it is and what it isn't; It's about integrating individual clinical expertise and the best external evidence," published by several of the originators of EBM, including Professor David Sackett (Available on the website of the Center for Evidence Based Medicine (http://www.cebm.net/?o=1014) affiliated with the University of Oxford):</p> <p>"Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannized by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient."</p>		<p>memorialized in section 9792.21(b).</p> <p>Agree: In fact, the article is a document that the DWC relied upon in our rulemaking pertaining to section 9792.21(b).</p> <p>Agree: The DWC agrees with commenter's statements regarding "Good doctors" and her summary of ODG's reiteration in their Copyright Page.</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter states that the ODG also recognizes that guidelines cannot take into account the unique circumstances of every patient, and what treatments have worked for them. As explained on the ODG Copyright Page:</p> <p>"These publications are guidelines, not inflexible proscriptions, and they should not be used as sole evidence for an absolute standard of care. Guidelines can assist clinicians in making decisions for specific conditions and also help payers make reimbursement determinations, but they cannot take into account the uniqueness of each patient's clinical circumstances." http://www.odg-twc.com/preface.htm# <i>Comments on Chronic Pain Treatment Guidelines</i></p>			
Chronic Pain Medical Treatment Guidelines – General Comment	During her review of the proposed Chronic Pain Treatment Guidelines, commenter notes that in some cases there has been wholesale removal of certain provisions of the ODG as to specific medical treatments. Commenter opines that by eliminating references to available	Diane Worley California Applicants’ Attorneys Association (CAAA) September 1, 2015	Disagree: Deletions from the source ODG document were made to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS. For example, if the source	None.

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	<p>evidence based medicine in these guidelines, the evidentiary status of that medicine as well as the scientific basis for the recommendations for treatment risks being destroyed.</p> <p>Commenter opines that taking a "smorgasbord" approach to an EBM guideline in which the guideline is not adopted in its entirety but is edited and adapted reduces the EBM status of the guideline. Commenter states that all guidelines must be taken as a whole and must be treated as a whole. Commenter opines that if we subtract one part we may reduce the efficacy and scientific basis for the remaining part of the guideline.</p> <p>Commenter states that EBM is a careful and deliberate construct and should only be modified by that same process.</p> <p>Commenter states that Labor Code section 4604.5 (b) mandates:</p> <p>(b) The recommended guidelines set forth in the schedule adopted pursuant to subdivision (a) shall</p>		<p>ODG document references another ODG guideline that is not part of the current or proposed MTUS, then that reference was removed and replaced with a reference to the corresponding guideline in the current or proposed MTUS. See responses to R. McLaughlin (beginning on pg. 184) for specific reasons why sections where removed.</p> <p>Disagree: The entire MTUS is constructed using a "patch-work" approach. The MTUS incorporates by reference guidelines from ODG, ACOEM and the state of Colorado. Some changes must be made to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS. If a physician disagrees with a recommendation in the MTUS or if the MTUS does not address an injury or condition, a regulatory process is already</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>reflect practices that are evidence and scientifically based, nationally recognized, and peer reviewed. The guidelines shall be designed to assist providers by offering an 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.</p> <p>Commenter states that an MTUS which ignores this mandate should not be valid. Commenter opines that as the MTUS is an "analytical framework for the evaluation and treatment of injured workers", rather than an "analytical mandate", the "art" of medicine and individual clinical expertise must be integrated into this discussion.</p> <p>Commenter states that the goal of revising the chronic pain guidelines should be to expand and possibly introduce other EBM treatment modalities to provide as many treatment options for injured workers and their treating physicians as</p>		<p>in place that must be followed to evaluate whether the recommendation found outside the MTUS is warranted.</p> <p>Agree in part; Disagree in part: Agree: Commenter correctly cites Labor Code section 4604.5(b) and the DWC agrees that the MTUS provides an "analytical framework for the evaluation and treatment of injured workers". Disagree: The DWC disagrees with any implication that the MTUS somehow ignores this mandate. As noted, earlier the DWC believes the practice of medicine is both an art and science.</p> <p>Disagree: The goal of revising the chronic pain guidelines and the MTUS in general, is to provide an analytical framework for the evaluation and treatment of injured workers. The recommended guidelines in the MTUS are carefully selected because they</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>possible. Commenter opines that a one size fits all treatment approach in the guidelines simply won't be workable in the "real" world.</p> <p>Commenter states that an example of some key changes in the proposed MTUS Chronic Pain guidelines which do not comply with the mandate of Labor Code section 4604.5 and the definition of EBM, are the guidelines for home health services. Page 89 of the proposed Chronic Pain treatment Guidelines for Home health services provides that:</p> <p>Services described under (2) for personal care services and (3) for domestic care services should be covered only when (1) skilled care by a licensed medical professional is medically justified.</p> <p>Commenter notes that home health services range from skilled nursing and therapy services provided by home health agencies or other home care providers to unskilled personal care or chore services that may be</p>		<p>provide guidance for the most effective treatment for work related injuries or conditions.</p> <p>Disagree: The proposed Home Health Care Services recommendations comply with Labor Code section 4604.5 because it "reflects practices that are evidence and scientifically based...." Ellenbecker (2008) contains the evidence base for 7 domains of home health care, thus establishing an analytical framework that is evidence-based.</p> <p>Disagree: See above.</p> <p>Disagree: See above. In addition, the recommendations in the proposed guideline allows room for the provision of home health care services that is tailored to the injured</p>	<p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>provided by family members or other personal care aides. Commenter opines that limiting the scope and type of home health care services in a treatment guideline without an evidentiary or scientific basis to support the limitation is setting an arbitrary review process in conflict with the established principles of EBM. The course and scope of the injured workers' need for home health care services begins with a physician assessment, although a nurse case manager or treating psychologist, may have recommendations to be considered by the prescribing physician which can be reviewed and incorporated into the assessment. Commenter states that a cookie cutter approach to the provision of home health care services will be disastrous to many injured workers. Commenter opines that the proposed draft of the home health care services treatment guideline also exceeds statutory authority.</p> <p>Commenter recommends that personal care services and domestic</p>		<p>worker's specific clinical needs provided that it is medically necessary. This clearly is not a cookie-cutter approach as commenter states. See above with regards to the issue of statutory authority.</p> <p>Disagree: The proposed guidelines allow personal care</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>care services must be covered if found medically necessary, whether or not skilled (licensed nurse or therapist) home health services are being provided at the same time. If there is medical justification that someone needs home health services to include household tasks, grooming, bathing and cleaning, then the guidelines must include this.</p> <p>Commenter states that reference to CMS 2015, as a guide for when these services should be provided, and for a determination of the scope, and frequency of these services is not appropriate as Medicare/CMS simply determines eligibility for coverage by Medicare/CMS for home health services. It does not hold itself out to be a “treatment guideline”, and it most certainly is not “evidence based” or “peer reviewed” nor does it provide a required analytical framework.</p>		<p>services and domestic care services if found medically necessary whether or not skilled home health care services are being provided at the same time. Commenter is specifically concerned about the Medicare/CMS citation in the Home Health Care Services section. Commenter is correct that policy position documents such as those published by Medicare/CMS should not be used to support a recommendation in the MTUS. Here, the (CMS, 2014) citation is not used to support a recommendation pertaining to medical necessity, rather, the CMS citation describes the characteristics of someone who may need home health care services. This citation was left in the proposed guideline because it offers an important operational description, not a recommendation pertaining to medical necessity. This operational description is nationally recognized by the</p>	

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			<p>medical community and is even incorporated in the Ellenbecker 2008 study. Finally, CMS was also cited in the previous MTUS Chronic Pain Guidelines and was approved by the Office of Administrative Law in 2009.</p>	
Chronic Pain Medical Treatment Guidelines – General Comment	<p>Commenter opines that science dictates that you must follow the proper steps, such as in a recipe, and if you do not, you change the recipe, hence the science. Commenter states that evidence-based medicine is the recipe for the science of medical care. Evidence-based medicine is defined as a systematic approach to making clinical decisions which allows the integration of the best available research evidence, with clinical expertise and patient values being taken into account. Commenter opines that evidence-based medicine is the recipe to be followed for care. When the recipe calls for four eggs, you have to use four eggs. The Labor Code requires that all guidelines be based on evidence-based medicine. Based on commenter’s review, the</p>	<p>Robert McLaughlin California Applicants’ Attorneys Association (CAAA) Oral Comment September 1, 2015</p>	<p>Agree: Commenter correctly states that evidence-based medicine is defined as a systematic approach to making clinical decisions which allows the integration of the best available research evidence, with clinical expertise and patient values being taken into account.</p> <p>Disagree: Commenter incorrectly assumes that if the DWC deletes recommendations or incorporates recommendations from other guidelines, that this violates the principals of evidence-based medicine. Recommendations from ACOEM or ODG or any other</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Chronic Pain Medical Treatment Guidelines is a recipe taken from ODG, but where ODG required four eggs, a lot of times the division only uses two eggs. The recipe is not the same.</p> <p>Commenter provides specific examples, because he notes the wholesale removal to parts of the ODG Guidelines to make the Chronic Pain Management Guidelines. For example, on page 47 of the Guidelines, Chronic Pain Programs and Functional Restoration Programs are addressed. Commenter notes that removal of the ODG section called Outcomes in Terms of Body Parts. In this omitted section, shoulders and other upper extremity disorders are discussed. The omitted section addresses a large cohort study that concluded that an Interdisciplinary Functional Restoration Program is equally effective for patients with chronic upper extremity disorders, including the elbow, shoulder and wrists and hand. It goes on to address knee and other lower extremity disorders. The omitted</p>		<p>reputable guideline are more than likely supported by the same research evidence. There may be slight variance dependent on the date of publication and the research evidence available at that time. Evidence-based medicine utilizes “the best available research evidence.” Therefore, if we borrow the commenter’s recipe analogy, the recipe is found in the underlying research evidence that support recommendations, NOT whether or not all the recommendations are taken from a particular guideline.</p> <p>Disagree: Portions of page 47 were removed because they are body part specific (Shoulder, Knee, and Neck), instead readers are referred to the corresponding MTUS Clinical Topic guideline for that body part, in addition, a reference to see the proposed MTUS Opioids Treatment Guidelines for recommendations on the</p>	<p>None.</p>

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	<p>section cites the cohort study and states that it shows that chronic lower extremity injuries involving the hip, knee, ankle and foot and low back pain is effective. Commenter states there is a problem when the Division omits this information. Commenter opines that not only has the recipe changed but it is harder to figure out the recipe. Commenter recommends retaining the omitted sections. He opines that this will make it easier for the doctor, for the employers to realize, oh, Functional Restoration Program for the shoulder, it states it right here. Commenter opines that this might escalate the treatment plan for a heightened UR review, instead of the adjuster just being able to authorize it. Therefore, commenter opines that this is also adding costs.</p> <p>Commenter states that another example is the TENS unit for chronic pain, on page 158 of the Guides. Commenter states that in the ODG version, the criteria is set for the use of the TENS units. It provides 8 very specific criteria of when a TENS unit is appropriate in dealing with chronic</p>		<p>use of opioids was added, to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Disagree: Portions of page 158 were removed because they are body part specific (Low back, Knee, Neck, Ankle and foot, Elbow, Forearm, Wrist and Hand, and Shoulder), instead readers are referred to the corresponding “MTUS chapters on specific body parts” to maintain internal</p>	<p>None.</p>

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	<p>pain. Commenter notes that the complete section was removed. Commenter would like to know what and what is the evidence-based medicine for removing the entire section. Commenter opines that there must be some rationale for doing this that he simply cannot understand.</p> <p>Commenter states, as did Dr. Wayland during his testimony, that manual therapy manipulation is noted to be effective in the ODG for low back, neck and upper back, head, hip, and shoulder. Commenter notes that this entire section has been removed from the proposed guidelines. Commenter questions why this was taken out. Commenter opines that this is especially important and requires clarification so it's easy for everybody to understand when this treatment is allowed. Commenter opines that is important, if you're going to be able to restrict medications, that there are other options available for those people to treat their chronic pain.</p>		<p>consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS. See previous response.</p> <p>Disagree: Portions of page 109 were removed because it references ODG's Low Back Chapter and Neck Chapter neither of which are in the current MTUS. In addition, it provides recommendations to other specific body parts (Head, Hip, Elbow, Shoulder, Ankle & Foot, Forearm, Wrist, & Hand, and Knee) and for Carpal tunnel syndrome all of which are currently covered in the specific body-part chapters in the MTUS. Readers are instructed to "See also specific body-part chapter in the MTUS" to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS. See previous responses.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter cites the example of a police officer that had to have all his manipulations stopped, because it was no longer being authorized. It's not provided for under Chronic Pain Guidelines. Commenter states that the police officer is now on opiate medication that was approved. However, he can't go to work because he cannot be driving a car and carrying a gun while taking Vicodin.</p> <p>Commenter cites another example of omission is the section regarding current research which is referenced in the ODG. This section states that a recent comprehensive meta-analysis of all clinical trials, manipulations for low back conditions, has concluded that there is good evidence for its use in chronic low back pain. And then it cites the authority Lawrence 2008.</p> <p>Commenter states that these treatment options must be available in order to appropriately treat injured workers.</p>		<p>Disagree: The Current Research section was removed because it references ODG's Low Back Chapter which is not in the current MTUS. Readers are instructed to "See also specific body-part chapter in the MTUS" in this case the current Low Back Chapter to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS.</p> <p>Agree: These treatment options are available to injured workers, there is no prohibition in the proposed guidelines. Readers are merely instructed to find the recommendations in the current MTUS or proposed MTUS guidelines instead of from the source ODG guidelines which are not part of the MTUS.</p>	<p>None.</p> <p>None.</p>
Chronic Pain Medical Treatment	Commenter states that there is not a very good reference to the Pain	Robert McLaughlin California Applicants'	Disagree: The proposed guideline does not violate the	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines – General Comment	Patient Bill of Rights in the Chronic Pain Guidelines. Commenter notes that there is one good reference in the old one, on page 6, and with chronic contractible pain patients; however, there is nothing for injured workers. Commenter opines that injured workers need this option in order to avail themselves of opiate medications under the Pain Patient Bill of Rights. Commenter notes that it is in the Health and Safety Code. Commenter opines that this is a protection for injured workers that shouldn't be used in every case. Commenter acknowledges the need for caution as there is opiate over-prescription. However, commenter opines that pain management specialists should be able to avail themselves of that option for their patients.	Attorneys Association (CAAA) Oral Comment September 1, 2015	Pain Patient Bill of Rights because it does not interfere with the rights of patients or of physicians to practice. It systematically contains recommendations supported by the best medical evidence for the safe and effective use of opioid therapy.	
Opioid Medical Treatment Guidelines – General Comment	Commenter supports the consistency throughout the guidelines regarding the process that a physician should go through when they are prescribing an opioid medication. This includes checking the CURES database for documentation of other opioid medications that the patient may be	Diane Worley California Applicants' Attorneys Association (CAAA) Written Comment September 1, 2015 Robert McLaughlin	Agree.	None.

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	<p>taking, urine drug testing, and the tracking of change in pain levels and function.</p> <p>Commenter opines that the documentation of a patient’s pain level is fundamental in assessing and managing the patient’s need for opioid medications. Because of this, commenter opines that this requirement be added to the acute and subacute guidelines as well.</p> <p>Commenter is concerned that the level of documentation required of a prescribing physician may not be realistic in all cases.</p> <p>For example, in the Acute and Subacute periods, the prescribing physician is asked to document the patient’s: “1) pharmacologic therapy with non-opioid medications; 2) Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury; and 3) Complementary/alternative modalities, such as acupuncture, massage, and yoga.” Commenter</p>	<p>September 1, 2015 Oral Comment</p>	<p>Disagree: Commenter’s suggested change is unnecessary because the proposed guidelines already recommend the assessment of pain at every visit for patients with both acute and subacute pain.</p> <p>Disagree: The proposed Opioids Treatment Guidelines allow the option to go straight to opioids if "there are reasonable expectations that only opioids will produce immediate pain relief and sleep immediately following the injury". The conjunction “and/or” is before each of the options and it appears the commenter has missed option “(c)” which is stated above.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>states that it may not be appropriate for all patients to go through this entire regimen of care prior to the prescribing of an opioid medication for acute or subacute injuries.</p> <p>Commenter states that allowing the prescribing physician to use their clinical judgment as to which medications/treatments are appropriate for their patients and not mandating that certain treatments be provided first for every injured worker regardless of their type of injury, would be most consistent with the definition of Evidence Based Medicine. While well-intended, commenter opines that these documentation requirements are unworkable and in many cases could lead to unnecessary delays and denials of care.</p> <p>For example, Utilization Review often requires lesser levels of care before a Functional Restoration Program is approved. Even when trained physicians with a multitude of years of experience know that a patient will fail piecemeal treatment,</p>		<p>Disagree: Prescribing physicians are supposed to use their clinical judgment and the proposed Opioids Treatment Guidelines allow this. See above.</p> <p>Disagree: See above.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>they are often told by UR reviewers other treatment modalities must be tried first. When this other treatment is requested, it is sometimes also denied. Precious resources and time are wasted. The clinical judgment of the physician is ignored. Commenter recommends that the level of documentation of prior treatment set forth in the guidelines be advisory only, so that it may be tailored to the individual needs and history of each patient.</p> <p>Commenter recommends that language be added to the guidelines to clarify that if medications/services noted in the guidelines are requested by the treating physician, including drug urine screening tests, that it would be expected that the request be approved consistent with the guidelines to avoid delays and billing disputes.</p> <p>There are additional documentation requirements in the Acute and Subacute period following an injury (initial 1-4 weeks), that commenter opines are excessive. For example,</p>		<p>Disagree: Commenter's suggested added language will not be incorporated because it is unnecessary. If the treating physician requests treatment consistent with the proposed guidelines, the request should be approved as the guidelines are to be used by both treating and reviewing physicians.</p> <p>Disagree: The contraindications listed should be considered by any physician prescribing opioids because opioids carry a significant risk.</p>	<p>None.</p> <p>None.</p>

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	<p>the prescribing physician is required to document in the medical record that the following conditions are not present:</p> <ul style="list-style-type: none"> Depression Anxiety Personality disorder Untreated sleep disorders Current or past substance abuse Drug-seeking behavior Other psychotropic medications Post-traumatic stress disorder Cognitive impairment Chronic obstructive pulmonary disease Severe obesity Balance problems/fall risk Osteoporosis Renal failure <p>Commenter opines that an orthopedic surgeon would not be qualified to make all these assessments, so this would require that for each injured worker where a short-term regimen of opioid medications is being prescribed, that the patient be referred to a number of other medical specialists, (e.g., psychiatrists,</p>		<p>After a physician has considered the contraindications listed, then the documentation requirement can be fulfilled with a simple indication that the contraindications are not present. However, if any of these conditions are present, then written documentation must be provided to justify the use of opioids.</p> <p>Disagree: Any physician should be able to assess the risk to benefit ratio of any treatment prescribed. If a physician is not able to consider all of the contraindications listed, including orthopedic surgeons, then they should not be</p>	None.

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	<p>cardiologists, urologists, primary care physicians) for an evaluation before the medication could be prescribed. Commenter states that this will certainly delay care and force the patient to endure, what could be very severe pain levels with inadequate pain medications, while they wait to get appointments and evaluation dates.</p> <p>Commenter opines that when a patient reaches the chronic stage of pain management, these more comprehensive evaluations may be essential but not routinely in the acute phase. Commenter recommends that these additional documentation requirements be eliminated from the guidelines for acute and subacute injuries.</p> <p>Commenter supports a well thought out coordination between any proposed list of formulary drugs (which is expected in the future), the Opioid prescription guidelines, the Medical Board of California's prescription guidelines for Schedule II and III drugs, the Chronic Pain</p>		<p>prescribing opioids and should refer the patient out to someone who is qualified to prescribe opioids.</p> <p>Disagree: See above.</p> <p>Agree: Although the Prescription Drug Formulary is not part of this rulemaking, any subsequent regulations pertaining to the Prescription Drug Formulary will be coordinated with these recommendations. This</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>treatment guidelines, and ODG's guidelines. Commenter opines that to do otherwise, will create a major problem for injured workers in the future when their treating physicians must run the gauntlet of "dueling presumptions" from the formulary, and other treatment guidelines which will nearly be impossible to do .</p> <p>To avoid this to the utmost extent possible, commenter states that the MTUS present guidelines that rarely require use of the Hierarchy of evidence. Commenter states that by coordinating the development of guidelines which rarely require the Hierarchy of evidence to obtain approved care, the intended goals of using Evidence Based Medicine to deliver appropriate medical care to injured workers should be achieved.</p>		<p>comment goes beyond the scope of this rulemaking.</p> <p>Disagree: The MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1 is applied to evaluate the quality and strength of evidence used to support recommendations that are at variance with one another. Use of the Hierarchy of Evidence is the third-step when applying the above methodology. Competing recommendations arise in the very limited situation when: 1) if a medical condition or injury is not addressed by the MTUS, or 2) if the MTUS' presumption of correctness is being challenged. A methodology and hierarchy of</p>	<p>None.</p>

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			evidence is necessary to comply with the statutory mandates of Labor Code section 4604.5.	
Chronic Pain and Opioid Medical Treatment Guidelines – General Comment	Commenter recommends that the revisions to the current chronic pain and opioid treatment guidelines also allow continuation of medication management that promotes functional stability rather than requiring functional improvement. Commenter opines that to do otherwise would discard clinical judgment and the true meaning of Evidence based medicine by ignoring how well an injured worker is doing before their treatment is withdrawn. Commenter opines that chronic pain or illness usually is an extended or life-long process and functional improvement, although it may be an aspiration, is often not a realistic goal. In cases where medication management provides functional stability, this allows an injured worker to continue working and decreases treatment costs. In many cases, functional maintenance is the best outcome that can be achieved and taking away	Diane Worley California Applicants’ Attorneys Association (CAAA) September 1, 2015	Disagree: The goal of medical treatment in the workers’ compensation system is to “cure and relieve from the effects of the injury”. This means that returning the injured worker to pre-injury health status is always the desired goal. Each patient needs to be assessed on a case by case basis to determine the appropriate functional goals. However, it is the intention of the DWC to ensure that evidence-based recommendations are made for medical treatment for chronic pain and the use of opioid therapy. Not all patients will fully recover, but the proposed MTUS guidelines help ensure that patients are offered the best medical treatment options during recovery. The DWC disagrees that the proposed	None.

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	medications, without any alternative treatment options can result in functional decline as a real possibility. Guidelines which fail to recognize the importance of functional stability for an injured worker would be inconsistent with the definition of Evidence based medicine.		guidelines harm patients who reach maximum medical improvement, but rather, helps them by ensuring their ongoing care is evidence-based.	
General Comment	<p>Commenter states that he is a physiatrist and pain specialist.</p> <p>Commenter opines that the primary concern that should be addressed is the continued misuse of the guidelines by the UR "specialists" to deny ALL pain relieving medications. Commenter states that the UR reports are widely known to be ghostwritten (some entirely outside of this country) and then signed by biased UR doctors, the majority of whom are outside of California. Commenter states that the major UR companies: [REDACTED] incentivize utilization denial and the denial rate for all treatments in my clinic approaches 60-70%.</p> <p>Commenter states that the guidelines</p>	Matthew D. Johnson DO, Board Certified PM&R September 1, 2015 Written Comment	<p>Disagree: Commenter's concerns about Utilization Reviewers goes beyond the scope of this rulemaking. No specific sections of the proposed regulations were addressed.</p> <p>Disagree: The</p>	<p>None.</p> <p>None.</p>

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	<p>should be definitive in that what is required for prescribing medications and treatments. Commenter recommends that these items should be authorized for periods of at least 6 months so that the adjuster cannot simply keep playing the numbers until they hit a friendly UR doc. Commenter states that the guidelines language should be CONCRETE and not open to arbitrary interpretation by physicians outside of the system who are incentivized to deny treatment.</p> <p>Commenter opines that the current system is so critically flawed that he can't imagine any change which could make it worse so he is excited to see what happens next.</p>		<p>MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS' recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.</p> <p>Disagree: See Above.</p>	None.
9792.24.2(a)	<p>Commenter notes that this section currently states that an edited version of ODG is being adopted. Commenter encourages the adoption of ODG for chronic pain guidelines without modification to the ODG guidelines. Commenter supports the adoption of the most current version of guidelines on an ongoing basis. Commenter opines that this approach</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: The entire MTUS is constructed using a "patch-work" approach. The MTUS incorporates by reference guidelines from ODG, ACOEM and the state of Colorado. Some changes had to be made to maintain internal consistency within the treatment guidelines that form</p>	None.

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	<p>is permissible under Labor Code 5307.27 which states that the administrative director will adopt a medical treatment utilization schedule that incorporates evidence-based, peer-reviewed, nationally recognized standards of care. Commenter states that the ODG guidelines meet those requirements and are reviewed and updated on a regular basis giving workers' compensation the benefit of the most up to date reviews and guidelines available. Commenter notes that in the chronic pain guidelines there were changes made, either intentionally or unintentionally, that created internal inconsistencies in the guidelines. For example, the MTUS ODG guideline for Hydromorphone on page 93 uses a hyperlink to refer the user to the Opioid Specific Drug List on page 139. Commenter notes that the MTUS guidelines removed the drug from the list while the original ODG list includes it. Commenter opines that this creates an internal inconsistency in the drafted guidelines.</p>		<p>the Clinical topics and Special topics sections of the MTUS. For example, if the source ODG document references another part of the ODG guideline that is not part of the current or proposed MTUS as in the Hydromorphone example used by Commenter, then that reference was removed and replaced with a reference to the corresponding guideline in the current or in this case the proposed MTUS Opioids Treatment Guidelines. If a physician disagrees with a recommendation in the MTUS or if the MTUS does not address an injury or condition, a regulatory process is already in place that must be followed to evaluate whether the recommendation found outside the MTUS is warranted.</p>	

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	<p>Commenter opines that the adoption of the ODG chronic pain guidelines without modification and based on the most current published version would keep guidelines up to date with the most current research and avoid internal consistency issues. Commenter understands that the chronic pain guidelines are to work in conjunction with the opioid guidelines, but a separate paragraph at the beginning of the guidelines could do that by simply stating the reader must also consult the opioid guidelines as appropriate.</p> <p>Commenter recommends the following revised language:</p> <p>(a) The Chronic Pain Medical Treatment Guidelines (May, 2009) <u>[insert effective date of regulations]</u>, consisting of two parts, are adopted and incorporated by reference into the MTUS. Part 1 is entitled Introduction. Part 2 is entitled Pain Interventions and Treatments the “Official Disability Guidelines (ODG) <u>Treatment in Workers’ Compensation</u></p>		<p>Disagree: In order to properly incorporate the ODG guidelines by reference into our regulations, subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the document by title and date of publication or issuance." Therefore, incorporating “on an ongoing basis so that the most current published version of ODG will be utilized as the effective MTUS Chronic Pain Medical Treatment Guideline” without stating the date of publication or issuance is not allowed.</p>	None.

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	<p>– Pain (Chronic)” consisting of an edited version from the Official Disability Guidelines published on April 6, 2015, which the Division of Workers’ Compensation has adapted with permission from the publisher. The ODG guidelines are adopted on an ongoing basis so that the most current published version of ODG will be utilized as the effective MTUS Chronic Pain Medical Treatment Guideline. These guidelines replace Chapter 6 of the ACOEM Practice Guidelines, 2nd Edition (2004). Where the clinical topic sections of the MTUS in the series of sections commencing with 9792.23.1 et seq., make reference to Chapter 6 or when there is a reference to the “pain chapter,” or “pain assessment,” the chronic pain medical treatment guidelines will apply instead of Chapter 6. A copy of the eChronic pPain mMedical tTreatment gGuidelines may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at</p>			

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9792.24.2(b), (c) and (d)	<p>http://www.dwc.ca.gov.</p> <p>Commenter notes that section 9792.24.2(b) indicates that the Chronic Pain Medical Treatment Guidelines apply “as determined by the following topics:” and then provides a listing of circumstances currently listed under 9792.24.2(c) and (d). Commenter notes that the listing does not align under the subsection but instead continues the numbering as (c) and (d).</p> <p>Commenter recommends that the numbering be changed as follows:</p> <p>9792.24.2(c) be changed to 9792.24.2(b) (1)</p> <p>9792.24.2(d) be changed to 9792.2(b) (2)</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The DWC will not adopt commenter’s suggested changes but recognizes clarification was needed in proposed section 9792.24.2(b) to make clear that the Chronic Pain Medical Treatment Guidelines apply when the patient has chronic pain as defined in section 9792.20.	Section 9792.24.2(b) is amended by deleting the phrase “as determined by following the clinical topics” and adding the phrase “as defined in section 9792.20.”
9792.24.2(b)	Commenter notes that the regulations as written address applicability of the Chronic Pain Medical Treatment Guidelines when 1) treatment is covered in the clinical topics sections but is not addressed in the Chronic Pain Medical Treatment Guidelines and 2) when treatment is addressed in both the Chronic Pain Medical	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree in part; Agree in part: Disagree: The DWC will not adopt commenter’s suggested changes because a more concise amendment can be made. Agree: Clarification can be made to make clear the Chronic Pain Medical	Section 9792.24.2(b) is amended to add the phrase “or if the treatment is only addressed in the Chronic Pain Medical Treatment Guidelines, then...”

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	<p>Treatment Guidelines and the clinical topics section. Commenter states that the regulations do not address the possibility that a treatment is addressed in the Chronic Pain Medical Treatment Guidelines but is not addressed in the clinical topics section of MTUS.</p> <p>Commenter recommends the addition of a new subsection as follows:</p> <p>9792.24.2(b)(3) When the treatment is addressed in the Chronic Pain Medical Treatment Guidelines but is not addressed in the clinical topics section of MTUS, the Chronic Pain Medical Treatment Guidelines shall apply.</p>		Treatment guidelines apply if the treatment is only covered in the proposed Chronic Pain Medical Treatment guidelines.	
Chronic Pain Medical Treatment Guidelines – Part 1 and Part II	Commenter supports the implementation of chronic pain and opioid guidelines. Commenter recommends adopting the ODG Guidelines for Chronic Pain without modification and to adopt the guidelines in their most recent published format.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: In order to properly incorporate the ODG guidelines by reference into our regulations, subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the document by title and date of	None.

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	<p>Commenter recommends adding the following paragraph to the top of Part 2: Official Disability Guidelines (ODG) Treatment in Workers' Compensation—Pain (Chronic) before the table begins:</p> <p>The Chronic Pain Guidelines must be used in conjunction with the MTUS Opioid Treatment Guidelines. Therefore clinicians should always cross reference the Opioid Treatment Guidelines when addressing the utilization of opioids.</p>		<p>publication or issuance.” Therefore, incorporating the “most current version” without stating the date of publication or issuance is not allowed. Also, allowing the MTUS to be automatically updated whenever ODG updates their guidelines is an unlawful delegation of the DWC’s regulatory authority and will not be permitted by the Office of Administrative Law.</p> <p>Disagree: This added clarification is unnecessary. Cross-referencing between the MTUS guidelines is a given. For example, the Low Back Chapter may cross-reference with the proposed Chronic Pain Medical Treatment Guidelines and then with the proposed Opioids Treatment Guidelines.</p>	None.
Opioid Medical	Commenter references page 1,	Jill Rosenthal, MD	Agree: This was a	“Executive

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Treatment Guidelines – Part I – Executive Summary	<p>opening paragraph, third sentence, “The Medical Treatment Utilization Guidelines (MTUS) Opioids Treatment Guidelines”.</p> <p>Commenter recommends this statement be amended for the purposes of consistency to read as follows:</p> <p>“The Medical Treatment Utilization Guidelines <u>Schedule</u> (MTUS) Opioids Treatment Guidelines”</p>	Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	typographical error.	Summary” is amended to delete the word “Guideline” and replace it with the word “Schedule” to correct a typographical error.
Opioid Medical Treatment Guidelines – Part I – Executive Summary	<p>Commenter notes that page 1, second paragraph, states:</p> <p>“This Guideline is based on the best available medical evidence and has three main goals: (1) to provide a set of best practices and universal precautions for safe and effective prescribing of opioids for acute (lasting up to four weeks), subacute (lasting four to 12 weeks), and chronic (lasting three or more months) pain due to a work related injury;”.</p> <p>Commenter recommends that, for the purposes of consistency and to allay</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Although commenter’s suggested change is reasonable, the DWC will keep the reference to Chronic Pain to “three or more months” to remain consistent with the definition of Chronic Pain in section 9792.20.	None.

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	<p>any confusion regarding timeframes for acute, subacute, and chronic pain, the guidelines consistently reference weeks for each category of acute, subacute, and chronic pain.</p> <p>Commenter recommends the following revised language:</p> <p>“This Guideline is based on the best available medical evidence and has three main goals: (1) to provide a set of best practices and universal precautions for safe and effective prescribing of opioids for acute (lasting up to four weeks), subacute (lasting four to 12 weeks), and chronic (lasting greater than 12 weeks) pain due to a work-related injury;”</p>			
Opioid Medical Treatment Guidelines – Part I – Executive Summary	<p>Commenter references page 1, third paragraph.</p> <p>Commenter states that the first sentence addresses a list of items that are not addressed in the Opioid Treatment Guidelines and includes a reference to pain “immediately following catastrophic injuries”. Commenter recommends that a set</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Commenter recommends adopting the definition of catastrophic injury from Labor Code section 4660.1(c)(2)(B) instead of the proposed guideline description which states “Catastrophic injuries in which significant recovery of physical function is not	None.

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	<p>description or definition of “catastrophic injuries” be adopted to avoid confusion. Commenter states that later in guidelines it is described as follows: “Catastrophic injuries in which significant recovery of physical function is not expected, such as severe burns, crush, or spinal cord injury, are exempt from many of the recommendations in this guideline.”</p> <p>Commenter recommends taking the definition from 4660.1(c)(2)(B) and this description to create a single definition of the guidelines that states:</p> <p>“Catastrophic Injury” means an injury resulting in loss of limb, paralysis, severe burn, or severe head injury (including traumatic brain injury) from which significant recovery of physical function is not expected.</p> <p>Commenter states that this definition would be consistent with</p>		<p>expected, such as severe burns, crush, or spinal cord injury...”</p> <p>The DWC will not incorporate commenter’s suggestion because the definition in Labor Code section 4660.1(c)(2)(B) is for permanent disability rating purposes and is taken from the AMA’s legal definition. The proposed guideline serves the purpose of determining medical necessity. Clearly, there is overlap between the two but they do serve different purposes.</p> <p>Disagree: See above.</p> <p>Disagree: The current explanation contained in the proposed MTUS Opioids</p>	<p>None.</p> <p>None.</p>

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	<p>4660.1(c)(2)(B) but include the lack of medical recovery component which is anticipated under 4660.1. Commenter recommends that this terminology be used consistently throughout the guidelines. If further clarity is desired or permitted, commenter recommends that a more thorough definition could be developed using the AMA Guidelines or other state definitions such as Georgia. Commenter notes that Georgia defines catastrophic injury under OCGA 34-9-200.1(g) which states:</p> <p>"Catastrophic injury" means any injury which is one of the following:</p> <ul style="list-style-type: none"> (1) Spinal cord injury involving severe paralysis of an arm, a leg, or the trunk; (2) Amputation of an arm, a hand, a foot, or a leg involving the effective loss of use of that appendage; (3) Severe brain or closed head injury as evidenced by: <ul style="list-style-type: none"> (A) Severe sensory or motor disturbances; (B) Severe communication disturbances; 		<p>Medical Treatment Guideline: "Catastrophic injuries in which significant recovery of physical function is not expected, such as severe burns, crush, or spinal cord injury, are exempt from many of the recommendations in this guideline" provides a clear explanation of a catastrophic injury without going into unnecessary detail that is meant to determine permanent disability rating issues.</p> <p>Disagree. See above.</p>	<p>None.</p>

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	<p>(C) Severe complex integrated disturbances of cerebral function;</p> <p>(D) Severe disturbances of consciousness;</p> <p>(E) Severe episodic neurological disorders; or</p> <p>(F) Other conditions at least as severe in nature as any condition provided in subparagraphs (A) through (E) of this paragraph;</p> <p>(4) Second or third degree burns over 25 percent of the body as a whole or third degree burns to 5 percent or more of the face or hands;</p> <p>(5) Total or industrial blindness; or</p> <p>(6)(A) Any other injury of a nature and severity that prevents the employee from being able to perform his or her prior work and any work available in substantial numbers within the national economy for which such employee is otherwise qualified; provided, however, if the injury has not already been accepted as a catastrophic injury by the employer and the authorized treating physician has released the employee to return to work with restrictions, there shall be a rebuttable presumption, during a period not to</p>		Disagree. See above.	None.

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	<p>acute injury” as both terms are used and appear to overlap. Commenter references the following description:</p> <p>“1.3 Severe Acute Injuries (e.g., fractures, crush injuries, major trauma, other injuries with significant tissue damage)”.</p> <p>Commenter questions what is the difference between a “catastrophic injury” and a “severe acute injury” or if they are the same thing.</p> <p>Commenter questions if “catastrophic injury” is a sub-category of a severe acute injury since generally a catastrophic injury within the industry frequently an injury of such severity that the person is unable to return to work at their normal job or any other job.</p>		<p>because this is a continuum. Disagree: The difference between the two is clear and the distinguishing factor is that with severe acute injuries recovery of physical function is expected; whereas with catastrophic injuries “significant recovery of physical function is not expected...” Physicians should use their clinical judgment in determining when the guidelines apply to a particular patient’s clinical condition immediately following an occupational injury.</p>	
<p>Opioid Medical Treatment Guidelines – Part I – Executive Summary</p>	<p>Commenter references page 2, sixth bullet point:</p> <p>“Although all doses of opioids carry risks, providers should be increasingly vigilant for doses above 80 mg/day morphine equivalent dose (MED), as the known risk of adverse events rises while the evidence for</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010),</p>	<p>None.</p>

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	<p>increased benefit remains weak”.</p> <p>Commenter recommends that this threshold be lowered to 50 mg/day morphine equivalent dose as this is supported by ODG as well as literature referenced in the Opioid Treatment Guidelines (77. Dunn, K.M, et al., Opioid prescriptions for chronic pain and overdose: a cohort study. Ann InternMed, 2010.)</p> <p>Commenter recommends this change be made throughout the proposed regulations but will attempt to note each section containing this change.</p>		<p>with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.	
Opioid Medical Treatment Guidelines – Part I – Executive Summary	Commenter references page 2, seventh bullet point. Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.	
Opioid Medical Treatment Guidelines – Part I – Executive Summary	<p>Commenter references page 3, second subset bullet point, “Screening identifies patients with high risk of addiction or serious adverse events, substance misuse, and psychosocial factors that may contribute to misuse”.</p> <p>Commenter recommends that the</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Commenter’s suggested language will not be incorporated because it does not strengthen the statement or make it more likely that the recommendation will be followed. This summary bullet is discussed in detail later in the guideline.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>wording be amended as follows to strengthen the statement and ensure that screenings are completed per recommendations:</p> <p><u>“Screening is completed to identify patients with high risk of addiction or serious adverse events, substance misuse, and psychosocial factors that may contribute to misuse.”</u></p>			
Opioid Medical Treatment Guidelines – Part I – Executive Summary	<p>Commenter references page 3, first bullet point:</p> <p>“Patients on chronic opioid treatment should be carefully managed, after the following have been documented”.</p> <p>Commenter recommends the statement be amended to read as follows in order to strengthen the statement regarding required documentation:</p> <p>“Patients on chronic opioid treatment should be carefully managed <u>and documentation of ongoing management shall include:</u>”</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.	None.
Opioid Medical Treatment	Commenter references page 3, “Clinically meaningful reduction in	Jill Rosenthal, MD Sr. Vice President &	Disagree: Suggested language is accurate but the assessment	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Guidelines – Part I – Executive Summary	<p>pain and functional improvement”.</p> <p>Commenter recommends the addition of the word “sustained” in front of functional improvement, revised as follows:</p> <p>“Clinically meaningful reduction in pain and <u>sustained</u> functional improvement”</p>	Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	of function as a result of the opioid is recommended at every visit. Ongoing monitoring will necessarily assess sustainability of function. Commenter’s suggested revision will not be incorporated because it is unnecessary.	
Opioid Medical Treatment Guidelines – Part I – Executive Summary	<p>Commenter references page 3, second to last bullet point.</p> <p>Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.</p>	
Opioid Medical Treatment Guidelines –A2 – Abbreviated Treatment	Commenter recommends that the guidelines consistently reference the timeframes for acute, subacute, and chronic pain in weeks versus months.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015	Disagree: Acute Pain is already defined as “pain lasting up to four (4) weeks”. For Subacute Pain it is defined pain lasting “beyond one (1)	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Protocols	<p>Commenter recommends the following revised language:</p> <ul style="list-style-type: none"> ·Opioids for Acute Pain (pain lasting up to 4 weeks) ·Opioids for Post-operative Pain ·Opioids for Subacute Pain (pain lasting from 4-12 weeks) ·Opioids for Chronic Pain and Chronic Opioid Treatment (pain lasting greater than 12 weeks) 	Written Comment	month” and for Chronic Pain it is defined as “pain lasting three (3) or more months”. We will leave the references to “month” in because it is consistent with our current regulatory definition of Chronic Pain set forth in section 9792.20(b).	
Opioid Medical Treatment Guidelines – A2 – Summary Recommendations – Opioids for Acute Pain	Commenter appreciates the efforts to provide a summary chart of the guidelines but is concerned that users will look to the chart and no further despite the caution against doing so. Commenter recommends that if the chart is retained it be carefully cross checked with any new revisions to assure it is completely in alignment with the actual guideline.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The summary chart will be retained and the DWC will carefully cross check if there are any new revisions in the future to assure it is completely in alignment with the actual guideline.	None.
Opioid Medical Treatment Guidelines – A3.2 – Workers’ Compensation Context	Commenter references page 10, last paragraph. Commenter recommends that the guidelines consistently reference the timeframes for acute, subacute, and chronic pain in weeks versus months.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Acute Pain is already defined as “pain lasting up to four (4) weeks”. For Subacute Pain it is defined pain lasting “beyond one (1) month” and for Chronic Pain it is defined as “pain lasting three	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter recommends the following revised language:</p> <p>“For purposes of the Opioids Treatment Guidelines, acute pain is of sudden onset and is expected to last up to four weeks (one month); in the occupational context, acute pain is linked clearly to a specific event, injury, or illness. Subacute pain is pain that lasts between four and 12 weeks (or one and three months). Chronic pain is defined as pain that lasts more than <u>12 weeks (three months or greater)</u>.”</p>		(3) or more months”. We will leave the references to “month” in because it is consistent with our current regulatory definition of Chronic Pain set forth in section 9792.20(b).	
Opioid Medical Treatment Guidelines – A3.5 – Opioid Safety	<p>Commenter references page 13, second paragraph, second sentence. The statement currently reads, “In combination with other central nervous system (CNS) depressants, opioids can induce acute respiratory failure as defined by a decrease in the partial pressure of oxygen in arterial blood (PaO2)”.</p> <p>Commenter states that an opioid by itself can result in the conditions listed. Commenter recommends the for accuracy, and to help ensure the risks of opioid use are clearly</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: An opioid by itself can result in the conditions listed and the phrase “Alone or” will be added for accuracy.	3.5 Opioid Safety: Overdose, Serious Adverse Events, and Substance Misuse/Abuse is amended to add the phrase “Alone or” for accuracy.

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	<p>outlined, the following revised language:</p> <p>“<u>Alone or</u> in combination with other central nervous system (CNS) depressants, opioids can induce acute respiratory failure as defined by a decrease in the partial pressure of oxygen in arterial blood (PaO2). “</p>			
Opioid Medical Treatment Guidelines – A3.8 – Goals and Objectives	<p>Commenter references page 16, second bullet point. The statement currently reads, “To provide a set of best practices and universal precautions for safe and effective prescribing of opioids for acute, subacute, and chronic pain”. Commenter recommends the addition of “post-operative” to the list of subjects covered within the guidelines.</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Agree: the phrase “post-operative” should be included on this list for accuracy.</p>	<p>3.8 Goals and Objectives is amended to add “post-operative” to the list for accuracy.</p>
Opioid Medical Treatment Guidelines – Part 1 – Section 1 - 11	<p>Commenter notes that the formatting within the Part I of the Opioid Treatment Guidelines Sections 1 through 11 is inconsistent from section to section as well as within individual sections. Commenter recommends the document be consistently formatted utilizing numbers for each individual</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Agree: Formatting corrections were made so that paragraphs and sections are clearly identified and a consistent pattern is followed.</p>	<p>Formatting was amended to follow a consistent pattern broken up into two sections “A. Summary Information” and “B. Recommendations”. In each of the two sections, a consistent</p>

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	statement/recommendations and lower case letters for any subset within an individual statement/recommendation. Commenter recommends that this format be consistently applied to the entire the document for clarity as well as for ease of finding and references the information contained within.			numbering system is followed. See Table of Contents for the pattern followed.
Opioid Medical Treatment Guidelines – Opioids for Acute Pain	Commenter references 1 Opioids for Acute Pain (Up to Four Weeks after Date of Injury or Pain Onset). Commenter recommends that this section be ordered linearly from least significant injury recommendations to most severe. Commenter recommends making section 1.1 Mild Acute Injuries, section 1.2 Moderate to Severe Acute Injuries, and section 1.3 Severe Acute Injuries	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The order of these sections will be linearly from least significant injury recommendations to most severe.	The subsections for 1. Opioids for Acute Pain (up to four weeks after injury or pain onset) is rearranged beginning with 1.1. Mild Acute Injuries, 1.2 Moderate to Severe Acute Injuries, and 1.3 Severe Acute Injuries.
Opioid Medical Treatment Guidelines – Opioids for Acute Pain	Commenter references 1 Opioids for Acute Pain (Up to Four Weeks after Date of Injury or Pain Onset). Commenter notes that sections 1.1, 1.2, and 1.3 all address opioid use for acute injuries of varying degrees (mild, moderate to severe, and severe) and that the current content is	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The order of these sections will be linearly from least significant injury recommendations to most severe. Changing this remedies the inconsistencies in the ordering, phrasing, and the language used.	The subsections for 1. Opioids for Acute Pain (up to four weeks after injury or pain onset) is rearranged beginning with 1.1. Mild Acute Injuries, 1.2 Moderate to Severe

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	similar but inconsistent with regards to phrasing, language, and ordering. Commenter recommends that these inconsistencies are remedied and that to the extent possible, the ordering, phrasing, and language used be kept consistent throughout the sections.			Acute Injuries, and 1.3 Severe Acute Injuries.
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	Commenter notes that sections 1.1, 1.2, and 1.3 all address opioid use for acute injuries of varying degrees (mild, moderate to severe, and severe) and that the current content is similar but inconsistent with regards to phrasing, language, and ordering. Commenter recommends that these inconsistencies are remedied and that to the extent possible, the ordering, phrasing, and language used be kept consistent throughout the sections.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The order of these sections will be linearly from least significant injury recommendations to most severe. Changing this remedies the inconsistencies in the ordering, phrasing, and the language used.	The subsections for 1. Opioids for Acute Pain (up to four weeks after injury or pain onset) is rearranged beginning with 1.1. Mild Acute Injuries, 1.2 Moderate to Severe Acute Injuries, and 1.3 Severe Acute Injuries.
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	Commenter references 1.1 Moderate to Severe Acute Soft Tissue Injuries, page 20. Commenter recommends that the words “Soft Tissue” be removed from the subject heading as it appears too limiting for the subject matter and is contradictory to the examples provided which include moderate to severe radiculopathy.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: Use of the words “soft tissue” is overly restrictive in the context of a moderate to severe acute injury.	1.2 Moderate to Severe Acute Injuries is amended to remove “soft tissue” from the section title and whenever referenced in this section to clarify that the recommendations that follow are not limited to soft-tissue

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				injuries.
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.1 Moderate to Severe Acute Soft Tissue Injuries, page 20, first paragraph. “A brief course of short-acting opioids is an option to provide analgesia for moderate to acute severe pain...”</p> <p>Commenter notes that there appears to be a typo in the sentence. Commenter recommends the following revised language:</p> <p>“A brief course of short-acting opioids is an option to provide analgesia for moderate to <u>severe acute</u> pain”</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: Use of the words “soft tissue” is overly restrictive in the context of a moderate to severe injury.	1.2 Moderate to Severe Acute Injuries is amended by deleting the first use of the word “acute” to correct a typographical error. The phrase “soft tissue” is deleted from this section to clarify that the following guidelines are not limited to soft-tissue injuries.
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.1 Moderate to Severe Acute Soft Tissue Injuries, page 20, section 2, second bullet point. The statement currently reads, “Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.”</p> <p>Commenter recommends the addition of “home exercise program” to the list of items already present.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The addition of a home exercise program is not needed as physical activity and physical therapy are already mentioned, and these could also include a home exercise program.	None.
Opioid Medical	Commenter references 1.1 Moderate	Jill Rosenthal, MD	Disagree: Commenter’s	None.

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Treatment Guidelines – 1. Opioids for Acute Pain	to Severe Acute Soft Tissue Injuries, page 20, section 2, third bullet point. The statement currently reads “Complementary/alternative modalities, such as acupuncture, massage, and yoga. [62]” Commenter recommends utilizing the language as written in section 1.3 on page 24 which states “Complementary/alternative modalities, such as acupuncture, massage, and yoga <u>as relevant to the clinical condition.</u> [62]”. This statement should remain consistent throughout the section on Opioids for Acute Pain.	Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	suggested language “as relevant to the clinical condition” will not be incorporated because it is already implied as no treatment can be medically necessary if not relevant to the clinical condition. This concept of relevancy to the clinical condition is already integral to delivery of medical treatment and does not require reiteration.	
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	Commenter references 1.1 Moderate to Severe Acute Soft Tissue Injuries, page 20, section 3, second bullet point. The statement currently reads, “If CURES indicates the use of other opioid medications, but the assessment otherwise supports the use of opioids, prescribe only a limited supply of opioids at the lowest feasible dose under carefully monitored conditions. (See Section 3.3.4, Use of CURES to Ensure Safe and Effective Opioid Use)”	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The language as stated is clear without an exact repetition of the subsequent language.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter recommends adding the following language as is utilized in a similar segment in 1.2, page 23, third bullet point, number 1:</p> <p>“If CURES indicates the use of other opioid medications not revealed by patient history, but the assessment otherwise supports the use of opioids, prescribe only a limited supply of opioids at the lowest feasible dose under carefully monitored conditions. (See Section 3.3.4, Use of CURES to Ensure Safe and Effective Opioid Use)”</p>			
<p>Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain</p>	<p>Commenter references 1.1 Moderate to Severe Acute Soft Tissue Injuries, page 21, section 4. This section currently states:</p> <p>“Provide documentation in the medical record that the following conditions that are relative contraindications to initiating opioids are not present: depression, anxiety, personality disorder, untreated sleep disorders, current or past substance abuse, drug-seeking behavior, other psychotropic medications, post-traumatic stress disorder (PTSD),</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Agree: With Commenter that the list of relative contraindications be kept consistent throughout the Document.</p>	<p>1.2 Moderate to Severe Acute Injuries is amended by adding the phrases “particularly sleep apnea,” “cerebrovascular disease,” and “chronic hepatitis, cirrhosis,” to the list of conditions noted as relative contraindications to initiating opioids to maintain consistency</p>

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	<p>cognitive impairment, chronic obstructive pulmonary disease (COPD), severe obesity, balance problems / fall risk, osteoporosis, and renal failure. If these conditions are present, written documentation must be provided to justify the use of opioids. [7, 44, 63-81]”</p> <p>Commenter recommends that the list of relative contraindications be kept consistent throughout the document and recommends utilizing the language from 1.4 Opioids for Post-Operative pain, page 27, section 3 which includes the following list of relative contraindications: “Anxiety, depression, personality disorder, current or past substance abuse, drug-seeking behavior, untreated sleep disorders (particularly sleep apnea), use of other psychotropic medications, PTSD, cognitive impairment, cerebrovascular disease, balance problems / fall risk, COPD, chronic hepatitis, cirrhosis, renal failure, severe obesity, and osteoporosis. [7, 44, 63-81]”</p>			with other similar lists of conditions in the document.
Opioid Medical	Commenter references 1.1 Moderate	Jill Rosenthal, MD	Agree in part; Disagree in part:	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatment Guidelines – 1. Opioids for Acute Pain	<p>to Severe Acute Soft Tissue Injuries, page 21, section 5, first bullet point. The statement currently reads “If sedative hypnotics such as anti-histamines or benzodiazepines are being prescribed by a different treating physician (for example, for a non-industrial condition), it is important to communicate the risk to the other provider to facilitate coordinated patient care.”</p> <p>For inclusivity, Commenter recommends the following revised language:</p> <p>“If sedative hypnotics such as anti-histamines or benzodiazepines are being prescribed by a different treating physician (for example, for a non-industrial condition), it is important to communicate the risk to the patient and other provider to facilitate coordinated patient care.”</p>	Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: Communication of risk to the patient is essential. Disagree: with commenter’s suggestion to add the phrase “patient and” because the intent of this recommendation is to encourage communication to other prescribers of sedative hypnotics. Patient communication is fully addressed in multiple sections of the guideline, but not the need to communicate with other prescribers where it is emphasized here.	
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	Commenter references 1.1 Moderate to Severe Acute Soft Tissue Injuries, page 21, section 5, second bullet point. The statement currently reads “Opioid use is not recommended for patients actively performing safety	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Language is clear as written, unlikely that an injured worker with a moderate to severe acute injury would be driving or operating heavy equipment, but the	None.

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	<p>sensitive jobs. [82]”</p> <p>Commenter recommends that this bullet point be made its own numbered section utilizing the language as written in section 1.4, page 29, section 13 which expands upon the concept of risks while driving or in safety-sensitive work situations and states:</p> <p>“Caution patients about the potential adverse effects of opioid medications, including impacts on alertness. Driving and operation of heavy equipment should be, discouraged while on these medications. The use of opioids is contraindicated in patients performing safety-sensitive jobs. [82] (See Appendix B, Written Opioid Treatment Agreement [Sample])”</p>		<p>warning is already in the existing language.</p> <p>Disagree: See above.</p>	<p>None.</p>
<p>Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain</p>	<p>Commenter references 1.1 Moderate to Severe Acute Soft Tissue Injuries, page 21, bottom of the page, number 1. The statement currently reads “Prescribe weaker opioids and the lowest effective dose. Stronger opioids may be considered only if</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: The recommendations contained in these sections are evidence-based and may or may not apply to all sections suggested. A specific recommendation is made in Appendix D Select</p>	<p>None.</p>

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	<p>weaker ones are ineffective or not tolerated. The FDA categorizes drugs into five Schedules (from I to V). [83] Schedule V drugs (weakest) have the lowest potential for abuse and Schedule I drugs (strongest) are considered to have the highest potential for abuse. [84]”.</p> <p>Commenter recommends utilizing language from 1.2, page 23, bottom of page, number 2 which adds the Statement:</p> <p>“Long acting opioids should not be used for the treatment of acute pain. [61]”.</p> <p>For consistency purposes, commenter recommends this latter statement be added to all sections containing the former recommendation.</p>		<p>Black Box Warnings: Important Safety Information on Long-Acting Opioids, Morphine Long Acting Products.</p> <p>Disagree: See above.</p> <p>Disagree: A blanket prohibition against all long acting opioids is not the intent of the guideline, but should assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices or absolute prohibitions against a particular treatment.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.1 Moderate to Severe Acute Soft Tissue Injuries, page 21, bottom of page under number 2 a.</p> <p>Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day. Commenter also recommends removal of the reference to opioid naïve patients as the threshold is the same for all patients without delineation between opioid naïve and non-naïve patient populations.</p> <p>Commenter recommends the following revised language:</p> <p>“a. <u>Doses should not exceed 50</u> mg/day morphine equivalent dosage (MED). [77, 88, 89]”</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.</p> <p><u>Disagree that the reference “opioid naïve” be removed so that the threshold be the same for all patients without delineation between opioid naïve and non-naïve patient populations. There is a significant clinical difference between the two that is intentionally acknowledged by the current language. Section 1.1 Moderate to Severe Acute Soft Tissue Injuries addresses</u></p>	<p><u>None.</u></p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p><u>short-term opioid therapy for an acute injury such as a fracture, crush injury or similar condition where the patient may experience extreme pain. The MED threshold of 80 mg could well be inadequate to control extreme pain in a patient who is already receiving opioid analgesics on a daily basis. This recommendation is accompanied by a full set of precautions and specific actions to monitor effects to prevent adverse outcomes as outlined in section 3.3.8. Opioid Titration and Dosing Threshold.</u></p>	
<p>Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain</p>	<p>Commenter references 1.2 Mild Acute Injuries, pages 23 and 24.</p> <p>Commenter notes that the use of bullet points in this section to denote individual topics varies from the use of numbers in other sections. For consistency and clarity, commenter recommends that the formatting of</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Aside from the general formatting revisions made and beginning the “1. Opioids for Acute Pain (Up to Four Weeks After Injury or Pain Onset)” section with “Mild Acute Injuries” rather than “Moderated to Severe Acute Soft-Tissue Injuries” this</p>	<p>No change were made as a result of the comment, but the order was reversed so that the “1. Opioids for Acute Pain (Up to Four Weeks After Injury or Pain Onset)” section</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	this section be modified and numbers be utilized at the start of each content item with lower case letters utilized as subsets within the broader subject/content. This formatting should stay consist within in all sections of the document.		section uses bullet points and numbers consistent with other sections. Formatting	begins with “Mild Acute Injuries” rather than “Moderate to Severe Acute Soft-Tissue Injuries” for better flow.
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.2 Mild Acute Injuries, page 23, first bullet point, second subset bullet point. The statement currently reads, “Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.”</p> <p>Commenter recommends the addition of “home exercise program” to the list of items already present.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The addition of a home exercise program is not needed as physical activity and physical therapy are already mentioned, and these could also include a home exercise program.	None.
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.2 Mild Acute Injuries, page 23, first bullet point, third subset bullet point. The statement currently reads:</p> <p>“Complementary/alternative modalities, such as acupuncture, massage, and yoga. [62]”</p> <p>For consistency commenter recommends utilizing the language as</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Addition of the suggested language is not needed for clarification. All treatment to injured workers should be relevant to the clinical condition so this does not need to repeated throughout.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>written in section 1.3 on page 24 which states:</p> <p>“Complementary/alternative modalities, such as acupuncture, massage, and yoga <u>as relevant to the clinical condition.</u> [62]”.</p> <p>Commenter recommends that this statement be used consistently throughout the section on Opioids for Acute Pain to avoid internal inconsistencies and discrepancies in usage.</p>			
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.2 Mild Acute Injuries. Commenter recommends adding recommendations regarding introduction of sedative-hypnotics if considering opioids. Commenter notes that this recommendation is present in both sections 1.1 (see page 21, section5) and 1.3 (see page 25, section 5).</p> <p>Commenter recommends that the following statement be added to section 1.2 Mild Acute Injuries for accuracy and consistency purposes:</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Section 1.2 Mild acute injuries was moved to precede the other two sections. Opioids are not recommended for mild acute injuries and this section is less detailed in general. The recommendations for Moderate to Severe Acute Injuries should apply if opioids are considered for analgesia.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>“Do not introduce sedative-hypnotics, including anti-histamines (H1-blockers) and benzodiazepines, if considering prescribing opioids. Attempt to discontinue these medications in patients receiving them if prescribing opioids. [91] (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics)</p> <ul style="list-style-type: none"> • If sedative hypnotics such as anti-histamines or benzodiazepines are being prescribed by a different treating physician (for example, for a non-industrial condition), it is important to communicate the risk to the other provider to facilitate coordinated patient care.” 		Disagree: See above.	None.
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.3 Severe Acute Injuries (e.g., fractures, crush injuries, major trauma, large burns, other injuries with significant tissue damage), page 24.</p> <p>Commenter recommends better delineation of the term “large</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The severity levels of burns are well established and are included here as broad examples and are not intended to provide guidance on a specific injury. There are other categories of burn injury that might also be included, such as	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>burns” and suggests the following language:</p> <p>“1.3 Severe Acute Injuries (e.g., fractures, crush injuries, major trauma, <u>third degree burns with involvement of > 15% TBSA</u>, other injuries with significant tissue damage)”</p>		extensive second-degree burns so the suggested language may be too limiting.	
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.3 Severe Acute Injuries, page 24, section 2, second bullet point. The statement currently reads:</p> <p>“Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.”</p> <p>Commenter recommends the addition of “home exercise program” to the list of items already present.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The addition of a home exercise program is not needed as physical activity and physical therapy are already mentioned, and these could also include a home exercise program.	None.
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	<p>Commenter references 1.3 Severe Acute Injuries, page 25, first bullet point (under subset of section 3 on prior page). The statement currently reads:</p> <p>“If the search indicates that other opioids are being used, the patient</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Commenter’s suggestion to add the phrase “not revealed by patient history” is unnecessary because the language as stated is clear. See above.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>should be questioned about the additional medications. If the clinical assessment supports the use of additional opioids, only a limited supply should be prescribed under carefully monitored conditions.”</p> <p>Commenter states that this statement is inconsistent with verbiage used in other sections. For consistency purposes, Commenter recommends utilization of the language used in 1.1, page 20, section 3, second bullet point with changes that commenter has recommend. Commenter recommends the following revised language:</p> <p>“If CURES indicates the use of other opioid medications <u>not revealed by patient history</u>, but the assessment otherwise supports the use of opioids, prescribe only a limited supply of opioids at the lowest feasible dose under carefully monitored conditions. (See Section 3.3.4, Use of CURES to Ensure Safe and Effective Opioid Use)”</p>			
Opioid Medical Treatment	Commenter references 1.3 Severe Acute Injuries, page 25, sections 5	Jill Rosenthal, MD Sr. Vice President &	Disagree: Commenter’s suggested changes are all	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Guidelines – 1. Opioids for Acute Pain</p>	<p>and 6. Commenter notes duplicative recommendations listed under section 6 regarding use of sedative hypnotics; commenter recommends removal of this duplicative statement.</p> <p>Commenter notes that the second bullet point under section 6 which states “Opioid use is not recommended for patients actively performing safety-sensitive jobs. [82]” is utilized in prior sections along with the recommendations in section 5.</p> <p>For consistency purposes and in alignment with prior recommendations made, commenter recommends that these two sections be amended to read as follows:</p> <p>“5. Do not introduce sedative-hypnotics, including anti-histamines (H1-blockers) and benzodiazepines, if considering prescribing opioids. Attempt to discontinue these medications in patients receiving them if prescribing opioids. [91] (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics)</p>	<p>Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>covered in this section and the order in which it is discussed does not carry substantive weight. In addition, the statement, “If sedative hypnotics such as anti-histamines...” although stated twice, is triggered by two different situations, one for sedative-hypnotics and the other for use of illicit substances.</p> <p>Disagree: with commenter’s suggestion to add the phrase “patient and” because the intent of this recommendation is to encourage communication to other prescribers of sedative hypnotics. Patient communication is fully addressed in multiple sections of the guideline, but not the need to communicate with other prescribers where it is emphasized here.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<ul style="list-style-type: none"> • If sedative hypnotics such as anti-histamines or benzodiazepines are being prescribed by a different treating physician (for example, for a non-industrial condition), it is important to communicate the risk to the <u>patient and</u> other provider to facilitate coordinated patient care. • Caution patients about the potential adverse effects of opioid medications, including impacts on alertness. Driving and operation of heavy equipment should be discouraged while on these medications. The use of opioids is contraindicated in patients performing safety-sensitive jobs. [82] (See Appendix B, Written Opioid Treatment Agreement [Sample]) <p>6. Document that there is no use of illicit substances or of substances that</p>			

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>should not be taken concomitantly (e.g., sedating medications including alcohol and benzodiazepines). [33]</p> <p>The use of illicit substances is a contraindication to opioid treatment. (See Section 7, Concurrent Use of Benzodiazepines and Other Sedative Hypnotics)</p>			
<p>Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain</p>	<p>Commenter references 1.3 Severe Acute Injuries, page 26, top of page, number 2 a.</p> <p>Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day. Commenter also recommends removal of the reference to opioid naïve patients as the threshold is the same for all patients without delineation between opioid naïve and non-naïve patient populations.</p> <p>Commenter recommends the following revised language:</p> <p>“a. <u>Doses should not exceed 50</u> mg/day morphine equivalent dosage (MED). [77, 88, 89]”</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.</p>	
<p>Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain</p>	<p>Commenter references 1.4 Opioids for Post-operative Pain, page 27, first bullet point, first sentence. The statement currently reads: “Opioid use for a limited duration is recommended for management of</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Agree: The typographical error should be amended.</p>	<p>1.4. Opioids for Post-operative Pain, first bullet point is amended to delete the double reference to “management” so that it now states,</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>postoperative pain management in addition to other treatments, especially during the immediate post-operative period and for moderate to extensive surgical procedures (e.g., arthroplasty, lumbar fusion).”</p> <p>Commenter notes a typo and recommends the removal of the word “management” as follows:</p> <p>“Opioid use for a limited duration is recommended for management of post-operative pain management in addition to other treatments, especially during the immediate post-operative period and for moderate to extensive surgical procedures (e.g., arthroplasty, lumbar fusion).”</p>			<p>“Opioid use for a limited duration is recommended for post-operative pain management...”</p>
<p>Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain</p>	<p>Commenter references 1.4 Opioids for Post-operative Pain, page 27, second bullet point, number 2. The statement currently reads:</p> <p>“Prior to surgery and to prescribing opioids, the CURES database is checked and the results documented. If the search indicates that other opioids are being used, the patient should be questioned about the</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Commenter’s suggested change does not offer any substantive change to the proposed text. The text as written “If the search indicates that other opioids are being used...” is clear and the phrase “not revealed by patient history” will not be incorporated.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>additional medications. If the clinical assessment supports the use of additional opioids, only a limited supply should be prescribed under carefully monitored conditions.”</p> <p>For consistency purposes, commenter recommends utilization of the language used in 1.1, page 20, section 3, second bullet point with changes as indicated above in comment 25.</p> <p>Commenter recommends the following revised language:</p> <p>“Prior to surgery and to prescribing opioids, the CURES database is checked and the results documented. If CURES indicates the use of other opioid medications <u>not revealed by patient history</u>, but the assessment otherwise supports the use of opioids, prescribe only a limited supply of opioids at the lowest feasible dose under carefully monitored conditions.”</p>			
Opioid Medical Treatment Guidelines – 1. Opioids for Acute	Commenter references 1.4 Opioids for Post-operative Pain, page 28, first bullet point, number 1. The statement currently reads:	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co.	Disagree: This section is intended to address post-operative treatment.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Pain	<p>“1. Avoid introducing sedative-hypnotics including anti-histamines (H1-blockers) and/or benzodiazepines before surgery. Attempt to discontinue these medications in patients who are receiving them prior to surgery. [33]”.</p> <p>Zenith recommends the addition of the following language to read:</p> <p>“Avoid introducing sedative-hypnotics including anti-histamines (H1-blockers) and/or benzodiazepines before or after surgery. Attempt to discontinue these medications in patients who are receiving them prior to surgery. [33]”</p>	September 1, 2015 Written Comment		
Opioid Medical Treatment Guidelines – 1. Opioids for Acute Pain	Commenter references 1.4 Opioids for Post-operative Pain, page 28, first bullet point, number 5a. Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day. Commenter also recommends removal of the reference to opioid naïve patients as the	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010),	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>threshold is the same for all patients without delineation between opioid naïve and non-naïve patient populations.</p> <p>Commenter recommends the following revised language:</p> <p>“a. <u>Doses should not exceed 50</u> mg/day morphine equivalent dosage (MED). [77, 88, 89]”.</p>		<p>with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.	
Opioid Medical Treatment Guidelines – 2. Opioids for Subacute Pain	<p>Commenter references the section heading. Commenter recommends that the guidelines consistently reference the timeframes for acute, subacute, and chronic pain in weeks versus months. Commenter recommends the following revised language:</p> <p>“2. Opioids for Subacute Pain (pain lasting from 4-12 weeks)”</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Referencing the timeframe for acute, subacute and chronic pain in weeks will remain because it is consistent with our regulatory definition of Chronic Pain in section 9792.20(b).</p>	<p>None.</p>
Opioid Medical Treatment Guidelines – 2. Opioids for Subacute Pain	<p>Commenter references the opening paragraph. The statement currently reads:</p> <p>“If pain extends beyond the acute phase, i.e., beyond one (1) month following onset, a multidisciplinary approach to treatment should be continued (or initiated if not yet used), including cognitive-behavioral therapy, activity coaching, graded exercise, and other treatments such as acupuncture.”</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Commenter’s suggested language “when appropriate for the clinical condition” will not be incorporated because it is already implied as no treatment can be medically necessary if not appropriate for the clinical condition. This concept of appropriateness to the clinical condition is already integral to delivery of medical treatment and does not require reiteration.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter notes that the statement seems to imply a requirement for the listed items.</p> <p>Commenter recommends that the following language be utilized to incorporate the idea of care that is clinically appropriate to the individual circumstances of the case:</p> <p>“If pain extends beyond the acute phase, i.e., beyond one (1) month following onset, a multidisciplinary approach to treatment should be continued (or initiated if not yet used) <u>when appropriate for the clinical condition</u>, including cognitive-behavioral therapy, activity coaching, graded exercise, and other treatments such as acupuncture.”</p>			
Opioid Medical Treatment Guidelines – 2. Opioids for Subacute Pain	<p>Commenter references page 30, section 4b. The statement currently reads:</p> <p>“The following conditions are relative contraindications to continuing opioids during the subacute phase: Depression, anxiety, personality disorder, untreated sleep disorders,</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: With Commenter that the list of relative contraindications be kept consistent throughout the Document.	2. Opioids for Subacute Pain (1-3 Months), 4 th item is amended by adding the phrases “particularly sleep apnea,” “cerebrovascular disease,” and “chronic hepatitis,

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	<p>past substance abuse, drug seeking behavior, other psychotropic medications, PTSD, cognitive impairment, COPD, severe obesity, balance problems / fall risk, osteoporosis, and renal failure. If any of these conditions are present, written documentation should be provided in the medical record to justify the use of opioids. [7, 44, 63-81]”</p> <p>Commenter recommends that the list of relative contraindications be kept consistent throughout the document by utilizing the language from 1.4 Opioids for Post-Operative pain, page 27, section 3 which includes the following list of relative contraindications: “Anxiety, depression, personality disorder, current or past substance abuse, drug-seeking behavior, untreated sleep disorders (particularly sleep apnea), use of other psychotropic medications, PTSD, cognitive impairment, cerebrovascular disease, balance problems / fall risk, COPD, chronic hepatitis, cirrhosis, renal failure, severe obesity, and</p>			<p>cirrhosis,” to the list of conditions noted as relative contraindications to initiating opioids to maintain consistency with other similar lists of conditions in the document.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	osteoporosis. [7, 44, 63-81]”			
Opioid Medical Treatment Guidelines – 2. Opioids for Subacute Pain	Commenter references page 31, section 5, second bullet point. The statement currently reads, “Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.” Commenter recommends the addition of “home exercise program” to the list of items already present.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The addition of a home exercise program is not needed as physical activity and physical therapy are already mentioned, and these could also include a home exercise program.	None.
Opioid Medical Treatment Guidelines – 2. Opioids for Subacute Pain	<p>Commenter references page 31, section 9a. The statement currently reads, “Do not exceed a dose of 80 mg/day MED for opioid-naïve patients (those who are not already on higher doses of opioids). [77, 88, 89]”</p> <p>Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day. Commenter also recommends removal of the reference to opioid naïve patients as the threshold is the same for all patients without delineation between opioid naïve and non-naïve patient populations.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter recommends the following revised language:</p> <p>“a. <u>Doses should not exceed 50</u> mg/day morphine equivalent dosage (MED). [77, 88, 89]”</p>		<p>over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.</p>	
<p>Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and</p>	<p>Commenter references page 32, opening paragraph. The statement currently reads:</p> <p>“The term “chronic pain” is defined</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015</p>	<p>Disagree: Commenter’s suggestion that the guidelines</p>	<p>Although commenter’s</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chronic Opioid Treatment	<p>in this guideline as pain lasting longer than three (3) months from the initial onset of injury pain (i.e., over 12 weeks). Patients with chronic pain may be candidates for treatment with opioids if pain management and functional improvement have not been achieved with a multidisciplinary treatment approach, including passive and active movement, cognitive behavioral therapy, and other practices such as acupuncture. Patients who require treatment with opioids to relieve pain or improve function for durations longer than three (3) months are considered as being on chronic opioid treatment.”</p> <p>Committer recommends that the guidelines consistently reference the timeframes for acute, subacute, and chronic pain in weeks versus months. Committer also notes that the statement implies a requirement of the listed treatment instead of treatment as is clinically appropriate based on individual case facts.</p> <p>Committer recommends the</p>	Written Comment	<p>reference timeframes for acute, subacute and chronic pain in weeks versus months will not be incorporated. However, the definition for chronic pain should be consistent according to definition of chronic pain set forth in section 9792.20 that is defined as “pain lasting three or more months from the initial onset of pain.”</p> <p>Disagree: Acute Pain it is already defined as “pain lasting up to four (4) weeks”. For Subacute Pain it is defined pain lasting “beyond one (1) month” and for Chronic Pain it is defined as “pain lasting three (3) or more months”. We will leave the references to “month” because it is consistent with our current regulatory definition of</p>	<p>suggestions did not prompt this action, it is important to note that the definition of chronic pain has been amended from “pain lasting longer than three (3) months” to “pain lasting three or more months from the initial onset of pain.”</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>following revised language:</p> <p>“The term “chronic pain” is defined in this guideline as pain lasting longer than <u>twelve (12) weeks</u> from the initial onset of injury pain (i.e., over <u>3 months</u>). Patients with chronic pain may be candidates for treatment with opioids if pain management and functional improvement have not been achieved with a multidisciplinary treatment approach, including passive and active movement, cognitive behavioral therapy, and other practices <u>when appropriate for the clinical condition</u>. Patients who require treatment with opioids to relieve pain or improve function for durations longer than <u>twelve (12) weeks</u> are considered as being on chronic opioid treatment.”</p>		Chronic Pain set forth in section 9792.20(b).	
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references page 33, middle of page, number 1. The statement currently reads:</p> <p>“Check CURES to ensure that narcotic medications are not being prescribed by other providers. (See Section 3.3.4, Use of CURES to Ensure Safe and Effective Opioid</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The word “narcotics” is used here because we wanted to identify all controlled substances that might impact opioid prescriptions, not just opioids but other drug classes such as benzodiazepines.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Use) If CURES indicates the simultaneous use of other narcotic medication not revealed by patient history, justification should be provided for chronic opioid therapy.”</p> <p>Commenter notes that this is the only section that references “narcotics”; other sections refer to “opioids”. For consistency purposes, commenter recommends that the word “opioids” be substituted in each instance that “narcotics” is used in the statement.</p>			
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	Commenter references page 33, middle of page, number 3. The statement currently reads, “Use urine drug testing for initiation and monitoring of chronic opioid therapy.” Commenter recommends adding the word “random” in front of “urine drug testing” as random urine drug screenings are the recommended best practice as noted in Table 2. Timing and Frequency of UDT.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: This list is an overview, the topic of urine drug screen is covered thoroughly in section 3.3.6 Use of Urine Drug Testing (UDT) which states, “Conduct UDT on a random basis during chronic opioid treatment...”	None.
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid	Commenter references 3.1 Comprehensive Evaluation and Assessment of Patient, page 34, number 4. Commenter recommends adding subset 4a to address subjective versus objective findings.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Suggested language is not evidence-based, see introduction to the proposed MTUS Chronic Pain Medical Treatment Guidelines for evidence-based content on	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatment	<p>Commenter recommends the following revised language:</p> <p>“a. Caution should be used if significant discrepancies are noted between subjective complaints and objective physical exam findings”</p>		pain.	
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.1 Comprehensive Evaluation and Assessment of Patient, page 34, number 5, second bullet point. The statement currently reads, “A history of substance abuse, misuse, or addiction.” Commenter recommends adding “drug seeking behavior” to the list of items.</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Substance abuse, misuse and addiction, includes behaviors such as “drug seeking behavior” and are not needed for clarification.</p>	None.
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.1 Comprehensive Evaluation and Assessment of Patient, page 35, first bullet point, second paragraph. The statement currently reads, “These conditions are relative contraindications to chronic opioid therapy, and in their presence, written documentation should be provided in the medical record to justify the use of these medications and show that other alternatives have been considered and are not feasible.”</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: All considered treatment does not need to be “tried and failed”, patient-centered factors or other clinical considerations may make some alternatives unacceptable. These alternatives, however, would have been considered and should be documented in the clinical record.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter recommends adding the following language:</p> <p>“These conditions are relative contraindications to chronic opioid therapy, and in their presence, written documentation should be provided in the medical record to justify the use of these medications and show that other alternatives have been <u>tried and failed or</u> considered and are not feasible.”</p>			
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.1 Comprehensive Evaluation and Assessment of Patient, page 35, second bullet point. The statement currently reads, “Social factors that may impact pain management including: employment, job satisfaction, marital history, social network, and history of legal problems. [7]”</p> <p>Commenter recommends adding “known preadolescent sexual abuse” to the list of items already present.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	<p>Agree in part; Disagree in part: Agree: that preadolescent sexual abuse is a known risk factor. Disagree: that “known preadolescent sexual abuse” needs to be specified, as it is one of many social risk factors that could impact the patient’s response to opioid therapy. Language as written intends to include preadolescent sexual abuse.</p>	None.
Opioid Medical Treatment Guidelines – 3.	Commenter references 3.2 Consideration of Alternative Treatments for Chronic Pain and	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer	Disagree: The addition of a home exercise program is not needed as physical activity and	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Chronic Opioid Treatment, page 35, second bullet point. The statement currently reads, “Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury.”</p> <p>Commenter recommends the addition of “home exercise program” to the list of items already present.</p>	Zenith Insurance Co. September 1, 2015 Written Comment	physical therapy are already mentioned, and these could also include a home exercise program.	
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.2 Consideration of Alternative Treatments for Chronic Pain and Chronic Opioid Treatment, page 35, third bullet point. The statement currently reads “Complementary/alternative modalities, such as acupuncture, massage, and yoga. [62]”</p> <p>Commenter recommends utilizing the language as written in section 1.3 on page 24 which states “Complementary/alternative modalities, such as acupuncture, massage, and yoga <u>as relevant to the clinical condition</u>. [62]”. This statement should remain consistent throughout the guidelines.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Treatment for workers’ compensation injury is required to be relevant to the accepted injury. The addition of language “as relevant to the clinical condition” does not substantively enhance or clarify the current text as written.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.3.1.1 Screening for Drug Misuse/Abuse, page 36, section 1b. The statement currently reads, “During the opioid trial or during chronic opioid treatment, screening should be performed, as needed, to identify current abuse/misuse of opioid medications.”</p> <p>Commenter states that random testing is preferred so that patients are not aware of when the next test will be administered.</p> <p>Commenter recommends the following revised language:</p> <p>“During the opioid trial or during chronic opioid treatment, <u>random</u> screening should be performed, as needed, to identify current abuse/misuse of opioid medications.”</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	<p>Agree in part; Disagree in part: Agree: that random screening should be performed. Disagree: that text needs to be changed here. Section 3.3.6. (4) b Use of Urine drug testing (UDT), Frequency of UDT states: “Conduct UDT on a random basis during chronic opioid treatment, and adjust in frequency as relevant after assessment for risk of abuse, misuse, or diversion (references cited)”.</p>	None.
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.3.1.1 Screening for Drug Misuse/Abuse, page 37, section 3. The statement currently reads:</p> <p>“Initiate chronic opioid treatment only if the screening tools identify a</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Language as written does not require additional “strengthening” by making additional demands on the physician to document “specific actions” and “all” identified risks. Language is	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>predicted increased risk for substance misuse/abuse and other alternatives are not viable; in this case, provide documentation in the medical record that attempts are being made to address the identified risks.”</p> <p>Commenter recommends this statement be strengthened by making the following suggested amendment: “Initiate chronic opioid treatment only if the screening tools identify a predicted increased risk for substance misuse/abuse and other alternatives are not viable; in this case, provide documentation in the medical record <u>of the specific actions and</u> attempts are being made to address <u>all</u> identified risks.”</p>		clear as stated.	
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.3.1.1 Screening for Drug Misuse/Abuse, page 37, section 5. The statement currently reads:</p> <p>“Avoid routine genomic testing to predict adverse effects of opioids, including the potential for abuse, as this type of testing not recommended. [54, 94]”</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree in part; Disagree in part: Agree: the reason for not recommending genomic testing is a lack of evidence. Disagree: that language requires clarification, because references are given that demonstrate the lack of efficacy. Commenter’s suggested language will not be incorporated.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter notes that in the rationale for this section it is made clear that evidence to support genetic testing is currently lacking. However, as written, section 5 does not clearly indicate this. Commenter recommends that section 5 be amended to provide clarity on the issue and suggests the following language:</p> <p>“Avoid genomic testing to predict adverse effects of opioids, including the potential for abuse, as <u>evidence that genetic testing reliably predicts the potential for abuse is currently lacking.</u> [54, 94]”</p>			
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.3.1.3 Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse, page 38, section 1. The statement currently reads, “Use a validated tool to screen for depressive symptoms (e.g., PHQ-9) to document results prior to initiating a trial of chronic opioid treatment. [60]”</p> <p>Commenter notes an apparent typo in the text and recommends that the</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: There is a typographical error that needs to be corrected.	Section 3.3.1.3. Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse, item #1 the word “to” is deleted and replaced with the word “and” to correct a typographical error.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	word “to” after the parenthesis be changed to “and”.			
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	Commenter references 3.3.1.3 Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse, page 38, section 2. The statement currently reads, “Assess and document the presence of other mental health conditions such as anxiety disorder, severe sleep disorder, PTSD or suicidal ideation.” Commenter recommends adding “known history of preadolescent sexual abuse” to the list of items already present.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree in part; Disagree in part: Agree: that preadolescent sexual abuse is a known risk factor. Disagree: that “known preadolescent sexual abuse “needs to be specified, as it is one of many social risk factors that could impact the patient’s response to opioid therapy. Language as written intends to include preadolescent sexual abuse.	None.
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.3.1.3 Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse, page 38, section 3. The statement currently reads, “Document mental health conditions identified by screening tools and obtain a consultation with a licensed mental health professional prior to initiating a trial of chronic opioid treatment.”</p> <p>Commenter notes that this statement implies a requirement and recommends that the statement be</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: If mental health conditions are identified, the medical evidence strongly suggests consultation with a licensed mental health professional prior to initiating a trial of chronic opioid treatment. If a mental health condition is identified but a referral to a mental health professional was not made, then patient factors must be documented explaining why the referral was not medically appropriate. Clinical	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	modified to include a statement that consultation should occur “if warranted”.		assessments are made on a case-by-case basis.	
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	Commenter references 3.3.2 Patient Treatment Agreement and Informed Consent, page 39, section 3a. The statement currently reads, “Revisit the treatment agreement more frequently if warranted and modified if needed.” Commenter notes an apparent typo in the text and recommends that the word “modified” be changed to “modify”.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: There is a typographical error that needs to be corrected.	Section 3.3.2. Patient Treatment Agreement and Informed Consent, item #3a. the word “modified” is deleted and replaced with the word “modify” to correct a typographical error.
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	Commenter references 3.3.2 Patient Treatment Agreement and Informed Consent, page 39, section 3b. The statement currently reads, “Modify the treatment agreement update it as necessary if the patient does not adhere to the treatment plan” Commenter notes an apparent typo in the text and recommends the words “update it” be removed from the sentence.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: There is a typographical error that needs to be corrected.	Section 3.3.2. Patient Treatment Agreement and Informed Consent, item #3b. the phrase “update it” is deleted to correct a typographical error.
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and	Commenter references 3.3.2 Patient Treatment Agreement and Informed Consent, page 39. Commenter recommends adding a section 5 to this guideline to address	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015	Disagree: 3.3.2 Patient Treatment Agreement and Informed Consent, item 4. states: “Document in the medical record any misuse,	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Chronic Opioid Treatment	<p>consideration of tapering/weaning if a patient does not adhere to the agreed upon treatment plan. Commenter recommends that the following language be added as 3.3.2.5:</p> <p>“Consideration should be given to tapering/weaning if the patient does not adhere to the agreed upon treatment plan as written. If a determination is made to continue opioid treatment after non-compliance with a treatment plan, documentation must include a rationale as to why continuation is appropriate, how the non-compliance is being monitored and addressed, and when weaning/tapering will next be considered. This information should be reviewed with the patient and documented in an updated Patient Treatment Agreement”</p>	Written Comment	<p>abuse, or diversion that is identified while the patient agreement is in effect. Provide documentation if the original agreement terms are modified addressing the issue of concern and why and how the original agreement was modified.”</p> <p>Tapering is then described in Section 4. Tapering Opioids. See 4.1 Indications for tapering Opioids, Item 1, bullet 5. And the rationale that follows.</p> <p>Additional clarification is not needed in section 3.3.2.5.</p>	
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.3.8 Opioid Titration and Dosing Threshold, page 49, section 1. Dosage threshold and increases, opening paragraph, second sentence. The statement currently reads, “For dosages above 80 mg/day MED, 10 providers should be increasingly vigilant, as the known</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>risk of adverse events increases while the evidence for increased benefit remains weak. [77, 88, 89]”</p> <p>Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day.</p>		<p>200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.	
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	<p>Commenter references 3.3.8 Opioid Titration and Dosing Threshold, page 50, section 3. Criteria for dosage increase, number 3e. The statement currently reads, “Aberrant behavior: Evaluate for possible drug abuse-related behavior. No evidence should exist for a current substance use disorder. If the patient has had a history of opioid use disorder, the concurrence of an addiction specialist is required to continue opioid treatment as well as for dose escalation.”</p> <p>Commenter recommends that an addiction specialist be “strongly recommended” rather than “required” as is currently written as there may be circumstances where this specialist is not warranted or the service can be provided by the prescribing physician.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	<p>Agree in part; Disagree in part: Agree: The word “required” is too prescriptive and will be removed. Disagree: Commenter’s suggestion that the phrase “strongly recommended” will not be incorporated because the word “recommended” is sufficient.</p>	Opioids Treatment Guidelines, B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Pain Treatment, 3.3.8. Opioid Titration and Dosing Threshold, item 3.e. is amended by deleting the word “required” and replacing it with the word “recommended” to clarify the Opioids Medical Treatment Guidelines along with the other guidelines set forth in the MTUS are

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices.
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	Commenter references 3.3.9 Maintenance of Chronic Opioid Treatment, page 52, section 2d. The statement currently reads, “Aberrant behavior: Current substance use disorder or evidence of diversion. If the patient has had a history of opioid use disorder, the concurrence of an addiction specialist is required to continue opioid treatment as well as for dose escalation” Zenith recommends that an addiction specialist be “strongly recommended” rather than “required” as is currently written as there may be circumstances where this specialist is not warranted or the service can be provided by the prescribing physician.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree in part; Disagree in part: Agree: The word “required” is too prescriptive and will be removed. Disagree: Commenter’s suggestion that the phrase “strongly recommended” will not be incorporated because the word “recommended” is sufficient.	Opioids Treatment Guidelines, B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Pain Treatment, 3.3.9. Maintenance of Chronic Opioid Treatment, item 3.d. is amended by deleting the word “required” and replacing it with the word “recommended” to clarify the Opioids

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				Medical Treatment Guidelines along with the other guidelines set forth in the MTUS are designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices.
Opioid Medical Treatment Guidelines – 3. Opioids for Chronic Pain and Chronic Opioid Treatment	Commenter references 3.3.9 Maintenance of Chronic Opioid Treatment, page 52, section 3. The statement currently reads, “Conduct semiannual attempts to wean to lower than 80 mg/day MED in patients whose dose is above 80 mg/day MED, and who have been on that dose or higher for at least 180 days (i.e., six [6] months). [77, 88, 89]” Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Opioid Medical Treatment Guidelines – 4. Tapering Opioids	<p>Commenter references 4.1 Indications for Tapering Opioids, page 53, opening paragraph, first sentence. The statement currently reads, “Tapering, also known as weaning, refers to <u>reducing</u> the gradual reduction of the prescribed dose of opioids to the lowest dose effective in controlling pain and improving function.”</p> <p>Commenter notes an apparent typo in the text and recommends removing the word “reducing” as underlined above.</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Agree: The typographical error will be corrected.</p>	<p>Section 4.1 Indications for Tapering Opioids first paragraph is amended to delete the word “reducing” because it is a typographical error.</p>
Opioid Medical Treatment Guidelines – 4. Tapering Opioids	<p>Commenter references 4.1 Indications for Tapering Opioids, page 54, first paragraph, last sentence. The statement currently reads, “Patients who have been taking over 80 mg/day MED for over six (6) months and who are making their semiannual weaning attempt need only wean to below 80 mg/day MED. [77, 88, 89]”</p> <p>Commenter recommends that the referenced morphine equivalency dose be changed from 80 mg/day to 50 mg/day.</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day 200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.</p>	
Opioid Medical	Commenter references page 56,	Jill Rosenthal, MD	Disagree: The results of the	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Treatment Guidelines – 6. Consultation with Specialists	<p>second paragraph. The statement currently reads, “Consultation may be considered medically necessary in the following situations, based on clinical assessment.” Zenith notes that while consultation may be appropriate, consideration should also be given to transfer of care to a more appropriate specialist for ongoing treatment.</p> <p>Commenter recommends the following revised language:</p> <p>“Consultation <u>or referral to an appropriate specialist</u> may be considered medically necessary in the following situations, based on clinical assessment.”</p>	Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	consultation by a specialist may result in ongoing treatment as a secondary specialist provider. DWC does not intent only a single consultative visit is medically appropriate in all cases. Any consultative visit in a worker’s compensation case may lead to ongoing treatment by that physician as a secondary specialist provider and needs no additional clarification here or any other time consultative visits are mentioned throughout the MTUS.	
Opioid Medical Treatment Guidelines – 9. Managing Peri-operative Pain in Workers on Chronic Opioid Treatment Undergoing Elective Surgery	<p>Commenter references page 60, section 2. Day of Surgery, c. The statement currently reads, “Consider the use of other non-opioid analgesic adjuncts (e.g. gabapentin, ketamine or lidocaine) for opioid-sparing effects.”</p> <p>Commenter is concerned regarding the inclusion of ketamine in the list of suggested non-opioid analgesic adjuncts. Ketamine is a powerful</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: This only refers to day of surgery, intra-operatively, by the anesthesiologist and this recommendation is based on medical evidence.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>general anesthetic and schedule III controlled substance.</p> <p>Commenter recommends removal of this medication (ketamine) from the list of examples and suggests inclusion of another non-opioid analgesic such as Ketorolac as an alternative.</p>			
<p>Opioid Medical Treatment Guidelines – 10. Opioid Use in Catastrophic Injuries</p>	<p>Commenter references page 61, opening paragraph, first sentence. The statement currently reads, “Catastrophic injuries in which significant recovery of physical function is not expected, such as severe burns, crush, or spinal cord injury, are exempt from many of the recommendations in this guideline.”</p> <p>Commenter recommends using a consistent definition of “Catastrophic Injury.” Commenter recommends the following language:</p> <p>“Catastrophic injuries resulting in loss of limb, paralysis, severe burn, or severe head injury (including traumatic brain injury) from which significant recovery of physical function is not expected. “</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Commenter’s suggested revisions will not be incorporated because the important part of the definition of “Catastrophic injuries” is the phrase “in which significant recovery of physical function is not expected” not the sample laundry list of injuries. No changes will be made because the proposed definition contains the phrase “in which significant recovery of physical function is not expected”.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Opioid Medical Treatment Guidelines – Appendix A2a	Commenter references Pain Numeric Rating Scale, page 73, number 4. Commenter notes that the numbering from 0 to 10 is missing and recommends the form be updated to include numbering for consistency.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The typographical error will be corrected to add the scale from 0 – 10 on, number 4.	Appendix A2a, item #4 is amended to add the scale from 0 -10 for consistency with the other items.
Opioid Medical Treatment Guidelines – Appendix A2c	<p>Commenter references Graded Chronic Pain Scale (GCPS) (Longer Survey), page 75, numbers 1, 4, 5, 6, and 7.</p> <p>Commenter notes that Number 1 currently reads, “How would you rate your facial pain on a 0 to 10 scale at the present time, that is, right now, where 0 is “no pain” and 10 is “pain as bad as could be”?” Commenter recommends the removal of the word “facial” to allow for a more general assessment of pain. The same correction is suggested for numbers 4, 5, 6 and 7.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The word “facial” will be deleted because it is typographical error.	Appendix A2c, items #1, 4, 5, 6 and 7 the word “facial” is deleted to correct a typographical error.
Opioid Medical Treatment Guidelines – Appendix B	<p>Commenter references Written Opioid Treatment Agreement (Sample), page 82, Box, Respiratory. The statement currently reads, “Reduced ability to breathe during sleep; could lead to death”.</p> <p>Commenter recommends the</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree in part; Agree in part: Disagree: Proposed language is included in the sample patient agreement intended to inform the patient of risks of opioid use, and warning “reduced ability to breathe during sleep; could lead to death” may	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>following language be added to the sentence to imply any reduced ability to breath and not only during sleep:</p> <p>“Reduced ability to <u>breathe (especially during sleep)</u>; could lead to death”</p> <p>Commenter states that the word</p>		<p>convey a more credible risk and may be more accurate as loss of consciousness usually accompanies respiratory arrest. In addition, the language in Appendix B: Written Opioid treatment Agreement (Sample) is a proprietary tool adapted with permission from Reed Group, Ltd. Other resources include the Southern Oregon Opioid Prescribing Guidelines, 2014 and the Washington state Agency Medical Director’s Group (AMDG) Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain, 2010. The proposed edit does not provide a substantive change to the proposed language and in addition, this tool does not include recommendations for medical necessity but is included only as a sample for the recommendation to provide informed consent.</p> <p>Agree: The word “breath” will be amended because it is a</p>	<p>Appendix B, Table 1. Adverse Opioid Effects by Organ System, under “Respiratory” the word “breath” is amended to “breathe”</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	“breath” should be changed to “breathe”.		typographical error and should be “breathe”.	to correct a typographical error.
Opioid Medical Treatment Guidelines – Appendix B	<p>Commenter references Written Opioid Treatment Agreement (Sample), page 82, first line. The statement is regarding goals for performing various functions and includes 3 areas where goals are appropriate; “return to work, household chores or other physical or mental activities”. There is then space provided for placing a specific goal for improved function; “Goal for improved function _____”.</p> <p>Commenter recommends that each goal be specified and that a space be provided for each goal. Commenter recommends the following revised language:</p> <p>“Opioids will be initially prescribed to me on a trial basis. The primary goal of this treatment is to improve my ability to perform various functions, including return to work, household chores or other physical or mental activities. If significant demonstrable improvement in my functional</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Although commenter’s recommendations are sound, this is a sample tool and the instructions are clear that there are 3 areas, not necessary to include a space for each. DWC intends the physician to adapt the form to the individual patient and to include all pertinent goals for functional improvement.</p>	<p>None.</p>

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	<p>capabilities does not result from this trial, my prescriber will likely end the trial</p> <p>Goal for return to work _____</p> <p>Goal for household chores _____</p> <p>Goal for other physical or mental activities _____”</p>			
Opioid Medical Treatment Guidelines – Appendix B	<p>Commenter references Written Opioid Treatment Agreement (Sample), page 83, section entitled “I agree to the following (initial each), ninth item.</p> <p>Commenter recommends an addition be made subsequent to item 9 and recommends the following language:</p> <p>“I agree to allow my prescribing physician to notify my other healthcare providers of these pain medications and that I have a pain management agreement in place should he/she believe this necessary”</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: This change would require additional HIPAA-compliant release forms not included in the enclosed sample agreement. This suggestion may be appropriate for some patients, however, and providers may elect to incorporate such a suggestion.	None.
Opioid Medical Treatment	Commenter references Written Opioid Treatment Agreement	Jill Rosenthal, MD Sr. Vice President &	Agree: There is a typographical error that will be	Appendix B: Written Opioid Treatment

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Guidelines – Appendix B	<p>(Sample), page 84, first item. The statement currently reads, “I understand that lack of improvements in function or a later loss of those functional benefit(s) are reasons <u>or</u> my prescriber to discontinue opioid medications”.</p> <p>Commenter notes an apparent typo in the text and recommends the word “or” underlined above be changed to the word “for”.</p>	Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	corrected.	Agreement (Sample) is amended to delete the word “or” and replace it with the word “for” to correct a typographical error in the following listed agreement: “I understand that lack of improvements in function or a later loss of those functional benefit(s) are reasons for my prescriber to discontinue opioid medications.”.
Opioid Medical Treatment Guidelines – Appendix B	Commenter references Written Opioid Treatment Agreement (Sample), page 84, item 11. The statement currently reads, “I agree that an abnormal urine, blood, or saliva test will likely result in an end to the treatment with opioids. This includes a finding of a substance not expected (e.g., marijuana and/or illicit drugs)”. Commenter recommends adding the following language:	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Commenter’s suggested additional language is already covered in this Opioid Treatment Agreement “I agree to obtain opioids from one designated licensed prescriber” and does not need to be repeated.	None.

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	<p>“I agree that an abnormal urine, blood, or saliva test will likely result in an end to the treatment with opioids. This includes a finding of a substance not expected (e.g., marijuana and/or illicit drugs) <u>or other opioids not provided by my prescribing physician.</u>”</p>			
Opioid Medical Treatment Guidelines – Appendix C	<p>Commenter references Guidance on Conducting and Interpreting Urine Drug Testing (UDS), page 86, opening paragraph. The statement currently reads, “In the context of using opioids for treating CNCP, UDS can be used to as a tool for...”</p> <p>For clarity and to ensure readers are familiar with the meaning of the abbreviation, commenter recommends that the abbreviation “CNCP” be written out in its full form as this is the first time it is used. Commenter also recommends this be added to the list of acronyms on page 115.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The acronym CNCP will be clarified to mean “Chronic Non-cancer Pain”. Also, it will be added to list of acronyms.	Appendix C. Guidance on Conducting and Interpreting Urine Drug Testing (UDT), subsection 2.2 Monitoring for Compliance the acronym CNCP will be clarified to mean “Chronic Non-cancer Pain”. Also, added to the list of “Acronyms”.
Opioid Medical Treatment Guidelines – Appendix C	Commenter references Guidance on Conducting and Interpreting Urine Drug Testing (UDS), page 87, section 2. Clinical Usefulness of UDS.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015	Agree: The numbering error will be corrected.	Appendix C. Guidance on Conducting and Interpreting Urine Drug Testing (UDT),

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	<p>Commenter notes that subsection 2.2 Baseline Measure of Risk should actually be labeled as subsection 2.1 and recommends that this change is made.</p>	<p>Written Comment</p>		<p>subsection 2.2. Baseline Measure of Risk is amended to 2.1 instead of 2.2. to correct a numbering error.</p>
<p>Opioid Medical Treatment Guidelines – Appendix C</p>	<p>Commenter references Guidance on Conducting and Interpreting Urine Drug Testing (UDS), page 87, section 2. Clinical Usefulness of UDS, subsection 2.2. Monitoring for Compliance. The statement currently reads, “During an opioid trial or after a patient is established on LTOT, UDS can be useful...”</p> <p>For clarity and to ensure readers are familiar with the meaning of the abbreviation, commenter recommends that the abbreviation “LTOT” be written out in its full form as this is the first time it is used. Commenter also recommends this be added to the list of acronyms on page 115.</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Agree: The acronym LTOT will be clarified to mean “Long-term Opioid Therapy”. Also, it will be added to list of acronyms.</p>	<p>Appendix C. Guidance on Conducting and Interpreting Urine Drug Testing (UDT), subsection 2.2 Monitoring for Compliance the acronym LTOT will be clarified to mean “Long-term Opioid Therapy”. Also, added to the list of “Acronyms”.</p>
<p>Opioid Medical Treatment Guidelines – Appendix C</p>	<p>Commenter references Guidance on Conducting and Interpreting Urine Drug Testing (UDS), page 89, section 4 Interpreting Unexpected Results of UDS, chart, subsection 2- UDS</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015</p>	<p>Disagree: The recommendations to check CURES and consider discontinuation by tapering are discussed extensively</p>	<p>None.</p>

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	<p>positive for non-prescribed opioid or benzodiazepine. The Actions for the Physicians section currently reads, “Repeat UDS regularly. Ask the patient if they accessed opioids from other sources. Assess for opioid misuse/addiction. Review/revise treatment agreement.”</p> <p>Commenter recommends the addition of two items to the list of items already present; 1) Check CURES and 2) Consider discontinuation of LTOT via tapering</p>	Written Comment	elsewhere and do not need to be repeated here in the summary table.	
Opioid Medical Treatment Guidelines – Appendix C	<p>Commenter references Guidance on Conducting and Interpreting Urine Drug Testing (UDS), page 89, section 4 Interpreting Unexpected Results of UDS, chart, subsection 3- UDS positive for illicit drugs. The Possible Explanations sections last item currently reads, “Cannabis is positive for patients taking dronabinol (Marinol®), THC: CBD Sativex®) or”.</p> <p>Commenter notes that this item appears incomplete and recommends revision to either delete the word “or” from the end of the item or complete</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The item will be completed by adding the phrase “using medical marijuana” to correct a formatting error that had mistakenly hidden this text from view in the 45-Day Comment Period version.	Appendix C. Guidance on Conducting and Interpreting Urine Drug Testing (UDT), subsection 4 Interpreting Unexpected Results of UDS row 3 in the Table under the column Possible Explanations the phrase “using medical marijuana” is added to correct a formatting error.

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	the item as originally intended.			
Opioid Medical Treatment Guidelines – Appendix C	<p>Commenter references Guidance on Conducting and Interpreting Urine Drug Testing (UDS), page 89, section 4 Interpreting Unexpected Results of UDS, chart, subsection 3- UDS positive for illicit drugs. The Actions for the Physicians section currently states,” Repeat UDS regularly. Assess for abuse/addiction and refer for addiction treatment as appropriate Ask about medical prescription of dronabinol, THC: CBD or medical marijuana access program.”</p> <p>Commenter recommends the addition of one item to the list of items already present; 1) Consider discontinuation of LTOT via tapering.</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: The recommendations to consider discontinuation of LTOT by tapering is discussed extensively elsewhere and do not need to be repeated here in the summary table.	None.
Opioid Medical Treatment Guidelines – Appendix D	<p>Commenter references Select Black Box Warnings, page 98, Morphine Long-Acting Products: Avinza, last paragraph.</p> <p>Commenter notes that there are several typo’s in the paragraph whereby two words are not separated by a space. Commenter recommends this be rectified by use of the</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Agree: The typographical spacing errors will be corrected.	Appendix D. Select Black Box Warnings under Avinza, a single space is added between the following words in the second paragraph; between “capsules” and “are” and the in the third paragraph;

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	<p>following corrected text:</p> <p>“PATIENTS MUST NOT CONSUME ALCOHOLIC BEVERAGES WHILE ON AVINZA THERAPY. ADDITIONALLY, PATIENTS MUST NOT USE PRESCRIPTION OR NON-PRESCRIPTION MEDICATIONS CONTAINING ALCOHOL WHILE ON AVINZA THERAPY. CONSUMPTION OF ALCOHOL WHILE TAKING AVINZA MAY RESULT IN THE RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF MORPHINE”</p>			<p>between “on” and “avinza”; “use” and “prescription”; “containing” and “alcohol”; and “alcohol” and “while” to correct typographical errors.</p>
<p>Opioid Medical Treatment Guidelines – Appendix F</p>	<p>Commenter references Opioid Dose Calculations. Commenter states that due to the importance of this section and its relevance to the treatment guidelines as a whole, she recommends that this section be moved into the main body of the guidelines as its own section, following section 5. Documentation of Morphine Equivalents and prior to section 6. Consultation with Specialists. Commenter opines that</p>	<p>Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment</p>	<p>Disagree: Commenter’s suggestion that Appendix F be moved into the main body of the guidelines will not be incorporated because a sufficient summary is already provided in the main body, see Section 3.3.8. The important message the DWC conveys is, “Based on a review of the best and most recently available scientific evidence to date, 80</p>	<p>None.</p>

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	doing so will ensure that the information provided in Appendix F becomes a greater focus for treating physicians.		mg/day MED has been identified in this Guideline as the dose at which increased vigilance should be exercised.”	
Opioid Medical Treatment Guidelines – Appendix F2	Commenter references Equianalgesic Dose Table for Converting Opioid Doses, page 109. Commenter recommends that both Tramadol and Tapentadol be included in the list of Opioids. Commenter states that these medications are highly utilized in the workers’ compensation arena and should therefore have representation amongst the list of other opioids.	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: This table is used by permission from the Washington State Agency Medical Directors Group Interagency (AMDG) Guideline on Opioid dosing for Chronic Non-cancer Pain, 2010 and is used with permission. DWC is not able to incorporate the recommendations.	None.
Opioid Medical Treatment Guidelines – Definition of Key Terms	<p>Commenter references pages 113 and 114. Commenter notes that the term “Tolerance” is defined under the subheading of Substance Use Disorder on page 113 as follows:</p> <p>“10. Tolerance, as defined by either of the following:</p> <p>a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect.</p> <p>b. A markedly diminished effect with</p>	Jill Rosenthal, MD Sr. Vice President & Chief Medical Officer Zenith Insurance Co. September 1, 2015 Written Comment	Disagree: Various definitions of tolerance are found in the literature. The two descriptions found in the guideline are complementary and are not contradictory and will remain for this reason.	None.

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	<p>continued use of the same amount of an opioid.”</p> <p>Commenter states that “tolerance” is again defined in its own section on page 114 as follows:</p> <p>A condition in which higher doses of a drug are required to produce the same effect achieved during initial use; often associated with physical dependence. [134]</p> <p>Commenter recommends that a single definition of the term “Tolerance” be used consistently within the document. Commenter recommends that the latter definition provided on page 114 remain in place and that the use of the term “tolerance” on page 113 as part of the definition for Substance Use Disorder then reference the complete definition on page 114. Thereby making the reference to tolerance on page 113 appear as follows:</p> <p>“10. Tolerance to currently prescribed doses of opioid medications (see definition of</p>			

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Guidelines – Part 1 – Executive Summary	<p>Guidelines regarding the process that a physician should go through when they are prescribing an opioid medication. This includes checking the CURES database for documentation of other opioid medications that the patient may be taking, urine drug testing, and the tracking of change in pain levels and function.</p> <p>Commenter states that there can be significant delays in physicians gaining access to the CURES database. Delays of at least 6 months have been reported to her organization.</p> <p>Commenter recommends that the guidelines to be changed to encourage physicians to apply for access to the CURES database. Commenter states that once their access has been granted, physicians should regularly check the CURES database before prescribing opioids.</p>	<p>Compensation Committee California Orthopaedic Association September 1, 2015 Written Comment</p> <p>Diane Przepiorski September 1, 2015 Oral Comment</p>	<p>Disagree: The evidence strongly recommends checking CURES and CURES is undergoing continuous enhancements to improve functionality.</p> <p>Disagree: See Above.</p>	<p>None.</p> <p>None.</p>
Opioid Medical Treatment Guidelines – Part 1: Executive	Commenter references Opioids for Chronic Pain and Chronic Opioid Treatment Comprehensive Evaluation and Assessment of	Lesley Anderson MD Chair, Workers’ Compensation Committee	Disagree: Commenter recommends that the documentation of a patient’s pain level be added to the	None.

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Summary, Introduction, and Recommendations – Section 3.1.4	<p>Patient, and notes that the prescribing physician is asked to document the severity of the patient's pain levels.</p> <p>Commenter opines that the documentation of a patient's pain level is fundamental in assessing and managing the patient's need for opioid medications. Because of this, commenter recommends that this requirement be added to the acute and subacute guidelines.</p>	<p>California Orthopaedic Association September 1, 2015 Written Comment</p> <p>Diane Przepiorski September 1, 2015 Oral Comment</p>	<p>acute and subacute sections. However, the proposed guideline already includes the assessment and documentation of pain levels for both the acute and subacute pain at every visit.</p>	
Opioid Medical Treatment Guidelines – Part 1 – Executive Summary – Section 1	<p>Commenter notes that in the Acute and Subacute periods, the prescribing physician is asked to document the patient's: "1) pharmacologic therapy with non-opioid medications; 2) Physical activity, including rest, passive and active range of motion, and physical therapy with graded exercise matched to the injury; and 3) Complementary/alternative modalities, such as acupuncture, massage, and yoga."</p> <p>Commenter opines that it may not be appropriate for all patients to go through this entire regimen of care prior to the prescribing of an opioid medication. The documentation of</p>	<p>Lesley Anderson MD Chair, Workers' Compensation Committee California Orthopaedic Association September 1, 2015 Written Comment</p> <p>Diane Przepiorski September 1, 2015 Oral Comment</p>	<p>Disagree: Other than for Mild-Acute Injuries, the proposed Opioids Treatment Guidelines allow the option to go straight to opioids if "there are reasonable expectations that only opioids will produce immediate pain relief and sleep immediately following the injury". The conjunction "and/or" is before each of the options and it appears the commenter has missed option "(c)" which is stated above.</p>	None.

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	<p>prescribing physician to use their clinical judgment as to which medications/treatments are appropriate for their patients and not to mandate all of these medications/treatments for every injured worker regardless of their type of injury. Commenter opines that while well-intended, these documentation requirements are unworkable and in many cases could be unnecessary and lead to unnecessary delays in taking a patient to surgery.</p> <p>Commenter questions whether Workers' Compensation payers will agree that these evaluations are work-related, so it is unclear whether injured workers will be expected to use their group health insurance to cover these evaluations, so that they can receive the appropriate medications for their work-related injury. Commenter opines that this will create Workers' Compensation billing disputes.</p> <p>Commenter recommends that language be added to the guidelines</p>		<p>Disagree: <u>As long as the injury is work related, there will be no need to use group health insurance to cover these evaluations.</u> Other than for Mild-Acute Injuries, the proposed Opioids Treatment Guidelines allow the option to go straight to opioids if "there are reasonable expectations that only opioids will produce immediate pain relief and sleep immediately following the injury". The conjunction "and/or" is before each of the options and it appears the commenter has missed option</p>	<p>None.</p>

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	to clarify that if medications/services noted in the guidelines are requested by the treating physician, including drug urine screening test, that the payers would be expected to approve the request consistent with the guidelines.		<p>“(c)” which is stated above.</p> <p><u>Disagree: that evaluation of contraindications would require referral to another physician. Co-morbid conditions can be identified by the medical history, review of systems, and routine pre-operative test results.</u></p> <p><u>Disagree: that referrals to group health would be needed in order for patients to receive medications. Initial evaluations are covered by workers’ compensation and billing disputes are avoided by using the utilization review and other administrative processes. Many patients in the worker’s compensation system have co-morbid conditions such as obesity, hypertension, or diabetes, that impact the treatment of occupational injury or illness and may require coordination with group health providers, this is not unique to opioid therapy</u></p>	<p><u>None.</u></p> <p><u>None.</u></p>

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			<p><u>and does not place an undue burden on the patient or claims administrator. The recommendations must first be guided by patient safety.</u></p> <p>Disagree: The DWC intends that all recommendations are only applicable when appropriate for the particular patient, there is no need to state “the payers would be expected to approve the request consistent with the guidelines.</p>	None.
Opioid Medical Treatment Guidelines – Part 1 – Executive Summary – Section 1 Section 2	<p>Commenter opines that the documentation requirements in the Acute and Subacute period (initial 1-4 weeks) are excessive. Commenter notes that the proposed regulations require the prescribing physician to document in the medical record that the following conditions are not present:</p> <p>Depression Anxiety Personality disorder</p>	<p>Lesley Anderson MD Chair, Workers’ Compensation Committee California Orthopaedic Association September 1, 2015 Written Comment</p> <p>Diane Przepiorski September 1, 2015 Oral Comment</p>	Disagree: The contraindications listed should be considered by any physician prescribing opioids because opioids carry a significant risk. After a physician has considered the contraindications listed, then the documentation requirement can be fulfilled with a simple indication that the contraindications are not present. However, if any of	None.

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	<p>Untreated sleep disorders Current or past substance abuse Drug-seeking behavior Other psychotropic medication Post-traumatic stress disorder Cognitive impairment Chronic obstructive pulmonary disease Severe obesity Balance problems/fall risk Osteoporosis Renal failure</p> <p>Commenter states that an orthopaedic surgeon is not qualified to make these assessments, so this will require that for each injured worker that the orthopaedic surgeon is contemplating a short-term regimen of opioid medications, the patient will need to first be referred to a number of other medical specialists, (e.g., psychiatrists, cardiologists, urologist, primary care) for these evaluations before the medication could be prescribed. Commenter states that this will certainly delay care and force the patient to endure, what could be very severe pain levels with inadequate pain medications, while</p>		<p>these conditions are present, then written documentation must be provided to justify the use of opioids.</p> <p>Disagree: Any physician should be able to assess the risk to benefit ratio of any treatment prescribed. If a physician is not able to consider all of the contraindications listed, including orthopedic surgeons, then they should not be prescribing opioids and should refer the patient out to someone who is qualified to prescribe opioids.</p> <p><u>Disagree: Most physicians, especially those that would be expected to have need to treat patients with opioids, should not need the services of several</u></p>	<p>None.</p> <p><u>None.</u></p>

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	<p>they wait to get appointments/evaluations with all of the physicians.</p> <p>Commenter questions whether Workers' Compensation payers will agree that these evaluations are work-related, so it is unclear whether injured workers will be expected to use their group health insurance to cover these evaluations, so that they can receive the appropriate medications for their work-related injury. Commenter opines that this will create Workers' Compensation billing disputes. Commenter opines that while well-intended, these documentation requirements are unworkable and in many cases could be unnecessary.</p> <p>Commenter states that once a patient reaches the chronic stage of pain management that these more comprehensive evaluations are important, not routinely in the acute phase.</p> <p>Commenter recommends the</p>		<p><u>other medical specialists in order to perform an appropriate evaluation prior to starting a patient on opioids. As referrals to a number of other medical specialists are not expected to be needed, the associated hypothetical problems with delayed care, appropriate insurance coverage, and billing disputes are not anticipated.</u></p> <p><u>Disagree: The evaluations that are recommended for the acute use of opioids are different from those evaluations recommended during the chronic phase of opioid treatment. Each phase of opioid treatment is associated with recommended evaluations</u></p>	<p><u>None.</u></p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>following revised language:</p> <p>1. Section 1.1.4 - Opioids for Acute Pain - be amended to say, "Provide documentation in the medical record, <u>when appropriate</u>, that the following conditions that are relative contraindications to initiating opioids are not present. . ."</p> <p>2. Section 1.3 .4 - Severe Acute Injuries - be amended to say, "Provide documentation in the medical record, <u>when appropriate</u>, that the following conditions that are relative contraindications to initiating opioids are <u>not</u> present . . ."</p> <p>3. Section 2.4 (b)- Opioids for Subacute Pain - be amended to say, "Note the following contraindications, <u>when appropriate</u>, to continued opioid treatment. . . "</p> <p>4. The guidelines be clarified that if medications/services noted in the guidelines are requested by the treating physician, including drug urine screening test, that the payers</p>		<p><u>appropriate to that situation.</u></p> <p>Disagree: See above. These documentation requirements are reasonable. Employers or their Workers' Compensation payers are only expected to pay for medical treatment that is reasonable and necessary to cure or relieve the injured worker from the effects of his or her injury. The guideline does not suggest that the physician treat the conditions that are identified, if they are not work-related.</p> <p>Disagree: Patient morbidity and mortality can result from treatment for acute pain, especially in the outpatient setting.</p> <p><u>Disagree that additional language "when appropriate" be added to section 1.1.4. The proposed guideline intends that the treating physician documents the presence or absence of relative</u></p>	<p>None.</p> <p>None.</p> <p><u>None.</u></p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	would be expected to approve the request consistent with the guidelines.		<p><u>contraindications to ensure patient safety. Such documentation is not overly burdensome and evidence supports the practice.</u></p> <p><u>Disagree with suggestions to add modifier “when appropriate” to section 1.3.4- Severe acute injuries and section 2,4 (b) Opioids for Subacute Pain for the same reasons as above.</u></p> <p><u>Disagree that the proposed guideline requires further clarification that payers would be expected to approve the request, including requests for urine drug screens. This guideline is intended to provide evidence-based clinical recommendations only.</u></p> <p>Disagree: See above. Agree that all recommendations in the proposed guideline apply when appropriate. The manner of documentation may vary, this guideline does not specify</p>	<p><u>None.</u></p> <p><u>None.</u></p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<p>the particular manner of documentation, the goal is to ensure physicians identify and consider the relative risk factors.</p> <p>Disagree: The proposed guidelines, if used to establish medical necessity through the UR process, are sufficient to ensure payment for urine drug screening as required by the UR regulations.</p>	None.
<p>Opioid Medical Treatment Guidelines – Part 1 – Executive Summary – Section 1.4.3</p>	<p>Commenter notes that this section, Opioids for Post-operative Pain, requires that patients with the following list of conditions be closely monitored as inpatients:</p> <ul style="list-style-type: none"> Depression Anxiety Personality disorder Untreated sleep disorders Current or past substance abuse Drug-seeking behavior Use of other psychotropic medication Post-traumatic stress disorder Cerebrovascular disease Chronic hepatitis Cirrhosis 	<p>Lesley Anderson MD Chair, Workers’ Compensation Committee California Orthopaedic Association September 1, 2015 Written Comment</p> <p>Diane Przepiorski September 1, 2015 Oral Comment</p>	<p>Disagree: A history of these clinical conditions may have significant impact in the treatment of post-operative pain and sensitivity to opioids. Strong evidence suggests that they be identified and if present, monitored. This list is not extraordinary and should be identified during the pre-operative history if not before.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Cognitive impairment Chronic obstructive pulmonary disease Severe obesity Balance problems/fall risk Osteoporosis Renal failure</p> <p>Commenter opines that it is unclear who is expected to do this monitoring. Commenter states that inpatients are already closely monitored in the inpatient setting, so this section is unnecessary.</p> <p>Commenter recommends that this section be deleted.</p>		<p>Disagree: The DWC intends this guideline to inform all treating physicians of injured workers in the California workers' compensation system and is not specific to a particular facility type unless otherwise stated. This is especially significant as many surgical procedures are currently done in ambulatory surgery centers. This section will not be deleted.</p>	<p>None.</p>
<p>Opioid Medical Treatment Guidelines – Part 1 – Executive Summary</p>	<p>Commenter states that her organization is getting complaints from their members who want to get patients off Norco or limit the amount of the opioid medications, and they are trying to get approval for Lidocaine patches that -- not from a clinical person at all, but numb the</p>	<p>Diane Przepiorski California Orthopaedic Association September 1, 2015 Oral Comment</p>	<p>Disagree: The proposed MTUS Chronic Pain Medical Treatment Guidelines includes a Procedure/Topic on Topical Analgesics and includes criteria for the use of Lidocaine patches.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>nerve endings so that the patient doesn't feel as much pain. Commenter states that this is a very good option if you are trying to get away from opioid medications. Commenter states that the UR system is denying these requests.</p> <p>Commenter opines that the effectiveness of these guides will come down to how UR interprets these regulations and tries to work in a collaborative arrangement to try to help patients manage their pain.</p>		<p>Physicians who wish to use Lidocaine patches for another indication should describe the clinical scenario and cite any relevant guideline or quality study using the methodology outlined in CCR 8, §9792.20 et seq.</p>	
<p>General Comment</p>	<p>Commenter states that when promulgating the use of treatment guidelines that the Division must keep in mind that the guidelines are not used exclusively by treating physicians. Rather, the Legislature requires that the guidelines be used by injured employees and their physicians, claims examiners, utilization review physicians, IMR, employers, applicants' attorneys, defense attorneys, judges at the WCAB and the reviewing courts. Commenter opines that the workers' compensation community must have treatment guidelines that are as</p>	<p>Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) September 1, 2015 Written Comment</p>	<p>Agree: The DWC agrees with commenter's statement.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>straightforward and clear as modern medical science can make them.</p> <p>Commenter notes that under Labor Code Section 4610, utilization review physicians must determine the appropriateness of requested treatment within very tight time frames. Commenter states that treatment guidelines that provide clear direction, are well supported by scientific medical evidence, and are based on graded peer reviews are essential for the utilization review system to function as intended. Conversely, commenter opines that a treatment guideline that is indefinite and overly conditional is in conflict with the statutory requirements and fosters confusion and disputes.</p>		<p>Agree in part; Disagree in part: Agree: With commenter’s description of UR’s role and the tight time frames for their decisions. Disagree: With commenter’s statement that “a guideline that is indefinite and overly conditional is in conflict with the statutory requirements” because guideline recommendations must be supported by the best available medical evidence. If the medical evidence is indefinite and conditional, then the recommendation will mirror that which supports it.</p>	None.
9492.24.2	<p>Commenter recommends the following revised language:</p> <p>(a) The Chronic Pain Medical Treatment Guidelines (May, 2009) [<u>insert effective date of regulations</u>], consisting of two parts, are adopted and incorporated by reference into</p>	<p>Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment</p>	<p>Disagree: The title of the document incorporated by reference is the “Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines.” This is</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>the MTUS. Part 1 is entitled Introduction. Part 2 is entitled Pain Interventions and Treatments, the <u>“Official Disability Chronic Pain Medical Treatment Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)”</u> consisting of an edited version from the <u>Official Disability Guidelines published on April 6, 2015</u>, which the Division of <u>Workers’ Compensation has adapted with permission from the publisher</u>. These guidelines replace Chapter 6 of the <u>ACOEM Practice Guidelines, 2nd Edition (2004)</u>. Where the clinical topic sections of the MTUS in the series of sections commencing with 9792.23.1 et seq., make reference to Chapter 6 or when there is a reference to the “pain chapter,” or “pain assessment,” the chronic pain medical treatment guidelines will apply instead of Chapter</p>		<p>what should be cited by UR or IMR physicians. However, Part 2: is correctly entitled the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” because it is an edited version of the Official Disability Guidelines published on April 6, 2015. The DWC has adapted the introduction to fit the MTUS and made some formatting changes to comport with the overall MTUS format. However, the DWC was unable to change the content of the procedure summaries and references. The Work Loss Data Institute (ODG) is the only one who can make those changes. Subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the document by title and date of publication or issuance." Therefore, it is necessary to entitle Part 2 as the “Official</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>6. A copy of the eChronic pPain mMedical tTreatment gGuidelines may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at.</p> <p>Commenter states that the proper title for Part 2 is “Chronic Pain Medical Treatment Guidelines” or “Chronic Pain Guidelines” as the Division is not adopting the ODG Guidelines, but rather a modified version of those Guidelines. Commenter opines that naming the guidelines “Official Disability Guidelines (ODG)” causes unnecessary confusion over whether references and citations to the guidelines refer to the modified version adopted in 9792.24.2 and specified in 9792.21.1(a)(1) or to the most current version of the Official Disability Guidelines as defined in 9792.20(i) and specified in 9792.21.1(a)(2)(A). The commenter has observed this to be a problem while reviewing UR and IMR</p>		Disability Guidelines (ODG) Treatment in Workers' Compensation – Pain (Chronic)”.	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	reviewer determinations, as it is often unclear whether the citations are referring to the ODG version adopted into the MTUS or the current version of ODG's guidelines.			
Chronic Pain Medical Treatment Guidelines – General Recommendations	Commenter states that the proposed revised MTUS Chronic Pain Medical Treatment Guidelines have room for improvement. Commenter opines that it is not always clear in the guidelines what, if anything, is actually recommended, and/or under what conditions a recommendation applies. Multiple studies pertaining to a treatment procedure/modality/good are typically described in the Guideline document, and frequently the descriptions include the study recommendations, which may be at odds with one another; however often there is nothing or little to indicate an MTUS Chronic Pain Medical Treatment Guidelines recommendation. Commenter states that some guideline users take the position that if a study is described in the MTUS guidelines, its recommendations are MTUS recommendations. Other guideline users take the position that such	Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) September 1, 2015 Written Comment	Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS' recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommendations are the study’s and not MTUS recommendations. Commenter states that it is important that the MTUS guidelines are clear. If they are not, commenter states that the injured employees will not be protected from deleterious and unnecessary care and will not be assured of effective care.</p>			
Chronic Pain Medical Treatment Guidelines – General Recommendation	<p>Commenter recommends that the Division ensure each procedure, modality and good has a clear recommendation (“recommended” or “not recommended”).</p> <p>Commenter opines that regulations that say a certain action “should” occur can be ignored with impunity, leaving physicians who request or provide inappropriate treatment free to continue doing so. Commenter states that in the context of utilization review such regulatory language is useless because it cannot be enforced. In order to prevent inappropriate treatment, and assure provision of effective treatment, commenter opines that the terms in the guidelines adopted in regulation need to be prescriptive rather than permissive.</p>	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment	Disagree: The words “recommended” or “not recommended” are generally included at the beginning of each Procedure/topic, and very often further criteria are included. All recommendations must be supported by scientific medical evidence. The recommendations are as clear as the supporting evidence allows. However, as commenter mentions, there are a few sections that do not contain recommendations. These sections will contain helpful descriptions or definitions or refer readers to another section of the guideline that will contain related recommendations. It is	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that the purpose of the Medical Treatment Utilization Guideline is not only to suggest good practices to practicing physicians; it determines standards that define what is reasonably required under Labor Code section 4600. In utilization review and independent medical review it is the standard used to protect an injured employee from deleterious and unnecessary medical care and to ensure the provision of appropriate medical care. Commenter states that “shoulds” and “should not” impede those responsibilities.</p>		<p>not required that all sections contain recommendations. The intent of an evidence-based guideline is to assist the physician by making evidence-based recommendations, not to provide a step by step directive for how to practice medicine. Specific individual patient factors should always be considered and evaluated. In addition, use of the word “should” or the phrase “should not” does not impede a UR or IMR reviewer’s responsibilities, but rather, it is a strong suggestion that they consider the documentary evidence provided and/or the injured workers’ specific clinical situation.</p>	
<p>Chronic Pain Medical Treatment Guidelines – General Recommendation</p>	<p>Commenter recommends that the Division insert between the two columns of the Part 2 table a Recommendations column where each procedure, modality or topic is identified as “recommended” or “not recommended” and where frequency,</p>	<p>Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015</p>	<p>Disagree: Adding two additional columns is unnecessary because the second column usually begins with the procedure summary recommendation before it delves into the additional</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>duration, intensity and appropriateness (conditions) may be addressed.</p> <p>Commenter opines that adding a column that will clearly indicate the recommendation status will ensure that injured employees receive effective and timely medical care, and are protected from untimely, harmful and unnecessary care. It will also add certainty and reduce the confusion that generates so many disputes, delays and attendant administrative and financial burdens.</p>	Written Comment	details of the treatment procedures. Commenter’s suggestion will lead to unnecessary repetition of information.	
Chronic Pain Medical Treatment Guidelines – General Recommendation	<p>Commenter recommends that the Division retitle the last column “Supporting Medical Evidence,” and in that column provide a link to each supporting study and its strength of evidence determined per section 9792.25.1, and remove irrelevant citations from the column.</p> <p>Commenter opines that separating supporting studies and information from the MTUS recommendation will improve the quality of medical care for injured employees and add clarity as described in the preceding</p>	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment	Disagree: The second column or last column is already titled “Summary of medical evidence” and contains much of the information suggested by commenter to be included in her suggested “Supporting Medical Evidence” column. However, commenter suggests that some of the citations should be removed because they are irrelevant. The DWC agrees with ODG’s inclusion of these citations because they provide a complete, nuanced	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommendation.</p> <p>Commenter states that adding the strength of evidence rating will conform to the standards and methodology in section 9792.25.1 for evaluating the quality of the evidence supporting the recommendations. It is necessary to indicate the strength of evidence/consensus pursuant to section 9792.25.1 for each so that the strength of alternative evidence can be properly compared. This is necessary when a physician challenges the presumption of correctness pursuant to sections 9792.21(d)(2) and 9792.21.1(a)(2)(C), and when reviewing physicians must determine the level of the evidence cited by the physician pursuant to section 9792.25.1(a)(4) and compare it with the level of the evidence that underlies the MTUS recommendation.</p> <p>Commenter opines that if the quality and strength of evidence/consensus pursuant to section 9792.25.1 is not provided for each recommendation,</p>		<p>perspective for the recommendation.</p> <p>Disagree: Commenter also suggests that the DWC should replace all of ODG's ratings with a rating according to the methodology set forth in section 9792.25.1. This request entails over 800 pages of revisions to ODG's guideline that the DWC is incorporating by reference. The DWC has chosen to incorporate an existing, well-respected guideline because we have limited resources and are not primarily in the guideline making business. Requiring UR and IMR physicians to assess the underlying medical evidence pursuant to section 9792.25.1 is merely requiring them to do what they're supposed to be doing when there are competing recommendations.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>both the UR and IMR physicians must identify and assess the underlying medical evidence pursuant to 9792.25.1(a)(4), creating an unnecessary additional burden and uncertainty.</p> <p>Commenter opines that some citations that appear in the guidelines table are irrelevant and unnecessary. Commenter recommends that they be removed, as they do not appear to relate to a recommendation and/or do not appear to assist a physician in determining the most appropriate course of treatment.</p>		<p>Disagree: Commenter suggests that some of the citations should be removed because they are irrelevant. The DWC agrees with ODG’s inclusion of these citations because they provide a complete, nuanced perspective for the recommendation.</p>	<p>None.</p>
<p>Chronic Pain Medical Treatment Guidelines – General Recommendation</p>	<p>Commenter recommends that the Division improve the formatting of the Part 2 table by providing clearer subsection headings, spacing between subsections, and by removing duplicate subheadings.</p> <p>Commenter opines that much of the material runs together and could be made more user friendly with formatting changes such as additional spacing. Some sections that address specific procedures, modalities or goods include duplicate headings</p>	<p>Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment</p>	<p>Disagree: “Part 2: Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” is ODG’s Procedure Summaries. Any changes to this section must come from and be approved by ODG/WLDI.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	where only a single heading is necessary (“Dosing” headings are an example).			
Chronic Pain Medical Treatment Guidelines – General Recommendation	<p>Commenter recommends that the Division replace verbiage that conflicts with the definition of chronic pain in section 9792.20 with verbiage that conforms to that definition.</p> <p>Commenter states that according to section 9792.20, as used in Article 5.5.2 of the regulations, chronic pain means pain lasting three or more months from the initial onset of pain. Commenter opines that if this language is not revised, there will be confusion and disputes over whether or not the pain is chronic and which guideline section is applicable.</p>	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment	Agree: The definition for chronic pain should be consistent according to definition of chronic pain set forth in section 9792.20 that is defined as “pain lasting three or more months from the initial onset of pain.”	Section 9792.23(b)(1) is amended by deleting the phrase “that persists beyond the anticipated time of healing” and replaced with the phrase “lasting three or more months from the initial onset of pain.”
Chronic Pain Medical Treatment Guidelines – General Recommendation	<p>Commenter recommends deleting chapter recommendations for treatment of non-chronic pain, including recommendations for acute pain, sub-acute pain and initial treatment.</p> <p>Commenter states that these chronic pain medical treatment guidelines do not apply when pain is not chronic,</p>	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment	Agree in part; Disagree in part: Agree: The proposed Chronic Pain Medical Treatment Guideline recommendations apply when pain is chronic. Disagree: Material that describes and differentiates treatment for acute and subacute pain in the context of chronic pain is intended to	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>therefore these guidelines may not address non-chronic pain (pain of less than three month’s duration, which would include acute pain, sub-acute pain and initial treatment.</p> <p>Commenter notes that acute pain, sub-acute pain and initial treatment are addressed in the other MTUS sections. Commenter opines that if recommendations for non-chronic pain are not deleted, this will also result in confusion and disputes over whether or not the pain is chronic, and which guideline section is applicable.</p>		clarify which treatment is appropriate for chronic pain. Recommendations for treatment in this proposed guideline are for Chronic Pain	
Chronic Pain Medical Treatment Guidelines – General Recommendation	<p>Commenter recommends that the Division retitle part 2 of the MTUS Chronic Pain Medical Treatment Guidelines “Chronic Pain Medical Treatment Guidelines” to avoid confusion with ODG’s own guidelines.</p> <p>Commenter notes that the Division is not adopting the ODG Guidelines, but rather a modified version of those Guidelines. Commenter opines that naming the guidelines “Official Disability Guidelines (ODG)” causes unnecessary confusion over whether the references and citations</p>	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment	Disagree: The title of the document incorporated by reference is the “Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines.” This is what should be cited by UR or IMR physicians. However, Part 2: is correctly entitled the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” because it is an edited version of the Official Disability Guidelines	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>refer to the modified version adopted in 9792.24.2 and specified in 9792.21.1(a)(1) or to the most current version of the Official Disability Guidelines as defined in 9792.20(i) and specified in 9792.21.1(a)(2)(A). Commenter has observed this to be a problem while reviewing UR and IMR reviewer determinations, where it is often unclear whether the ODG version adopted into the MTUS or the current version of ODG’s guidelines is being cited.</p>		<p>published on April 6, 2015. The DWC has adapted the introduction to fit the MTUS and made some formatting changes to comport with the overall MTUS format. However, the DWC was unable to change the content of the procedure summaries and references. The Work Loss Data Institute (ODG) was the only one who can make those changes. Subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the document by title and date of publication or issuance." Therefore, it is necessary to entitle Part 2 as the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)”.</p>	
9792.24.4(b)	<p>Commenter recommends the following revised language: <u>(b) The Opioids Treatment Guidelines describe the appropriate use of opioid</u></p>	Brenda Ramirez Claims & Medical Director California Workers’	Disagree: Commenter’s suggestion to add the phrase “during all treatment including” will not be	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>medications <u>during all treatment, including treatment as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain. These guidelines apply when alternative therapies do not provide adequate pain relief and the use of opioid medications is being considered as part of the treatment regimen.</u></p> <p>Commenter opines that this will clarify that the Opioid Treatment Guidelines are not limited to treatment provided as a part of a multidisciplinary treatment regimen, but are applicable in all treatment regimens, including when treatment is provided by a single physician in a single discipline.</p>	<p>Compensation Institute (CWCI) September 1, 2015 Written Comment</p>	<p>incorporated because it is unnecessary. The current iteration with the phrase “as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain” already includes treatment provided by a single physician in a single discipline.</p>	
<p>Opioid Medical Treatment Guidelines – General Recommendation</p>	<p>Commenter recommends that the Division consider adopting the ACOEM V.3 Opioid Treatment Guideline (2014) in lieu of the proposed Guideline.</p> <p>Commenter notes that Labor Code section 4604.5 requires that the recommended guidelines in the MTUS reflect practices that are evidence and scientifically based,</p>	<p>Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment</p>	<p>Disagree: The DWC had already spent over two years preparing the proposed Opioids Treatment Guidelines when ACOEM published its Opioid Treatment Guideline in the Spring of 2014. The DWC, however, reviewed the ACOEM Opioid Treatment Guideline and incorporated some of its recommendations</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>nationally recognized, and peer reviewed. Commenter states that the proposed MTUS Opioids Treatment Guideline, however, is based on recommendations found to be in common among other existing guidelines rather than being a guideline that is based directly on the best scientifically based, nationally recognized, and peer reviewed current medical evidence.</p> <p>Commenter opines that adopting a single guideline that is based directly on a review of available medical evidence offers the advantage of internal consistency, as opposed to a guideline that includes recommendations from disparate guidelines that are based on differing standards. It also offers treating physicians and reviewers the efficiency of optional on-line interactive tools.</p> <p>Commenter notes that the ACOEM V.3 Opioid Treatment Guideline (2014) was released in February, 2014 and is the most current opioid treatment guideline available. This</p>		<p>in this proposal.</p> <p>Disagree: The proposed Opioids Treatment Guidelines are evidence and scientifically based, by adopting recommendations from nationally recognized and peer reviewed guidelines and studies.</p> <p>Disagree: The proposed Opioids Treatment Guidelines are based on nationally recognized and peer reviewed guidelines and studies and includes recommendations from the ACOEM V.3. Opioids Treatment Guideline (2014). See MTUS Opioids Treatment Guidelines Part 2: supplemental materials. The scientific evidence used to support recommendations in reputable guidelines are very similar. Although the methods to evaluate medical evidence may vary, the conclusions are similar as they are based on the</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>guideline is peer-reviewed and nationally recognized, and is based on a rigorous review of higher-grade medical evidence and on expert consensus when higher-grade evidence was unavailable or inconsistent. The guideline is user-friendly and suitable for use by treating physicians and reviewers. Commenter opines that it appears to be superior in most or all respects to the other guidelines reviewed, and to the DWC’s proposed guideline.</p> <p>Commenter has additional recommendation in the event that the Division rejects this recommendation.</p>		<p>current medical evidence.</p> <p>Agree in part. Disagree in part: Agree: That ACOEM offers optional on-line interactive tools that may assist with efficiency. However, those tools are not free and would require the purchase of ACOEM’s on-line subscription.</p> <p>Disagree: That ACOEMs guideline “appears to be superior in most or all respects” to the DWC’s proposed guideline. Commenter is entitled to her opinion</p>	None.
Opioid Medical Treatment Guidelines – General Recommendation	<p>Commenter recommends that the Division replace “should” with “shall.”</p> <p>Commenter opines that regulations that say a certain action “should” occur can be ignored with impunity, leaving physicians who inappropriately prescribe opioids free to continue doing so. Commenter states that in the context of utilization review such regulatory language is</p>	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment	Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions because it provides a framework for the most effective treatment for work related illness or injury. The MTUS’ recommendations	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>useless because it cannot be enforced. To prevent inappropriate prescribing of opioids, and assure appropriate prescribing, commenter states that the terms in opioid treatment guidelines adopted in regulation need to be prescriptive rather than permissive. Commenter states that the purpose of the Medical Treatment Utilization Guideline is not only to suggest good practices to practicing physicians; it determines standards that define what is reasonably required under Labor Code section 4600. In utilization review and independent medical review it is the standard used to protect an injured employee from deleterious and unnecessary medical care and to ensure the provision of appropriate medical care. Commenter opines that “shoulds” and “should nots” impede those responsibilities.</p>		<p>provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.</p>	
<p>Opioid Medical Treatment Guidelines – General Recommendation</p>	<p>Commenter opines that the Division replace the proposed 80 mg per day MED standard with the 50 mg per day MED standard.</p> <p>Commenter notes that according to the available medical evidence, the death rate (hazard ratio) accelerates</p>	<p>Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015 Written Comment</p>	<p>Disagree: There are differing evidence-based recommendations regarding increasing risk for opioids using mg/day morphine equivalent dosage (MED), ranging from 50 mg/day MED (ACOEM, 2014) to mg/day</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>for morphine equivalent doses (MEDs) above 50 mg per day, as demonstrated in the three studies cited in Appendix E of Part 1 and Supplement 1 of Part 2, and clearly illustrated in Figure 2 of the section on Acute Pain (page 20) in the ACOEM V.3 Opioid Treatment Guideline (2014). Commenter states that even though other guidelines, including the Medical Board of California’s guideline, recommend higher daily MED limits, the medical evidence supports a 50 mg MED per day standard. Labor Code section 4604.5 requires the recommended guidelines in the MTUS to reflect practices that are evidence and scientifically based, nationally recognized, and peer reviewed, therefore commenter opines that the 50 mg MED per day standard is the correct standard for the MTUS.</p> <p>Commenter states that A3.9 of Part 1, on page 17 states that where common recommendations across guidelines were lacking (the case here) recommendations in high-level studies were to be adopted, or else the</p>		<p>200 MED (VA/DoD, 2010), with most in the range of 100 - 120 mg/day MED. The best evidence to date suggests that the risk/benefit ratio of opioids increases above 50 and sharply increases definitely above 100 mg/day MED. The proposed MTUS recommendation of 80 MED is conservative compared to recommendations over 100. The Medical Board of California also chose 80 MED for its Guidelines for Prescribing Controlled Substances for Pain (2014) as a trigger for pain consultation and additional caution. The MED is only one of a series of controls to ensure the safe and effective use of opioids. Treatment should always start with the lowest effective dose, pain and functional progress should be monitored and documented, with greater vigilance at higher doses. Additional measures include pain agreements, use of CURES, urine drug testing</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommendations of a major guideline were to be adopted, even if other guidelines did not replicate them, provided they aligned with the goals and objectives of the Opioids Treatment Guideline. The ACOEM recommendation for a 50 mg MED per day standard aligns more strongly with those goals and objectives than does an 80 mg MED per day standard, and particularly so with the first two:</p> <ul style="list-style-type: none"> • To prevent and reduce opioid-related long-term disability, morbidity, mortality, and substance misuse and abuse • To provide a set of best practices and universal precautions for safe and effective prescribing of opioids for acute, subacute, and chronic pain. 		<p>and other strategies to ensure safety and efficacy in addition to monitoring of daily morphine equivalent dose, all clearly described in the MTUS proposed Opioid guideline.</p>	
Opioid Medical Treatment Guidelines – General Recommendation	<p>Commenter recommends that the Division specify that employees shall be precluded from performing safety-sensitive tasks such as driving and operating heavy machinery while taking opioids.</p>	<p>Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) September 1, 2015</p>	<p>Disagree: The MTUS constitutes the standard for the provision of medical care in accordance with Labor Code §4600 for all injured workers diagnosed with industrial conditions</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter notes that all large epidemiological studies found an increased risk of car accidents for working age adults taking opioids that ranged from 29% to 800%. Commenter opines that merely discouraging injured employees from operating heavy equipment and driving while on these medications is inadequate and dangerous, not only for these injured employees, but for others around them as well.</p>	Written Comment	because it provides a framework for the most effective treatment for work related illness or injury. The MTUS' recommendations provide users with guidance but are not a prescriptive mandate that precludes physicians from considering specific clinical situations.	
Opioid Medical Treatment Guidelines – General Recommendation	<p>Commenter requests that the Division consider prohibiting the dispensing of opioids to injured employees from physician offices and clinics.</p> <p>Commenter states that in 2007, the DWC curtailed differential pricing for repackaged drugs dispensed from physicians' offices by narrowing a loophole in the pharmacy fee schedule regulations. The effect was an immediate reduction in both the volume and the amounts paid for these drugs.¹³ Commenter opines that because financial incentives for dispensing drugs from doctors'</p>	Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) September 1, 2015 Written Comment	Disagree: The DWC does not have the authority to prohibit physician prescribing in the office setting. It is beyond the scope of the MTUS to limit physician prescription authority, which is governed by the Medical and Pharmacy Boards of California.	None.

¹³ Swedlow, A., Gardner, L., Ireland, J. Differences in Outcomes for Injured Workers Receiving Physician-Dispensed Repackaged Drugs in the California Workers' Compensation System. CWCI Research Brief, February 2013.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>offices still exist, it is no surprise that dispensing drugs from physicians' offices is associated with higher drug utilization than dispensing drugs from pharmacies. Commenter notes that a 2013 Workers Compensation Research Institute study examined the impact of Florida's ban on physician dispensing of stronger opioids that took effect in July 2011 and provided evidence that physician dispensing is associated with patients receiving more opioids than necessary.¹⁴</p>			
<p>Opioid Medical Treatment Guidelines – General Recommendation</p>	<p>Commenter recommends that the Division ensure that opioids are prescribed by a single physician and dispensed from a single pharmacy by requiring the prescribing physician to consult CURES before writing each opioid prescription, except in emergency situations, and document the results of the CURES inquiry in the injured worker's medical record.</p> <p>Commenter states that all dispensers of opioids and other Schedule II, III, and IV prescription drugs, including pharmacies, clinics and physicians must provide weekly dispensing</p>	<p>Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) September 1, 2015 Written Comment</p>	<p>Agree in part; Disagree in part: Agree: that use of CURES is strongly recommended by the evidence and is well described in the proposed regulation. Agree with benefits described. Disagree: that DWC should "require" use of CURES. The DWC is not able to require physicians to check CURES. Physician practice is governed by the Medical Board of California and use of CURES by the California Department of Justice and the California State Board of Pharmacy. The</p>	<p>None.</p>

¹⁴ Thumula, V. Impact of Banning Physician Dispensing of Opioids in Florida. WCRI, July 2013.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>reports to the Controlled Substance Utilization Review and Evaluation System (CURES), which is California’s Prescription Drug Monitoring Program (PDMP). The program allows pre-registered users, including physicians and pharmacists, to access timely patient history on controlled drugs. Commenter states that physicians can reduce the epidemic of opioid overdoses and diversions by confirming through CURES that patients are not illegitimately or surreptitiously obtaining opioids and other scheduled drugs from other physicians and pharmacies. Commenter opines that requiring physicians to check with CURES before writing the prescription will save lives. Commenter states that suggesting they do so is helpful, but is not as effective as requiring them to do so.</p>		<p>DWC intends the proposed Opioids Medical Treatment Guidelines to promote the use of CURES by physicians considering or providing opioid therapy to patients in the California workers’ compensation system.</p>	
<p>Opioid Medical Treatment Guidelines – General Recommendation</p>	<p>Commenter recommends that the Division specify “recommended” or “not recommended” and the strength of evidence/consensus for each recommendation.</p> <p>Commenter opines that it is necessary</p>	<p>Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) September 1, 2015</p>	<p>Disagree: The words “recommended” or “not recommended” are generally included at the beginning of each Procedure/topic, and very often further criteria are included. All recommendations</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>to indicate the recommendation status as well as the quality and strength of evidence/consensus pursuant to section 9792.25.1 for each recommendation, so that the strength of alternative evidence can be properly compared. This is necessary when a physician challenges the presumption of correctness pursuant to sections 9792.21(d)(2) and 9792.21.1(a)(2)(C), and when reviewing physicians must determine the level of the evidence cited by the physician pursuant to section 9792.25.1(a)(4) and compare it to the level of evidence that underlies the MTUS recommendation. Commenter opines that if the recommendation status and the quality and strength of evidence/consensus pursuant to section 9792.25.1 is not provided for each recommendation, both the UR and IMR physicians must identify and assess the underlying medical evidence pursuant to 9792.25.1(a)(4), creating an unnecessary additional burden and uncertainty. Commenter states that since the proposed Opioids Treatment Guidelines adopt</p>	Written Comment	<p>must be supported by scientific medical evidence. The recommendations are as clear as the supporting evidence allows. However, as commenter mentions, there are a few sections that do not contain recommendations. These sections will contain helpful descriptions or definitions or refer readers to another section of the guideline that will contain related recommendations. It is not required that all sections contain recommendations. Commenter also suggests that the DWC should replace all of ODG's ratings with a rating according to the methodology set forth in section 9792.25.1. This request entails over 800 pages of revisions to ODG's guideline that the DWC is incorporating by reference. The DWC has chosen to incorporate an existing, well-respected guideline because we have limited resources and are not primarily in the guideline</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>recommendations that are found to be in common among other existing guidelines, reviewing physicians may have to identify the underlying medical evidence for the recommendation in each of these existing guidelines and assess the quality and strength of every one; a daunting, time consuming and perhaps impossible task that may well result in differing conclusions and therefore uncertainty.</p>		<p>making business. Requiring UR and IMR physicians to assess the underlying medical evidence pursuant to section 9792.25.1 is merely requiring them to do what they're supposed to be doing when there are competing recommendations.</p>	
<p>Opioid Medical Treatment Guidelines – General Recommendation</p>	<p>Commenter requests that the Division consider requiring the use of one or more specific screening tools.</p> <p>Commenter opines that requiring the use of one or more specific screening tools will ensure a thorough screening and evaluation before prescribing opioids.</p>	<p>Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) September 1, 2015 Written Comment</p>	<p>Disagree: DWC is unable to "require" the use of a screening tool, although a number of appropriate tools are described and highly recommended based upon the medical evidence.</p>	<p>None.</p>
<p>Chronic Pain Medical Treatment Guidelines – Chronic Pain/Functional Restoration Program (FRPs)</p>	<p>Commenter opines that clarifications necessary with the current Guidelines Draft in terms of FRP/Chronic Pain Programs:</p> <p><u>Admission into FRP</u></p> <p>Commenter notes that Page 49 has eligibility criteria that are broad and inclusive; however, UR uses these</p>	<p>Yehuda Gertel Psy.D., Q.M.E. Clinical Health Psychologist September 1, 2015 Written Comment</p>	<p>Disagree: The proposed eligibility criteria are inclusive and offer clear guidance. Any request for FRP should follow this guidance and be well supported by the clinical documentation.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>other parts of the guidelines to deny.</p> <p>Commenter notes that Page 45 lists 5 criteria for admission (decreased pain, decreased medication use, improved function, return to work, decreased utilization of the health care system).</p> <p>Then it says that "patients should show motivation to improve and return to work." Commenter questions if this is the criteria. Does a patient need to be able to RTW? What if the patient is retired? Commenter states that he has received many UR treatment denials stating that the patient is not going to RTW.</p> <p>Commenter notes that CCR 9792.20 says that functional improvement means a clinically significant improvement in ADLs or a reduction of work restrictions. That's it. Commenter opines that there is a contradiction between the MTUS and CCR in terms of justifying functional restoration program. Commenter has received an IMR determination that</p>		<p>Agree in part; Disagree in part: Agree: The DWC does not intend "functional improvement" to only mean return to work. § 9792.20(e) "Functional improvement" means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the medical evaluation and treatment; and a reduction in the dependency on continued medical treatment.</p> <p>Disagree: The proposed MTUS Chronic Pain Medical Treatment Guidelines – Chronic Pain/Functional Restoration Program (FRPs) recommendations do not conflict with the definition of Functional Improvement in section 9792.20(e), it provides additional details but they are consistent.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>used 9792 to uphold a UR determination. Commenter questions if this may be the only grounds for FRP approval.</p> <p>Commenter references that Page 50, Number 9 lists only RTW and reduction of medical treatment utilization as grounds for treatment. Commenter opines that his issue needs to be clarified and needs to be consistent. Commenter would like to know what the criteria are for FRP treatment in terms of patient profile, justifying admission into an FRP and in term of gains made justifying further treatment.</p> <p>Commenter notes that on Page 50, Item 4 discusses optional or controversial surgery. Commenter would like to know what this means. Commenter references a patient who is trying to avoid a “regular” surgery because they are fearful of the side effects. Commenter would like to know if this person is eligible for treatment. Commenter would like to know what would happen if doctors are in dispute about whether they are</p>		<p>Disagree: Commenter’s interpretation is too narrow. Number 9 states, “This cautionary statement should not preclude patients off work for over two years from being admitted to a multidisciplinary pain management program with demonstrated positive outcome in this population.” DWC intends functional restoration to include an increase in activities in daily living and that each case should be reviewed on a case-by-case basis. Every functional restoration program is also unique and should be evaluated on the goals, features and success of the program. The proposed guideline describes many criteria in detail based upon the medical evidence. In addition, the DWC is unable to comment on particular patient scenarios and the UR process because it goes beyond the scope of this rulemaking.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>eligible. Commenter would like to know if a UR can select whichever opinion they want in this type of situation. Commenter states that he has received many treatment denials due to an doctor pulling one opinion that a patient is a surgical candidate.</p> <p>Commenter references long term disabled patients which is discussed at length on pages 47 and 48 but there is no conclusion drawn as to whether long term legacy patients should have access to FRP programs. Commenter receives many denials saying the patient is a delayed recovery and not eligible for FRP. Commenter would like to know who is eligible, what gains can justify a FRP.</p>		<p>Disagree: DWC intends functional restoration to include an increase in activities in daily living and that each case should be reviewed on a case-by-case basis. Every functional restoration program is also unique and should be evaluated on the goals, features and success of the program. The proposed guideline describes many criteria in detail based upon the medical evidence. Many factors go into the evaluation of medical necessity for FRPs and delayed recovery is one factor.</p>	None.
Chronic Pain Medical Treatment Guidelines – Interpretation and	Commenter states that he works with groups of patients over a span of four to six weeks for five hours every day. Commenter states that his patients are	Yehuda Gertel Psy.D., Q.M.E. Clinical Health Psychologist	Disagree: Goes beyond the scope of this rulemaking because commenter is expressing concerns regarding	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Utilization Review	<p>having difficulty and experiencing many delays getting treatment approved under utilization review. Commenter states that it is common to see injured workers get treatment approval for a period of one to three weeks and then subsequently get denied for a period of a month or two, during which time the patient reverts back to baseline which is creating an ongoing problem.</p> <p>Commenter states, that in his experience, many utilization review physicians are failing to follow the regulations, failing to follow the guidelines and failing to adhere to the five day time frame. Commenter has submitted many complaints to the DWC regarding UR organizations. Commenter has complained to URAC.</p> <p>Commenter supports the adoption of ODG Guideline for the MTUS as he finds them to be more comprehensive and specific; however, he is concerned that UR doctors do not know how to interpret them correctly. Commenter objects to the concept of</p>	September 1, 2015 Oral Comment	<p>UR and IMR decision quality and does not directly address the proposed regulations.</p> <p>Disagree: Goes beyond the scope of this rulemaking because commenter is expressing concerns regarding UR and IMR decision quality and does not directly address the proposed regulations.</p> <p>Disagree: Goes beyond the scope of this rulemaking because commenter is expressing concerns regarding UR and IMR decision quality and does not directly address the proposed regulations. In</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>taking medical treatment decisions away from the treating physician and applying objective guidelines. Commenter opines that many doctors are not good at interpreting these guidelines.</p> <p>Commenter states that he is finding complete inter-rater unreliability when it comes to decisions. Commenter will get IMR decisions back and they will approve treatment, and then another IMR treatment will come back and they won't approve. And when you look at the scope of treatment of, and the scope of expertise of the IMR, you'll find that it was a family medicine practitioner located in Virginia. Commenter opines that something needs to be changed within the system -- the way the medical treatment decisions are made so that they're made -- if the DWC wants them to be systematic. Commenter would like them to be systematic.</p>		<p>addition, Labor Code section 4600(b) mandates that medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment based on the MTUS.</p> <p>Disagree: Goes beyond the scope of this rulemaking because commenter is expressing concerns regarding UR and IMR decision processes and does not directly address the proposed regulations.</p>	None.
Chronic Pain Medical Treatment Guidelines -	Commenter states that she is a patient suffering from chronic pain that has been in the Workers Comp system for	Juli Johnson Injured Worker September 1, 2015	Agree in part; Disagree in part: Agree: Commenter provides her personal anecdote of her	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
General Comment	<p>10 years. Commenter states that over the years she has felt that she was treated fairly by her insurance carrier. They approved everything that her physician felt was necessary for my care (such as MRI's, physical therapy, a pain counselor, EMG's, and medication).</p> <p>Lately she feels like they are "playing games" by not approving her medications. Commenter stresses that she is not taking any opioids. Commenter states that she is still unable to do many of the things that she used to do, which is very hard on her. However, she wasn't suffering in pain and could modify her daily activities with the medications.</p> <p>Even though these medications help me very much, commenter states that the insurance company continues denying them and then and her physician has to keep justifying them. Then they will approve two medications for a few months but deny her other one. Commenter questions why she is made to suffer in this way.</p>	Written Comment	<p>experience as a patient in the worker's compensation system. We assume she is accurately stating her personal experience.</p> <p>Disagree: Goes beyond the scope of this rulemaking because commenter does not address the proposed regulations.</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter was told by her physician that “all the insurance companies are denying care lately.” Commenter also hears the same thing from other Workers Comp patients that she knows.</p> <p>Commenter states that she is very proactive in her care and exercise and does things to help her feel better.</p> <p>Commenter states that the proposed regulations definitely need to be revised so that chronic pain patients get the care they need.</p> <p>Commenter hopes that in the future physicians will be able to provide to patients the care that they need.</p>		<p>Agree: The DWC is updating the Chronic Pain Medical Treatment Guidelines so that patients get the reasonable and necessary care that they need.</p> <p>Agree: The DWC is updating the Chronic Pain Medical Treatment Guidelines so that physicians will have guidance for the evaluation and treatment of injured workers and patients get the reasonable and necessary care that they need.</p>	<p>None.</p> <p>None.</p>
Chronic Pain Medical Treatment Guidelines – Functional	Commenter notes that within the current Acupuncture Treatment Guideline a patient can have six acupuncture visits/ treatment as an	Eduardo Lin, M.D. Oasis Pain and Wellness Center September 1, 2015	Disagree: The Procedure/Topic on Acupuncture in the Chronic Pain Medical Treatment Guidelines refers the reader to	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Restoration Program	<p>initial trial. If after six treatments the patient shows functional improvement, the patient is allowed to have additional treatment. Commenter states that the Acupuncture treatment guideline is an evidence-based. Commenter opines that this proposed treatment guideline, ODG Guideline, would eliminate that. Commenter states that the proposed guideline allows for four acupuncture treatments. After four sessions, patient has to show decrease of pain medication. Commenter opines that there will be technical difficulties coordinating care. Commenter states that when acupuncture is provided by the acupuncturist to the patient, the acupuncturist cannot oversee patient of the medication usage; there is no way to determine if the patient has cut back on their medications. Commenter questions how the patient will return to the doctor to discuss the use of medication and opines that this will interrupt the treatment.</p>	Oral Comment	the current MTUS Acupuncture Guidelines. The section on Functional Restoration Programs and Chronic Pain Programs refers to multidisciplinary programs, not stand-alone treatment such as acupuncture. Commenter mentions, "After four sessions, patient has to show decrease of pain medication" this purported requirement is nowhere to be found in our proposed Chronic Pain Medical Treatment Guidelines.	
Chronic Pain Medical Treatment Guidelines –	Commenter is concerned with opioid usage and acknowledges that too many patients use opioids for the	Eduardo Lin, M.D. Oasis Pain and Wellness Center	Agree: The current MTUS Acupuncture Guideline will continue to be used. This	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Functional Restoration Program	<p>wrong reason. Conversely, commenter states that there are also patients that need the pain medication and that there is no reason to deny access for these patients.</p> <p>Commenter requests that the Division continue use of current acupuncture medical treatment guideline to regulate use of acupuncture treatment.</p> <p>Commenter opines that it is more comprehensive, covers all body parts and is tight into functional assessment and improvement in order to allow patient to continue or not with treatment. Commenter states that the ODG guidelines will deny access to acupuncture by limiting ability to allow treatment.</p> <p>Commenter requests that the Division please allow Patients to engage in functional restoration treatment programs for more than 4 weeks. Commenter states that the current treatment guideline will allow patients to continue treatment without limiting treatment to 4 weeks as compared to ODG guide which</p>	September 1, 2015 Written and Oral Comment	<p>rulemaking only pertains to the Chronic Pain Medical Treatment Guidelines and the Opioids Medical Treatment Guidelines and where appropriate, references the current MTUS Acupuncture Guideline. See Above.</p> <p>Disagree: Current language does allow patients to engage in functional restoration programs longer than 4 weeks. The 4 week duration is a “general recommendation” proposed text states: “(12) Total treatment duration should generally not exceed 4 weeks (20 full-days or 160 hours), (or the equivalent in part-day sessions if required by part-time work, transportation, childcare, or comorbidities). (Sanders, 2005) If treatment in</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>allows a maximum of 4 weeks only of treatment. Commenter states that many of his patients do improve and benefit from FRP treatment up to 6 weeks. He has observed that most patients in his clinic have been able to cut down their opioid pain medications over 40% or more after completing their FRP program. Commenter state that this reduction in opioid pain medications persist even years after FRP treatments.</p>		<p>excess of 4 weeks is required, a clear rationale for the specified extension and reasonable goals to be achieved should be provided. Longer durations require individualized care plans explaining why improvements cannot be achieved without an extension as well as evidence of documented improved outcomes from the facility (particularly in terms of the specific outcomes that are to be addressed).”</p>	
Chronic Pain Medical Treatment Guidelines	<p>Commenter is concerned and opposed to the current proposed changes in Chronic Pain Medical Treatment Guideline to ODG guideline that she opines will reduce the number of acupuncture treatments and Carpal tunnel syndrome without Evidenced Based input and review. Commenter opposes the proposal in ODG to determine evidence of reduced pain based on the pain medication reduction which she opines is arbitrary and has no merit for the injured workers.</p>	Michelle Lau L.Ac, OMD, President Council of Acupuncture and Oriental Medicine September 1, 2015 Written Comment	Disagree: There are no changes to the current MTUS Acupuncture Guideline. The current MTUS Acupuncture Guideline will continue to be used. This rulemaking only pertains to the Chronic Pain Medical Treatment Guidelines and the Opioids Medical Treatment Guidelines and where appropriate, references the current MTUS Acupuncture Guideline.	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that there has been acupuncture treatment for California injury workers in the DWC system since 1989 and that acupuncture treatment is efficacy and cost saving. Commenter states that her organization has been working closely with DWC for more than 10 years, beginning in 2003, under the DWC instruction and following up the RAND Corporation criteria to develop and publish the CAOMA Evidence Based Acupuncture guideline in 2004, which was accepted by National Guideline Clearing House. Commenter states that the current DWC medical guideline for acupuncture is evidence based utilizing many studies and clinical trials. Commenter state that acupuncture treatment has been working for many conditions and functional pain management including Carpal Tunnel.</p> <p>Commenter notes that according to CCR 8, Section 9792.24.1, Acupuncture Medical Treatment Guideline clearly states the frequency and duration of Acupuncture</p>		<p>Agree: The current MTUS Acupuncture Guideline will continue to be used. This rulemaking only pertains to the Chronic Pain Medical Treatment Guidelines and the Opioids Medical Treatment Guidelines and where appropriate, references the current MTUS Acupuncture Guideline.</p> <p>Agree.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>treatments. It also clearly states which apply to acupuncture when referenced in the clinical topic of medical treatment Guidelines in the series of sections commencing with 9792.23.1 et seq., or in the chronic pain medical treatment guidelines contained in section 9792.24.2.</p> <p>Commenter states that the proposed changes to Chronic Pain Medical treatment Guideline shall not violate current Acupuncture medical Treatment Guidelines. Commenter opines that adopting the ODG change for acupuncture treatments will harm and create denying access for the injury worker, decreasing the merit for cost saving for DWC.</p>		<p>Disagree: There are no changes to the current MTUS Acupuncture Guideline. The current MTUS Acupuncture Guideline will continue to be used. This rulemaking only pertains to the Chronic Pain Medical Treatment Guidelines and the Opioids Medical Treatment Guidelines and where appropriate, references the current MTUS Acupuncture Guideline.</p>	<p>None.</p>
<p>Chronic Pain and Opioid Medical Treatment Guidelines – General Comment</p>	<p>Commenter supports the general direction taken in the draft regulations and acknowledges the MEEAC for their tireless efforts.</p> <p>Commenter recommends adopting the ODG Guideline intact without</p>	<p>Jeremy Merz California Chamber of Commerce</p> <p>Jason Schmelzer California Coalition on Workers’</p>	<p>Disagree: In order to properly incorporate the ODG</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>substituting unique California guidelines for opiates. Commenter opines that the regulation should adopt “the most current version” of the ODG Guideline since it is continually updated. Commenter notes that all standard Guidelines and Formularies throughout the healthcare industry across the United States are updated regularly with concurrent Evidence Based Medical Information to prevent undue patient morbidity and mortality resulting from outdated information.</p> <p>Commenter supports that the DWC has chosen to adopt the Official Disability Guidelines (ODG) for treatment of Chronic Pain. Commenter opines that the manner in which the DWC is adopting ODG for Chronic Pain is problematic. Commenter opines that it is essential that the DWC instead add language to the effect that the MTUS Chronic Pain Medical Treatment Guidelines not be based on an actual dated version of ODG but rather allow for automatic updates, which for ODG occur monthly. Commenter states</p>	<p>Compensation September 1, 2015 Written Comment</p>	<p>guidelines by reference into our regulations, subdivision (c)(4) of section 20 of title 1 of the California Code of Regulations requires that the regulatory text "identifies the document by title and date of publication or issuance." Therefore, incorporating the “most current version” without stating the date of publication or issuance is not allowed. Also, allowing the MTUS to be automatically updated whenever ODG updates their guidelines is an unlawful delegation of the DWC’s regulatory authority and will not be permitted by the Office of Administrative Law.</p>	

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	<p>that doing so ensures patients are receiving medical care that is reliant on the most current evidenced based medicine, without the delay of strength of evidence regulation when this chapter becomes outdated. The pace of change regarding medical information requires regular updates to any Guidelines or Formulary. This has been unequivocally documented by numerous healthcare studies.</p> <p>Commenter states that there are a host of situations where new medications, procedures, and approaches towards clinical medicine change rapidly. This has occurred with remarkable speed absent any scientific evidence of positive effect and appropriate use in the Workers' Compensation area. For example, in the early part of the 2000's utilization of the IDET procedure (lately proven as ineffective and possible harmful) and other therapies greatly increased with no clear benefit, ultimately causing likely damage to claimants and vastly increased costs to the system. Last year there was extensive controversy over the use of a new</p>		<p>Disagree: For the reasons stated above. In addition, if a physician feels that there is evidence to rebut any recommendation in the MTUS, then the requesting physician may attempt to rebut the MTUS. Rebutting the MTUS requires submitting additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated using the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1, where important considerations including study</p>	<p>None.</p>

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	<p>narcotic called Zohydro, a pure hydrocodone product that the FDA approved even though their medical advisory group recommended against the approval of this medication. Prompt updates to ODG reflected the science for and against to enable the work comp community to make the best possible decisions. Commenter states that in order to bypass reforms aimed at physician dispensing in 2011, repackagers created a new formulation of Cylobenzaprine HCL (7.5mg) and Tramadol HCL (150mg) where the need for that new formulation was not validated. Commenter states that group Health, Medicare, and Medicaid programs are able to change formulary and guidelines in a prompt and concurrent fashion as Evidence Based opinions become available. Commenter opines that to not do so will result in documented additional morbidity and mortality due to lack of concurrent and ongoing adoption of the most contemporary EBM Guidelines.</p> <p>In this area of medicine commenter sees the most acute need for the</p>		<p>design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine.</p> <p>Disagree: If a physician feels that there is evidence to rebut any recommendation in the</p>	<p>None.</p>

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	<p>creation of a single treatment guide that is, Nationally Recognized, Scientifically/Evidenced Based and Peer Reviewed. Commenter states that ODG meets all of these criteria with the added feature of their board constantly updating their guides. Commenter opines that the DWC also agrees with ODG recommendations with respect to Chronic Pain as it has elected to adopt its version dated April 2015. Commenter opines that to only adopt ODG's guideline as a snapshot frozen in time could potentially be creating more harm than good. Commenter is referring to those medical providers that are always attempting to exploit the system, who in this context can use the inconsistencies that would occur between the latest dated version of ODG and the regular updates to provide dangerous medications to injured workers.</p> <p>Commenter notes that it has been suggested that there is no regulatory authority to allow for the MTUS to be automatically updated.</p> <p>Commenter suggests that such</p>		<p>MTUS, then the requesting physician may attempt to rebut the MTUS. Rebutting the MTUS requires submitting additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated using the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1, where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine.</p> <p>Disagree: The Official Medical Fee Schedule is exempt from the APA requiring rulemaking review by the Office of Administrative Law because it “establishes or fixes rates,</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>authority exists and is already in place in regard to fee schedules that are tied to Medicare. Committer states that ODG provides for ease of management, potentially reducing costs because of consistency with other states. Commenter opines that the ODG reduces the possibility of politics influencing the direction of the Chronic Pain Treatment Guideline and would also fit nicely should the DWC look to adopt a Formulary Chapter also based on ODG.</p> <p>With respect to the Opioid Chapter, commenter is circumspect about carving out treatment guidelines specific to opioids versus other potentially addictive and detrimental prescription medications. Commenter is unclear as to how the very real probability of a Formulary Chapter would be defined under MTUS and how it will synchronize with the Opioid Chapter. Commenter opines that carving out treatment areas adds continued confusion for providers to an already fragmented and complex Guidelines system. Commenter</p>		<p>prices or tariffs” and, therefore, rulemaking is governed by Government Code section 11340.9(g). The MTUS does NOT fall under this narrow exception and requires the Office of Administrative Law to review rulemaking pertaining to the MTUS.</p> <p>Disagree: Commenter’s concern about carving out treatment guidelines specific to opioids versus other potentially addictive and detrimental prescription medications should be alleviated by realizing similar opioids guidelines are already published such as ACOEM’s Opioids Guidelines and the California Medical Board’s Opioids Guidelines. The DWC will certainly keep the upcoming formulary</p>	None.

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	<p>opines that to suggest that California is unique in regards to its population and treatment requirements based upon the practice of scientifically based medicine is not logically consistent with concepts involved in optimal healthcare. Commenter states that fragmentation of Guidelines is suggestive of issues other than those of optimal treatment patterns for claimants in the system.</p> <p>Commenter states that there is an end-stakeholder fiscal cost to implement MTUS in terms of converting the chapters into business practices that should be taken into consideration. Commenter states that the existing EBM guidelines such as ODG are already more widely adopted, electronically-integrated and in use in multiple jurisdictions. Commenter opines that the MTUS remains very much a manual process for the end user which may be a limiting factor in its applicability in delivering real-time care causing its use to be relegated to UR only.</p>		<p>regulations in mind when completing this rulemaking.</p> <p>Disagree: The proposed Chronic Pain Medical Treatment Guidelines and the Opioids Treatment Guidelines will be electronically available for free for the end user. Section 9792.21(c) makes it clear that “The MTUS shall be the primary source of guidance for treating physicians and physician reviewers for the evaluation and treatment of injured workers.”</p>	None.

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Chronic Pain and Opioid Medical Treatment Guidelines – General Comment	<p>Commenter states that he has been in medical practice for five decades in the San Francisco Bay Area and during these years has treated many Workers’ Compensation patients. Commenter is board certified in Neurological Surgery and in Pain Medicine. In the 1970s commenter became intrigued by Pain Medicine and was responsible for organizing and shaping the development of the specialty of pain medicine. Commenter founded the American Academy of Pain Medicine (AAPM), the California Academy of Pain Medicine (CAPM), the American Board of Pain Medicine (ABPM), the Foundation for Pain Medicine (FPM) and many other organizations. Over the years commenter has served as the Executive Medical Director of AAPM, the Executive Vice President of ABPM and as CEO, President and board director of these and many other organizations. Commenter has provided our office with a fact sheet on pain that was recently published by the AAPM [Copy provided upon request].</p>	<p>Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment</p>	<p>Agree: Commenter provided the DWC documentation that was recently published by the AAPM.</p>	<p>None.</p>

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	<p>Commenter’s review of the proposed guidelines focuses primarily on the early part of the documents addressing ideology and premises pertaining to opioids and chronic pain. Commenter opines that these documents are based on sound references and promote acceptable medical practice. Commenter opines that they are heavily nuanced, promoting cost savings and functional recovery. Commenter notes that they stress the dangers, side effects and abuses of opioids, but hardly ever mention the major benefits. Commenter states that the proposed guidelines fail to recognize a balance of patient safety and well-being as essential to medical practice. Commenter opines that the discussions of pain patho-physiology and classification include sound principles intermingled with confusing archaic concepts. Commenter states that the Chronic Pain guideline bases its classification on “acute” and “chronic” pain pointing out, he opines, appropriately, that chronic pain is</p>		<p>Disagree. The DWC believes the proposed guidelines present a balanced approach to the appropriate treatment of chronic pain and for the use of opioids that is supported by the best available medical evidence.</p> <p>Disagree: The proposed MTUS Chronic Pain Medical Treatment Guidelines does specify the physiological differences between acute vs.</p>	<p>None.</p> <p>None.</p>

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	<p>much more than just long lasting pain – it includes major neuro-pathological changes which represent the essence of chronic pain. Commenter notes that none of this is included in the Opioid guides, which uses a taxonomy of “acute”, “operative”, “sub-acute” and “chronic” pain on purely a temporal basis.</p> <p>Commenter opines that since these guidelines are likely to be used not only in Workers’ Compensation but in other medical arenas, it is important that they be congruent with established medical practice, MBC guidelines and expert medical opinion such as established by the CMA, AMA, AAPM and other organizations.</p>		<p>chronic pain and they are in agreement with accepted models of pain</p> <p>Agree: The DWC believes these proposed guidelines are in line with established medical practice.</p>	None.
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	<p>In the first paragraph, commenter notes the term “conservative management” and questions how this is defined.</p> <p>Commenter emphasizes the phrase “manage all chronic pain conditions.”</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Agree: For clarification, a definition of conservative management is added.	PART 1: Introduction is revised to define “conservative management” by adding, “that is, a treatment approach designed to avoid surgical and other

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				medical and therapeutic measures with higher risk of harm compared to benefit. (Singh, 2013)” for clarity.
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	<p>Commenter references Page 1, Definitions: Pain. Commenter opines that the IASP pain definition, “an unpleasant sensory or emotional experience associated with actual or potential tissue damage” is a dated concept.</p> <p>Commenter references the following sentence:</p> <p>“This definition describes pain as a subjective experience; therefore, unlike hypertension or diabetes, there is no objective measurement for pain intensity.”</p> <p>Commenter states that this is true for intensity but not true for the presence of pain.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	<p>Disagree: The 21 year old defined concept is commonly used and is the accepted definition cited by IASP (International Association for the Study of Pain) and others.</p> <p>Agree: There is no objective measurement or physiologic biomarkers for pain itself, not pain intensity. The word “intensity” will be deleted.</p>	<p>None.</p> <p>PART 1: Introduction is amended to delete the word “intensity” after “pain” for accuracy.</p>
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	Commenter references Page 1, Types of Pain (Acute vs Chronic). Commenter recommends the following revised text:	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015	Disagree: Commenter’s suggestion to use “are” instead of “is” will not be incorporated. The singular	None.

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	<p>“Although acute and chronic pain is <u>are</u> considered separately below, an individual can experience them simultaneously. Furthermore, current research shows that pain exists more on a continuum than in discrete categories of “acute” or “chronic” pain.”</p> <p>Commenter states that the concept of pain is a continuum, as in all other spectrum disorders, is a complex concept that warrants further exploration. Commenter questions, under present definitions, how once can experience acute and chronic pain at the same time.</p> <p>Commenter recommends the following revised text:</p> <p>“Therefore it is important to identify persons at risk for the development of chronic pain and to establish preventative <u>preventive</u> measures to reduce the likelihood of pain persistence.</p>	Written Comment	<p>form is correct in this context.</p> <p>Disagree: Current research and thinking is that pain exists on a continuum. Definitions of Acute and Chronic Pain are accordingly less rigid, however for the purpose of the guidelines, these concepts were simplified to make them more usable.</p> <p>Disagree: Use of preventative is interchangeable with preventive and is a common variant of the adjective corresponding to <i>prevent</i>.</p>	<p>None.</p> <p>None.</p>
Chronic Pain Medical Treatment	Commenter references Page 2, Types of Pain (Mechanisms).	Phillip M. Lippe, MD FACS, FAANS(L),	Disagree: There are a number of ways pain can be broadly	None.

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Guidelines – Part 1: Introduction	Commenter opines that this is a mixed bag of taxonomy and classification which is confused/confusing.	FACPM September 1, 2015 Written Comment	categorized and pain criteria can overlap, however, this model is generally accepted.	
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	Commenter references Page 2, Types of Pain (Mechanisms). Commenter states that Nociceptive pain is general seen with acute pain.	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: Not accurate because Nociceptive pain can be seen with chronic pain.	None.
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	Commenter references Page 2, Types of Pain (Mechanisms). Commenter states that Inflammatory Pain is a patho-dynamic mechanism that activates acute/nociceptive pain.	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: The statement is accurate but not relevant to guideline content. There are overlapping types of pain in these concepts that cannot be separated.	None.
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	Commenter references Page 2, Types of Pain (Mechanisms). Commenter opines that the definition of “neuropathic pain” stops short of declaring neuropathic pain a neuro-biologic disease/illness which he opines is an important concept.	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: See above.	None.
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	Commenter references Page 2, Types of Pain (Mechanisms). Commenter opines that the definition for “unknown causes” is a straw man.	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: A variety of terms and mechanisms have been applied such as central sensitivity syndrome.	None.

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	<p>Commenter opines that most of these are considered neuropathic pain.</p>			
<p>Chronic Pain Medical Treatment Guidelines – Part 1: Introduction</p>	<p>Commenter references Page 2, Overview. Commenter emphasizes the following sentence:</p> <p>“Pain is a uniquely individual and subjective experience that depends on a variety of biological, psychological, and social factors, and different population groups experience pain differentially.”</p>	<p>Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment</p>	<p>Disagree: Statements are accurate as stated and they remain contemporary.</p>	<p>None.</p>
<p>Chronic Pain Medical Treatment Guidelines – Part 1: Introduction</p>	<p>Commenter references Overview, first paragraph and Page 3.</p> <p>Commenter opines that this entire paragraph is objectionable and takes pain out of the bounds of medicine. Commenter states that it forgets that the bio-medical model includes recognition of symptom, disease and illness. Commenter states that pain is all three.</p> <p>Commenter references the last sentence of paragraph one and page three:</p> <p>“Similar to what has been learned about other chronic diseases, chronic</p>	<p>Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment</p>	<p>Disagree: Current, accurate as stated.</p>	<p>None.</p>

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	<p>pain ultimately affects (and is affected by) any intrinsic an extrinsic aspects of a person’s life.”</p> <p>Commenter agrees and states that, yes, it is called an illness.</p>			
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	<p>Commenter emphasizes Overview, second paragraph and Page 3, Key issues.</p> <p>In the third paragraph, commenter references the term “biopsychosocial model of pain” and states that this is referred to as an illness.</p> <p>In the third paragraph, commenter references the phrase “...chronic pain resembles many other chronic diseases.” Commenter state that what chronic pain resembles is an illness. Commenter opines that a disease is purely a patho-physiologic process stripped of human co-morbidities. Commenter states that diabetes is a disease the same in a dog as in a human. Commenter states that illness is not.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: Current, accurate as stated.	None.
Chronic Pain Medical Treatment Guidelines – Part	Commenter references Pain Mechanisms, fourth paragraph on Page 3.	Phillip M. Lippe, MD FACS, FAANS(L), FACPM	Disagree: Current, accurate as stated.	None

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1: Introduction	Commenter finds this paragraph confusing and untrue.	September 1, 2015 Written Comment		
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	<p>Commenter references Pain Mechanisms, second, third and fourth paragraphs on Page 4.</p> <p>Commenter objects to taking the “biopsychosocial model” out of the realm or medicine. Commenter opines that it is simply the recognition of a medical disorder expressed as a disease.</p> <p>Commenter opines that this section confuses neuropathy or neurogenic pain with neuropathic pain.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: Current, accurate as stated.	None.
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	<p>Commenter references Models, first paragraph, page 5.</p> <p>Commenter opines that this section is confusing as it conflates a number of diverse concepts.</p> <p>Commenter references the term “standards of care.” Commenter opines that this terminology is wrong. Commenter states that Models do not set standards of care; physician practices do.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Agree: The DWC is applying the term broadly but for clarity will change.	Part 1: Introduction, Models, first paragraphs is amended by deleting the phrase “standards of” and replacing it with the phrase “guidance for” for clarification.

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Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	<p>Commenter references Models, Acute vs. Chronic Pain Model, page 5.</p> <p>Commenter states that this section is well written but opines that it confuses because of taxonomy. Commenter states that terms of acute and chronic have temporal denotation and connotation and should be used in context. Commenter state that they are explained better in the patho-physiologic mode as nociceptive and neuropathic pain.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: Previous sections define pain, this is the Models section. The purpose of the section is to compare models used to describe pain and is accurate as stated.	None.
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	<p>Commenter references Models, Illness Behavior Model, page 5.</p> <p>Commenter states that pain is a symptom as well as a disease and illness. Commenter states that as an illness it has a host of epi-phenomena. Commenter opines that these are common to many chronic illnesses and are not unique to pain. Commenter opines that workers’ compensation involvement exacerbates this.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: Although commenter’s statement is true, the addition of “epiphenomena” is unnecessary because the paragraph already contains a sufficient amount of examples to make the point.	None.
Chronic Pain Medical Treatment Guidelines – Part 1: Introduction	Commenter references Models, Biomedical vs. Biopsychosocial Model, page 6.	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015	Disagree: The Biopsychosocial Model is well established and well accepted in the field of chronic pain and many other	None.

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	<p>Commenter opines that this is an antiquated concept prosed by Engle in 1977 who was operating on sheer ignorance. Commenter states that pain is not something that cannot be adequately explained by the bio-medical model and opines the division should resist any effort to take it outside of the realm of medicine.</p>	<p>Written Comment</p>	<p>disease conditions, of which chronic is just one.</p>	
<p>Chronic Pain Medical Treatment Guidelines – Part 1: Introduction</p>	<p>Commenter references Models, Medical vs. Self-Management Model, Model, page 7.</p> <p>Commenter agrees with the concept that pain is best resolved in a partnership between patient and physician. Commenter opines that this is difficult in the workers’ compensation area.</p>	<p>Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment</p>	<p>Agree.</p>	<p>None.</p>
<p>Chronic Pain Medical Treatment Guidelines – Part 1: Introduction</p>	<p>Commenter references Models, Subacute Delayed Recovery, page 8. Commenter specifically refers to the following sentence:</p> <p>“If necessary, patients should be directed to resources capable of addressing psychosocial barriers to recovery.”</p>	<p>Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment</p>	<p>Disagree: Someone who is capable of addressing psychosocial barriers is likely referring to psychologists but could be a number of other specialists, including a pain specialist. No change is required.</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter opines that he is not sure what these are and states that it is more appropriate to send the patient to a pain specialist.			
Opioid Medical Treatment Guidelines – Part 1: Executive Summary	<p>Commenter references the following statement from Page 2:</p> <p>“Although all doses of opioids carry risks, providers should be increasingly vigilant for doses above 80 mg/day morphine equivalent dose (MED), as the known risk of adverse events rises while the evidence for increased benefit remains weak.”</p> <p>Commenter would like to see references for this statement.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: This is the Executive Summary and this statement is repeated throughout the guidelines and gives sufficient references. See MTUS Opioids Treatment guidelines Part 2: supplementary Materials, Section I. Dosing Threshold for findings and selected references from the evidence-based guidelines used to determine the 80 mg/day MED dosage as cause for vigilance. Guidelines listed in this section include ACOEM 2011; ACOEM, 2014; APS/AAPM, 2009; ASIPP, 2012; Canadian Guideline, 2010, ODG, Utah, 2009; VA/DoD, 2010; WA Interagency Guidelines, 2010 Update, WA Workers’ Comp guidelines, 2013.	None.
Opioid Medical Treatment Guidelines – Part 1: Executive	<p>Commenter references the following statements from Page 2:</p> <p>“Results of periodic urine drug</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015	Disagree: This is supported by multiple studies. See MTUS Opioids Treatment guidelines Part 2: supplementary	None.

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Summary	<p>testing (at point of care initially and verified by a federally certified laboratory) performed on a random basis two to four times a year during chronic treatment, and if the provider is concerned about misuse, abuse or diversion.”</p> <p>Commenter states that this is not routine and should only be done if the physician deems it to be appropriate.</p> <p>“When titrating the dose of opioids used for treatment of chronic pain to achieve maximal improvement in pain and function, decisions to increase opioids should be made jointly by both the provider and the patient. It is the responsibility of the provider to inform the patient that current evidence shows a dose-related increase in adverse events.”</p> <p>“Clinicians should conduct semiannual attempts to wean patients whose dose has been 80mg/day MED or higher for at least six months to lower than 80mg/day MED.”</p> <p>Commenter would like to see</p>	Written Comment	<p>Materials, Section F. Urine Drug Testing for findings and selected references on the topic of urine drug testing. Guidelines listed in this section include ACOEM 2011; ACOEM, 2014; APS/AAPM, 2009; ASIPP, 2012; Canadian Guideline, 2010, ODG, Utah, 2009; VA/DoD, 2010; WA Interagency Guidelines, 2010 Update, WA Workers’ Comp guidelines, 2013.</p> <p>Disagree: See MTUS Opioids Treatment guidelines Part 2: supplementary Materials, Tapering I and Tapering II for findings and selected references on the topic of tapering/weaning. See above for a list of guidelines listed in these sections.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	references to back up off of these statements.			
Opioid Medical Treatment Guidelines – Part 1: Executive Summary – Summary Recommendations – OPIOIDS FOR ACUTE PAIN	<p>Commenter references the chart on page 6, column Considerations. Commenter recommends the following revised sentence:</p> <p>Only consider opioids for acute mild pain if non-opioid pain treatments are contraindicated or ineffective.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Disagree: Evidence strongly supports use of opioids only for moderate to severe pain.	None.
Opioid Medical Treatment Guidelines – Part 1: Executive Summary	<p>Commenter references A3.2 Workers’ Compensation Context, page 10.</p> <p>Commenter states that appropriate use of any medication, including opioids, is to assure patient well-being and patient safety. Commenter opines that this entire document focuses heavily on safety but does not balance this with consideration of well-being (pain relief). Commenter opines that his is an opio-phobic approach, possibly driven by cost considerations.</p> <p>Commenter states that taxonomy of acute, sub-acute and chronic are clearly based on temporal considerations. Commenter</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	<p>Disagree: The DWC does not view these proposed guidelines as “opio-phobic” and it the recommendations are certainly NOT driven by cost considerations. Safety and well-being are very closely related.</p> <p>Disagree: Cost benefit analyses were not considered in the formulation of these</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>questions where previous description went describing chronic in terms of neuropathic.</p>		<p>guidelines, only medical evidence of safety and efficacy.</p> <p><u>Disagree: Opioids Treatment Guidelines do not provide descriptions of neuropathic pain. Commenter is referred to the Chronic Pain Medical Treatment Guidelines for this information.</u></p>	<p><u>None.</u></p>
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary</p>	<p>Commenter references A3.3 Evidence of Effectiveness of Opioid Use in the Acute Period, page 11. Commenter specifically references the following statement:</p> <p>“However, non-opioid medications also may cause adverse health effects and may not be tolerated by some patients.</p> <p>Commenter opines that this statement deserves far more emphasis. Commenter states that NSADS are dangerous and in many cases have a poorer risk/benefit ratio than opioids.</p>	<p>Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment</p>	<p>Disagree: Non-opioid medications such as NSAIDS are not specifically addressed in the proposed MTUS Opioids Treatment Guidelines but are included in the MTUS Chronic Pain Medical Treatment Guidelines so further emphasis is not needed here.</p>	<p>None.</p>
<p>Opioid Medical Treatment Guidelines – Part</p>	<p>Commenter references A3.4 Evidence of Effectiveness of Long-Term Opioid Use, page 11.</p>	<p>Phillip M. Lippe, MD FACS, FAANS(L), FACPM</p>	<p>Disagree: The statement “These disparate conclusions are sometimes based on the</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
1: Executive Summary	<p>Commenter specifically references the following sentence:</p> <p>“These disparate conclusions are sometimes based on the integration of new findings and, at other times, on different interpretations of the same data.”</p> <p>Commenter opines that, yes, not everyone agrees and that is the point. Commenter states that this document is one sided.</p>	September 1, 2015 Written Comment	integration of new findings and, at other times, on different interpretations of the same data.” is true. The DWC disagrees with commenter’s statement that the proposed guideline are one sided. However, commenter has made it clear that this is his opinion.	
Opioid Medical Treatment Guidelines – Part 1: Executive Summary	<p>Commenter references A3.4 Evidence of Effectiveness of Long-Term Opioid Use, page 12. Commenter specifically references the following sentence:</p> <p>“The Opioids Treatment Guidelines emphasize the need to balance the use of opioids to treat pain with measures of effectiveness, by monitoring pain, function, and progress towards reduced disability.”</p> <p>Commenter states that this is a wonderful aspiration, but opines that this is not accomplished in this document. Commenter references</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	<p>Agree: that the goals of the guideline are positive as that is the goals of pain relief and functional recovery are core principles in the treatment of injured workers.</p> <p>Disagree: that the proposed guideline does not assist clinicians in that goal and promotes a biopsychosocial approach to pain management. Furthermore, interdisciplinary approaches are supported by the evidence and recommended throughout the guideline.</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Argoff’s paper.</p> <p>Commenter references the following statement:</p> <p>“Effective treatment of pain involves using multiple modalities and a multidisciplinary approach. For guidance on the effectiveness of treatment for chronic pain with non-opioid therapies, see the MTUS Chronic Pain Medical Treatment Guidelines.”</p> <p>Commenter states that the MTUS Chronic Pain Medical Treatment Guideline does not classify “acute pain” and describes “acute” and “chronic” pain differently.</p>			
<p>Opioid Medical Treatment Guidelines – Part 1: Executive Summary</p>	<p>Commenter references A3.5 Opioid Safety: Overdose, Serious Adverse Events, and Substance Misuse/Abuse, page 13. Commenter specifically references the following sentence:</p> <p>“Serious Adverse Events: According to the US Centers for Disease Control and Prevention (CDC), deaths associated with prescription opioids rose from 4,000 in 1999 to over</p>	<p>Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment</p>	<p>Disagree: There is increasing evidence of morbidity and mortality associated with the used of prescription opioids. Further information can be found at the Centers for Disease Control (CDC) website which shows the trend continues through 2010 with 22,134 deaths attributable to opioids. The commentator is</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			reason.	
Opioid Medical Treatment Guidelines – Part 1: Executive Summary	<p>Commenter references A3.6 Scope and Target Audience for the Opioids Medical Treatment Guidelines, page 15. Commenter specifically references the following sentence:</p> <p>“...any policy in this arena must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use.</p> <p>Caution should also be exercised in extrapolating these recommendations to the non-workers’ compensation population.”</p> <p>Commenter questions if we have <u>two</u> standards of care.</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	<p>Disagree: Recommendations supported by medical evidence are made throughout the proposed Opioids Medical Treatment Guidelines.</p> <p><u>Disagree: As stated in section A1 of the Executive Summary, “The Opioids Treatment Guidelines do not address pediatric pain, labor pain, pain immediately following catastrophic injuries, or cancer/end-of-life pain. For additional information on the appropriate use of opioids for the treatment of noncancer pain that is not related to work can be found in the <i>Medical Board of California Guidelines for Prescribing Controlled Substances for Pain.</i>” So, the DWC Guidelines under review here have a specific audience for whom they are appropriate. Other guidance would be the appropriate standard of care for other patient groups such as those noted above.</u></p>	<p>None.</p> <p><u>None.</u></p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Opioid Medical Treatment Guidelines – Part 1: Executive Summary	<p>Commenter references B. Recommendations, page 19. Commenter emphasizes the following paragraph:</p> <p>“The Evidence Levels for individual studies cited as the basis for recommendations were evaluated based on the DWC Medical Treatment Utilization Schedule (MTUS) Methodology for Evaluating Medical Evidence and are listed in the reference section. This methodology is intended only for the evaluation of individual studies, not guidelines; thus, the Evidence Level for recommendations based on guidelines was not evaluated. The reader is referred to the relevant guideline for further information on studies supporting these recommendations.”</p>	Phillip M. Lippe, MD FACS, FAANS(L), FACPM September 1, 2015 Written Comment	Agree: The Commenter emphasized this paragraph and the DWC agrees that this is an important paragraph. However, no suggested change was provided by commenter.	None.
Opioid Pain Medical Treatment Guidelines – General Comment	Commenter states that there are a small percentage of doctors who prescribe opioid medications, over prescribe, and there are some workers who go in for a relatively minor injury, and instead of coming back to work and living a productive life, turn into drug addicts.	Bruce Wick California Professional Association of Specialty Contractors September 1, 2015 Oral Comment	Agree: The DWC has read and accepts this comment. The DWC is attempting to strike a balance between appropriate treatment of pain among injured workers and safety in the use of opioids for that purpose. Commenter provided	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that his organization has no control over this. Commenter opines that self-policing is hard for any association, and that the California Medical Association has not been able to self-police those people who over prescribe these opioids. Commenter states that his organization has no expertise or authority to protect their workers, and that their workers can't protect themselves. Commenter opines that it's hard for an injured worker to go into a doctor anyway, since they're not paying for the treatment, and that it's even harder for them to say, why are you doing this and is this really good for me? Commenter states that the employers of California and their workers need the Division to protect their workers from these predatory over prescribers, and needs the Division to pass these guidelines to help injured workers. Commenter appreciates the Division's efforts.</p>		<p>no additional suggested changes to the proposed regulations.</p>	
<p>Opioid Medical Treatment Guidelines – Part 1, B3.2</p>	<p>Commenter states that the use of Class 2 and Class 3 opioids has exploded in this State since the reforms of 2004 and 2005.</p>	<p>Wayne Whalen, DC Board Member and Past President Chiropractic</p>	<p>Disagree: Neither the DWC nor the MTUS established the 24 visit cap on chiropractors, physical therapists or</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
<p>Consideration of Alternative Treatments For Chronic Pain and Chronic Opioid Treatment</p>	<p>Commenter states that, according to CWCI, opioid use has increased six fold since 2002, half of them for alleged minor injuries. Commenter notes that the CWCI also says that about 53 percent of Class 2 drugs are used for low back disorders. Commenter opines that this is no coincidence. Commenter states that if you eliminate conservative treatment options like PT and chiropractic care for injured workers with an arbitrary cap, patients have to pick something else to do, and many of them are left to choose opioids or they elect to take their care outside the workers' compensation system shifting costs to other payers.</p> <p>Commenter states that he and his colleagues are frustrated that the DWC has elected not to list chiropractic care as one of the options in the proposed Section 3.2, even though all most every other type of alternative treatment was included, such as massage and yoga.</p> <p>Commenter states that there is robust Level 1 evidence that chiropractic</p>	<p>Association September 1, 2015 Written <u>Oral</u> Comment</p>	<p>occupational therapy. That cap was established via statute and is memorialized in Labor Code section 4604.5(c)(1).</p> <p>Disagree: Omitting chiropractic care as one of the alternative therapies to opioid treatment does not preclude consideration of chiropractic care for chronic pain. In fact, because chiropractic care is among the most prevalent treatments sought by injured workers, it is fully addressed in the Manual therapy &</p>	<p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>care and a particular manipulation is effective, cost effective and has higher patient satisfaction based on numerous guidelines and studies published in prestigious journals like JAMA, Annals of Internal Medicine and Spine. In fact, the DWC's own Chronic Pain Guidelines clearly indicate manipulation has efficacy, particularly for spinal related conditions.</p> <p>Commenter states that chiropractors perform about 90-plus percent of all manipulations in this country. Commenter states that chiropractic is a profession, not a treatment modality. Commenter states that chiropractors routinely use manipulation, but also provide evaluation in management services, physiotherapy, therapeutic exercise, ergonomic and lifestyle advice, diagnostic services like X-rays and other services all of which are supported by evidence-based guidelines and the MTUS. Commenter states that chiropractors a one-stop shop, minus drugs and surgery.</p>		<p>manipulation sections of the MTUS Chronic Pain Medical Treatment guidelines as well as in most of the MTUS' clinical topics guidelines and is recommended when incorporated in the plan of care with associated improvement in function.</p> <p>Agree: Chiropractors are a profession and not a treatment modality. Also agree chiropractors provide important services to California's injured workers.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter opines that the Division purposely left chiropractic care off of the list because chiropractors are considered mainstream. Commenter notes that PT and OT are specifically mentioned. Commenter opines that chiropractors have a fairly long history of being treated differently, some might say, unfairly, despite the evidence that their care is effective, less costly and has higher patient satisfaction. Commenter opines that therapy used should specifically include chiropractic care as a listed option.</p> <p>Commenter requests that the Division add chiropractic care as a reasonable alternative under Section 3.2 of the guidelines.</p>		<p>Disagree: Omitting chiropractic care as one of the alternative therapies to opioid treatment does not preclude consideration of chiropractic care for chronic pain. In fact, because chiropractic care is among the most prevalent treatments sought by injured workers, it is fully addressed in the Manual therapy & manipulation sections of the MTUS Chronic Pain Medical Treatment guidelines as well as in most of the MTUS' clinical topics guidelines and is recommended when incorporated in the plan of care with associated improvement in function.</p>	None.
Chronic Pain and Opioid Medical Treatment Guidelines – Chiropractic Care	<p>Commenter states that back pain is the second leading cause of physician visits, second only to childbirth or hospitalizations. It's the most prevalent chronic medical condition and the number one cause of long-term disability. Commenter opines that that efficacy of chiropractic care</p>	<p>Chris Forsyth Director of Governmental Relations and Chief Operating Officer California Chiropractic Association</p>	<p>Disagree: Omitting chiropractic care as one of the alternative therapies to opioid treatment does not preclude consideration of chiropractic care for chronic pain. In fact, because chiropractic care is among the most prevalent</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>in treating these issues is not new to us. Commenter questions why chiropractic care has been omitted form the list of alternatives to chronic pain management and chronic opioid treatment. Commenter assumes that it was an oversight; that the documentation and studies are so overwhelming and ad nauseam that there was no thought that it was needed to be added and be made obvious.</p> <p>Commenter notes that one of the modalities of treatment that athletes receive to get them back to work is chiropractic care. Commenter states that every single NFL team in this country has at least one chiropractor; many have two -- the Baltimore Ravens being one of them. Commenter spent some time with the Raiders' chiropractic team over the weekend at a symposium on sports rehabilitation. Commenter states that the NFL recognizes what their players needed to get back on the field and get back to work. Commenter notes that there are 27 medical personnel for every NFL</p>	<p>September 1, 2015 Oral Comment</p>	<p>treatments sought by injured workers, it is fully addressed in the Manual therapy & manipulation sections of the MTUS Chronic Pain Medical Treatment guidelines as well as in most of the MTUS' clinical topics guidelines and is recommended when incorporated in the plan of care with associated improvement in function.</p> <p><u>Disagree: Omitting chiropractic care as one of the listed alternative therapies to opioid treatment does not preclude consideration of chiropractic care as an alternative to opioid treatment. In fact, the recommendation in the Opioids Treatment Guidelines is that non-opioid alternative treatment for pain should be tried whenever possible. Any complementary/alternative modality, including chiropractic care, would be recommended and evaluated</u></p>	<p><u>None.</u></p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>team and a chiropractor is required to be one of them. Commenter opines that the injured workers in California deserve the same option.</p>		<p><u>based on the merits of the evidence base supporting that treatment request.</u></p> <p>Agree: Although we assume the statistics provided by commenter regarding NFL teams are correct, the DWC agrees that injured workers have the option of seeing a chiropractor in California for an industrial injury provide it is reasonable and necessary.</p>	None.
Chronic Pain and Opioid Medical Treatment Guidelines – Chiropractic Care	<p>It is commenter’s observations that over the last decade, California has consistently cut back care for physical medicine to the detriment of our injured workers. Commenter states that Chiropractors keep the police officers, the firefighters and nurses on the job, after they have experienced significant back injuries. Commenter states that two years ago, the division prohibited Chiropractors from being designated primary treating physicians, after that had been designated as many years prior.</p>	<p>Monica Miller Contract Lobbyist California Chiropractic Association September 1, 2015 Oral Comment</p>	<p>Disagree: Omitting chiropractic care as one of the alternative therapies to opioid treatment does not preclude consideration of chiropractic care for chronic pain. In fact, because chiropractic care is among the most prevalent treatments sought by injured workers, it is fully addressed in the Manual therapy & manipulation sections of the MTUS Chronic Pain Medical Treatment guidelines as well</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that there have been underground regulations related to chiropractic visits and what a visit actually looks like, it's not when they treat the patients, commenter states that it's when the patient actually walks through the door. Due to this, commenter state that patients are hitting that 24-visit cap much faster, and that's been a challenge for injured workers. Commenter states that injured workers are not able to get access to the care that they need, the care that evidence and studies demonstrate that gets them and keeps them back on the job.</p> <p>It is commenter's hope that non-inclusion of chiropractic care as an alternative to opioid was an oversight. Commenter requests that chiropractic care been included on the list of alternative treatments.</p>		<p>as in most of the MTUS' clinical topics guidelines and is recommended when incorporated in the plan of care with associated improvement in function. In addition, neither the DWC nor the MTUS established the 24 visit cap on chiropractors, physical therapists or occupational therapy. That cap was established via statute and is memorialized in Labor Code section 4604.5(c)(1). To be clear, chiropractic care is included in the proposed clinical guidelines.</p> <p><u>Disagree: Omitting chiropractic care as one of the listed alternative therapies to opioid treatment was not an oversight as the list is intended as examples of complementary/alternative care and not a complete listing of modalities to consider. Any complementary/alternative modality, including chiropractic care, would be</u></p>	<p><u>None.</u></p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			<u>recommended and evaluated based on the merits of the evidence base supporting that treatment request.</u>	
Chronic Pain and Opioid Medical Treatment Guidelines – General Comment	<p>Commenter shares the COA's concerns about the CURES database. Commenter opines that everybody puts great faith in CURES, except perhaps physicians. Commenter states that he does not want to institutionalize its use before its ready.</p> <p>Commenter is concerned about the sheer heft of the new guidelines. Commenter opines that if a working clinician has only a few minutes to see a patient would like to look up something very quickly, he/she may be unable to quickly locate the information that they are searching for.</p> <p>Commenter is concerned regarding the guides and the consistency between the proposed guidelines and that the Medical Board is currently promulgating and the upcoming formulary. Commenter is concerned</p>	Don Schinske WOEMA and ACOEM September 1, 2015 Oral Comment	<p>Disagree: CURES database has undergone recent enhancements and strong evidence supports its use by physicians.</p> <p>Disagree: The proposed guidelines cover a variety of clinical conditions and medical treatments and make it easier for the physician to find the appropriate evidence-based recommendation because it is more up-to-date and comprehensive.</p> <p>Disagree: The proposed MTUS Opioids Treatment Guideline is essentially consistent with the Medical Board of California’s “Guidelines for Prescribing Controlled</p>	<p>None.</p> <p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	that with all of these new guidelines coming out that it will be difficult for the casual workers' compensation provider to interpret. Commenter requests there be adequate time provided to perform a consistency check. Commenter opines that there will be a need to develop some user guides for medical professionals to follow, whether it's complied by the medical societies together or independently.		Substances for Pain". The formulary regulations will also need to go through the rulemaking process which will provide plenty of time for the DWC and all stakeholders to check for consistency and make suggested comments for revisions.	
Chronic Pain and Opioid Medical Treatment Guidelines – General Comment	Commenter is an injured worker that would like to explain her workers' compensation story so that the Division can understand how the MTUS Guidelines has rarely benefited and generally hindered her healing process. Commenter requests that the DWC update the Guidelines so that UR isn't a dirty word for injured workers and that if her Pain Management Specialist or her surgeon prescribes a reasonable medication or equipment, that it will be approved and not sent to UR so many times that she had the number installed on her telephone.	Andrea Smith Injured Worker September 1, 2015 Oral Comment	Agree in part; Disagree in part: Agree: that the MTUS guidelines under consideration should allow that reasonable and medically-necessary medical treatments be available to injured workers as that is the ultimate goal of the MTUS. Disagree: Commenter's suggestion to update the guidelines, "so that UR isn't a dirty word" and that treatment requests are approved and "not sent to UR so many times" fails to provide specific suggestions on how to improve the guidelines. Also, these	None. None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that she is currently 31-years-old. She was injured January 2009, at the age of 25. At the time she was told it was all in her head and was sent back to work with 800 milligrams of Ibuprofen. Commenter states that X-rays were not originally interpreted correctly and that this mistake was discovered by a QME two years later. Commenter states that this misidentified fracture had started to cause nerve damage, foot drop and had her in extreme sustained pain. Only after the commenter retained a lawyer and multiple requests for surgery were denied, did her surgeon finally receive authorization to perform an anterior posterior L5-S1 fusion. This occurred three years after commenter's injury. Thereafter, it was determined that a secondary fracture was present that probably</p>		<p>comments go beyond the scope of this rulemaking because they suggest changes to the Utilization Review regulations. No changes will be made.</p> <p>Agree: The DWC accepts that commenter's summary of her medical history and experience is correct.</p> <p>Disagree: The MTUS Chronic Pain Medical Treatment Guidelines and Opioids treatment Guidelines both offer a wide variety of non-pharmaceutical and non-surgical interventions for management of chronic pain, supported by the medical evidence that can be very helpful.</p> <p>Injured workers are encouraged to discuss all options further with treating physicians, including pain specialists, as it is not DWC's intent, nor the intent of these</p>	<p>None.</p> <p>None.</p>

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>occurred during the lengthy approval delays.</p> <p>Commenter states that throughout this ordeal, here surgeon and pain management specialist fought continuously for adequate, effective pain medicine, equipment and rehabilitation services. Pain medication was put on hold often, even after refilled dates had passed, resulting in extreme pain and unneeded stress. Commenter notes that this caused multiple trips to the emergency room for relief. Only after her attorney become involved, was she able to received prompt approval.</p> <p>Commenter opines that there should be a better system in place to avoid visits to the E.R. as a last resort. Commenter notes that emergency medicines are more severe and only result in short-term relief. Commenter states that pain management with long-acting medications can slow or stop the needless cycle. Commenter opines that long-acting medications, physical</p>		<p>guidelines, to leave injured workers in pain.</p> <p>However, the DWC appreciates the point that it is the injured worker who has the most at stake and that the right medical treatment be given at the right time. Patients' safety and effectiveness are the paramount concerns in selecting evidence-based guidelines.</p> <p>Disagree: Although the DWC has read and accepts commenter's summary of her personal experiences, she did not provide any suggested changes to the proposed regulations. Her comments go beyond the scope of this rulemaking.</p>	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>therapy, pain management physicians working in conjunction would save patients, their family members and costs. Commenter notes that these three major components were successfully acting together, that the last seven years of her life would have been less desperate.</p> <p>Commenter states that at the present time, her long-time pain prescription has been denied without option for appeal or justification. Commenter notes that here most recent CT scan identified a bulging disc near her surgical site, but she has absolutely no pain relief available. Commenter states that she would prefer not to need pain medication, but as of now, it's her only option. Commenter would like to know what she can do now to obtain relief.</p>			
Chronic Pain Medical Treatment Guidelines – Spinal cord Stimulation	Commenter’s company manufactures and distributes spinal cord stimulation systems for the treatment of patients who have chronic and retractable pain in trunk and limbs. Commenter commends the division for maintaining the spinal cord stimulation as a treatment option for	Susan Drawat St Jude Medical September 1, 2015 Oral Comment	Disagree: The DWC is in the process of incorporating by reference the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” published on April 6, 2015. The proposed	None.

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>failed back surgery syndrome in the medical treatment guidelines. Commenter opines that this is an essential step in the right direction for California injured workers in order to maintain access to this important treatment option. Commenter states that further clarity is needed in the new guidelines as related to spinal cord stimulation as the treatment for FBSS. Commenter agrees with the representatives from Medronic that the 2015 low back chapter has an important literature summary that supports FBSS. Commenter states that the proposed chronic pain MTUS guideline references the older version, the 2004 ACOEM low back chapter, and this omits nearly eleven years of data and clinical trials that supports the use of SCS for FBSS. Commenter opines that if this is not updated to the 2015 version, injured workers will be denied SCS treatment for FBSS which will result in additional administrative burdens that will cause unnecessary delays in obtaining this treatment. Commenter states that it is important to have a more current FBSS literature</p>		<p>guideline does not address the routine of SCS for failed back surgery syndrome (FBSS) patients. Currently, it references the MTUS Low Back Complaints guideline which incorporates by reference the 2004 ACOEM low back chapter. Commenter recommends that the nearly eleven years of data and clinical trials that supports the use of SCS for FBSS be included in the proposed MTUS Chronic Pain Chapter section on SCS. However, doing this is an attempt to amend the current MTUS recommendations in the Low Back Chapter via this rulemaking. The DWC is unable to amend the MTUS' Low Back Chapter without going through the formal rulemaking process to amend that regulatory section. However, the DWC is in the process of evaluating and updating the treatment guidelines for the Low Back.</p>	

MTUS CHRONIC PAIN AND OPIOIDS TREATMENT GUIDELINES	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	included in the chronic pain section.		If a physician feels that there is evidence to rebut any recommendation in the MTUS, then the requesting physician may attempt to rebut the MTUS. Rebutting the MTUS requires submitting additional scientific evidence to substantiate medical necessity as described in §§ 9792.21 and 9792.21.1. This evidence is then evaluated using the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1, where important considerations including study design and sources of bias are considered. This ensures that injured workers have access to the most current evidence-based medicine.	
General Comment	Referring to earlier speakers, commenter states that Dr. Prager said that there's ambiguity; Mr. Roxborough spoke about what appears to be artificial or arbitrary changes and rushing to get Senate	Steve Cattolica California Society of Industrial Medicine and Surgery California Society of Physical Medicine and	Disagree: The proposed guidelines necessarily present the available evidence which may at times appear contradictory. This is a well-recognized feature of the	None.

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	<p>regulations completed before it's completely clear what the landscape is; Mr. Wick spoke about needing protection. Commenter opines that not only do the employers need protection from inappropriate treatment but they need protection against high costs, the commenter doubts that the ambiguities and the inconsistencies are going to work to that end.</p> <p>Commenter states that Diane Pazeprorski talked about the over documentation, commenter opines it is in fact an almost impossible level of documentation by the physicians. Commenter states that both chiropractors Whalen and Jacob spoke about an entire body of treatment omitted, perhaps arbitrarily. Commenter notes that Ben Roberts from Prium spoke about the need for clarity. Commenter states that Dr. Rosenberg spoke about vagueness. Commenter states that Mr. Schinske spoke about not institutionalizing something that's not quite ready; Mr. McLaughlin from CAAA spoke about not picking and choosing</p>	<p>Rehabilitation September 1, 2015 Oral Comment</p>	<p>medical literature and inherent in the scientific process as evidence accumulates over time. Physicians are capable of interpreting the information and applying to their clinical practice. The value of the guidelines is that the evidence for a particular practice is summarized using strength of evidence standards, thus making the job of the physician easier, not more difficult, to ensure the safe and effective treatment of injured workers.</p> <p>Disagree: Physicians are professionally trained to efficiently document pertinent clinical findings. See response to Pazeprorski.</p> <p>Disagree: See response to Whalen and Jacob.</p> <p>Disagree: See response to Ben Roberts.</p>	<p>None.</p> <p>None.</p> <p>None.</p>

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	<p>elements of the treatment which may be available, the evidence that may be available messing with the recipe so to speak. Commenter states that his organization has addressed formulary in their comments. Commenter opines that the community needs to be told how to deal with dual presumptions when one part of the body of evidence says one thing and the interpretation of that evidence in another place says something else. Commenter states that this situation is ripe for controversy, friction and higher costs. Commenter opines that no one want to turn these guides into a cookbook; however, to the extent possible, he would like for the division to add the clarity that was requested earlier in this hearing and the consistency that is necessary.</p> <p>Commenter offers the following analogy: The division cannot be the scarecrow at the crossroads so when Dorothy comes to it and says "which way do I go," all of a sudden, one arm goes one way and one arm goes the other way. This means that some</p>		<p>Disagree: See responses to R. McLaughlin.</p> <p>Disagree: The MTUS guideline recommendations are based on the strength of evidence of the medical literature. The DWC cannot make recommendations that are not supported by the</p>	<p>None.</p> <p>None.</p>

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	<p>people will go in different directions. Commenter opines that these medical treatment guidelines should not be that vague.</p> <p>Commenter opines that the MTUS is supposed to be a dependable document that will avoid having to use a hierarchy of evidence in order to get the approval or get the authorization for approved therapies. Commenter states that if these documents provide no direction, it's simply a smorgasbord of possibilities, and therefore not a guideline at all.</p>		<p>literature. Clinical decision-making using an evidence-based approach is now a normal part of patient care as science is continually evolving. The vast majority of treatment is clearly covered by the MTUS guidelines with little friction. These general comments do not provide specific examples of conflicts or lack of clarity.</p>	
<p>Chronic Pain Medical Treatment Guidelines – 9792.24.2 – General Comment</p>	<p>Commenter is concerned regarding the coordination of the component guidelines that together comprise the MTUS. Commenter is also concerned about preserving efficient access to therapies when recommendations differ within and between those component guidelines.</p> <p>Commenter states that he recently raised this same issue with respect to the upcoming outpatient formulary that is the subject of AB 1124 and the Administrative Director’s initiative to implement such a formulary.</p>	<p>Steve Cattolica California Society of Industrial Medicine and Surgery California Society of Physical Medicine and Rehabilitation September 1, 2015 Written Comment</p>	<p>Disagree: The DWC and MEEAC carefully coordinate the component guidelines that together comprise the MTUS. Our responses to several commenters who questioned why the DWC deleted some ODG sections, the original source document of the proposed Chronic Pain Medical Treatment Guidelines, is a good example of our careful coordination efforts. There should not be conflicting recommendations from the</p>	<p>None.</p>

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	<p>Commenter described the situation with the term “dueling presumptions.” That is, the circumstance when a treating physician is faced with a presumed correct recommendation from one component of the MTUS that is in conflict with another presumed correct recommendation from a different area.</p> <p>Commenter states that the Division’s written response to this was complex. It included a detailed explanation of how the treating physician is to use the Hierarchy of Evidence (8CCR, Section 9792.25.1) in order to overcome one of the conflicting presumptions. Commenter states that the Division reminded him that it is the obligation of the utilization reviewer to use the same process when reviewing the evidence provided by the requesting physician. Commenter opines that while the Hierarchy and its process is vital in some instances; the wide-spread, routine use of the Hierarchy <i>within</i> the MTUS does not bode well for use of the</p>		<p>guidelines in the MTUS.</p> <p>Disagree: As stated above, there should be no conflicting recommendations from the guidelines in the MTUS. The Methodology for Evaluating Medical Evidence, of which the hierarchy of evidence is a part of, was designed to provide a process to evaluate competing recommendations found either outside the MTUS or when a recommendation found in the MTUS conflicts with a recommendation found outside the MTUS.</p>	<p>None.</p>

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	<p>MTUS in a real world of treating physicians, utilization review and the goal of timely delivery of care to an injured worker in need.</p> <p>Commenter states that while some incongruities should be expected as time goes by, he opines that the Division has an obligation to build an infrastructure for requesting treatment and receiving authorization that minimizes conflicts caused by the incongruities when it is within its power to do so. When incongruities are imbedded into the MTUS, commenter explicitly requests that the Division cite the medical evidence that requires the inconsistency to be present.</p> <p>Commenter opines that the use of the Hierarchy of Evidence is meant to be an occasional rather than regular event. Commenter opines that by definition, its use should not be required on a routine basis when navigating within the recommendations found in the MTUS.</p>		<p>Disagree: There should be no conflicting recommendations from the guidelines in the MTUS.</p> <p>Agree: The Methodology for Evaluating Medical Evidence, of which the Hierarchy of Evidence is a part of, was designed to provide a process to evaluate competing recommendations found either outside the MTUS or when a recommendation found in the MTUS conflicts with a</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter states that the Chronic Pain Guideline provides the following example:</p> <p>The proposed MTUS guideline for use of a Spinal Cord Stimulator (SCS) contains a literature review of SCS for Complex Regional Pain Syndrome (CRPS) and clear criteria for use of the SCS therapy. However, for Failed Back Surgery Syndrome, the proposed guideline states: “For use in failed back surgery syndrome (FBSS), see MTUS Low Back Complaints”. This instructs the reader to refer to a recommendation within the American College of Occupational and Environmental Medicine (ACOEM) 2004. Commenter notes, and as pointed out by others, this reference is outdated and inappropriate. Despite ample level-one evidence published since 2004 to the contrary, Spinal Cord Stimulators will remain unavailable from the MTUS. Commenter opines that this omission will result in inappropriate denials and treatment</p>		<p>recommendation found outside the MTUS.</p> <p>Disagree in part: Although the proposed Chronic Pain Medical Treatment Guidelines’ recommendation on Spinal Cord Stimulators (SCS) does not directly address the routine of SCS for failed back surgery syndrome (FBSS) patients, instead it references the MTUS Low Back Complaints guideline which incorporates by reference the ACOEM Practice Guidelines, 2nd Edition (2004) and states, “Implantable spinal cord stimulators are rarely used and should be reserved for patients with low back pain for more than six months duration who have not responded to the standard nonoperative or operative interventions.” FBSS as an indication for SCS has not been omitted. Commenter recommends that the proposed MTUS Chronic Pain Chapter</p>	None.

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	<p>delays for patients with FBSS when treating physicians otherwise properly request SCS.</p> <p>Commenter references the need for internal consistency of component guidelines, and states that when the clinical treatment section of the MTUS is updated, the reference in these Chronic Pain Guidelines for SCS use in FBSS will suddenly result in quick authorizations rather than protracted denials, friction and higher costs that will remain commonplace – all to the detriment of the injured worker.</p> <p>Commenter recommends that the DWC use this opportunity to make clear to users of the Chronic Pain Guidelines that it intends to provide coverage to injured workers who have been diagnosed with FBSS. Commenter opines that this could be accomplished by including the appropriate ODG clinical literature and coverage criteria for FBSS within the MTUS Chronic Pain Chapter. Commenter opines that the inclusion of the literature search is within the</p>		<p>section on SCS contain updated evidence published since 2004. However, doing this would be an attempt to amend the current MTUS recommendations in the Low Back Chapter via this rulemaking. The DWC is unable to amend the MTUS’ Low Back Chapter without going through the formal rulemaking process to amend that regulatory section. However, the DWC is in the process of evaluating and updating the treatment guidelines for the Low Back.</p> <p>Disagree: Deletions,</p>	<p>None.</p>

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	<p>Division’s authority and would certainly help clear up would-be issues over authorization.</p> <p>Commenter notes that 8CCR Section 9792.24.2 (a) instructs the community that the Chronic Pain Guidelines, Part I, includes an edited version of the Official Disability Guidelines (ODG) published on April 6, 2015. In addition to being edited by the Division, this paragraph also states that above mentioned guidelines have been “adapted” with the permission of the publisher, the Work Loss Data Institute.</p> <p>Commenter states that the Division has not provided any evidence based reason for any edits to the ODG Chronic Pain Guidelines.</p> <p>Commenter states that the Division did not make an effort to point out where the changes appear.</p> <p>Commenter would like to know why.</p> <p>For instance, commenter notes the following edits:</p> <ul style="list-style-type: none"> • Chiropractic care was 		<p>adaptations or edits from the source ODG document were made to maintain internal consistency within the treatment guidelines that form the Clinical topics and Special topics sections of the MTUS. Any citations in the source ODG document which directs readers to another section of the ODG guideline that is already addressed in an existing MTUS guideline or the proposed MTUS Opioids Treatment Guidelines, was amended to direct readers to the corresponding MTUS guideline. Principles of EBM were neither used nor required in order to make these deletions from the source ODG document because the corresponding MTUS guideline already contains the necessary citations to the supporting medical evidence. It is not clear which edits commenter is referring to because there are many references to chiropractic care,</p>	

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	<p>completely omitted. Despite evidence attesting to its effectiveness</p> <ul style="list-style-type: none"> • Hwave therapy was omitted. Despite their wide use by group health insurers, including some that participates preferred provider organizations in California’s workers’ compensation system, • the criteria for us of TENS units was omitted. <p>It is the commenters understanding that use of the Hierarchy of Evidence, is the main method that treating physicians and utilization review physicians are to use to substantiate a Request for Authorization or a denial of authorization. Commenter opines that if it is within the Division’s power to prevent unnecessary documentation, time and expense, it should do so.</p> <p>Commenter requests that the Division provide, in writing within the Chronic Pain Guidelines, the medical evidence basis for each edit and</p>		<p>Hwave therapy and TENS throughout these proposed guidelines. Commenter Robert A. McLaughlin provides a detailed laundry list of all the deletions, adaptations or edits made in the proposed Chronic Pain Medical Treatment Guidelines. See the DWC’s responses beginning on page #179.</p> <p>Disagree in part; Agree in part: Disagree: The use of the MTUS Methodology for Evaluating Medical Evidence in 8 CCR section 9792.25.1 is the main method that should be used. The Hierarchy of Evidence is only a part of the MTUS Methodology for Evaluating Medical Evidence. Agree: The DWC has attempted to prevent unnecessary documentation in these proposed guidelines.</p> <p>Disagree: See Above.</p>	<p>None.</p> <p>None.</p>

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	<p>variance from the ODG Chronic Pain Guidelines. Commenter opines that it is the Division’s obligation to do so.</p> <p>Commenter recommends the following Revised language:</p> <p>(a) The Chronic Pain Medical Treatment Guidelines (May, 2009) [<u>insert effective date of regulations</u>], consisting of two parts, are adopted and incorporated by reference into the MTUS. Part 1 is entitled Introduction. Part 2 is entitled Pain Interventions and Treatments; the <u>“Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)”</u> consisting of an edited version from the <u>Official Disability Guidelines published on April 6, 2015, which the Division of Workers’ Compensation has adapted with permission from the publisher. Notwithstanding, those <u>Notwithstanding, those</u> <u>edits, all medically appropriate guidelines and applicable law shall be considered when requesting or authorizing treatment for chronic pain.</u> These guidelines replace</u></p>		<p>Disagree: Commenter’s suggested language is substantively incorrect and will not be incorporated.</p>	<p>None.</p>

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	<p>Chapter 6 of the ACOEM Practice Guidelines, 2nd Edition (2004). Where the clinical topic sections of the MTUS in the series of sections commencing with 9792.23.1 et seq., make reference to Chapter 6 or when there is a reference to the “pain chapter,” or “pain assessment,” the chronic pain medical treatment guidelines will apply instead of Chapter 6. A copy of the eChronic pPain mMedical tTreatment gGuidelines may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov.</p> <p>(b) The eChronic pPain mMedical tTreatment gGuidelines apply when the patient has chronic pain as determined by following the clinical topics.</p> <p>(c) When a patient is diagnosed with chronic pain and the treatment for the condition is covered in the clinical topics sections but is not addressed in</p>			

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	<p>the cChronic pPain mMedical tTreatment gGuidelines, the clinical topics section applies to that treatment.</p> <p>(d) <u>When a patient is diagnosed with chronic pain and the treatment for the condition is covered in</u> both the eChronic pPain mMedical tTreatment gGuidelines and the specific guideline found in the clinical topics section of the MTUS, the eChronic pPain mMedical tTreatment gGuidelines shall apply.</p> <p>(e) Appendix D - Chronic Pain Medical Treatment Guidelines - Division of Workers' Compensation and Official Disability Guidelines References (May, 2009) is incorporated by reference into the MTUS as supplemental part of the Chronic Pain Medical Treatment Guidelines. A copy of Appendix D may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov.</p>		<p>Disagree: Commenter's suggested language will not be incorporated although revisions were made to proposed section 9792.24.2(d) as a result of suggestions made by other commenters.</p>	<p>Section 9792.24.2(d) is amended by adding the phrase "a patient has chronic pain" and the phrase "or if the treatment is only addressed in the Chronic Pain Medical Treatment Guidelines, then..." in addition to capitalizing the letters "c" and "t" in the phrase "Clinical Topics" to correct a typographical error.</p>

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Opioid Treatment Guidelines – 9792.24.4 – General Comment	<p>Commenter opines that the Opioid Treatment Guidelines present a very similar dilemma for providers and employers that he outlines for the Chronic Pain Treatment Guidelines. Commenter notes that the Opioid Guidelines will be presumed correct, as will the soon to be developed outpatient formulary. Commenter states that the Medical Board of California has established guidelines for the prescribing Schedule II and III drugs. Commenter states that these guidelines form a standard of care by which licensees are measured. California’s Health and Safety Code outlines all Californian’s statutory right to appropriate pain medication. Commenter states that together, these four form a path that must be navigated by the physicians of California. Commenter opines that the “dueling presumptions” that will exist between them must be reconciled. Commenter opines that since the two MTUS guidelines are both evidence-based, that evidence should be outlined in both and in common to both. Commenter states</p>	<p>Steve Cattolica California Society of Industrial Medicine and Surgery California Society of Physical Medicine and Rehabilitation September 1, 2015 Written Comment</p>	<p>Disagree: California law requires physicians practicing medicine in the workers’ compensation system to follow the evidence-based Medical Treatment Utilization Schedule. The MTUS does not conflict with regulations concerning the prescription of controlled prescription medications, and in fact promotes the best evidence for prescribing opioids as described in the Medical Board of California’s Guidelines for Prescribing Controlled substances for Pain (2014). Commenter refers to the Prescription Drug Formulary which is not addressed in these proposed regulations.</p> <p>Disagree: Only the MTUS is considered “presumptively correct” pursuant to Labor Code section 4604.5. As stated above, the DWC and MEEAC carefully coordinate the component guidelines that</p>	<p>None.</p> <p>None.</p>

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	<p>that each should come to the same conclusion and where they do not, he opines that it is the Division’s obligation to proactively reconcile those conflicts as much as possible so that therapy authorizations will not be unnecessarily delayed. Utilization review programs and providers need this clarity.</p> <p>Commenter recommends that the clinical sections of the MTUS be updated before or at the very least at the same time as, the Chronic Pain Guidelines and Opioid Treatment Guidelines. Commenter acknowledges that this request represents a departure from the current sequence of events; however, he opines that this assures a better match, more efficiency, much less friction and we are certain, lower overall costs for the workers compensation community that must use the MTUS. Commenter opines that it is within the power of the Division to implement this strategy and opines that in the long run, claims administrators, providers and injured workers – and maybe even</p>		<p>together comprise the MTUS. Our responses to several commenters who questioned why the DWC deleted some ODG sections, the original source document of the proposed Chronic Pain Medical Treatment Guidelines, is a good example of our careful coordination efforts. There should not be conflicting recommendations from the guidelines in the MTUS.</p> <p>Agree in part; Disagree in part: Agree: The DWC agrees that ideally it would be better to update all of the clinical topics sections of the MTUS along with the Chronic Pain Guidelines and the Opioids Treatment Guidelines. Disagree: The staggered updates to the MTUS guidelines do not result in “dueling presumptions” that commenter repeatedly refers. As already stated, great care is taken to make sure the recommendations in the</p>	None.

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	<p>the court system – will be much better off. Commenter questions why the Division would want to perpetuate the friction, delays and costs caused by “dueling presumptions” and guidelines that are at cross purposes.</p> <p>The commenter recommends the following revised language:</p> <p><u>(a) The Opioids Treatment Guidelines [insert effective date of regulations] consisting of two parts, is entitled “The Guideline for the Use of Opioids to Treat Work-Related Injuries,” and is adopted and incorporated by reference into the MTUS. Part 1 contains the executive summary, abbreviated treatment protocols, background information, complete recommendations, and appendices with useful tools for clinicians. Part 2 contains supplemental information consisting of a discussion of the medical evidence supporting the recommendations and a summary of recommendations from other guidelines that were reviewed. These</u></p>		<p>MTUS are consistent.</p> <p>Disagree: Commenter’s suggested language is substantively incorrect and will not be incorporated.</p>	<p>None.</p>

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	<p><u>guidelines replace the existing parts of the MTUS that refer to opioid use. Notwithstanding, this replacement, the weight of available evidence pursuant to Section 9792.25, other medically appropriate guidelines within the MTUS and applicable law shall also be considered when requesting or authorizing opioids. A copy of the Opioids Treatment Guidelines may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at http://www.dwc.ca.gov.</u></p> <p><u>(b) The Opioids Treatment Guidelines describe the appropriate use of opioid medications as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain. These guidelines apply when alternative therapies do not provide adequate pain relief and the use of opioid medications is being considered as part of the treatment regimen.</u></p>			