MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
Date of Hearing	Commenter notes that the hearing date of September 6, 2017, conflicts with a large industry conference, the CWC & Risk Conference in Dana Point, where she is exhibiting. Commenter recommends an alternative date for the hearing in order to facilitate greater attendance.	Sharon Douglas, CEO – Rehabwest August 7, 2017 Written Comment	Disagree: Although it is unfortunate commenter cannot attend, an alternative hearing date will not be set. Written comments, however, were accepted until September 6, 2017.	None.
General Comment	Commenter and his organization supports the proposed update to the MTUS that incorporates by reference the most recent chapters of the ACOEM Practice Guidelines and opines that this will insure that injured workers, clinicians and payors can avail themselves of the most efficacious treatments, as well as help ensure smoother implementation and operation of the ACOEM-based drug formulary.	Robert Blink, MD President Western Occupational & Environmental Medical Association (WOEMA) August 17, 2017 Written Comment	Agree.	None.
9792.23.1 9792.24.2	Commenter recommends that the Division consider all the factors in the current medical environment in California Workers' Compensation before eliminating a potentially life changing treatment to patients who have severe spine pain or chronic radiculopathy.	JienSup Kim, MD Medical Director PM&R Pain Management August 25, 2017 Written Comment	Disagree: Pursuant to Labor Code section 4604.5(b), "recommended guidelines set forth in the schedule…shall reflect practices that are evidence and scientifically based, nationally recognized and peer reviewed." For the DWC to consider "all the factors in the current medical	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			environment in California Workers' Compensation" when selecting the recommended guidelines in the MTUS is a broader standard than allowed by statute.	
	Commenter states that Spinal Cord Stimulation (SCS) is currently in a phase of rapid development and has made enormous progress since ACOEM was written and he opines that even with the current updates to the ACOEM, the guidelines are unable to make proper recommendations about a treatment that is changing as fast as technological devices. Commenter notes that changes in SCS have recently make leaps and bounds in its ability to provide pain relief, improving function, allowing patients to return to an active life and reducing a chronic pain patient's dependence on opioid medications.		Disagree: ACOEM considers all of the scientific evidence currently available. Although there may be a very slight lag time between the publication of a new study and the incorporation into ACOEM's recommendations, pursuant to the California Code of Regulations, Title 8, section 9792.21(d), new studies may be cited to support a treatment request.	None.
	Commenter states that long-term use of Opioids is risky and that there are daily news stories about the "Opioid Crisis" and notes that the Division's proposed treatment guidelines eliminate SCS,		Agree in part; Disagree in part: Agree: Long-term use of Opioids is risky. Disagree: Spinal Cord Stimulator implantation is recommended for short-to intermediate-term relief for highly select CRPS patients and for those patients, they should be informed of this	None.

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	which is an effective treatment for many chronic pain patients. Commenter has been using spinal cord stimulators in carefully selected patients for more than fifteen years. Commenter states that in the right patient with chronic low back pain, with chronic radiculopathy, with Failed Back Surgery Syndrome, spinal cord stimulation can change an impaired disabled individual who is using handfuls of medications that has trouble walking, dressing and even preparing simple meals to one who is independent, active, and reengages in life. Commenter opines that the consequence of eliminating SCS as a treatment option for injured workers within the California Workers' Compensation system will be more opioid usage and dependence, which will increase the incidence of addiction. More spine surgeries. More disabled individuals. More workers who will never have the chance to improve and return back to gainful employment.		treatment option. They should also understand that this intervention has no quality evidence of greater than 3-year benefit during which time there is unequivocal patient commitment. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate. Disagree: The Opioids Guideline is part of the MTUS, which should prevent the scenarios described by commentator.	None.

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	Commenter states that the ACOEM guidelines, proposed for adoption by the state of California, are proposed in order to help control runaway costs within the Worker Compensation system; however, he would like to point out that the guidelines are not crafted to address all possible scenarios. Treatment of complex cases of pain and nerve damage should be left up to expert medical provider who have direct contact with the patient. Commenter states that the decision to limit a specific treatment to a population of patients who have limited options is very disheartening. Commenter opines that treatment decisions should be made after direct interaction with a patient. It is after meeting and speaking with a patient, performing a directed exam, reviewing medical records, examining prior imaging studies, and understanding what treatments have been tried and failed that SCS is considered.		Agree in part; Disagree in part: Agree: The MTUS guidelines do not address all possible scenarios. Disagree: The current statutory scheme governing medical treatment in California's workers' compensation system mandates use of the MTUS, with review of Requests For Authorization of treatment from Utilization Reviewers and Independent Medical Reviewers. This statutory scheme replaced the "treating physician's presumption" beginning with the passage of SB899 in 2004.	None.
	Commenter states that current scientific and medical research literature has many studies that show that SCS when used appropriately reduces cost,		Disagree: Long-term use of Opioids is risky. Disagree: Spinal Cord Stimulator implantation is recommended	None.

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	improves outcomes, and improves function. Commenter would like to know why the Division of Workers' Compensation (DWC) proposal is removing a treatment option that has been shown reduce use of opioids, reduce the need for additional spinal fusion surgery, reduce the level of disability and improve function which is and should remain as our primary goal. Commenter requests that the DWC reconsider adopting these guidelines. Commenter opines that these guidelines were written by inexperienced individuals and will make permanent changes to a system that is becoming increasingly dysfunctional. Commenter states that the California Division of Workers' Compensation enacts regulations that makes it increasingly difficult to find specialists and even hospital systems who is still taking Work Comp patients. In the Inland Empire where the commenter lives and practices medicine, in southern California, the		for short-to intermediate-term relief for highly select CRPS patients and for those patients they should be informed of this treatment option. They should also understand that this intervention has no quality evidence of greater than 3-year benefit during which time there is unequivocal patient commitment. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate. Disagree: The ACOEM Guidelines are developed following a methodology that is defined and made public. There are Panels for each guideline topic with experts in	None.

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	number of specialty practices that have stopped taking Work Comp patients is alarming. This results in marked increase in difficulty with access to specialty care. The delays in getting scheduled with specialists is compounded by having to travel much further to get to clinics that still accept Work Comp patients. Traveling two hours to get to a physician and then waiting hours to be seen is becoming more the norm than the exemption. Commenter notes that the DWC already has Utilization Review in place. In addition, for addressing conflicting medical opinions between a treating physician and a UR physician, the State of California the Independent Medical Review (IMR) in place. Commenter questions why it is necessary to have further restrictions on care enacted by the DWC. Commenter opines that the proposed change to ACOEM is unnecessary and redundant and will only serve to prevent individuals from getting care that could really help them.		the covered fields. The Evidence-based Practice Chronic Pain Panel Chair is Dr.Steven D. Feinberg and he is a past president of the American Academy of Pain Medicine. Disagree: Although the DWC appreciates the concerns raised by commenter regarding access to specialty care, (i.e. travel time and wait times to be seen) those are issues beyond the scope of these proposed evidence-based updates to the MTUS. Disagree: The MTUS and the evidence-based updates to the MTUS follow the statutory mandate of Labor Code section 4604.5(b) which states, “recommended guidelines set forth in the schedule…shall reflect practices that are evidence and scientifically based, nationally recognized and peer reviewed.”	None. None.

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	Commenter states that SCS treatment is covered by Medicare and most all commercial health plans and by Workers' Compensation health plans in 49 other states. Commenter states that he continues to see California Workers' Compensation patients despite it becoming increasingly difficult to work within a system that continues to erect barriers to obtaining appropriate care because this population of patients are the foundation of our economy. These patients are the productive workers who have been injured on the job and want to get back to work or they are unable to work be improved enough to have a good quality of life. These are the individuals who have gone out and gotten a job and had been contributing to our society until they got hurt. Some continue to work and remain gainfully employed.		Disagree: ACOEM's methodology adheres to the criteria set forth by the National Academy of Medicine (formerly IOM); A Measurement Tool to Assess Systematic Reviews (AMSTAR); Grading of Recommendations Assessment, Development and Evaluation (GRADE); and Appraisal of Guidelines for Research and Evaluation (AGREE). ACOEM's review process is transparent and applied to recommendations in all of its guidelines. Rather than relying on Medicare and Workers' Compensation health plans in other states and their methodology to evaluate medical evidence, the DWC believes the transparent methodology applied by ACOEM maintains consistency in evaluating the available medical evidence throughout the MTUS.	None.
9792.23.1	Many commenters signed and mailed	Ann Shah, MD	Disagree: Spinal Cord	None.

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9792.24.2	the following form letter: "As someone who has personally benefited from neuromodulation therapy, I strongly support ensuring the injured workers of California have access to important, established non-opioid pain treatment options like spinal cord stimulation. Restricting access to chronic pain therapies for injured workers will place a greater burden on patients like me as it relates to chronic pain management and opioid dependency. Please consider this as you update the Medical Treatment Utilization Schedules (MTUS) regarding Chronic Pain and Low Back Disorders." Commenters often left additional comments supporting the continued use of spinal cord stimulation treatment, both patients who claim that it has helped them in their recovery and the doctors that treat them.	September 6, 2017 Ashwini Sharan, MD September 1, 2017 Betty Logle, Patient September 6, 2017 Bonnie Metsch, Patient (Late) September 12, 2017 David Kloth, MD (Late) September 11, 2017 Donna Thrasher, Patient September 5, 2107 D. W. Provenzano, MD September 1, 2017 Joseph Reyes, Patient August 30, 2017 Karen Raye Goe, Patient September 5, 2017	Stimulator implantation is recommended for short-to intermediate-term relief for highly select CRPS patients and for those patients they should be informed of this treatment option. They should also understand that this intervention has no quality evidence of greater than 3-year benefit during which time there is unequivocal patient commitment. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	

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		Maria Flete, Patient September 5, 2017 Mohammod Madhat, Patient September 5, 2017 Raymond Tatevossian, MD August 30, 2017 Scott Hill, Patient September 5, 2017 S.R. Lynch, Patient September 6, 2017 Thoha Pham, MD September 5, 2017		
9792.23.1 9792.24.2	Commenter notes that the most compelling evidence within their published peer-reviewed literature for long-term efficacious pain control is for two modalities: Exercise/physical therapy and spinal cord stimulation (SCS). Commenter has published a manuscript regarding an evidence-based approach to Failed Back Surgery	Kasra Amirdelfan, MD, Director of Medical Research IPM Medical Group September 5, 2017 Written Comment	Disagree: There are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly,	None.

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	Syndrome (axial low back and leg pain) in the journal of spine [Commenter enclosed the article "Treatment Options for FBSS"] Commenter notes that the evidence clearly shows very little efficacy, if at all, for medications and strong evidence, with Level I strength, for Spinal Cord Stimulation (SCS). Commenter laments that medications, despite their lack of evidence and astronomical expense, are never the focus of cuts and limitations during such reviews.		and have a significant revision rate. Disagree: Over 120 randomized trials have reported consistent evidence of modestly reduced short-term acute, subacute and chronic pain ratings associated with opioid use compared with placebo. However, opioids have been associated with numerous adverse effects. The ACOEM opioids guideline generally recommends a maximum daily oral dose of 50mg MED which is a lower threshold than the current Opioids MTUS guideline.	None.
	Commenter notes that there is also an increasing number of level I randomized controlled trials (RCT) within the published peer-reviewed literature demonstrating the compelling efficacy of SCS for the treatment of chronic pain. [Commenter enclosed the following three studies: "1. Comparison of 10-kHz High-Frequency and Traditional Low-		Disagree: ACOEM evaluated the study authored by Leonardo Kapural and does not give it a high rating because 50% of baseline outcomes measures (e.g. Oswestry Disability Index scores) not provided. No placebo group. Data suggests HF modestly superior, but	None.

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	Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain authored by Leonardo Kapural, 2. Dorsal root ganglion stimulation authored by Timothy Deer, and 3.Treatment Options for Failed Back Surgery Syndrome Patients with Refractory Chronic Pain, authored by commenter Kasra Amirdelfa”].		opioid use only 19% lower with HF and ODI improved 16.5U. In addition, there are potential conflicts of interest because the study was sponsored by grants from Boston Scientific and Nevro Corp. and personal fees received by the authors of the study. As far as studies 2 and 3, both were recently published in 2017 and it is not clear if ACOEM reviewed the studies cited by commenter but he is encouraged to submit these studies to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of evidence from any source. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and	

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			critical appraisal) for the development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused update to the ACOEM guidelines.	
	Commenter states that pain is being controlled far better than ever before with the new SCS devices and modalities on the market. Commenter notes that due to compelling evidence of superiority for one such treatments (Senza HF10 Therapy, Nevro Corporation, Redwood City, CA) The Centers for Medicare (CMS) recently granted an unprecedented in pain management, Pass Through Code for the Senza device. The Pass Through Code allows for increased reimbursement for the device to the facility from CMS for the implantation of the Senza device, as a testament to its efficacy and superiority. CMS has only granted this privilege 11 times in the past decade for devices in various applications in healthcare. None has even been for a pain-controlling device. Given the strength		Disagree: As noted above, ACOEM evaluated the first study authored by Leonardo Kapural and does not give it a high rating because 50% of baseline outcomes measures (e.g. Oswestry Disability Index scores) were not provided and there was no placebo group. Data suggests HF modestly superior, but opioid use only 19% lower with HF and ODI improved 16.5U. ACOEM's methodology adheres to the criteria set forth by the National Academy of Medicine (formerly IOM); A Measurement Tool to Assess Systematic Reviews (AMSTAR); Grading of Recommendations Assessment, Development and	None.

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	of the Kapural et. al study, HF10 therapy was awarded transitional pass-through status by the Centers for Medicare & Medicaid Services (CMS). CMS determined high-frequency SCS is reasonable and necessary for the treatment of Medicare beneficiaries and concluded that the published evidence demonstrates that the Senza System provides a substantial clinical improvement over low frequency, traditional SCS. CMS specifically noted that "a high frequency spinal cord stimulator operated at 10,000 Hz and paresthesia-free provides a substantial clinical improvement in pain management versus a low-frequency spinal cord stimulator." [Commenter enclosed "CMS Decision Regarding HF10"]		Evaluation (GRADE); and Appraisal of Guidelines for Research and Evaluation (AGREE). ACOEM's review process is transparent and applied to recommendations in all of its guidelines. Rather than relying on CMS methodology to evaluate medical evidence, the DWC believes the transparent methodology applied by ACOEM maintains consistency in evaluating the available medical evidence throughout the MTUS.	
	Commenter recognizes the need to curb expenses and costs, especially as they relate to pain management. This is not only true for the California DWC, but it is true also for pain management in the general population. Commenter states that far too much is spent on inefficacious and lackluster treatment options with no long-term pain control.		Disagree: The disagreement appears to be how the available medical evidence is being evaluated. SCS implantation is recommended for short-to intermediate-term relief for highly select CRPS patients and for those patients they should be informed of this	None.

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	However, in order to achieve the best outcome and simultaneously curb expenses, commenter recommends maintaining the modalities with strong medical evidence and reducing or eliminating the modalities with weak or no evidence within our published peer-reviewed literature. Commenter opines that it is time to reduce the utilization and authorization of medications and other modalities, which have little to no evidence and support SCS, exercise and physical therapy. Commenter opines that other modalities such as TENS units, H-Wave, etc. with little to no evidence should not be allowed. Commenter states that the curbing of medication authorization alone will save astronomical amount in costs and expenditures.		treatment option. However, there is no quality evidence of greater than 3-year benefit. Otherwise, SCS is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate. As far as the other modalities (i.e. medications, TENS units and H-wave), the rationale for the corresponding recommendations applied the same methodology to evaluate the available medical evidence used to evaluate the SCS recommendation.	
9792.24.2	Commenter notes that the Opioids Guideline (ACOEM April 20, 2017), p. 25, Urine Drug Testing states:	Robert Taber, MD, MPH September 5, 2017		

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	Baseline and random urine drug testing, qualitative and quantitative, is recommended for patients prescribed opioids for the treatment of subacute or chronic pain to evaluate presence or absence of the drug, its metabolites, and other substance(s) use. In certain situations, other screenings (e.g., hair particularly for information regarding remote use or blood (for acute toxicity) may be appropriate. Indications – All patients on opioids for subacute or chronic pain. Commenter disagrees with the recommendation for performing quantitative urine drug testing. A Urine Drug Screen (qualitative), usually by immunoassay, can be performed in a physician's office or in a laboratory. Substances are reported as present or absent at a predetermined cutoff threshold. These tests cannot identify a specific analyte (or drug) or distinguish between different drugs of the same class. There can be false positive and false negative results. Confirmatory drug testing, in a	Written Comment	Disagree: Urine drug testing should be done in federally certified labs. The certified labs use a 2-step process. The initial screening test is generally an enzyme-mediated immunoassay. Negative immunoassays conclude testing for a specific drug. However, the screening test method frequently cross-reacts with other drugs raising the possibility that positive tests are false positives due to cross-reacting substances. Therefore,	None.

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	laboratory, is performed using Gas chromatography/mass spectroscopy (GC/MS or GC/MS-MS) or LC/MS-MS. These methods identify the presence (or absence) of specific drugs. Quantitative drug testing, in a laboratory, also is performed using Gas chromatography/mass spectroscopy (GC/MS or GC/MS-MS) or LC/MS-MS. Such testing identifies the specific quantity of a drug that is present in the specimen. Commenter notes that in the Opioids Guideline (ACOEM April 20, 2017), other than mentioning qualitative and quantitative urine drug testing, the different types of drug testing are not described or discussed. The specific circumstances, in which each type of testing is recommended to be performed, are also not described. Commenter states that, in the Opioids Guideline (ACOEM April 20, 2017), no references were provided that support or recommend quantitative urine drug testing for patients prescribed opioids for the treatment of		if the screening test is positive, the certified labs do step 2, which is gas chromatography-mass spectroscopy (GS-MS). This test is more expensive, but detects the unique chemical "finger print" of every specific chemical. "Quick test" kits that use the screening immunoassay method permit in-office "point of collection" testing. Immunoassays are subject to false positive results as mentioned above and may not test for all classes of medications/drugs for which the prescribing physician should be testing. Accordingly, urine drug testing should be done in federally certified labs. This was described in the proposed Opioids Guideline pages 49-51. Disagree: The evidence for the Diagnostics and Monitoring section of the Opioids Guideline incorporated 14	None.

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	subacute or chronic pain, under any circumstances. The basis for this recommendation was not described.		studies into the analysis listed on page 51.	
	Commenter states that there are many commercial labs that perform urine drug testing services on patients in California. Some perform and bill for quantitative urine drug testing for numerous drugs/metabolites (as many as 50) in their test panel. The charges for such testing can greatly increase the cost of a single urine drug test to as much as $2,000 to $4,000.		Disagree: The choice of which test to order depends on what medications are being prescribed, and on what substances are potentially available for the patient to abuse. The prescribing physician must consult with the laboratory to determine which drugs are detectable by which tests, and then choose a test that would detect each prescribed controlled substance, and a test that would detect what other abusable drugs the person might be surreptitiously taking.	None.
	Commenter notes that per the ODG Guidelines, Quantitative urine drug testing is not recommended for verifying compliance without evidence of necessity. This is due in part to pharmacokinetic and pharmacodynamic issues including variability in volumes of distribution		Disagree: Commenter infers the ACOEM guideline recommends both Quantitative and Qualitative testing in all cases. That is incorrect. As stated above, certified labs use a 2-step process. The initial screening test is generally an	None.

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	(muscle density) and interindividual and intraindividual variability in drug metabolism. Any request for quantitative testing requires documentation that qualifies necessity. Limitations to UDT: <u>There is currently no way to tell from a urine drug test the exact amount of drug ingested or taken, when the last dose was taken, or the source of the drug</u>. [Emphasis added] Commenter states that there is no reliable relationship between urine drug concentration and amount of drug ingested. UDTs do not provide information regarding the length of time since last ingestion, overall duration of abuse, or state of intoxication. References: Gourlay D, Heit HA, and Caplan YH, Urine drug testing (UDT) Monograph: Urine Drug Testing in Clinical Practice, The Art and Science of Patient Care, Edition 4, 2010. Gourlay D, Heit HA, Caplan YH. Urine Drug Testing in Clinical Practice: Dispelling the Myths & Designing Strategies. Stamford, CT: PharmaCom		enzyme-mediated immunoassay. Negative immunoassays conclude testing for a specific drug. However, the screening test method frequently cross-reacts with other drugs raising the possibility that positive tests are false positives due to cross-reacting substances. Therefore, if the screening test is positive, the certified labs do step 2, which is gas chromatography-mass spectroscopy (GS-MS). Disagree: If there is an aberrant drug screen result (either positive for unexpected drugs or unexpected metabolites or unexpected negative results), the recommendation is for a careful evaluation of whether there is a plausible explanation. In the absence of a plausible explanation, those with an aberrant drug test showing an unexpected drug should have the opioid discontinued or weaned or	None.

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	Group, Inc. 3rd Edition. 2006. Moeller, Lee and Kissack, Urine Drug Screening: Practical Guide for Clinicians. Mayo Clin Proc. 2008. Heit H, Gourlay D. Urine Drug Testing in Pain Medicine. J Pain Symptom Manage 2004. Lum G, Mushlin B. Urine Drug Testing: Approaches to Screening and Confirmation Testing. Laboratory Medicine. 2004; 6(35): 368-373. Swotinsky R, Smith D. The Medical Review Officer's Manual, MROCC's Guide to Drug Testing, 3rd Edition, Massachusetts; OEM Press. 2006. Commenter states in light of the limitations of quantitative urine drug testing, the results of such testing (for patients prescribed opioids for the treatment of subacute or chronic pain) provide no additional useful information to the treating physician beyond what is provided by confirmatory urine drug testing. For many drug classes (e.g. benzodiazepines, barbiturates, antidepressants, etc.), when the results of a Urine Drug Screen (qualitative) are		those with a drug test that shows absence of the prescribed opioid (or metabolites) should have the opioid discontinued. The recommendation does not require the specific concentration and amount of drug ingested, information regarding the length of time since last ingested, overall duration of abuse or state of intoxication. Disagree: Commenter states quantitative urine drug testing provides no additional useful information to the treating physician beyond what is provided by confirmatory urine drug testing. This infers commenter is equating the qualitative immunoassay method as a confirmatory test. That is incorrect. The qualitative immunoassay test is what "Quick test" kits that permit in-office "point of	

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	negative, additional testing is not recommended or necessary. Unless/until there is good scientific evidence that has established the usefulness of quantitative urine drug testing (for patients prescribed opioids for the treatment of subacute or chronic pain), commenter opines that it is not appropriate for such testing to be recommended by the ACOEM Guidelines or the Medical Treatment Utilization Schedule (MTUS).		collection" uses and is generally used as the 1st step in federally certified labs. However, this is an initial screening test. It is NOT considered a confirmatory test. As already stated, the qualitative immunoassay test are subject to false positives. The 2nd step done in federally certified labs is gas chromatography-mass spectroscopy (CG-MS). This is considered the confirmatory test.	
9792.22	Commenter approves of amending the MTUS' medical treatment guidelines in section 9792.22, replacing the Initial Approaches to Treatment Guideline (ACOEM Practice Guidelines, 2nd Edition 2004) with ACOEM guideline entitled Initial Approaches to Treatment Guideline (ACOEM June 30, 2017). Commenter appreciates DWC's efforts to represent current evidence-based standards of care within the foundations of occupational medicine practice. Commenter is pleased that within the	Moses Jacob, DC WC Committee Chair Dawn Benton, MBA Executive Director Jillian Hacker, MBA Director of Government Affairs and Operations California Chiropractic Association September 5, 2017 Written Comment	Agree. Agree.	None. None.

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	objective function-based physical methods to track during treatment include treatment modalities utilized by chiropractors (along with physical therapists, occupational therapists, and other healthcare practitioners). Commenter encourages the adoption of guidelines that necessitate non-drug therapies as the first treatment option (where medically acceptable). Studies support the early utilization of drug-free care, including chiropractic care, for pain relief (PAINS Project Policy Brief). Commenter opines that first line treatment should incorporate non-drug therapies, and then, if patients need additional support, the second line of treatment should be over-the-counter anti-inflammatories or prescribed muscle relaxants.		Disagree: The phrase "and then, if patient needs additional support, the second line of treatment should be over-the-counter anti-inflammatories or prescribed muscle relaxants" is too strong. First line therapies are tailored to the individual patient and based upon the medical evidence, while it often consists of non-drug therapies, over-the-counter anti-inflammatories or prescribed muscle relaxants are often considered in first line therapies.	None.
9792.24.2	Commenter states the MTUS guidelines that were recently sent to me had a little typo. They spelled the word "chiropractoid."	Moses Jacob, DC WC Committee Chair California Chiropractic Association September 6, 2017	Disagree: The DWC was unable to find the word "chiropractoid" in the ACOEM guidelines. The DWC contacted commenter by telephone for clarification on	None.

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		Oral Comment	9/27/2017 but he was unable to locate the alleged typographical error.	
	Commenter states that the State of Rhode Island recently approved a bill [copy provided], that was signed into law by their Governor which states: "Patients with substance use disorder shall have access to evidence-based non-opioid treatment for pain. Therefore, coverage shall apply to medically necessary chiropractic care and osteopathic manipulative treatment performed by individuals licensed under their act." Commenter states that the problem is that the Governor of the State of California has signed it into law and that individuals cannot change the law. Commenter suggests that the Division consider the language in this particular bill from the State of Rhode Island as part of the solution to the MTUS.		Disagree: Similar language is already incorporated in the Opioids Guideline in the Discontinuation and Tapering of Opioids section beginning in page 32. The process includes the following language, "The provider should be supportive and engaged in the patient's care, management and concerns…Consider engaging the patient in other active therapies during taper . . . . Consider judicious use of passive therapies (e.g. acupuncture, TENS, manipulation) as adjuncts in assisting tapering." Page 33.	None.
	Commenter opines that ACOEM, which is consensus based, is not really the best science around.		Disagree: ACOEM evaluates existing medical literature (studies) in coming up with their recommendations. They	None.

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			do not conduct studies.	
9792.24.3	Commenter recommends that the division not delete the current MTUS postsurgical treatment guidelines. Commenter opines that the existing postsurgical treatment guidelines are comprehensive, well organized, and establish frequency and duration for most common surgical procedures. Commenter notes that the proposed update will delete the Postsurgical Treatment Guidelines (§9792.24.3). It is stated that these post-operative physical therapy (PT) guidelines will now be found in the clinical topics guidelines, chronic pain guidelines, or opioid guidelines. However, the updated guidelines as proposed fail to address frequency and duration for post-operative PT and many guidelines are inconsistent. California has two separate methods of determining the appropriate amount of PT/OT/Chiropractic care. These are: 1) Capped PT/OT/Chiro is limited to 24 visits per industrial injury (LC4604.5(c)(1)), and 2) Post-surgical PT and rehab (LC4604.5(c)(3)).	Debra Russell Senior Director Workers' Compensation Program Schools Insurance Authority September 5, 2017 Written Comment	Disagree: The current MTUS Postsurgical Treatment Guidelines were incorporated into the MTUS in 2009. The DWC is making evidence-based updates to this guideline in order to keep up with the evolving nature of scientific evidence. Disagree: Frequency and duration of post-operative PT (Physical Methods) are addressed as supported by the evaluated evidence. Frequency and duration may be specifically called out, or there may be other endpoints/goals that guide continued treatment. Severity of the situation and patient-specific factors may be a consideration as well. In addition, the guidelines are not inconsistent, although current evidence supports additional ways to categorize and analyze various physical methods. This additional information	None. None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter states that the proposed ACOEM guidelines are NOT tailored to CA.		may necessitate a more detailed and complicated evaluation of a patient's situation and the consideration of multiple physical method endpoints in arriving at the appropriate physical therapy order.	
	Commenter notes the following shortcomings of the proposed guidelines: - Proposed guidelines do not adequately distinguish between pre-operative and post- operative physical therapy.		Disagree: The proposed guidelines distinguish between pre-operative and post-operative PT as supported by the evaluated evidence. Frequency and duration may be specifically called out or there may be other endpoints/goals that guide continued treatment. Severity of the situation and patient-specific factors may be a consideration as well.	None.
	- Proposed guidelines do not contain a list of surgical procedures and a		Agree in part; Disagree in part: Agree: The proposed guidelines do not contain a list	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	corresponding appropriate post-operative physical therapy frequency and duration for most common surgical procedures. (Current Postsurgical Treatment Guidelines contain a comprehensive list of surgical procedures and corresponding appropriate frequency and duration of post op PT for each surgical procedure. (See 2017 LC edition, pages 859-867)).		of surgical procedures and a corresponding list of post-operative physical therapy procedure. The proposed guidelines are organized differently. However, the frequency and duration of post-operative PT (Physical Methods) are addressed as supported by the evaluated evidence. Frequency and duration may be specifically called out, or there may be other endpoints/goals that guide continued treatment. Severity of the situation and patient-specific factors may be a consideration as well.	
	- Proposed guidelines are inconsistent with regard to physical therapy recommendations, frequency and duration are not always specified, or frequency and duration are differ and are inconsistent.		Disagree: See above. In addition, the guidelines are not inconsistent, although current evidence supports additional ways to categorize and analyze various physical methods. This additional information may necessitate a more detailed and complicated evaluation of a patient's situation and the consideration	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			of multiple physical method endpoints in arriving at the appropriate physical therapy order.	
	- Proposed guidelines are woefully inadequate and are a significant downgrade from current MTUS postsurgical treatment guidelines.		Disagree.	None.
	Commenter provides the following examples of the inconsistencies in two of the proposed guidelines: ***Low Back Disorders Guideline:*** *Page 131 - Exercises recommended for acute, subacute, chronic,* ***post-operative*** *or radicular LBP: If a supervised program is felt to be needed, recommended frequency is 1-3 sessions a week, for up to 4 weeks, as long as objection functional improvement is occurring.* *(***comment: there is no distinction in pre and post op PT and no distinction in the type of surgery, i.e. discectomy should require less postop PT/rehab than fusion due to the complexity of the procedure.)*		Disagree: There is a distinction as evidenced by the use of the word "post-operative." However, as indicated above current evidence supports additional ways to categorize and analyze various physical methods. This additional information may necessitate a more detailed and complicated evaluation of a patient's situation and the consideration of multiple physical method endpoints in arriving at the appropriate physical therapy order. Commenter illustrates this point when she states, "discectomy should require less postop PT/rehab than	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			fusion due to the complexity of the procedure."	
	*Page 133 - General Exercise Approach**: Post-operative** exercising: treatment frequency of 1-3 sessions a week, progressing to 2-4 sessions a week is recommended, reassessment after 10 sessions with continuation based on demonstrated functional improvement. Upper range is 20 sessions. (***comment: inconsistent - page 131 recommends up to 12 PT, page 133 recommends up to 20 PT for postop PT).*		Disagree: Again, there is no inconsistency here but rather room for a clinical judgment call. Additional information may necessitate a more detailed and complicated evaluation of a patient's situation and the consideration of multiple physical method endpoints in arriving at the appropriate physical therapy order.	None.
	*Page 144 Strengthening and Stabilization Exercises – including post-operative treatment of LBP. (***comment: No frequency or duration of post op PT is included.)*		Disagree: See above.	None.
	Knee Disorders Guideline: *Page 343 – post op rehabilitation for knee arthroplasty: daily while in hospital, then 2-3x wk. (***comment: No duration is stated).*		Disagree: See above.	None.
	****comment: examples provided above are not comprehensive, these examples*			

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	are randomly selected to demonstrate inadequacy and inconsistency in the proposed guidelines. For the reasons outlined in the above discussion, commenter requests that the current MTUS postsurgical treatment guidelines as set forth in §9792.24.3 be retained in the updated MTUS Treatment Guidelines.		Disagree: See above.	None.
General Comment	Commenter supports the decision to incorporate the most recent version of the ACOEM Practice Guidelines into the MTUS. Commenter opines that the ACOEM Guidelines are comprehensive, well written, and superior to those portions of the MTUS that currently incorporate ODG. Commenter notes that the updated ACOEM Guidelines offer a number of valuable features, including Summary Recommendations (often absent in ODG). The Summary Tables are invaluable and provide a hierarchy of evidence as to what treatments are recommended, what treatments can be approved in certain circumstances, and	Siva Ayyar, MD September 5, 2017 Written Comment	Agree. Agree: The proposed ACOEM guidelines are more current than the portions of the MTUS that incorporate older ODG and ACOEM guidelines. Agree.	None. None. None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	what treatments should not be approved. Commenter appreciates that the updated ACOEM Guidelines have been posted on the DWC website in pdf form, which represents a big advantage over accessing web-based guidelines.		Agree: For rulemaking purposes, the DWC has posted the ACOEM guidelines on its website. However, commercial use of the ACOEM guidelines requires a license. The Reed Group publishes the ACOEM guidelines, which are copyrighted.	None.
General	Commenter opines that the adoption of ACOEM, which uses excessively narrow definition of meaningful medical evidence as a basis for its recommendations, limits the ability of treating physicians to provide meaningful pain treatment to injured workers with chronic pain. This is especially true of patients treated for, among other conditions, chronic pain.	William Wilson, MD September 6, 2017 Written Comment	Disagree: ACOEM's methodology adheres well-respected criteria set forth by the National Academy of Medicine (formerly IOM); A Measurement Tool to Assess Systematic Reviews (AMSTAR); Grading of Recommendations Assessment, Development and Evaluation (GRADE); and Appraisal of Guidelines for Research and Evaluation (AGREE).	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter notes that in restricting their reviewed medical evidence, ACOEM eliminates valid and useful well-conducted studies showing the valid place of spinal cord stimulation for neuropathic pain beyond complex regional pain syndrome. It sets a standard, which excludes treatments covered by commercial carriers, Medicare and most other state workers' compensations programs. Commenter states that denying treatment of neuropathic pain for treatment of conditions where proof of benefit has been demonstrated, DWC, using the ACOEM artificially narrowed definition of medical evidence will result in a lower standard of care for injured workers than those treated outside the California workers compensation system. Commenter opposes the limitations on the treatment of patients with chronic neuropathic pain that will result by relying on the ACOEM criteria.		Disagree: Spinal Cord Stimulators is not recommended for other injuries or conditions other than patients with complex regional pain syndrome because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate. Disagree: The standard of care for injured workers is not being lowered. Again, ACOEM's methodology adheres to the criteria set forth by the National Academy of Medicine (formerly IOM); A Measurement Tool to Assess Systematic Reviews (AMSTAR); Grading of Recommendations Assessment, Development and Evaluation (GRADE); and	None. None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Appraisal of Guidelines for Research and Evaluation (AGREE). There are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	
General	Commenter states that the Reed Group's development process follows its methodology that is defined and made public online at MDGuidelines.com. The process adheres to the criteria set forth by the National Academy of Medicine (formerly IOM); A Measurement Tool to Assess Systematic Reviews (AMSTAR); Grading of Recommendations Assessment, Development and Evaluation (GRADE); and Appraisal of Guidelines for Research and Evaluation (AGREE). Commenter states that his organization has documented the methods by which	Carlos Luna Director of Government Affairs Reed Group, Ltd. September 6, 2017 Written and Oral Comments	Agree: The commenter provides a high-level summary of ACOEM's guideline development process but he does not address the proposed evidence-based updates to the MTUS, which is the subject of this comment period. This response applies to all of commenter's comments except for the last one listed.	None.

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	ACOEM adheres to each set of criteria and each is available online at MDGuidelines.com. Commenter states that ACOEM accepts submissions of evidence from any source. Occasionally, unsolicited literature is received from device manufacturers, product manufacturers and clinicians interested in a given procedure, device or product. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the development of evidence-based guidance. When ACOEM receives unsolicited submissions from the industry, a new literature search is done on the topic to assure up-to-date capture of the relevant literature, the submitted literature is included, then analysis of the entire body of quality studies is done to ascertain whether the new evidence overturns existing evidence .		Agree: See above.	None.
	If there is a material change, it will be advanced through the process including external peer review and the guidelines are updated accordingly. If there is no		Agree: See above.	None.

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	material change the evidence is updated, but there is no need to notify consumers of the updated evidence. ACOEM communicates the results of the analyses to the party that submitted the evidence and/or suggestions, regardless of the source(s).			
	Commenter is unable to recall an instance when a device or drug manufacturer has submitted evidence that overturned guidance.		Agree: Commenter is stating his recollection.	None.
	Commenter provides the following high-level description of the review/evaluation process in developing the evidence-based practice guidelines from ACOEM (A full description of the process is available online at MDGuidelines.com):		Agree: See above.	None.
	The process for the development of ACOEM treatment guidelines and evidence-based products was developed by ACOEM's Guideline Methodology Committee (GMC) and includes participation of ACOEM's Evidence-based Practice Committee (EBPC), review and formulation of recommendations by the Panels,		Agree: See above.	None.

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	stakeholder input, external peer review, and review by the ACOEM Board of Directors. Members of the Guideline development groups are selected from applications of ACOEM members and nominees from relevant interest groups and professional organizations. All panel members are required to complete an application and an online questionnaire to:			
	i. outline qualifications and interests; ii. disclose potential conflicts of interest; and iii. indicate their willingness to adhere to confidentiality procedures.		Agree: See above.	None.
	Summaries of disclosures for all panel members are made available online. All members of the Guideline development groups are required to complete training in ACOEM's evidence-based medicine methodology.		Agree: See above.	None.
	The Board of Directors appoint one physician to chair the entire updating process and act as Editor-in-Chief of the Guidelines. This physician also serves as chair of the Evidence-based Practice Committee.		Agree: See above.	None.

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	To identify and guide the work of the Panel for each topic or disorder or body system, the Editor-in-Chief and the Research Team, in collaboration with the Evidence-based Practice Committee, and the chair of each of the Panels, works with the panels to identify clinical questions about important, useful, common, expensive, controversial or questionable work-related diagnoses, tests and procedures.		Agree: See above.	None.
	A sample list of Clinical Questions in the Key Domains of Occupational Medicine Practice are available online at MDGuidelines.		Agree: See above.	None.
	The Panels review and modify draft recommendations formulated by the Research Team. The Panels (and/or sub-Panels) review the evidence tables, evidence summaries, draft recommendations, and the original studies if needed. After review, the Panels conduct discussions, agree on the strength of evidence ratings for each topic, and finalize recommendations for all clinical questions. The Level of Evidence table created illustrates the minimum		Agree: See above.	None.

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	thresholds ACOEM uses for its evidence-based recommendations (Level of Evidence tables are available online at MDGuidelines.com). If sub-Panels are employed, the recommendations of the sub-Panel are forwarded to the entire Panel in aggregate for additional discussion. Each recommendation is reviewed, edited (if necessary), and clearly labeled as "Strongly Recommended," "Moderately Recommended," "Recommended," Consensus-Recommended," "Consensus-No Recommendation," "Consensus-Not Recommended," "Not Recommended," "Moderately Not Recommended," and "Strongly Not Recommended" (Evidence-based Recommendation Categories table is viewable online at MDGuidelines.com). The ACOEM evidence-based methodology results in clinical practice and management recommendations with the following attributes. • Validity o The recommendation should		Agree: See above.	None.

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	produce similar clinical outcomes in similar cases. • Reliability/reproducibility o A different panel of experts experienced with evidence-based methodology would come to the same recommendation given the same evidence base and decision making matrix. • Clinical applicability o The recommendation is applicable to a broad population. The recommendation states to which population it applies. • Clinical flexibility o The recommendation identifies known or generally expected exceptions to its use (e.g., comorbidities affecting biological response, genetic differences, psychosocial factors affecting functional recovery, etc.). • Clarity o The recommendation is clearly			

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	framed and understandable to clinicians and care managers using it. • Multidisciplinary process o The recommendation is developed with input from relevant disciplines using common methods of evidence analysis and structured consensus development about the strength of the evidence and the likely benefits, harms, and costs of the recommendation. • Scheduled review o The literature for recommendations is reviewed on an ongoing basis to assure currency. • Documentation o All steps, evidence analysis, critical discussions and decisions in the evidence-based practice process will be documented and archived. • Transparency o Records of deliberation that			

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	affect the evidence-based practice process and any revisions to analysis, recommendations, and conclusions will be available. • Board Review o ACOEM's Board of Directors will have the opportunity to review the recommendations and provide comments for the Panel to consider. ACOEM conducts external peer review of the *Guidelines* to: 1) Assure that all relevant high quality scientific literature related to the topics has been found; 2) Assure that the important evidence from the scientific literature relevant to the *Guidelines* has been accurately interpreted; 3) Solicit opinions on whether the findings and recommendation statements are appropriate and consistent with the evidence; and 4) Obtain general information on the *Guidelines'* conclusions and		Agree: See above.	None.

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	presentation from external topic experts.			
	These experts may also review the methodology used as well as summaries of the critically appraised evidence and the recommendations in each area. The *Guidelines* list the names of all peer reviewers, along with their affiliations. The Panels review the comments received from the external peer reviewers and make any final modifications to the *Guidelines*. In addition, a pre-publication version of all guidelines is posted at the *MDGuidelines* site for a period of two weeks for public comment.		Agree: See above.	None.
	To understand the needs and preferences of those individuals and organizations who use or are affected by the use of clinical practice guidelines in workplace settings and in the workers' compensation system, ACOEM solicits input from the following stakeholders: clinicians, health-care systems, labor representatives, workers/patients, employers, utilization reviewers, case managers, insurers and third party		Agree: See above.	None.

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	administrators, attorneys, regulators and policy makers. ACOEM solicits input from these stakeholders by inviting them to submit comments to us through their web site: https://acoem.formstack.com/forms/stakeholderpatientinput.			
	ACOEM also seeks input from stakeholders into the scoping of the guidelines by inviting them to submit comments to us through their website (https://acoem.formstack.com/forms/scopingclinicalquestions) on the list of clinical questions we research for each guideline.		Agree: See above.	None.
	During the entire evidence-based development process, a designated methodologist from ACOEM's Guideline Methodology Committee works with the Panels, editors and Research Team to ensure that this evidence-based methodology is being followed, both in the literature evaluation process and in the development of conclusion, rationale, and recommendation statements. The ACOEM Board of Directors may comment on the guidelines during the		Agree: See above.	None.

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	external review period. Their comments are reviewed by the Panel and any acceptable changes are made to the guideline reviewed.			
	The Panels and the Research Team have complete editorial independence from ACOEM and Reed Group, neither of which influences the Guidelines.		Agree: See above.	None.
	Chronic Pain Guideline Editor-in-Chief: Kurt T. Hegmann, MD, MPH, FACOEM, FACP		Agree: See above.	None.
	Evidence-based Practice Chronic Pain Panel Chair: Steven D. Feinberg, MD, MS, MPH		Agree: See above.	None.
	Dr. Steven Feinberg is Board Certified by the American Board of Physical Medicine and Rehabilitation, the American Board of Pain Medicine and the American Board of Electrodiagnostic Medicine. He is a California Qualified Medical Evaluator (QME). Dr. Feinberg is a past president (1996) of the American Academy of Pain Medicine. He served as a longtime member of the Board of Directors of		Agree: See above.	None.

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	the California Society of Industrial Medicine and Surgery (CSIMS) and served as Year 2001 President. In 2006, he received the Silver Scalpel Award from CSIMS. He serves on the Board of Directors of the American Chronic Pain Association (www.theacpa.org).			
	Evidence-based Practice Chronic Pain Panel Members: Gerald M. Aronoff, MD, DABPM, DABPN, FAADEP James Ausfahl, MD Daniel Bruns, PsyD, FAPA Beth D. Darnall, PhD Rachel Feinberg, PT, DPT Jill S. Galper, PT, MEd Lee Glass, MD Robert L. Goldberg, MD, FACOEM Scott Haldeman, DC, MD, PhD James E. Lessenger, MD, FACOEM Steven Mandel, MD Tom G. Mayer, MD Russell L. Travis, MD, FACS, FAADEP Pamela A. Warren, PhD Thomas H. Winters, MD, FACOEM		Agree: See above.	None.
	Panel members represent expertise in occupational medicine, physical		Agree: See above.	None.

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	medicine and rehabilitation, electrodiagnostic medicine, pain medicine, clinical psychology, psychiatry, neurology, electroencephalography, neurophysiology, neurosurgery, orthopedic surgery, physical therapy, exercise physiology, family medicine, legal medicine, medical toxicology, infectious disease, and chiropractic medicine. As required for quality guidelines (Institute of Medicine's (IOM) Standards for Developing Trustworthy Clinical Practice Guidelines and Appraisal of Guidelines for Research and Evaluation (AGREE)), a detailed application process captured conflicts of interest. The above panel has none to declare relevant to this guideline. Specialty Society and Society Representative Listing: American College of Physicians George Comerci, Jr., MD, FACP American Association of Neurological Surgeons and Congress of Neurological Surgeons – Joint Section on Pain		Agree: See above.	None.

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	Julie G. Pilitsis, MD, PhD Christopher J. Winfree, MD, FACS American Society of Anesthesiologists Michael E. Harned, MD Association for Applied Psychophysiology and Biofeedback Gabriel E. Sella, MD, PhD, MPH, MSc, FAADP, FAAFP, FACPM Other Reviewers: Douglas W. Martin, MD, FACOEM, FAAFP, FIAIME Commenter stresses that the ACOEM Guidelines are just guidelines. He states that his organization never advocates or endorses that a doctor be removed from the availability to treat their patient and he advocates that the patient with their physician remain in control of their clinical decisions.		Agree: ACOEM Guidelines are just guidelines that have been incorporated into the MTUS pursuant to Labor Code § 5307.27 and that the patient with their physician remains in control of their clinical decisions guided by Labor Codes § 4600(b) and 4604.5.	None.
9792.23.1 9792.24.2	Commenter opines that the proposed guidelines will significantly limit access to care for injured workers for the following reasons:	Mary E. Ryan Senior Program Manager State Government Affairs	Disagree: The Proposed guidelines will not significantly limit access to "reasonable and necessary" care. See below responses.	None.

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	• The ACOEM Guidelines ignore clinical and economic publications, which provide significant evidentiary support for the use of spinal cord stimulators (SCS) and intrathecal drug delivery systems (IDDS).	Medtronic Neuromodulation August 30, 2017 Received September 6, 2017 Written and Oral Comment	Disagree: The ACOEM Guidelines do not ignore clinical and economic publications supporting SCS and IDDS, however, ACOEM has concluded there are no quality studies for either SCS or IDDS warranting a recommendation, with the exception of SCS for patients with CRPS.	None.
	• The interventional pain medical community was not given the opportunity to thoroughly review and provide feedback on the ACOEM Guidelines.		Disagree: The ACOEM Guidelines are developed following a methodology that is defined and made public. There are Panels for each guideline topic with experts in the covered fields. The Evidence-based Practice Chronic Pain Panel Chair is Dr. Steven D. Feinberg and he is a past president of the American Academy of Pain Medicine.	None.
	• The result of this lack of review is that, for both the chronic pain and low back chapters, DWC is		Disagree: The ACOEM Guidelines do not ignore clinical and economic	None.

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	proposing to eliminate important treatment options for injured workers, options that are available to workers' compensation, Medicare and commercially insured enrollees throughout the United States.		publications supporting SCS and IDDS, however, ACOEM has concluded there are no quality studies for either SCS or IDDS warranting a recommendation, with the exception of SCS for patients with CRPS.	
	Commenter states that for the patient population with inadequate pain relief or intolerable side effects from medication, both SCS and IDDS provide important treatment options. Alternatives for chronic pain management are particularly important in the fight against prescription opioid abuse.		Agree in part; Disagree in part: Agree: Alternatives to opioids for chronic pain management are important. Disagree: ACOEM has concluded there are no quality studies for either SCS or IDDS warranting a recommendation, with the exception of SCS for patients with CRPS.	None.
	Commenter notes that under current MTUS guidelines, SCS and IDDS are recommended treatments for patients with chronic pain who meet the guideline criteria. This is not the case under the proposed MTUS (ACOEM) guidelines. In its low back chapter, ACOEM does not recommend SCS for the treatment of chronic low back pain, radicular pain syndromes or failed back		Disagree: Spinal Cord Stimulator implantation is recommended for short-to intermediate-term relief for highly select CRPS patients and for those patients they should be informed of this treatment option. They should also understand that this intervention has no quality	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	surgery syndrome. In the Chronic Pain Chapter, IDDS is not recommended for chronic persistent pain or chronic nonmalignant pain conditions. SCS is recommended only for a sub-set of patients suffering from complex regional pain syndrome. Commenter opines that if the ACOEM guidelines are adopted as proposed by the DWC, SCS and IDDS are two examples of treatment options that will likely become unattainable for most chronic pain patients. Commenter is unclear whether DWC has adequately evaluated the proposed MTUS guidelines to understand and communicate these types of changes to injured workers and their treating physicians.		evidence of greater than 3-year benefit during which time there is unequivocal patient commitment. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate. The public comments received indicates the public understands of these changes. Moreover, the DWC is creating an educational webinar on the evidence-based updates to the MTUS that will be rolled out shortly after the AD Order is in effect.	
	Commenter states that IDDS and SCS are well-established treatment options with demonstrated efficacy and effectiveness in selected patients. Both		ACOEM's methodology adheres to the criteria set forth by the National Academy of Medicine (formerly IOM); A	None.

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	therapies are available to almost all commercially insured enrollees in the U.S., are covered by Medicare National Coverage Determinations, and are covered services by nearly all Workers' Compensation agencies throughout the United States. In contrast, the ACOEM Guidelines dismiss most of the clinical and economic publications which provide support for the use of SCS and IDDS. Commenter states that if adopted, the ACOEM guidelines will result in injured workers' being denied treatment that is currently recommended under MTUS. Commenter understands that the MTUS presumption may be rebutted by the preponderance of medical evidence; however, this adds significant administrative burdens to the treating physician and allows for a different standard of care for patients with the same medical conditions.		Measurement Tool to Assess Systematic Reviews (AMSTAR); Grading of Recommendations Assessment, Development and Evaluation (GRADE); and Appraisal of Guidelines for Research and Evaluation (AGREE). ACOEM's review process is transparent and applied to recommendations in all of its guidelines. Rather than relying on Medicare National Coverage Determinations and Workers' Compensation agencies and their methodology to evaluate medical evidence, the DWC believes the transparent methodology applied by ACOEM maintains consistency in evaluating the available medical evidence throughout the MTUS.	
	According to its website, ACOEM relies exclusively on Randomized Controlled Trials (RCTs) and excludes all other levels of evidence from its evidence review.		Disagree: Studies that do not meet the highest scientific standards are not excluded from ACOEMs evidence review, they are reviewed.	None.

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	(https://www.acoem.org/guidelines_methodology.aspx). Additionally, ACOEM uses panels of experts to review the articles and evidence tables and agree on the strength-of-the-evidence ratings. Commenter notes for both the Chronic Pain Chapter and the Low Back Chapter, ACOEM's list of contributors does not include a pain society or known interventional pain physician. Although there is a disclaimer that organizations listed do not necessarily support or endorse the guideline, and that some organizations wish to remain anonymous, it is disconcerting that the very physicians who are trained in interventional pain procedures do not appear to have been consulted. Commenter opines that this omission calls into question whether the recommendations reflect the consensus of the expert medical community.		However, ACOEM only selects the scientific studies that meets the highest available rating (e.g., randomized controlled trials) for critical appraisal. The ACOEM Guidelines are developed following a methodology that is defined and made public. There are Panels for each guideline topic with experts in the covered fields. The Evidence-based Practice Chronic Pain Panel Chair is Dr. Steven D. Feinberg and he is a past president of the American Academy of Pain Medicine.	None.
	Commenter states that not all research questions can be answered through RCTs, because of both practical and/or ethical issues. Even when evidence is available from high-quality RCTs, evidence from other study types may		Disagree: Studies that do not meet the highest scientific standards are not excluded from ACOEMs evidence review, they are reviewed. However, ACOEM only	None.

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	still be relevant. For example, long-term durability of effect and long-term adverse event data are best observed in a longitudinal, real-world environment outside the confines of a tightly controlled clinical trial designed to test efficacy. Other payers do not rely exclusively on RCTs and consider other types of clinical data when determining coverage policies. Commenter opines that ACOEM's recommendations need to be considered in this context.		selects the scientific studies that meet the highest available rating (e.g., randomized controlled trials) for critical appraisal to support its guideline recommendations. The MTUS Methodology for Evaluating Medical Evidence, California Code of Regulations section 9792.25.1 provides a method in which to evaluate medical evidence that includes lower level evidence. However, it will be difficult to overcome a recommendation supported by the highest available rating.	
	Commenter notes that the DWC notice contains a link to the new web address (http://go.reedgroup.com/mtus) where interested parties will have to obtain the updated ACOEM guidelines. This establishes that anyone (physicians, insurers or utilization review companies) who needs access to the guidelines will have to pay an annual fee. Commenter states that this is the first time the DWC will mandate a user fee for Californians who need access to this information.		Disagree: For rulemaking purposes, the ACOEM guidelines are posted in the DWC's website. However, commercial use of the copyrighted ACOEM guidelines requires a license. A similar arrangement has been in place since 2007. This is not new.	None.

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	Commenter notes that just last week, The National Center for Health Statistics, a division of the Centers for Disease Control and Prevention, (CDC) released new estimates that drug overdoses killed 64,070 people in the US last year, a 21 % increase over the 52,898 drug overdose deaths recorded in 2015.		Agree.	None.
	Commenter states that the epidemic of drug overdoses is killing people at almost double the rate of both firearm and motor vehicle-related death. Bipartisan legislation passed by Congress last summer, the Comprehensive Addiction and Recovery Act (CARA) created a task force to develop best practices for acute and chronic pain management, to include the use of FDA approved medical devices for the treatment of pain. At his confirmation hearing, FDA Commissioner Gottlieb said that his first priority would be finding ways to fight the nation's opioid crisis. He called for re-evaluating the current framework for how the FDA develops alternatives to opioid drugs, and is also		Agree.	None.

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	looking at medical devices and medically assisted therapy to help people struggling with addiction.			
	Commenter states that the point of providing these two federal government examples is to show that policy makers are looking for a comprehensive response to this national crisis, to include FDA approved medical devices for the treatment of chronic pain. If adopted, commenter opines that these guidelines will needlessly deny injured workers access to alternatives to treat their chronic pain, treatments that would be available if they were covered by commercial or Medicare policies.		Agree in part; Disagree in part. Agree: Policy makers are looking for a comprehensive response to the drug addiction crises. Disagree: There are few quality studies evaluating SCS and IDDS. There are no SCS studies, which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS and IDDS are invasive with reported serious complications, costly, and have a significant revision rate.	None.
	Commenter is aware of § 9792.25 of Title 8, California Code of Regulations that allows for a variance from MTUS, a method to overcome MTUS presumption of correctness. Commenter is concerned that relying on this process will result in inconsistent treatment for injured Workers with the same underlying		Disagree: There are only two limited situations that may warrant treatment based on recommendations found outside of the MTUS guidelines, first if a medical condition or injury is not addressed by the MTUS or second, if the MTUS'	None.

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	chronic pain conditions. Commenter requests that the DWC consider the recommendations of pain management specialists and patients to change the MTUS to ensure California's injured workers have access to neuromodulation therapies.		presumption of correctness is challenged. For both situations, the methodology to evaluate the medical evidence is already carefully addressed in the regulations and Commenter's concerns regarding inconsistencies should not be an issue. Disagree: See all of above.	None.
General Comment	Commenter supports the proposed regulations to update California's Medical Treatment Utilization Schedule. Commenter's organization has long supported evidence-based medicine as the best strategy for delivering high-quality medical care to injured workers. Commenter states that in order to maximize the benefit of evidence-based medicine for injured workers, an effective rollout will be key. Commenter recommends that, as part of the implementation process, the DWC develop a training regimen for physicians to ensure that they understand the revised guidelines and	Jason Schmelzer CCWC Jeremy Merz AIA Kevin McKinley CalChamber September 6, 2017 Written Comment	Agree. Agree: The DWC currently has an on-line educational course on the MTUS to access here is the URL address: www.dir.ca.gov/dwc/CaliforniaDWCCME.htm The DWC also has plans to	None. None.

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	know how to properly document medical treatment requests. Comment notes that the data suggests that much of the Utilization Review (UR) and Independent Medical Review (IMR) currently conducted in California could be avoided if medical treatment requests were both properly documented and more in-line with evidence-based standards. Commenter bases this assertion on the fact that the clear majority of UR decisions are upheld by IMR (91.2% in 2014). Commenter opines that the only explanation for this result is that medical treatment requests are not in line with the MTUS, or not properly documented. Commenter states that a strong education campaign will help reduce friction and speed delivery of care to injured workers.		provide a webinar on the MTUS that includes these evidence-based updates.	
Effective Date	Commenter seeks clarification as to the effective date of the proposed updates to the MTUS. Unlike in its recent update to the MTUS formulary, DWC has not indicated the date upon which the new MTUS guidelines will become effective. Commenter requests clarification as to how DWC will treat ongoing treatment authorized pursuant	Stacey Wittorff Legal Counsel Center for Legal Affairs California Medical Association September 6, 2017 Written Comment	Disagree: The evidence-based updates to the MTUS will become effective once the AD publishes the order pursuant to Labor Code § 5307.27(a). Ongoing treatment inconsistent with the recommendations found in these evidence-based updates to the MTUS should	None.

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	to existing MTUS guidelines when authorized treatment is inconsistent with the proposed updated guidelines. Commenter recommends that any treatment authorized pursuant to existing MTUS guidelines continue until the injured worker's treating physician determines it is no longer medically appropriate. Commenter opines that it is necessary that DWC make clear the effective date as well as a plan to transition from existing MTUS guidelines to the proposed MTUS guidelines for ongoing treatment so that injured workers and their physicians can ensure appropriate medical care is not interrupted.		be carefully modified unless there is a successful challenge to the MTUS' presumption of correctness. Any modification to ongoing treatment must follow the treatment recommendations found in the applicable guideline (e.g. proper tapering of opioids).	
9792.23	Commenter's primary concern with the adoption of the proposed MTUS update is not only with the substance of the guidelines, but also with their application. Labor Code §4604.5 provides that the MTUS guidelines "shall be presumptively correct on the issue of extent and scope of medical treatment" but that "[t]he presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines	Stacey Wittorff Legal Counsel Center for Legal Affairs California Medical Association September 6, 2017 Written Comment	Agree: Commenter accurately describes the MTUS statutes.	None.

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	reasonably is required to cure or relieve the injured worker from the effects of his or her injury." A "preponderance of the evidence" in this case means that when compared to the MTUS guideline, evidence suggesting a variance from the guideline "has more convincing force and the greater probability of" appropriateness. (Labor Code §3202.5). However, the experience of many of commenter's organization physician members who treat injured workers is that the MTUS are frequently applied inflexibly. Commenter has long been concerned that strict application of the MTUS results in delays in the provision of appropriate, effective medical care such that the ability of the injured worker to return to work is delayed. Commenter recommends that in its focus on evidence based medicine (EBM), DWC not fail to consider a wide range of treatments that, while not necessarily meeting the rigorous standards for EBM, actually result in better outcomes for patients. Commenter recommends that the DWC issue guidance or		Disagree: Commenter incorrectly suggests the medical treatment guidelines is the MTUS. The MTUS is more than just medical treatment guidelines. It is a set of regulations that provide an analytical framework for the evaluation and treatment of injured workers. Therefore, the analytical framework for the evaluation and treatment of injured workers (the MTUS) must be strictly applied. Regulations already exist that guide how medical evidence is evaluated to determine if the recommendations in the MTUS is rebutted by a	None.

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	regulations regarding the appropriate application of the "preponderance of the evidence" standard as applied to requests for treatment outside the MTUS.		preponderance of medical evidence (see 9792.21, 9792.21.1, and 9792.25.1).	
9792.24.2	Commenter notes now the DWC has proposed new treatment guidelines altering the current MTUS and relying on ACOEM Guidelines and chapters. Commenter states that the majority of injured workers with pain have chronic pain which has lasted much longer than 90 days, and which is beyond the current timeframe for ACOEM.	Francis Riegler, MD QME – President Universal Pain Management American Society of Interventional Pain September 6, 2017 Written and Oral Comments	Disagree: ACOEM's guidelines addresses pain lasting longer than 3 months in their guidelines and ACOEM's Chronic Pain guideline addresses comprehensive psychological and behavioral aspects of pain lasting longer than three months (90 days).	None.
	Commenter notes that none of the physicians contributing to the ACOEM low back chapter are specialists in chronic pain management.		Disagree: Although it is not clear if none are specialists in chronic pain management, it is clear that the Panel Chairperson for the Chronic Pain guideline is past president of the American Academy of Pain Medicine.	None.
	Commenter treats injured workers that are in pain and knows that certain patients could benefit from a treatment modality such as spinal cord		Disagree: Although commenter does not provide a name, the DWC has not relied upon any one particular	None.

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	stimulation, or a lumbar facet injection, or a sacroiliac joint injection; however, now the state of California via the DWC has relied upon the advice of a physician who has not practiced medicine in a long time, who is a neurologist, and who does not even live in the state of California and adopted these proposed ACOEM Guidelines. The treatment you are contemplating, and which you know could materially benefit the patient, is all but precluded by the now current treatment Guidelines.		physician in its decision to adopt the ACOEM guidelines into the MTUS. Spinal Cord Stimulator implantation is recommended for short-to intermediate-term relief for highly select CRPS patients. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	
	Commenter contemplates what his options will now be: 1. State that there are proven treatments, which are covered by Medicare and private insurance, but that these treatments are not available under workers' compensation. 2. Send the patient away and tell		Disagree in part; Agree in part: Disagree: Commenter fails to mention other viable options e.g. physical therapy, exercise and other alternative treatments. Commenter also fails to mention the possibility of rebutting the MTUS' presumption of correctness.	None.

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	them that there is nothing else you can do, that they will just have to live with the pain. 3. Prescribe more Oxycontin. Commenter states that he will continue to put the patient's best interests first.		Finally, OxyContin should only be prescribed if it is medically necessary. Agree: The patients best interests should be first. Spinal Cord Stimulator implantation is recommended for short-to intermediate-term relief for highly select CRPS patients. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	None.
9792.23 9792.24.2	Commenter appreciates the extensive work of evidence-based Guideline from American College of Occupational and Environmental Medicine (ACOEM) for the MTUS. Commenter notes the guidance for	Wei Wei American Association of Chinese Medicine and Acupuncture September 6, 2017 Written & Oral	Agree: Commenter is stating her appreciation. Agree.	None. None.

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	using acupuncture that appears in Clinical Topics Guidelines and Chronic Pain Guideline instead of in a separate category within the guideline.	Comment		
	Commenter is happy to see that ACOEM has given the recommendation of acupuncture for various work related injuries. As indicated in the order, these are all based upon evidence within studies done by ACEOM. Commenter opines that acupuncture will now be better utilized for treating injured workers going forward.		Agree in part; Disagree in part: Agree: Commenter is stating her opinion about the ACOEM guidelines and its impact on injured workers. Disagree: ACOEM reviews and evaluates existing studies. These studies are not "done by ACOEM."	None.
	Commenter states that the treatment of acupuncture benefits injured workers in the following ways: 1. Acupuncture uses the holistic philosophy of Chinese Medicine to guide its direction in helping patients. It focuses not only the area that is injured. It helps to improve the overall health of the patients, which will then improve their performance at work more effectively. 2. Acupuncture is not only effective in		Disagree: Although acupuncture is selectively recommended in the ACOEM guidelines, commenter is stating her view of how acupuncture benefits injured workers and may not be supported by medical evidence.	None.

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	treating chronic persistent pain, but also helps to regulate the balance of the body's energy, to cushion the ability in dealing with stress, etc. Those effects have been proven by numerous modern researches as well. 3. Acupuncture is simple and safer than many other medical modalities. Acupuncture is not invasive and is widely accepted. History has proven the value of acupuncture. 4. Acupuncture can help employers to provide services to workers to get them back to work faster, less expensive, and less invasive than drugs & surgeries, especially the addiction to opioids. 5. Modern research show that Acupuncture & Asian medicine helps patients back to work faster. In conjunction of other modalities: Tai Qi, meditation, Yoga stretching, or other physical modalities, it can provide even faster healing. 6. Sometimes, patient in too much pain cannot participate in physical therapies or have side effects caused by using			

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	drugs, acupuncture is the best fit in these situations.			
	Commenter would like to be included in further discussions and presentations regarding evidence-based MTUS of Acupuncture and Asian medicine. Commenter states that there is much research, not only performed in Asia but performed by major US Universities in American that clearly support the use of acupuncture treatment.		Agree: The public, as well as commenter, is always welcome to provide input during the DWC's rulemaking.	None.
	Commenter opines that acupuncture has cost saving benefits.		Agree.	None.
	Commenter notes that acupuncturists in California have to learn basic anatomy, physiology, pathology, immunology, etc. in addition to being educated in Chinese medicine and acupuncture. Commenter notes that Acupuncturists are noted as "treating physicians" in Worker's compensation system.		Agree.	None.
	Commenter states that in June 2017, the FDA released the draft "Education Blueprint for Health Care Providers Involved in the Management or support		Agree in part; Disagree in part: Agree: The FDA published the draft version of this document May 11, 2017 for public	None.

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	of Patients with Pain." The report recommends the first line approach to manage acute and chronic pain to be non-pharmacological therapies and acupuncture is listed as one of the therapies. This approach better reduces the pain patients and cuts down on the dependency addiction problem as a result of opioid usage.		comment. Disagree: Since it is still going through the public comment period, any substantive recommendations in this document is still in draft form. In addition, it is not clear if ACOEM reviewed the study cited by Commenter but she is encouraged to submit this study to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of evidence from any source. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused	

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			update to the ACOEM guidelines.	
	Commenter notes that Mathew Bauer, LAc and John McDonald, PhD wrote a 35-page paper with 54 studies relating to acupuncture's working mechanism for various pain syndromes. The title of the paper is "Acupuncture in Pain Management". This is published by the Acupuncture Now Foundation. The American Society of Acupuncture published "The Acupuncture Evidence Project: A Comparative Literature Review" which offers a high quality comparative literature review on the effectiveness of acupuncture on the variety of health conditions.		Disagree: It is not clear if ACOEM reviewed the study cited by Commenter but she is encouraged to submit this study to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of evidence from any source. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused update to the ACOEM guidelines.	None.

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9792.23.5 9792.24.2	Commenter is in disagreement with the proposed Chronic Pain Guideline (ACOEM May 15, 2017) as well as the Low Back Disorders Guideline (ACOEM February 24, 2016). Commenter is disappointed to learn that DWC is proposing to drastically limit the use of SCS for neuropathic pain patients. Commenter requests that DWC consider maintaining the current MTUS guidelines for SCS rather than adopting the proposed ACOEM guidelines that will limit access of an opioid-free, proven therapy for injured workers who may have exhausted their options for controlling their chronic pain.	Tamara Rook, Senior Director Abbott Neuromodulation September 6, 2017 Written Comment	Disagree: The DWC is making evidence-based updates to the MTUS in order to keep up with the evolving nature of scientific evidence. Since the MTUS Treatment guidelines are presumptively correct it must be periodically updated. The current MTUS incorporates many of the ACOEM guidelines from 2004, including recommendations for the low back, neck and upper back involving SCS.	None.
	Commenter opines that the current MTUS guideline already meets the requirements of being "supported by the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines and peer-reviewed published studies, that are nationally recognized by the medical community, and has been endorsed by each of the academic pain programs in the State of California, and by the leading professional societies		Disagree: As noted above, the MTUS must be updated to keep up with the evolving nature of scientific evidence. Up-to-date recommendations supported by the best, currently available scientific evidence that help us understand the efficacy or harms of new medical treatment, drugs or diagnostic tools should be incorporated	None.

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	which support the evidence-based practice of pain medicine. Commenter states that the current MTUS Chronic Pain Guideline replaced a previous version of the ACOEM Chronic Pain Guideline. For reference, SCS is a form of neuromodulation used to relieve chronic intractable pain of neuropathic or ischemic origin and has historically been reserved to treat pain that has failed to respond to conventional measures. The Chronic Pain Guideline finds the evidence supporting SCS for neuropathic pain as "insufficient," however, the review and analysis of the literature used to reach that conclusion does not seem complete relative to the body of evidence cited in other systematic reviews. Commenter requests a comprehensive review of the full body of evidence that underpins the safety and efficacy of this therapy for appropriate patients. Commenter advocates that the Division perform a thorough review of the health technology assessments of SCS that have been completed by various governmental organizations around the world. [Commenter enclosed a summary of the evidence and health		into the MTUS. There are currently seventeen (17) evidence-based guidelines in the MTUS. Twelve (12) of those guidelines were initially published in 2004, one (1) was initially published in 2007, two (2) were initially published in 2009, one (1) was initially published in 2015 and one (1) was initially published in 2016. Since the initial publication of these guidelines, there have been many new developments that have not been incorporated into the MTUS. Although a treating physician or reviewing physician may rebut the MTUS' presumption of correctness, the MTUS Treatment Guidelines is the primary source to determine the standard of care in California's workers' compensation system. Disagree: There are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment	None.

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	technology assessments for reference, which is available upon request.] Commenter states that after careful review of the published literature that evaluates the use of SCS, almost all US commercial payers, Medicare, and workers' compensation programs in 48 states include SCS as a covered benefit when specific coverage criteria are met.		such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate. ACOEM's methodology adheres to the criteria set forth by the National Academy of Medicine (formerly IOM); A Measurement Tool to Assess Systematic Reviews (AMSTAR); Grading of Recommendations Assessment, Development and Evaluation (GRADE); and Appraisal of Guidelines for Research and Evaluation (AGREE). ACOEM's review process is transparent and applied to recommendations in all of its guidelines. Rather than relying on Medicare and other workers' compensation programs and their methodology to evaluate medical evidence, the DWC believes the transparent methodology applied by ACOEM maintains	

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			consistency in evaluating the available medical evidence throughout the MTUS.	
	Commenter notes that from a public policy and public health perspective, the abuse of opioids is close to being designated as a national emergency, and the need for non-opioid options to treat chronic pain has been identified as an urgent priority[1]. Chronic pain is often a driver of opioid use as patients seek relief and improvements to their quality of life. Fortunately, for patients, SCS therapy has been clinically proven to offer meaningful relief to patients suffering from chronic pain. However, under the proposed ACOEM Chronic Pain Guideline, access to this safe, proven, opioid-free therapy for managing chronic pain would be largely eliminated.		Agree in part; Disagree in part: Agree: There is plenty of abuse of opioids and there is a need to identify non-opioid treatment options. Chronic pains is often a driver of opioid use as patients seek relief from pain. Disagree: There are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	None.
	Commenter states that data from a recent study by Sharan[2] demonstrates		Disagree: It is not clear if ACOEM reviewed the study	None.

[1] Califf RM, Woodcock J, Ostroff S. A Proactive Response to Prescription Opioid Abuse. N Engl J Med 2016;374:1480-5.
[2] Sharan A, Riley J, Falowski SM, et al. Association of Opioid Usage with Spinal Cord Stimulation Outcomes. 2017 Annual Meeting of the North American Neuromodulation Society. Las Vegas, NV 2017.

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	that SCS was found to help decrease or stabilize opioid use in patients with chronic pain. Researchers used the private and Medicare insurance claims data from 5,476 chronic pain patients to evaluate their opioid usage prior to and after receiving a spinal cord stimulation implant. They found that SCS therapy was effective for patients at any level of opioid usage before implantation. The average daily opioid use was lowered or stabilized for 70% of patients receiving a successful SCS system implant. One year after implant, 93% of patients who continued SCS therapy had lower average daily morphine-equivalent doses than patients who had their SCS system removed. Commenter notes that the majority of patients in this study had a form of neuropathic pain including failed back surgery syndrome, neuritis, limb pain, other back pain and degenerative disc disease.		cited by Commenter but she is encouraged to submit this study to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of evidence from any source. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused update to the ACOEM guidelines.	
General Comment	Commenter welcomes this update of the MTUS Guidelines that ensures that treatment for injured workers is guided by evidence-based treatment guidelines that are internally consistent, and are	Denise Niber Claims & Medical Director California Workers' Compensation	Agree.	None.

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	the most current from ACOEM. Commenter appreciates that the Administrative Director proposes the updated guidelines to be in place by the effective date of the MTUS Drug Formulary.	Institute (CWCI) September 6, 2017 Written Comment		
9792.24.4	Commenter recommends that ACOEM clarify naloxone recommendation to indicate that there is no empirical difference between the various delivery systems for naloxone. Commenter notes that in its Opioids Guideline, ACOEM recommends naloxone (Narcan) for the prevention of overdose in those patients on greater than 50 mg MED and for those patients who have already overdosed but have not yet been tapered. Commenter opines that some stakeholders will interpret the Guideline to mean that only the nasal spray delivery of naloxone is recommended, while others may interpret this Guideline to mean that any delivery system of naloxone is recommended. Commenter notes the Initial Approaches to Treatment chapter of the ACOEM Guidelines includes a	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) September 6, 2017 Written Comment	Disagree: Guideline addresses use of naloxone. Narcan reference is provided as a Brand name example. Disagree: Guideline addresses use of naloxone. Narcan reference is provided as a Brand name example as is a common practice within the guidelines (e.g. use of OxyContin as a brand name example of Oxycodone HCL). Disagree: Although cost is certainly a consideration, the authorizing statutes for the	None. None. None.

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	"recommended – insufficient evidence" discussion that, absent evidence to the contrary, drugs in the same class are presumed to have the same degree of efficacy. In this same chapter, it is indicated that cost is a factor to consider in the use of *oral* pharmaceuticals. Although naloxone is not an oral pharmaceutical, cost efficiency is a significant issue for this particular drug. Despite these general approaches to medication treatment, commenter suggests clarification concerning the naloxone recommendation for the reasons outlined below: Narcan (two-pack) nasal spray kits cost about $125, whereas the Evzio "talking" two-pack auto-injector kit currently bears a Wholesale Acquisition Cost of $5,125. The makers of Evzio recently replaced the .4mg dose auto-injector kit with a 2mg version after receiving FDA approval. Even before that change, however, the price of Evzio skyrocketed in only one-year' time.		MTUS (Labor Codes section 5307.27, 4604.5, and 4600(b)) are silent about cost but clearly state that the MTUS "shall incorporate evidence-based, peer-reviewed, nationally recognized standards of care." Cost considerations are not factored into the MTUS recommendations. The DWC is evaluating other avenues to consider cost factors. Disagree: See above response.	None.

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	Using CWCI IRIS[1] paid data, for service years 2015 through 2016, CWCI found that 87 percent of all naloxone prescriptions in California workers' compensation were for the brand name auto-injector kit (Evzio). In addition, the Institute found that the average price paid for the Evzio kit soared from an average of $664.57 in 2015 to $3,549.43 in 2016 (including the $7.25 dispensing fee). In contrast, during that same two-year period, naloxone nasal spray kit (Narcan) was paid at an average of just $132.29; and the non-Evzio injectable naloxone kits (.4mg) were paid at an average of $51.53 (all including the dispensing fee).		Disagree: See above response.	None.
	Narcan nasal spray kits are currently available in both 2mg and 4mg versions. Narcan nasal spray is an appropriate therapeutic equivalent for Evzio's auto-injector kit, but at a mere fraction of the cost. Commenter		Disagree: See above response.	None.

[1] IRIS is CWCI's proprietary database containing data on employee and employer characteristics, medical service data, benefits, and administrative costs on approximately 5.3 million California workers' compensation claims.

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	recommends that the Division suggest that ACOEM amend its naloxone recommendation to clarify that there is no evidence that the "talking" auto-injector delivery of naloxone (Evzio) is superior to the nasal spray (Narcan) in saving lives.			
General Comment – Table of Contents	Commenter recommends creating a Table of Contents for all Guidelines with embedded links for ease of use. Commenter notes that the Table of Contents is missing in various proposed chapters (*e.g.* Elbow Disorders; Hand, Wrist, and Forearm Disorders; and Hip and Groin Guidelines chapters). Commenter opines that the tables and supporting studies in each subsection make searching 12 of 14 chapters overly laborious and time consuming. Commenter recognizes that users have the option of paying to use the Reed	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) September 6, 2017 Written Comment	Agree: Commenters suggestions regarding the Table of Contents, table, and supporting studies make are suggestions the DWC agrees with. However, the ACOEM guidelines are copyrighted material published by the Reed Group. The DWC has forwarded these suggestions to the Reed Group for consideration. In addition, we encourage commenter to submit this suggestion directly to ACOEM. They accept stakeholder input through the following web address https://acoem.formstack.com/forms/stakeholderpatientinp Agree: See above response. For rulemaking purposes, the	None. None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Group's website and search function (at MDGuidelines.com); however, some users will attempt to use the Guidelines posted on the Division's website. Commenter opine that enabling ease of use (especially for requesting physicians) is important.		DWC has posted the ACOEM guidelines on its website. However, commercial use of the ACOEM guidelines requires a license. As noted above, the Reed Group publishes the ACOEM guidelines, which are copyrighted.	
9792.22	Commenter recommends that ACOEM or the Division consider providing guidance on what "short term" means, as well as how often the need for home healthcare should be revisited (i.e., what does "regular intervals" mean?). Commenter notes that the Initial Approaches to Treatment Guidelines section states that home health care is selectively recommended "on a short term basis" after hospitalization or a major surgical procedure; when deficits in ADLs necessitate such; and in cases where it is needed to prevent re-hospitalization. Furthermore, it is noted that reassessments of the continuing medical need for home health care is to be done at "regular intervals." However, "short term" and "regular intervals" are not defined.	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) September 6, 2017 Written Comment	Disagree: The definitions for "short term" and "regular intervals" must be defined within the clinical context of the individual patient.	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.22	Commenter suggests communicating clear preference for FDA-approved and/or OTC monograph topicals whenever they are recommended, or referencing back to the Initial Approaches to Treatment on this subject in order to avoid confusion. Commenter recognizes that the Initial Approaches section provides a preference for individual topical FDA-approved drugs over compounded drugs. However, some topicals are "recommended" (*e.g.*, topical NSAIDs, topical capsaicin, and Lidocaine patches in the case of neuropathic pain) within the Chronic Pain Guidelines, without qualification or reference back to the Initial Approaches to Treatment section on this subject.	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) September 6, 2017 Written Comment	Disagree: The issues raised by commenter will not be dealt with in the "evidence-based updates" to the MTUS, which is the subject of this AD Order. These issues are ones that would be dealt within the MTUS Formulary Drug List and/or regulations.	None.
9792.20(d) 9792.9.1(e)(5)	Commenter recommends the following revised language to section 9792.20(d): "Evidence-Based Medicine (EBM)" means a systematic approach to making clinical decisions, which allows the integration of the best available research evidence with ***the treating physician's*** clinical expertise and patient values. ***Under no circumstance***	Steve Cattolica ADVOCAL September 6, 2017 Written Comment	Disagree: These evidence-based updates to the MTUS are being made pursuant to Labor Code section 5307.27(a) "through an order exempt from Sections 5307.3 and 5397.4, and the rulemaking provisions of the Administrative Procedure Act." The amendments proposed by	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	does EBM mean that the approach to making any specific clinical decision to approve or deny a request for medical treatment can be made based solely upon only one of the three components named in this definition. All three must be considered. Commenter does not expect the Division to mandate changes to the proposed American College of Occupational and Environmental Medicine (ACOEM) guidelines. Commenter expects the Division to exercise its authority to assure that these and any alternative treatment modalities or alternative guidelines proposed by treating physicians via a Request for Authorization (RFA) be given a thorough opportunity to be approved. Commenter opines that the utilization review and the Independent Medical Review process currently provides only marginal access to due process when a request for authorization has been denied. Commenter states that it is incumbent upon the Division to codify a procedure that assures the provision		commenter would not be considered evidence-based updates to the MTUS and, therefore, needs to be made pursuant to the rulemaking provisions of the APA. Disagree: Commenter suggests the DWC exercise its authority to establish procedures allowing review of a treatment request that is based on a recommendation found outside of the MTUS guidelines. His request goes beyond the scope of this AD Order to make evidence-based updates to the MTUS pursuant to Labor Code section 5307.27(a). Nevertheless, regulations already exist that guide how medical evidence shall be evaluated if a treatment request is made from a recommendation outside of the MTUS guidelines (see 9792.21, 9792.21.1, and 9792.25.1).	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	of a thorough opportunity to be approved. Commenter acknowledges that the following section is not a part of this order, but he would like to see the following revision to section 9792.9.1(e)(5): (5) The written decision modifying, ~~**delaying or**~~ denying treatment authorization shall be provided to the requesting physician, the injured worker, the injured worker's representative, and if the injured worker is represented by counsel, the injured worker's attorney. The written decision shall be signed by either the claims administrator or the reviewer, and shall only contain the following information specific to the request: (A) The date on which the DWC Form RFA was first received. (B) The date on which the decision is made. (C) A description of the specific course of proposed medical treatment for		Disagree: As commenter acknowledges, his proposed amendments to section 9792.9.1(e)(5) goes beyond the scope of this AD Order which is limited to making evidence-based updates to the MTUS pursuant to Labor Code section 5307.27(a). Commenter has suggested amendments to the regulations would need to be done pursuant to the rulemaking provisions of the Administrative Procedure Act.	None.

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	which authorization was requested. (D) A list of all medical records reviewed. (E) A specific description of the medical treatment service approved, if any. (F) A clear, concise, and appropriate explanation of the reasons for the reviewing physician's decision, including the clinical reasons regarding medical necessity and a description of the relevant medical criteria or guidelines used to reach the decision pursuant to section 9792.8. ***In accordance with the definition of Evidence Based Medicine, the explanation to modify or deny must also include the relative weights - expressed as a percentage that together, add to 100% - given to the following: the research evidence, the treating physician's clinical expertise and the patient's values***. If a utilization review decision to modify, ***or*** deny ~~**or delay**~~ a medical service is due to incomplete or insufficient information, the decision shall specify			

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the reason for the decision and specify the information that is needed.			
General Comment	Commenter states it is going to be hard to change the ACOEM Guidelines but luckily, there are regulations, the hierarchy of evidence process where a treating physician can make an alternative known, try to document it as best they can and hope that the UR or eventually the IMR physician agrees with them. But that is a heck of an alternative for people like you've heard from today who are in the midst of chronic pain, severe chronic pain while they sit through this process, it can take months.	Steve Cattolica ADVOCAL September 6, 2017 Oral Comment	Disagree: Prospective or concurrent UR decisions are made within 5 working days from receipt of the information reasonably necessary to make a determination. IMR determinations are made within 30 days of receipt of the request for review and supporting documentation reasonably necessary to make a determination. Currently IMR is averaging 12 days to render a determination well below its statutory requirement to render a medical necessity determination within 30 days.	None.
	Commenter states that evidence based medicine has three components as described by the famous Venn Diagram with three components - hard evidence, the clinical judgement of the physician and the patient's expectations. Commenter states those circles are not equal sized. His comments infer that he		Disagree: Commenter misinterprets the Venn Diagram describing evidence-based medicine (EBM). EBM is where all three circles overlap, not the size of each circle. The Venn Diagram illustrates that all three	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	believes they should be of equal size. The evidence circle is a little larger than the clinical judgment of the physician and patient expectation circles.		components should be considered. However, the weight given to each will vary. For example, if the treating physician recommends surgery and the medical evidence supports this request but the patient refuses surgery, then it will be the patient's expectations and values that will dictate the treatment.	
	Commenter suggests that the entirety of the MTUS be preceded by a preamble that speaks a little bit about the evidence-based medicine and how it is defined and the clinical judgment and the patient expectation ought to have equal weight. Commenter suggests the DWC put this in a regulation and not just make it a suggestion buried somewhere in ACOEM's documents or ODG's documents or whomever.		Disagree: Commenter's suggestion goes beyond the scope of this AD Order to make evidence-based updates to the MTUS pursuant to Labor Code section 5307.27(a). In addition, other than the statement about "equal weight", the CCR, title 8, section 9792.21(b) already states, "The MTUS is based on the principals of Evidenced-Based Medicine (EBM). EBM is a systematic approach to making clinical decisions which allows the integration of the best available evidence with clinical expertise and	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			patient values."	
	Commenter makes the above suggestion because the MTUS is supposed to be used as a component and a tool, not hard and fast, the practical application has been a hard and fast yes or no to treatment requests. Commenter states that the IMR process has not done a very good job of allowing doctors to be able to provide the care that they want and believe to be best for their patients.		Disagree: Commenter's request goes beyond the scope of this AD Order to make evidence-based updates to the MTUS pursuant to Labor Code section 5307.27(a). Nevertheless, regulations already exist that guide how medical evidence is evaluated if a treatment request is made from a recommendation outside of the MTUS guidelines (see 9792.21, 9792.21.1, and 9792.25.1).	None.
	Although commenter states he would not impugn the ACOEM guidelines, he questions the process used by ACOEM for reviewing its guideline proposals. Commenter provides as an example, ACOEM's review process of their upcoming Traumatic Brain Injury Guidelines (Commenter makes clear he understands this guideline is not being considered for adoption under the division' proposed MTUS guidelines). Commenter notes that the physician reviewer was provided with a draft of		Disagree: Commenter's request goes beyond the scope of this AD Order to make evidence-based updates to the MTUS pursuant to Labor Code section 5307.27(a). In addition, the process for development of ACOEM Guidelines involves many people, not just one physician. ACOEM uses several panels such as the Evidence-based Practice Panels (EBPPs or Panels).	None.

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	the guidelines on the 28th of December and asked to return them by the 27th of January, which gave the physician 28 days to review 888 pages. Commenter calculates that in order to review 888 pages in 28 calendar days that the reviewer would have to spend 5.3 hours a day reviewing the guidelines. Commenter notes that this is in addition to their regular 40-60 hour workweek. Commenter opines that this would be an impossible task. Commenter notes that ACOEM's instructions to the reviewer to comment on the appropriateness of the guideline findings and recommendations, the clarity and the technical accuracy, the completeness of the scientific literature evaluation, with a specific note about Random Randomized control trials being emphasized. Commenter states that he is not sure how a physician can complete this with regard to interventional pain procedures – implant something that is a placebo? Commenter notes that ACOEM has no obligation to change a recommendation based upon a reviewer's comments.		Multidisciplinary EBPPs are distinct panels of experts for each body part, system, or skill area covered by the Guidelines. For example, the EBPP for the Chronic Pain Guidelines includes 15 experts. Panels are often subdivided into areas of practice or research interest particularly when the panel has a large scope of work. ACOEM also has the Guideline Methodology Committee GMC). On an ongoing basis, the GMC refines, clarifies, and updates the methodology based on state-of-the-art internationally accepted methods. To ensure transparency, it publishes documents that describe and explain the methodology used for ACOEM evidence-based materials and products. Finally, all ACOEM guidelines includes participation of the EBPC, stakeholder input, external peer-review and review by the ACOEM Board.	

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	Commenter does not know how the Division can create a regulation that can be used as rote with this type of criteria, and he acknowledges that this is not ACOEM's problem to solve. He opines that this Division has been put into a situation that is unattainable incorporating these guidelines.		Disagree: Commenter's request goes beyond the scope of this AD Order to make evidence-based updates to the MTUS pursuant to Labor Code section 5307.27(a). Nevertheless, regulations already exist that guide how medical evidence is evaluated if a treatment request is made from a recommendation outside of the MTUS guidelines (see 9792.21, 9792.21.1, and 9792.25.1).	None.
9792.23.5 9793.24.2	Commenter is concerned regarding the DWC's adoption of the American College of Occupational and Environmental Medicine (ACOEM) medical treatment guidelines. Commenter states that doings so would eliminate the existing provisions relative to the Chronic Pain Medical Treatment Guidelines that the Division of Workers' Compensation (DWC) and stakeholders worked so hard to develop. Commenter's organization represents	Christy Bouma Governmental Advocate California Professional Firefighters September 6, 2017-Received September 11, 2017 (Late) Written Comment	Disagree: Spinal Cord Stimulator implantation is recommended for short-to intermediate-term relief for highly select CRPS patients and for those patients they should be informed of this treatment option. They should also understand that this intervention has no quality evidence of greater than 3-year benefit during which time there is unequivocal patient commitment. Otherwise, this	None.

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	firefighters. Commenter states that these injured firefighters must all have access to safe, clinically proven, cost-effective therapies to recover from their injuries as soon as possible. This requires ensuring that injured workers with Failed Back Surgery Syndrome (FBSS) and suffering from chronic pain have access to spinal cord stimulation (SCS) and implantable drug delivery systems (IDDS) as treatment options. Commenter notes that ACOEM's low back chapter, (SCS) is not recommended for the treatment of chronic lower back pain, radicular pain syndromes or FBSS; IDDS is not recommended for injured workers in ACOEM's chronic pain chapter.		modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	
	Commenter opines that many workers -- not just firefighters -- serving in critical capacities in California are at risk for back injuries. Multiple studies have shown that both SCS and IDDS are effective treatments 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. Moreover, SCS and IDDS are widely covered by		Agree in part; Disagree in part: Agree: Many workers, not just firefighters, are serving in critical capacities in California are at risk for back injuries. Disagree: There are few quality studies evaluating SCS and IDDS. There are no SCS studies, which compared SCS with a non-surgical treatment such as a quality multi-	None.

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	Medicare, workers' compensation plans in 49 other states and most commercial health insurers. Commenter states 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. Commenter recommends that the DWC consider amending their MTUS rule to incorporate guidelines that include access to SCS and IDDS for appropriately selected patients.		disciplinary rehabilitation program or sham procedure. SCS and IDDS are invasive with reported serious complications, costly, and have a significant revision rate. Moreover, rather than relying on Medicare or workers' compensation plans in other states, or commercial health insurers, the DWC believes the transparent state-of-the art internationally accepted methodology applied by ACOEM maintains consistency in evaluating the available medical evidence throughout the MTUS.	
	Commenter requests that the Medical Director engage the MEEAC to advise the division about incorporating evidence based guidelines into the MTUS and to welcome a public discussion before the DWC adopts the ACOEM Guidelines whole cloth to serve as California's MTUS that will govern the care of California's injured workers.		Disagree: The DWC followed that process. DWC's Executive Medical Director discussed the adoption of ACOEM with MEEAC and this 30-Day Comment period including the Public Hearing on September 6th welcomed public input.	None.
9792.23.5	Commenter states that recently there	Joshua Prager	Disagree: Physicians can be	None.

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9793.24.2	have been several landmark studies that are class A evidence demonstrating the efficacy of neuromodulation and the cost efficacy of it. Commenter provided a list of organized that have signed off on these documents: The American Academy of Physical Medicine and Rehabilitation, the American Pain Society, The American Society of Anesthesiologists, the American Society of Neuroradiology, the American Society of Regional Anesthesia and Pain Medicine, the American Society of Spine Radiology, the California Society of Anesthesiologists, the California Society of Interventional Radiology, the Spine Intervention Society, the North American Neuromodulation Society, the California Society of Industrial Medicine and Surgery. Commenter states that in addition to these organizations, he has had an administrative person sign from every academic pain program in the State of California. All of this took great effort on his behalf and he had to make many changes in order to get everyone to	Center for the Rehabilitation of Pain Syndromes September 6, 2017 Oral Comment	assured that innovative and successful therapies that are supported by appropriate evidence will be available to injured workers as ACOEM reviews the literature periodically to identify major changes in the evidence-based by content area. In addition, anyone may submit materials directly to the ACOEM guidelines development team for review and assessment of any potential changes to guideline recommendations. Thus far, despite the claims made by this commenter and several other commenters regarding the medical evidence supporting the use of SCS and IDDS, ACOEM has reviewed most of the studies cited by commenters and has concluded there are few quality studies evaluating SCS and IDDS. There are no SCS studies, which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham	

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	endorse it. Commenter states that he knows of no other document that has been endorsed by so many organizations supporting neuromodulation as part of the pain management continuum for all patient, not just for injured workers. Commenter points out the neuromodulation is a treatment that can eliminate all use of opioids during a period when the country is experiencing and opioid crisis. Commenter states that the National Institute of Health produced a document entitled "Pain in America" that stated that we need to seek alternative treatments to opioids. Additionally, commenter states that the DEA has come out with a document, Governor Christie of New Jersey has been appointed to run the President's Commission on Combating Drug Addiction and the Opioid Crisis. The U.S. Centers for Disease Control and Prevention has produced a set of guidelines. The National Academy of Sciences, Engineering, and Medicine has recently produced another document on the subject.		procedure. SCS and IDDS are invasive with reported serious complications, costly, and have a significant revision rate. It is not clear if ACOEM reviewed the study cited by commenter, but he is encouraged to submit this study to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of evidence from any source. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused update to the ACOEM guidelines.	

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	Commenter opines that the ACOEM guidelines is one of the most intellectually dishonest publications that he has even seen and that this organization sells guidelines as their principal method of generating revenue. Commenter states that it is ACOEM's protocol to have subject matter specialists involved in the creation of their guidelines. Commenter notes that of the 21 physicians and healthcare specialists involved in writing and researching these guidelines, not one of them was a board-certified pain physician or full-time pain physician. Commenter states that the physician specialties involved where from acupuncture, chiropractic and physical therapy. Commenter notes that these guidelines where not reviewed by a pain specialist and that the American Academy of Pain Medicine nor any other pain specialty organization were involved in writing and researching these guidelines. Commenter questions how the State of California can adopt these proposed guidelines when ACOEM did not following their own		Disagree: ACOEM's methodology adheres to the criteria set forth by the National Academy of Medicine (formerly IOM); A Measurement Tool to Assess Systematic Reviews (AMSTAR); Grading of Recommendations Assessment, Development and Evaluation (GRADE); and Appraisal of Guidelines for Research and Evaluation (AGREE). ACOEM's review process is transparent and applied to recommendations in all of its guidelines. Disagree: There are Panels for each guideline topic with experts in the covered fields. All ACOEM guidelines includes participation of the Evidence-based Practice Panel, stakeholder input, external peer-review and reviewed by the ACOEM Board. The Evidence-based Practice Chronic Pain Panel Chair is Dr. Steven D. Feinberg and he	None. None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	protocol for creating them. Commenter states that neuromodulation is a therapy that enables patients to stop taking pain medications and is one of the only types of therapy that you can try before having the procedure to see if it will work. Commenter states that it is fully reversible, unlike spine surgery where a nerve must be destroyed in order to eliminate pain.		is a past president of the American Academy of Pain Medicine. Disagree: Spinal Cord Stimulator implantation is recommended for short-to intermediate-term relief for highly select CRPS patients and for those patients they should be informed of this treatment option. They should also understand that this intervention has no quality evidence of greater than 3-year benefit during which time there is unequivocal patient commitment. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	None.

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9792.24.2	On May 27, 1992, two months before her wedding, at age 28, commenter was injured while working on the set of a children's television show. Commenter hurt her right wrist and hand and experienced immediate and excruciating pain that rendered her arm useless. Because she was a writer and right handed she was unable to continue working. She tried opiates, physical therapy, and occupational therapy and had multiple surgeries. None of these treatments worked and she continued to experience constant burning, stabling pain that interfered with every aspect of her life. Commenter stated that in 1999 she was diagnosed with complex regional pain syndrome. Commenter stated after seven years of suffering she experienced a miracle after she received a spinal cord stimulator and that after just one night she was able to get a good night's sleep for the first time in seven years. After the implant, she was able to stop using her wrist brace, stop-taking medication and lost weight. Commenter states that it does	Andrea Sherman Injured Worker Shindig Events September 6, 2017 Oral Comment	Disagree: Although the DWC is empathetic to Ms. Sherman's situation, we disagree that the DWC is eliminating the availability of neuro-modulation therapy for injured workers in California. In fact, since commenter stated she was diagnosed with complex regional pain syndrome, SCS would still be available to her.	None.

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	not eliminate all pain but reduced it substantially and, even though her first marriage failed due to her situation, after the implant she was able to participate in life again as a mother to her children and to develop an event planning business. Today, twenty years after first getting the SCS she is still using it daily, has remarried and is running a successful business. Commenter states that chronic pain is real and complicated and that opioids are not a solution. Commenter requests that the Division not eliminate coverage for neuro-modulation therapy for injured workers by making California the second only state to do so.			
9792.24.2	Commenter has been a police officer for 27 years. In 1998, she was involved in a traffic collision while on duty that resulted in multiple surgeries and chronic pain that started in her arms. She was on opioids for three years and felt conflicted about taking opioids to control her pain because she is a police officer whose job it was to arrest people on opioids. Commenter states that she was taking 200 milligrams of morphine a day and it	Susan Carnahan Injured Worker Police Officer Los Angeles September 6, 2017 Written Comment	Disagree: Although the DWC is empathetic to Officer Carnahan's situation, we disagree that the DWC is eliminating the availability of neuro-modulation therapy for injured workers in California. In fact, since commenter stated she was diagnosed with complex regional pain syndrome, SCS would still be available to her.	None.

MTUS EVIDENCE BASED UPDATES	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	still was not controlling her pain. She was diagnosed with complex regional pain syndrome. Commenter found a doctor that recommended neuromodulation and spinal cord stimulation. After she tried the spinal cord stimulator, she was finally able to function. Commenter says that her disease spread and it affects her entire body. She had to have a second spinal cord stimulator implanted to control the pain, but it is successful in controlling 50 to 70 percent of her pain depending on how bad it is on a given day. Commenter does not want to see this treatment option eliminated for her and other injured workers who need it to function. She does not want to go back on opioids and states that they do not work as well as SCS. Commenter does not want California to emulate Ohio, which has the highest opioid abuse in the country. Commenter requests that the Division continue to recommend SCS for patients with chronic pain in the treatment guidelines.			
9792.23.5 9792.24.2	Commenter is the Chief Medical Officer for Nevro, the manufacturer of the Senza Spinal Cord Stimulation (SCS). He is concerned about the	David Caraway, MD, PhD Chief Medical Officer	Disagree: Spinal Cord Stimulator implantation is recommended for short-to intermediate-term relief for	None.

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	DWC's proposal to update the MTUS with ACOEM guidelines, which state that "spinal cord stimulators are not recommended for treatment of acute, subacute, chronic low back pain, radicular pain syndromes or failed back surgery syndrome." He urges the DWC to reconsider because SCS is an accepted, reversible, minimally invasive therapy that provides significant relief to suffering chronic low back pain patients and it would be a disservice to limit workers' compensation patients' access to such an effective, non-opioid based treatment option.	Nevro Corp. September 5, 2017 Written Comment	highly select CRPS patients and for those patients they should be informed of this treatment option. They should also understand that this intervention has no quality evidence of greater than 3-year benefit during which time there is unequivocal patient commitment. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	
	SCS is an accepted therapy for treating chronic low back pain and FBSS as recognized by evidence from numerous published randomized control trials (RCTs), recognition from the FDA, CMS and numerous influential pain		Disagree: ACOEM evaluated the first study authored by Leonardo Kapural and does not give it a high rating because 50% of baseline outcomes measures (e.g.	None.

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	societies. Non-opioid options for treatment are in desperate need in light of recent CDC directives and the epidemic of tragic deaths associated with prescription opioid use. Commenter cites as evidence the 24-month results from the Kapural et al. study the results were most recently published in Neurosurgery and demonstrates the long-term superiority of HF10 therapy compared with traditional SCS in treating both leg and back pain.		Oswestry Disability Index scores) were not provided and there was no placebo group. Data suggests HF modestly superior, but opioid use only 19% lower with HF and ODI improved 16.5U.	
	Commenter knows ACOEM has already rated the Kapural et al study and mentions the recent independent, peer-reviewed, analysis that was performed of all the available RCTs in the SCS space (Grider et al. Effectiveness of Spinal Cord Stimulation in Chronic Spinal Pain: A Systematic Review *Pain Physician*: January 2016). Commenter states, the Kapural et al. study, for which there is now 24-month follow-up, received the highest ranking of any of the RCTs assessed per the Interventional Pain Management Techniques – Quality of Appraisal of Reliability and Risk Bias		Disagree: It is not clear if ACOEM reviewed the Grider et al. study cited by Commenter but he is encouraged to submit this study to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of	None.

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	Assessment (IPM-QRB) criteria. In addition, the SENZA-RCT 24-month outcomes was selected by the official journal of the Congress of Neurological Surgeons (CNS), *Neurosurgery* as the journal's Top Pain Paper of the Year. The strength of the Kapural et. al study, HF10 therapy was awarded transitional pass-through status by the Centers for Medicare & Medicaid Services (CMS).		evidence from any source. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused update to the ACOEM guidelines.	
	Commenter recommends that the DWC consider prospective clinical evidence from Europe (Al-Kaisy et al. Sustained effectiveness of 10kHz high-frequency spinal cord stimulation for patients with chronic pain and low back pain.). When evaluated at 24 months, HF10 patients saw sustained back and leg pain relief, accompanied by statistically and clinically significant improvement in ODI, with their baseline ODI of 55 reduced to 40 at 24 months. The results also demonstrated a significant reduction in opioid use.		Disagree: It is not clear if ACOEM reviewed the Grider et al. study cited by Commenter but he is encouraged to submit this study to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of evidence from any source. All literature is reviewed following	None.

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			the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused update to the ACOEM guidelines.	
9792.24.2	Commenter is concerned that this phrase found on page 802 of the proposed Chronic Pain Guideline is overly broad and conflicts with the definition of "conflict of interest" set forth in Labor Code section 139.3 and its exception set forth in Labor Code section 139.31(e). The proposed Chronic Pain Guideline on page 802 contains the following: "It is important to assess whether the patient has failed prior rehabilitation within the same facility or other similar programs, or whether conflicts of interests are involved in referral to the tertiary pain program." Commenter states, within the proposed regulation, there is no definition for the	Justin Kromelow CEO, HELP Practice Management, LLC September 6, 2017 Written Comment	Agree in part; Disagree in part: Agree: California Labor Codes section 139.3, 139.31(e), and 139.32 govern the issue of conflicts of interests and physician referrals. Disagree: The proposed Chronic Pain Guideline containing the sentence below on page 802: "It is important to assess whether the patient has failed prior rehabilitation within the same facility or other similar programs, or whether conflicts of interests are involved in referral to the tertiary pain program."	None. None.

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	term "conflict of interest" thus the term is overly broad, undefined, in conflict with California Labor Code section 139.32. The referral prohibitions of Labor Code section 139.3 specifically do not apply to any service for a specific patient that is performed within, or goods that are supplied by, a physician's office, or the office of a group practice, pursuant to Labor Code section 139.31(e). This establishes the legal basis on which physician referral for the tertiary program facility is allowed. Those services can be fully contained within the group medical practice. The proposed overly broad and undefined phrase "conflict of interest" on Page 802 stand in complete conflict with the statutes mentioned.		does not conflict with California Labor Codes section 139.3, 139.31(e), and 139.32 that govern the issue of conflicts of interests and physician referrals. The sentence found on page 802 is merely pointing out factors a physician should consider when referring a patient to a tertiary pain program. In fact, page 802 acknowledges that a patient can be referred to a tertiary pain program in the same facility with the phrase, "It is important to assess whether the patient has failed prior rehabilitation *within the same facility*…[emphasis added]	
9792.24.2	Commenter is a pain physician and anesthesiologist and has been in academics at UCSF for the past 5 years and joined Mt. Tam Orthopedics and Marin General Hospital on September 6, 2017. Neurostimulation has been an important component to the care of his patients. He studied at the University of	Ramana Naidu, MD Assistant Professor and Director UCSF Pain Committee September 6, 2017 Written Comment	Disagree: It is not clear if ACOEM reviewed the study cited by commenter but he is encouraged to submit this study to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp	None.

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	Washington. He is fully aware of what the state of Washington did based on the Judith A. Turner study from 2010. The study was important but had its limitations and left a number of questions. Did those patients want to return to work in the first place? How long was it from time of insult to implant? Furthermore, the technology has advanced since 2010.		ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of evidence from any source. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused update to the ACOEM guidelines.	
	The DWC and pain physicians are on the same side. We both want to provide therapies that actually get patients off opioids and back to work, living functional and prosperous lives. I welcome a conditional approval of SCS if X conditions are met. In fact, I would be as bold as to encourage patients to pay a small fee for commencing a trial. Paying into a therapy should force them to evaluate if they want to go through with it. It would be outlandish to remove this therapy altogether when		Agree in part; Disagree in part: Agree: The DWC and pain physicians both want therapies that actually get patients off opioids and back to work, living functional prosperous lives. Disagree: SCS is recommended for short-to-intermediate-term relief for highly select CRPS patients. This therapy is not being removed altogether. ACOEM has evaluated the Senza RCT	None.

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	we have the SENZA-RCT and ACCURATE Trials demonstrating better outcomes than we see with any medication or with surgery.		and does not give it a high rating because 50% of baseline outcomes measures (e.g. Oswestry Disability Index scores) were not provided and there was no placebo group. Data suggests HF modestly superior, but opioid use only 19% lower with HF and ODI improved 16.5U. However, it is not clear if ACOEM has reviewed the ACCURATE trials cited by commenter. He is encouraged to submit this study to ACOEM through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinp ACOEM conducts comprehensive updates to all of its guidelines every 3 to 5 years. However, ACOEM accepts submissions of evidence from any source. All literature is reviewed following the same processes (i.e., quality scoring, critiquing, and critical appraisal) for the	

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			development of evidence-based guidance. If there are major changes in literature, it may necessitate a focused update to the ACOEM guidelines.	
	There are many harms of opioids. Commenter will focus on two of them. First, driving or operating heavy machinery while on opioids risks public safety. Second, opioids make people more sensitive to pain. This is called opioids-induced hyperalgesia. Commenter uses neurostimulation in the right patient, as a method to get patients off opioids.		Agree: There are many harms of opioids including the two that commenter focused on. As stated above, SCS is recommended for short-to-intermediate-term relief for highly select CRPS patients and is a method to get patients off opioids.	None.
	Commenter concludes by stating that he welcomes reasonable conditions if the DWC feels people have not used these devices appropriately. However, do not punish hundreds of patients who could benefit from this therapy. It would be inexcusable to withdraw this therapy especially at a time when the technology is evolving at a rapid pace and the future looks bright.		Disagree: Spinal Cord Stimulator implantation is recommended for short-to intermediate-term relief for highly select CRPS patients and for those patients they should be informed of this treatment option. They should also understand that this intervention has no quality evidence of greater than 3-year benefit during which time	None.

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			there is unequivocal patient commitment. Otherwise, this modality is not recommended for other injuries or conditions because there are few quality studies evaluating SCS none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or sham procedure. SCS are invasive with reported serious complications, costly, and have a significant revision rate.	
9792.24.3	Currently, the postsurgical treatment guidelines apply to visits during the postsurgical physical medicine period only and to surgeries as defined in these guidelines. At the conclusion of the postsurgical physical medicine period, treatment reverts back to the applicable 24-visit limitation for chiropractic, occupational and physical therapy pursuant to Labor Code section 4604.5(d)(1) unless the patient sustains an exacerbation after treatment has been discontinued and its determined that more visits are medically necessary within the postsurgical physical medicine period. The proposed MTUS	Richard Katz, PT, DPT California Physical Therapy Association September 6, 2017 Written Comment	Agree in part; Disagree in part: Agree: The proposed regulatory change to section 9792.24.3, Postsurgical Treatment Guidelines, deletes the provision that explains "the postsurgical treatment guidelines apply to visits during the postsurgical physical medicine period only and to surgeries as defined in these guidelines. At the conclusion of the postsurgical period physical medicine period, treatment reverts back to the applicable 24-visit	The following change is made: **§ 9792.24.3. Post<u>operative</u> ~~surgical~~ ~~Treatment~~ <u>Rehabilitation</u> Guidelines.** Guidance for post~~surgical~~ <u>operative</u> <u>rehabilitation</u> treatment and evaluation are contained in the

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	postsurgical treatment guidelines for every clinical topics guideline specifies frequency and duration for postoperative rehabilitation. Such recommendations could potentially restrict a referring physician's ability to extend treatment beyond the 24-visit limitation thus creating barriers to medically necessary care. We recommend that the Division allow an exacerbation of an initial injury or impairment to exceed the 24-visit limit as described in the current postsurgical treatment guidelines.		limitation" for chiropractic, occupational therapy, and physical therapy pursuant to Labor Code section 4604(c)(1). The DWC accepts commenter's suggestion and revises section 9792.24.3 by reinserting a provision similar to the one quoted above. Disagree: Rather than using the language allowing an exacerbation of an initial injury to exceed the 24-visit limit, the DWC will clarify that treatment in accordance with post-operative rehabilitation recommendations will NOT count against the 24-visit limitation for chiropractic, occupational therapy, and physical therapy pursuant to Labor Code section 4604.5(c)(1).	Clinical Topics guidelines, and/or Chronic Pain Guideline, and/or Opioid Guideline. The post-operative rehabilitation treatment recommendations apply to visits during the post-operative period only and to surgeries as defined in those guidelines. At the conclusion of the post-operative period, treatment reverts back to the applicable 24-visit limitation for chiropractic, occupational therapy, and physical therapy pursuant to Labor Code section 4604.5(c)(1).
9792.23.5	National industry standards of practice for low back disorders far exceed one to two visits. Rather than	Richard Katz, PT, DPT California Physical	Disagree: The questionnaires and/or tools noted are referenced and discussed	None.

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	recommending a specific number of treatment visits, evidence-based guidelines recommend the use of validated self-report questionnaires to monitor a patient's level of disability and necessity of treatment. In addition, these guidelines identify the various diagnoses that fall under "low back disorders", further emphasizing the inherent problem with recommending one to two therapy visits for all patients with low back conditions (Delitto, 2012) The clinical course of low back pain can be described as acute, subacute, recurrent, or chronic. Given the high prevalence of recurrent and chronic low back pain and the associated costs, clinicians should place high priority on interventions that prevent (1) recurrences and (2) the transition to chronic low back pain. Clinician should use validated self-report questionnaires, such as the Oswestry Disability Index and the Roland-Morris Disability Questionnaire. These tools are useful for identifying a patient's baseline statue relative to pain, function, and disability and for monitoring a change in a patient's status throughout the	Therapy Association September 6, 2017 Written Comment	within the Low Back Disorders Guideline and the commenter is referred to there. If the commenter feels relevant information has not been considered by ACOEM, or that ACOEM has made an error in its evaluation of the evidence, then the commenter is encouraged to submit information to ACOEM for consideration. Anyone may submit input on proposed guidelines on the ACOEM website at the following URL: https://acoem.formstack.com/forms/stakeholderpatientinp	

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	course of treatment.			
9792.23.5	Under California's Business and Professions Code § 2630, "It is unlawful for any person or persons to practice, or offer to practice, physical therapy in this state for compensation received or expected, or to hold himself or herself out as a physical therapist, unless at the time of so doing the person holds a valid, unexpired, and unrevoked physical therapist license." Physical therapists and physical therapist assistants solely reserve the right to perform physical therapy interventions in the state of California. We recommend that the Physical Therapy or Occupational Therapy Definition, "These Guideline are not meant to restrict physical therapy to only being performed by physical therapists" be revised to reflects its true intent which is to allow physical modalities and rehabilitative procedures to be performed by appropriate licensed clinicians.	Richard Katz, PT, DPT California Physical Therapy Association September 6, 2017 Written Comment	Disagree. The ACOEM guidelines is published for a national audience. The definition referenced is provided within the context of a guideline that is not specific to the State of California. Further, this definition notes "Jurisdictions may differ on the qualification for licensure to perform these interventions." Thus, California Business and Professions Code § 2630 is the governing statute which allows physical modalities and rehabilitative procedures to be performed by appropriate licensed clinicians.	None.