

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
General Comment	<p>Commenter states that the community needs help in order to satisfy the incredibly difficult qualification process MAXIMUS has in place in order to approve medical care. Commenter opines that a 90% denial rate is absurd. Commenter states that MAXIMUS wants perfection in the PTP request for treatment and the slightest variance from MTUS will be used to deny care. Commenter states that medicine does not work like that. Commenter opines that if the treatment is helping the patient - even if it is not spot on with <u>every</u> one of the MTUS criteria – that it should be approved.</p> <p>Commenter states that he has seen PR-2's describing the benefits of proposed treatment which MAXIMUS summarily denies. Many times MAXIMUS will say there is no functional improvement years after the patient has reached MMI status. Commenter notes that the MTUS Guidelines must say that <u>substantial compliance</u> with the Guides is enough to get the care authorized. That if the patient has reached MMI status - the</p>	<p>John Don August 18, 2014 Written Comment</p>	<p>Reject: Labor Code section 5307.27 mandates the administrative director adopt a medical treatment utilization schedule that is evidence based. Moreover, Labor Code section 4604.5 states the MTUS shall be presumptively correct on the issue of extent and scope of medical treatment and that the MTUS' presumption is rebuttable by a preponderance of medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of his or her injury. The statutes require an evidence-based system. If a treating physician requests treatment outside of the MTUS, then he or she will need to support the reasonableness and necessity of the treatment request with medical evidence. Moreover, employers and their representative, at their discretion, may approve</p>	<p>None.</p>

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	<p>care cannot be denied sue to lack of functional improvement.</p> <p>Commenter opines that California workers deserve better than what they are getting now from MAXIMUS. Commenter opines that MAXIMUS was told that the PD increases was to be evened out with cost savings from IMR and thus they are bent on denying anything and everything that comes their way. MAXIMUS is making political decisions in denying treatment vs. legitimate medical decisions on what is in the patient's best interest.</p> <p>Commenter states that it is clear that a patient being taken off meds should be sent to detox. Commenter opines that MAXIMUS just doesn't seem to care about the health of the worker; they want their \$8 million a month and continue to enjoy lack of accountability. Commenter states that this is just not right.</p>		<p>medical treatment beyond what is covered by the MTUS or supported by the best available evidence.</p> <p>Reject: Goes beyond the scope of these proposed regulations. Currently, MAXIMUS is mandated to apply the MTUS.</p> <p>Reject: Goes beyond the scope of these proposed regulations. Currently, MAXIMUS is mandated to apply the MTUS.</p>	<p>None.</p> <p>None.</p>
9792.21	Commenter opines that there is some improvement in the style over substance format in the division's latest attempt to formulate a treatment	Charles G. Davis, DC August 28, 2014 Written Comment	Accept in part. Reject in part. Accept: Agree there is improvement in this version. Reject: Disagree that is merely	None.

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	<p>utilization schedule.</p> <p>Commenter notes that the Institute of Medicine (IOM) defines clinical practice guidelines as “Systematically developed statements to assist practitioners’ and patient decisions about appropriate health care for specific clinical circumstances”. Guidelines are also known as “parameters, practice protocols, practice standards, review criteria and preferred practice patterns” <i>Field M and Lohr K. Clinical practice guidelines: Directions for a new program. Institute of Medicine. Washington, D.C. National Academy Press; 1990.</i></p> <p>Medicare utilization review (UR) protocols, which were statutorily required to be based upon “Professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice.” <i>(Public Law 92-603, Section 249f, 42 United States Code, Section 1301).</i></p> <p>Commenter states that in 2011 the IOM defined clinical practice</p>		<p>an improvement in style but also in substance as a result of the comments received during the 45-day comment period.</p>	

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	<p>guidelines as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." Trustworthy guidelines should be based on a systematic evidence review, developed by panel of multidisciplinary experts, provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of the recommendations. Adverse reactions and alterative treatment must be mentioned.</p> <p>Commenter states that five questions must be answered in order to successfully apply information to an individual patient.</p> <ol style="list-style-type: none"> <li>1. Are the patients in these trials sufficiently similar to mine?</li> <li>2. Do the outcomes make clinical sense to me?</li> <li>3. Is the magnitude of benefit likely to be worthwhile for my patient?</li> <li>4. What are the adverse effects?</li> </ol>		<p>Accept in part. Reject in part. Accept: Agree, in principal with the quotations and citations provided by commenter from the Institute of Medicine. Reject: Disagree that the five questions are all inclusive. These factors are already incorporated into our proposed regulations in section 9792.25,</p>	<p>None.</p>

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	<p>5. Does the treatment fit in with my patient's values and beliefs? Williams HC. Applying trial evidence back to the patient. Arch Dermatol. 2003 Sep;139(9):1195-200.</p> <p>Commenter notes adverse reactions:</p> <p>Commenter opines that he is still amazed at the use of certain medications.</p> <p>About 1 to 2% of NSAID users experienced a serious gastrointestinal (GI) complication during treatment. Sostres C, Gargallo CJ, Lanas A. Nonsteroidal anti-inflammatory drugs and upper and lower gastrointestinal mucosal damage. Arthritis Res Ther. 2013;15 Suppl 3:S3.</p> <p>A total of 16,500 patients with rheumatoid arthritis or osteoarthritis die in a year from the gastrointestinal toxic effects of NSAIDs. Wolfe MM, Lichtenstein DR, Singh G. Gastrointestinal toxicity of nonsteroidal antiinflammatory drugs. N Engl J Med. 1999 Jun 17;340(24):1888-99.</p>		<p>but is missing important issues such as how bias factors into the equation.</p> <p>Reject: Goes beyond the scope of this rulemaking. Comments pertain to our upcoming Opioids Guideline and Chronic Pain rulemaking.</p>	None.

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	<p>The potential impact of these adverse events is highlighted by data from Spain, which show that the mortality rate associated with NSAID or aspirin is ≈5.6%, equivalent to 15.3 deaths per 100 000 users.</p> <p><i>Lanas A, Perez-Aisa MA, Feu F et al. A nationwide study of mortality associated with hospital admission due to severe gastrointestinal events and those associated with nonsteroidal anti-inflammatory drug use. Am J Gastroenterol 2005;100:1685-93.</i></p> <p>Symptomatic ulcers and potentially life-threatening complications have been found in up to 4% of patients per year. To put this risk into perspective, data from the USA in 2006 indicate that the risks of dying as a result of a car accident or firearm injury are approximately 15 and 10 per 100 000, respectively. NSAID-related lower GI complications are becoming more common and can have a significant impact on the patient.</p> <p><i>Lanas A. A review of the gastrointestinal safety data—a</i></p>			

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	<p><i>gastroenterologist's perspective. Rheumatology (Oxford). 2010 May;49 Suppl 2:ii3-10.</i></p> <p>Commenter notes alterative treatment:</p> <p>Manual therapy is limited but using medication to cause injury is appropriate.</p> <p>Chiropractic services proved to be better than physical therapist or physician services.</p> <p><i>Cifuentes M, Willetts J, Wasiak R. Health maintenance care in work-related low back pain and its association with disability recurrence. J Occup Environ Med. 2011 Apr;53(4):396-404.</i></p> <p><i>Descarreaux M, Blouin JS, Drolet M, Papadimitriou S, Teasdale N. Efficacy of preventive spinal manipulation for chronic low-back pain and related disabilities: a preliminary study. J Manipulative Physiol Ther. 2004 Oct;27(8):509-14.</i></p> <p><i>Shaw L, Descarreaux M, Bryans R, Duranleau M, Marcoux H, Potter B, Ruegg R, Watkin R, White E. A systematic review of chiropractic</i></p>			

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	<p><i>management of adults with Whiplash-Associated Disorders: recommendations for advancing evidence-based practice and research. Work. 2010;35(3):369-94.</i></p> <p>There is a wide variation in human response and tolerance data. This is due to the large biological variations among humans and to the effects of aging. Average values are useful in design but cannot be applied to individuals.</p> <p><i>King AI. Fundamentals of impact biomechanics: Part I--Biomechanics of the head, neck, and thorax. Annu Rev Biomed Eng. 2000;2:55-81.</i></p> <p>One of the variations is Catechol-O-methyltransferase as it relates to pain. Commenter questions how often the guidelines mention this.</p> <p><i>Gruber HE, Sha W, Brouwer CR, Steuerwald N, Hoelscher GL, Hanley EN Jr. A novel catechol-O-methyltransferase variant associated with human disc degeneration. Int J Med Sci. 2014 May 15;11(7):748-53.</i></p>			

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	<p><i>Omair A, Lie BA, Reikeras O, Holden M, Brox JI. Genetic contribution of catechol-O-methyltransferase variants in treatment outcome of low back pain: a prospective genetic association study. BMC Musculoskelet Disord. 2012 May 21;13:76.</i></p> <p><i>Jacobsen LM, Schistad EI, Storesund A, Pedersen LM, Rygh LJ, Røe C, Gjerstad J. The COMT rs4680 Met allele contributes to long-lasting low back pain, sciatica and disability after lumbar disc herniation. Eur J Pain. 2012 Aug;16(7):1064-9.</i></p> <p><i>Rut M, Machoy-Mokrzyńska A, Ręclawowicz D, Słoniewski P, Kurzawski M, Drożdżik M, Safranow K, Morawska M, Bialecka M. Influence of variation in the catechol-O-methyltransferase gene on the clinical outcome after lumbar spine surgery for one-level symptomatic disc disease: a report on 176 cases. Acta Neurochir (Wien). 2014 Feb;156(2):245-52.</i></p> <p><i>Dai F, Belfer I, Schwartz CE, Banco R, Martha JF, Tighioughart H,</i></p>			

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	<p><i>Tromanhauser SG, Jenis LG, Kim DH. Association of catechol-O-methyltransferase genetic variants with outcome in patients undergoing surgical treatment for lumbar degenerative disc disease. Spine J. 2010 Nov;10(11):949-57.</i></p> <p><i>Martínez-Jauand M, Sitges C, Rodríguez V, Picornell A, Ramon M, Buskila D, Montoya P. Pain sensitivity in fibromyalgia is associated with catechol-O-methyltransferase (COMT) gene. Eur J Pain. 2013 Jan;17(1):16-27.</i></p> <p>Commenter opines that the guidelines are incomplete and biased.</p>		<p>Reject: Disagree. This rulemaking pertains to the MTUS and how to evaluate medical evidence. His comments pertain to our upcoming Opioids Guideline and Chronic Pain rulemaking.</p>	<p>None.</p>
9792.21	<p>Commenter provides an example of a woman suffering from breast cancer. Example. Commenter questions what would happen if a woman that you loved needed a mammogram and subsequent treatment, (i.e., excision of</p>	<p>Dr. Lauren Papa August 28, 2014 Written Comment</p>	<p>Reject: Although DWC is sympathetic to the person described by commenter, Labor Code section 5307.27 mandates the administrative director adopt a medical</p>	<p>None.</p>

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	<p>the tumor, radiation and/or Chemo-therapy), but her doctor's hands were tied by medical guidelines that do not apply, resulting in the carrier's denial of treatment.</p> <p>Commenter gives another example of a woman desperately needing to undergo a mammogram, as recommended by her doctor, to properly diagnose the lump found in her breast.</p> <p>Hypothetically her doctor requests authorization from her PPO insurance carrier, but the carrier runs the information through the UR department. The UR reviewing physician looks at the doctor's documentation, of "lump left upper quadrant, right breast. Lesion does not move". The UR, physician reviewer, who has never examined the patient, denies the mammogram stating that her "doctor's documentation is not sufficient enough, per "MTUS Guidelines".</p> <p>Commenter states that because the</p>		<p>treatment utilization schedule that is evidence based. Moreover, Labor Code section 4604.5 states the MTUS shall be presumptively correct on the issue of extent and scope of medical treatment and that the MTUS' presumption is rebuttable by a preponderance of medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of his or her injury. The statutes require an evidence-based system. If a treating physician requests treatment outside of the MTUS, then he or she will need to support the reasonableness and necessity of the treatment request with medical evidence. Moreover, employers and their representative, at their discretion, may approve medical treatment beyond what is covered by the MTUS or supported by the best available evidence.</p>	

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	<p>patient's insurance carrier will not pay for this test, and neither you, your family or this woman you love has the funds to pay for a mammogram, you must now rely on IMR, i.e. Maximus to make the medical decision to certify or non-certify this mammogram.</p> <p>Commenter states that Maximus is overwhelmed and completely disorganized. Maximus takes 8 months to render a decision. The "<i>anonymous physician</i>" at Maximus decides to non-certify this mammogram. (Commenter notes that the reviewing physician at Maximus is anonymous so how can it be determined that the reviewer is actually a licensed physician?).</p> <p>Commenter notes that at this point it's been 8 months and it's too late, because the IMR reviewer (Maximus) took so much time to non-certify this much needed diagnostic study, the immovable lump in the left upper quadrant in the right breast metastasized. The woman you love, who was forced to rely on the PPO carrier's UR department and Maximus</p>		<p>Reject: Goes beyond the scope of this rulemaking.</p> <p>Reject: See previous response above.</p>	<p>None.</p> <p>None.</p>

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	<p>(IMR) for her to procure this much needed diagnostic study, never received a proper diagnosis or treatment and now has metastatic cancer and 6 months to live.</p> <p>Commenter states that this is what injured workers go through when their industrial injuries require necessary diagnostic studies and subsequently, appropriate medical treatment. Commenter states that it is fortunate that the majority of industrial injuries are mostly orthopaedic and neurological; not life threatening. Commenter states that denials for necessary medical diagnostic studies and treatment are being distributed far too often due to non-certification from the carrier's UR departments and subsequently IMR or Maximus.</p> <p>Commenter opines that if these proposed MTUS changes become even more stringent, resulting in more and more injured workers being denied treatment necessary for them to recuperate from their industrial injuries and return to work, we will watch as more injured workers</p>		<p>Reject: See previous response above.</p> <p>Reject: These proposed regulations do not change the standard for determining medical necessity. The MTUS is still the standard pursuant to Labor Code 4600 and if treatment is requested that attempts to rebut the MTUS'</p>	<p>None.</p> <p>None.</p>

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	<p>become permanently disabled and live off of social security/disability benefits.</p> <p>Commenter would like to know if the Division really believes that injured workers would prefer to stay off of work, with increasing symptoms resulting in decreasing health, feeling useless instead of being productive. Commenter invites the Division to sit in her waiting room and listen to the horror stories from my patients themselves.</p> <p>Commenter requests that the Division refrain from implementing the proposed MTUS changes. Commenter opines that they are senseless and will result in more disabled workers.</p> <p>Commenter states that she is a workers comp doctor who sees otherwise productive people become increasingly symptomatic, unhealthy and depressed when all they needed is appropriate medical treatment to cure and relieve their industrial injuries.</p>		<p>presumption of correctness or if the MTUS is silent on a particular medical condition or injury, then medical care will still be dictated by the best available evidence. These proposed regulations attempt to clarify the transparent, systematic methodology to evaluate medical evidence.</p> <p>Reject: Disagree. The proposed regulations merely clarify the process that is already in place.</p> <p>Reject: Disagree. The proposed regulations provide clarity so members of the public have a clear understanding of what is and how to determine appropriate medical treatment.</p>	<p>None.</p> <p>None.</p>
9792.21(g)(1)-(3)	This subsection sets forth guidelines	Peggy Thill	Accept in part. Reject in part	Section

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	<p>for applying a medical literature search sequence to find the best available medical evidence. “Search the most current version of ACOEM or ODG to find a recommendation applicable to the injured worker’s specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. <b>If the current version of ACOEM or ODG is more than five years old</b>, or if no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then (2)...then (3)...”</p> <p>Commenter states that a five year time frame may be interpreted as a limitation or an expiration date on the usage of said guidelines. Evidence in a medical treatment guideline older than five years may still be the best available medical evidence and should be used in making treatment decisions.</p>	<p>Claims Operations Manager</p> <p>Dinesh Govindarao, MD, MPH Chief Medical Officer State Compensation Insurance Fund August 28, 2014 Written Comment</p>	<p>Accept: Section 9792.21(g)(1)-(3) has been moved for organizational and clarification purposes to section new section 9792.21.1. In addition, the reference to “five years old” has been deleted.</p> <p>Reject: The definition for “Medical Treatment Guidelines” set forth in section 9792.20(g) will continue to contain the phrase “reviewed and updated within the last five years” because it is important that the most current versions of the guidelines are relied upon when a treatment request is made that is based on recommendations found outside of the MTUS or when MEEAC reviews guidelines to update the MTUS. The five year time period is necessary to give the phrase “most current version” context. Although as commenter succinctly states, “Evidence in a medical treatment guideline older than five years may still</p>	<p>9792.21(g)(1) - (3) has been moved for organizational and clarification purposes to new section 9792.21.1. and the reference to “five years old” has been deleted.</p>

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	<p>Commenter notes that this five year time frame was removed or revised in other modified sections of the text of proposed regulations. For example, the five year timeframe was deleted from the medical literature search sequence in <b>9792.21(g)(3)</b>. The reference to a five year time frame in the definition of “medical treatment guidelines” has also been updated in 9792.20(g). <u>Commenter opines that this should be consistent throughout the MTUS regulations.</u></p> <p>To promote consistency in these regulations and to eliminate disputes over whether or not guidelines are valid or outdated, commenter recommends removal of the five year limitations such as in 9792.21(g)(1) as follows: <u>“Search the most current version of ACOEM or ODG to find a recommendation applicable to the injured worker’s specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. If the current version of</u></p>		<p>be the best available medical evidence” because it may contain seminal scientific studies that are still the basis of unchanged recommendations. Guidelines that have not been updated or reviewed within the last five years may not be up-to-date, but it may still contain recommendations that are still valid and were merely carried over to updated versions of the guideline.</p>	

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	<p><u>ACOEM or ODG is more than five years old, or if</u> If no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then (2)...”</p>			
9792.25.1(a)(1)	<p>Commenter states that when making recommendations to approve or deny medical treatment requests, it is unreasonable to expect that physicians will find a sufficient number of equivalent studies on <b>specific medical treatment</b> to use as evidence. There are insufficient numbers of studies on injured workers in specific populations and settings with respect to most requested treatment.</p> <p>Commenter states that there are strong studies evaluating non-workers’ compensation patients, populations, interventions or settings. Commenter opines that it is not appropriate to invalidate a good treatment related study simply by saying it was not done in a workers’ compensation setting. Such studies can reasonably provide good evidence and be useful in</p>	<p>Peggy Thill Claims Operations Manager</p> <p>Dinesh Govindarao, MD, MPH Chief Medical Officer State Compensation Insurance Fund August 28, 2014 Written Comment</p>	<p>Reject in part. Accept in part. Reject: Commenter’s suggested language will not be adopted because applicability is a necessary element when analyzing the quality of evidence.</p> <p>Accept: Commenter’s concerns prompted changes to the organizational structure and language of this section to clarify that applicability is a necessary element when analyzing the quality of evidence but the phrase “applicable to the specific medical treatment or diagnostic test” is deleted and the focus will be whether the medical evidence used to support the recommendations are similar to the worker and</p>	<p>The organizational structure of section 9792.25.1 is amended to clarify the process that needs to be followed when applying the MTUS Methodology for Evaluating Medical Evidence. Section 9792.25.1(a)(2) has been re-numbered to replace 9792.25.1(a)(1) and states, “...the reviewing physician shall evaluate the quality of evidence by determining if the studies used to support the recommendations are</p>

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	<p>making medical treatment decisions.</p> <p>Commenter recommends eliminating the requirement of using equivalent studies as the source to approve or deny a medical treatment request. To promote the use of the best available medical evidence in making appropriate medical treatment recommendations, commenter suggests recommends the following revised language:</p> <p>“Determine if the recommendation is applicable to the specific medical treatment or diagnostic test requested by the injured worker. Applicability refers to the extent to which the individual patients, workers, subjects, interventions, and outcome measures are similar to the injured worker and his or her specific medical condition or diagnostic service request. If a recommendation evaluates a different population, setting, or intervention <u>the reasoning must be documented. The best available medical evidence must be used</u>”. <del>it should not be used as the source to approve or deny a medical treatment request. The</del></p>		his or her medical condition or injury.	<p>applicable to the injured worker and his or her medical condition or injury. Applicability refers to the extent to which the individual patients, subjects, settings, interventions, and outcome measures of studies used to support a recommendation are similar to the worker and his or her medical condition or injury. A recommendation supported by inapplicable studies should not be used as the source to support, deny, delay or modify an RFA. Reviewing physicians shall provide an explanation of their rationale in the</p>

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	<p><del>recommendation that evaluates a population, setting or intervention most similar to the injured worker should be used and the reasoning must be documented.</del></p>			<p>Utilization Review or Independent Medical Review decision if they conclude a recommendation is supported by studies inapplicable to the worker and his or her medical condition or injury.”</p>
<p>General comment</p>	<p>Commenter has the following concerns regarding the propose regulations:</p> <ol style="list-style-type: none"> <li>1. The proposed guidelines will require continued updating by MEEAC and rather than place those demands on our state resources, we suggest the DWC adopt a nationally recognized guideline, such as ODG, which is familiar to all physicians, readily available to all physicians and does not result in duplication or confusion. Adopting the current ODG guidelines ensures quality of care to injured workers and provides physicians a guideline that</li> </ol>	<p>Jason Schmelzer California Coalition on Workers' Compensation</p> <p>Jeremy Merz California Chamber of Commerce</p> <p>Faith Conley California State Association of Counties August 29, 2014 Written Comment</p>	<p>Reject: Labor Code section 5307.27 mandates the administrative director to adopt the MTUS. The MTUS has been constructed using a patch-work approach. Adopting and incorporating chapters from nationally recognized guidelines including ACOEM and ODG. The administrative director cannot delegate her regulatory power to ODG as commenters appear to suggest.</p>	<p>None.</p>

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	<p>they are readily familiar with in determining if proposed treatments are appropriate for the injured worker. It will reduce the frictional disputes arising from the misapplication of the current MTUS, which is overly complicated. Further, ODG, if adopted, are guidelines that are already annually reviewed and updated and that pass through the “Agree II” vetting process, developed through highly qualified medical experts with a history of the basis of the existing version. The background and qualifications of the experts developing ODG &amp; ACOEM are widely recognized by their peers and the payer industry as the best. Adoption of nationally recognized and accepted guideline would eliminate the duplication required by the proposed MTUS regulations and streamline the provision of appropriate treatment to our injured employees, enabling a</p>			

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	<p>quicker return to work.</p> <p>2. MTUS regulations as proposed do not meet the requirements of LC 4604.5 and LC 5307.27 in their totality. While portions of the proposed MTUS regulations are in part adoption of ODG, ACOEM and other sources they are not as a whole evidence and scientifically based, <b>nationally recognized, and peer reviewed.</b></p> <p>3. The proposed MTUS regulations, present a significant likelihood of potential penalties and disputes if a specific detail of a review is not performed properly, which will ultimately lead to more litigation. The current MTUS imposes an “Agree II” process, which was already applied by the creators of the nationally recognized guidelines (ODG &amp; ACOEM) thus this requirement upon UR and IMR physicians is duplicative and unnecessary.</p>		<p>Reject: Disagree. The guidelines and studies that are adopted and incorporated into the MTUS are “evidence and scientifically based, nationally recognized, and peer-reviewed.”</p> <p>Reject: A modified Agree II will only be applied by MEEAC and not by members of the public pursuant to section 9792.26(e). Currently, the process to be applied when there are competing recommendations is set forth in section 9792.25(c)(1) and is adopted from ACOEM. These proposed regulations set forth the MTUS Methodology for Evaluating Medical Evidence is more comprehensive because it allows for the evaluation of evidence that is not a randomized controlled trial and takes fewer steps to</p>	<p>None.</p> <p>None.</p>

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	<p>This is in complete contrast to the interests to reduce administrative burdens and efficiencies and to streamline the provision of benefits to our injured employees.</p> <p>4. The proposed MTUS refers to a hierarchy of evidence which includes evidence that falls outside of the statutory requirements of LC 4604.5 &amp; 5307.27, specifically “best available research evidence with clinical expertise and patient values.” This claimed evidence was already considered and evaluation by ODG and ACOEM as part of their guideline development during which they clearly explain why this claimed evidence was discounted as promotional evidence and not true scientific evidence. This hierarchy of evidence also fails the standards imposed by SCIF v WCAB (Sandhagen) 2008 73 CCC 981.</p>		<p>apply then the eleven (11) step process of our current regulations. This comports with the interest to reduce administrative burdens, and streamlines the provision of benefits to injured workers to make the process more efficient.</p> <p>Reject: The MTUS Methodology for Evaluating Medical Evidence is a transparent, systematic process that shall be applied by a reviewing physician if there are competing recommendations. Treating physicians are not required to formally apply the Methodology for Evaluating Medical Evidence but applying it will be the only way to determine if he or she can properly rebut the MTUS’ presumption of correctness. A methodology must be in place to evaluate evidence if there are competing recommendations cited. This</p>	None.

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	<p>5. Under LC 5307.2.7 the Division has the authority to list the guidelines which would benefit the treatment request and administrative process.</p> <p>Commenter notes that the proposed MTUS includes a requirement on physicians to perform a literature search and to search through the overly complicated MTUS in order to support the recommended treatment. Commenter opines that while nationally recognized guidelines, such as ODG, are more readily available and easier to navigate, requiring a treating physician to search for literature supporting their recommendations, takes the physician away from their true purpose, treating our injured workers. Commenter states that the requirements to review guidelines supporting treatment recommendations should fall squarely on the utilization review and IMR physicians.</p>		<p>process already exists and is set forth in section 9792.25(c)(1). Merely citing ODG or ACOEM may not be the best available evidence. Although both ODG and ACOEM are well respected, if there is a new study that contains a recommendation supported by better evidence than the ODG or ACOEM recommendations then that recommendations should guide medical care.</p> <p>Reject: The medical evidence search sequence is set forth in these proposed regulations in the interest of consistency and efficiency. No formal application of the MTUS Methodology for Evaluating Medical Evidence is required when applying the medical evidence search sequence. The reference to section 9792.25.1 in sections 9792.21.1(a)(2)(A), (B), and (C) is provided as instruction to the physician to choose the best available</p>	None.

<b>Medical Treatment Utilization Schedule</b>	<b>RULEMAKING COMMENTS 15 DAY COMMENT PERIOD</b>	<b>NAME OF PERSON/ AFFILIATION</b>	<b>RESPONSE</b>	<b>ACTION</b>
			evidence. The MTUS Methodology for Evaluating Medical Evidence will only be formally applied by reviewing physicians as set forth in section 9792.25.1 when competing recommendations are cited.	
9792.20(d)	<p>Commenter recommends a more stringent definition that does not allow for further limitation. Commenter recommends removing this proposed definition and adopting the most common definition of Evidence-Based Practice as defined by the Institute of Medicine, Evidence-Based Medicine. The Institute of Medicine defined EBM to mean that “to the greatest extent possible, the decisions that shape the health and health care of Americans—by patients, providers, payers, and policy makers alike—will be grounded on a reliable evidence base, will account appropriately for individual variation in patient needs, and will support the generation of new insights on clinical effectiveness” (IOM’s Roundtable on Evidence-Based Medicine, 2006). EBM is the</p>	<p>Jason Schmelzer California Coalition on Workers’ Compensation</p> <p>Jeremy Merz California Chamber of Commerce</p> <p>Faith Conley California State Association of Counties August 29, 2014 Written Comment</p>	Reject: Goes beyond the scope of the First 15-day comment period because no changes were made in the First 15-day comment period that was not already posted and reviewed during the 45-day comment period.	None.

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>framework for methodologically analyzing best evidence so that the care provided to each patient delivers the most value. The benefits of EBM will be to reduce discrepancies in care of patients and improve value of the healthcare delivered. (IOM, Evidence-Based Medicine, 2009.) Commenter likes this second definition as it considers not just decision making as it relates to the patient, but suggests a public health perspective and takes into account “payer” perspective.</p> <p>Alternatively, commenter recommends changing the proposed language to read as follows:</p> <p>(e) “Evidence-Based Medicine (EBM)” means a systematic approach to making clinical decisions which allows the integration of the best available research.</p>			
9792.20(g)	<p>Commenter is concerned about the five-year limitation. Commenter recommends removing “within the last five years.” Commenter notes that medical treatment guidelines are already defined in statute and this definition should point to the most</p>	<p>Jason Schmelzer California Coalition on Workers’ Compensation</p> <p>Jeremy Merz California Chamber</p>	<p>Reject: The MTUS remains valid even if it has not been updated in the last five years. Guidelines that have not been updated or reviewed within the last five years may not be up-to-date, but they are by no</p>	None.

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	<p>current version. Commenter opines that retaining the five-year limitation in regulations could lead to confusion and additional litigation and expense over whether or not MTUS remains valid since a self-imposed deadline has passed. Further, by reference to ACOEM 2nd Edition, in paragraph (b) of this section the regulations are referencing a Guideline that fails to meet its own standard.</p>	<p>of Commerce  Faith Conley California State Association of Counties August 29, 2014 Written Comment</p>	<p>means expired or invalid. The phrase that guidelines be “reviewed and updated within the last five years” will remain because it is important that the most current versions of the guidelines are relied upon when MEEAC reviews guidelines to update the MTUS or when a treatment request is made that is based on recommendations found outside of the MTUS. However, there may be seminal scientific studies that support recommendations in a medical guideline that have not been updated in the past 5 years or that may have carried over to updated versions of the medical guideline because it is still the best available medical evidence and the recommendations remain unchanged.</p>	
9792.20(h)	<p>Commenter recommends retaining the existing language as it complies with LC 4604.5 and LC 5307.27, as the proposed MTUS changes fail to comply with those statutes.</p>	<p>Jason Schmelzer California Coalition on Workers’ Compensation</p>	<p>Reject: To eliminate some guidelines that are questionably evidence-based, the phrase “or currently adopted for use by one or more</p>	None.

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	<p>“Nationally recognized” is applicable and appropriate if the most current version has been adopted for use by the United States federal government or a state government.</p>	<p>Jeremy Merz California Chamber of Commerce</p> <p>Faith Conley California State Association of Counties August 29, 2014 Written Comment</p>	<p>U.S. state governments or by the U.S. federal government” has been deleted.</p>	
9792.21(e)	<p>Commenter states that the DWC is redefining the premise of the hierarchy of evidence, previously noted in the regulations and that have been previously addressed by the various guidelines using the Agree II process in their development. Commenter is concerned that these changes alter the weight of evidence and may create the basis for legal challenge as to what is the appropriate evidence in determining the need for treatment. Commenter opines that when these legal challenges emerge, they will result in case law that will undo the intent of the legislature solely as the regulations fail to meet the statutory requirements. The regulations should apply medical standards. Commenter states that introducing legal standards</p>	<p>Jason Schmelzer California Coalition on Workers’ Compensation</p> <p>Jeremy Merz California Chamber of Commerce</p> <p>Faith Conley California State Association of Counties August 29, 2014 Written Comment</p>	<p>Reject: Disagree. The DWC has not redefined the premise of the hierarchy of evidence. Labor Code section 5307.27 mandates the administrative director adopt a medical treatment utilization schedule that is evidence based. Moreover, Labor Code section 4604.5 states the MTUS shall be presumptively correct on the issue of extent and scope of medical treatment and that the MTUS’ presumption is rebuttable by a preponderance of medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the</p>	None.

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	<p>in IMR is inappropriate and will result in for aforementioned litigation. Commenter recommends that the DWC reference 4610.5. The more prescriptive this regulation, the more chance for litigation as to whether we have applied this correctly. Commenter recommends that the proper application of the MTUS must remain with the UR/IMR, and not allow an opportunity for a legal attack on the hierarchy of evidence at the Appeals Board, caused by the addition of legal standards.</p> <p>Commenter also recommends striking “topical gap” as it is ambiguous.</p>		<p>effects of his or her injury. The statutes require an evidence-based system. If a treating physician requests treatment outside of the MTUS, then he or she will need to support the reasonableness and necessity of the treatment request with medical evidence. The transparent, systematic approach to evaluate medical evidence as set forth in these proposed regulations are intended for treating physicians, Utilization Review physicians and Independent Medical Review physicians and not the Appeals Board.</p> <p>Agree: Section 9792.21(e) is deleted and clarified with the addition of new sections.</p>	
9792.21	<p>Commenter notes that this language says the treating physician shall apply the medical research in their report. Commenter opines that requiring a</p>	<p>Jason Schmelzer California Coalition on Workers’ Compensation</p>	<p>Reject: The medical literature search is set forth in these proposed regulations in the interest of consistency and</p>	<p>None.</p>

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	<p>treating physician to take time away from the treatment of our injured workers to research the appropriateness of treatment if the complicated MTUS, is taking the physician away from their primary duties. Utilization Review and Independent Medical Review are in place, with the assets available to insure that the requested treatment is supported by the MTUS or other recognized guidelines meeting the statutory requirements of LC 4604.5 &amp; 5307.27. Commenter opines that applying national medical guidelines such as ODG, will greatly reduce likelihood of medical treatment disputes, given that ODG is more easily accessible, familiar to physicians, thereby reducing the likelihood of requests for unsupported medical treatment.</p>	<p>Jeremy Merz California Chamber of Commerce</p> <p>Faith Conley California State Association of Counties August 29, 2014 Written Comment</p>	<p>efficiency. No formal application of the MTUS Methodology for Evaluating Medical Evidence is required when applying the medical evidence search sequence. The reference to section 9792.25.1 in sections 9792.21.1(a)(2)(A), (B), and (C) is provided as instruction to the physician to choose the best available evidence. The MTUS Methodology for Evaluating Medical Evidence will only be formally applied by reviewing physicians as set forth in section 9792.25.1 when competing recommendations are cited.</p> <p>Reject: Merely citing ODG or ACOEM may not be the best available evidence. Although both ODG and ACOEM are well respected, if there is a new study that contains a recommendation supported by better evidence than the ODG or ACOEM recommendations then that recommendations</p>	<p>None.</p>

<b>Medical Treatment Utilization Schedule</b>	<b>RULEMAKING COMMENTS 15 DAY COMMENT PERIOD</b>	<b>NAME OF PERSON/ AFFILIATION</b>	<b>RESPONSE</b>	<b>ACTION</b>
			should guide medical care.	
9792.21(f)(3)	<p>Commenter states that if a physician submits any medical evidence, then that evidence would require IMR perform a search, deconstruct guidelines and determine the basis of the highest level of evidence according to 9792.25.1 (which is an overcomplicate 4-step algorithm). This will result in complicating the IMR reviewer process. Commenter recommends that this entire section be struck as it appears it will be create more problems rather than solutions. The entire section appears to deconstruct the various guidelines that have already been evaluated and accepted as EBM decisions. Commenter recommends applying LC 4610.5 language as the Labor Code section takes precedence over the rules, regulations and states the hierarchy of medical evidence.</p>	<p>Jason Schmelzer California Coalition on Workers' Compensation</p> <p>Jeremy Merz California Chamber of Commerce</p> <p>Faith Conley California State Association of Counties August 29, 2014 Written Comment</p>	<p>Reject: If a treating physician provides a citation to a guideline or study that contains a recommendation that is contrary to the recommendation the UR physician believes guides the injured worker's medical treatment, then a transparent, systematic process must be in place to evaluate the evidence supporting the competing recommendations. This requirement already exists and is currently set forth in section 9792.25(c)(1). These proposed regulations clarify this process and sets forth in detail the process that needs to be followed when there are competing recommendations. On top of the hierarchy pursuant to Labor Code section 4610.5 is the MTUS, which is precisely the subject of these proposed regulations.</p>	None.
9792.21(i) and (j)	<p>Commenter recommends that both sections (i) and (j) be deleted as this</p>	<p>Jason Schmelzer California Coalition</p>	<p>Reject: Section 9792.21(i) is deleted and replaced with the</p>	None.

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the regulations are extending beyond the UR requirements. If section (i) remains, commenter recommends changing the word “employer” to “Claims administrator” to alleviate any confusion.	<p>on Workers’ Compensation</p> <p>Jeremy Merz California Chamber of Commerce</p> <p>Faith Conley California State Association of Counties August 29, 2014 Written Comment</p>	<p>new section 9792.21.1(c) not because “the regulations are extending beyond the UR requirements” but rather to re-organize and clarify the process that must be followed by reviewing physicians if competing recommendations are cited.</p> <p>Accept in part: Clarification is made to section 9792.21(j) which has been re-numbered and re-lettered to section 9792.21.1(e) because the sections were re-organized for clarification purposes.</p>	Section 9792.21(j) is re-numbered and re-lettered to section 9792.21.1(e) and is revised to state, “Employers and their representatives.”
9792.25(a)(1)	Commenter notes that this section defines exactly what Agree II means and how it was intended to be used. Commenter opines that it was not intended for the purposes of UR or IMR. Guideline development takes months, if not years. To require use of this analysis by UR/IMR will result in: Complete failure of the system – severely slowing decision making process by UR and IMR physicians; Multiple legal challenges as to the analysis used by UR/IMR that based on the inclusion of this statement will	<p>Jason Schmelzer California Coalition on Workers’ Compensation</p> <p>Jeremy Merz California Chamber of Commerce</p> <p>Faith Conley California State Association of Counties August 29, 2014</p>	<p>Reject: This section provides a definition for the Appraisal of Guidelines for Research &amp; Evaluation II (AGREE II). These proposed regulations require a modified AGREE II to be applied by MEEAC when considering which guidelines to use when making recommendations regarding updates to the MTUS, see section 9792.26(e). These proposed regulations do not require UR or IMR reviewers</p>	None.

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	<p>result in the failure of the UR/IMR cost savings if not the entire process; subject the URO &amp; IMRO to significant penalties under the DWC audit process.</p> <p>Under 5307.27 mini NGC, can do a list of guidelines and cite the top tier guidelines, wherein if treatment is addressed, no further evaluation is required. As is, commenter opines that the regulations will do more harm than good, basically calling for reconstruction of the guidelines in making UR/IMR decisions.</p> <p>Commenter states that the language in this section is misapplied, as Agree II language is solely intended for the development of guidelines as cited by the Agree II developers. The regulations are requiring that IMR go through a guideline development analysis in making an IMR determination. Given that the Guideline analysis is already done by the entity creating the guideline, reference to that guideline should be sufficient.</p>	Written Comment	<p>to apply AGREE II.</p> <p>Reject: Labor Code section 5307.27 makes no reference to “mini NGC”. Commenter suggests that as long as a top tier guideline is cited then no further evaluation is required. This is incorrect because recommendations in top tier guidelines may also vary. A transparent, systematic process must be in place in order to evaluate the evidence used to support competing recommendations.</p> <p>Reject: See previous response.</p>	<p>None.</p> <p>None.</p>

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	<p>Commenter states that the problem with the algorithm is that the same article that the physician cites as supporting the treatment request are the articles that ODG and ACOEM have previously reviewed and vetted as evidence in making their determination as to what is appropriate Evidenced Based Medical Treatment. Commenters states that requiring the algorithm results in giving equal weight to evidence that the guideline developer had already determined was not appropriate evidence (e.g. Guidelines (ODG and ACOEM): often devalue studies provided solely by the manufacture of a product or creator of a treatment and look to the independent blinded or double-blinded studies to determine efficiency of a product or treatment before adopting same. If the sole evidence is that of the manufacturer, it has already been considered by the Guideline when they reach their determination that there is insufficient evidence to support the product or treatment and thus, it is not supported by EBM.) Commenter recommends that the definition of chronic pain be stricken</p>		<p>Reject: Although it is expected and we agree that top tier guidelines such as ODG and ACOEM have already gone through the vetting process, there may be occasions when a new, well-conducted study is published that has not yet been considered or vetted by the top tier guidelines. In addition, the proposed MTUS methodology for evaluating medical evidence takes into consideration the presence of bias.</p>	<p>None.</p>

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	and reference made to the EBM hierarchy “Agreed II” language.			
General Comment	<p>Commenter opines that this most recent proposed revision of the Medical Treatment Utilization Schedule (MTUS), while significantly improved from the initial proposal, still contains significant areas of concern.</p> <p>While the intent of the authors is appreciated, commenter states that the current attempt to create a regulatory process that drives the use of evidence-based medicine suffers from process and language that are predicted to produce very significant unintended consequences; and in some instances are at odds with the intent of the authors.</p> <p>Commenter opines that this enactment of the proposed MTUS will increase costs across the system, and that the application of a fundamentally distorted version of evidence-based medicine will result in poorer care for injured workers.</p> <p>Commenter states that while those</p>	Robert Ward Clinical Director CID Management August 29, 2014 Written Comment	Reject: Labor Code section 5307.27 mandates the administrative director adopt a medical treatment utilization schedule that is evidence based. Moreover, Labor Code section 4604.5 states the MTUS shall be presumptively correct on the issue of extent and scope of medical treatment and that the MTUS’ presumption is rebuttable by a preponderance of medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of his or her injury. The statutes require an evidence-based system. If a treating physician requests treatment outside of the MTUS, then he or she will need to support the reasonableness and necessity of the treatment request with medical evidence. Moreover, employers and their	None.

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>proposing the current draft may have a clear understanding in their minds of what they meant and intended, he opines that it is quite likely that the actual implementation will be based on a very literal interpretation by legal professionals. Commenter states that even if the DWC clearly articulates its intent to users of the MTUS elsewhere, the WCAB must and will ignore such assertions and rely instead on the specific language provided in the regulations. It does not appear that the authors of the proposed MTUS have adequately considered the process implications in this light.</p>		<p>representative, at their discretion, may approve medical treatment beyond what is covered by the MTUS or supported by the best available evidence.  Reject in part. Accept in part:  Reject: DWC is acutely aware of the process implications and the importance of making our intent clear.  Accept: Clarification will be made to further clarify the role of the MTUS, the medical evidence search sequence, and the MTUS Methodology for Evaluating Medical Evidence.</p>	<p>Section 9792.21 is re-organized to separate section 9792.21 regarding the role of the MTUS, from new section 9792.21.1 the medical evidence search sequence. Clarifying changes have been made to section 9792.25 the MTUS Methodology for Evaluating Medical Evidence to clearly point out when the evaluation process can end.</p>
<p>9792.21(f)(2)  9792.21(f)(3)  9792.21(g)(1)  9792.25.1</p>	<p>Commenter states that the first unintended consequence of these proposed regulations is as follows:   In any instance where a treating physician cites the MTUS, any guideline, and/or any per-reviewed</p>	<p>Robert Ward  Clinical Director  CID Management  August 29, 2014  Written Comment</p>	<p>Reject: Disagree. Of course, they can. In fact, the beginning of any search for evidence begins with the MTUS as mandated by section 9792.21.1. This is one of the things we clarified when we</p>	<p>Section 9792.21.1(a)(1) states, "Search the recommended guidelines set forth in the current MTUS to find a</p>

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	<p>publication, UR physicians and IMR physicians will be unable to consider the MTUS or any guideline as evidence.</p> <p>Commenter notes that proposed sections 9792.21(f)(2) and (f)(3) mandate that in the event that the treating physician includes a citation of any kind within their medical reporting or on their DWC Form RFA, that the reviewing physician must follow the process described in 9792.21(g). 9792.21(g)(1) requires that the material cited by the treating physician be rated by level of evidence according to the rating process described in 9792.25.1. Whichever source has the highest rating level would then be applied to the decision making process.</p> <p>Commenter states that the rating process in 9792.25.1 provides rating levels only for peer-reviewed publications. There is no rating for any other type of material, e.g. evidence based guidelines such as MTUS, ACOEM or ODG. Additionally, the rating system does not mention peer-</p>		<p>re-organized section 9792.21 and broke it up into two sections.</p> <p>Reject: No formal application of the MTUS Methodology for Evaluating Medical Evidence is required when applying the medical evidence search sequence. The reference to section 9792.25.1 in sections 9792.21.1(a)(2)(A), (B), and (C) is provided as instruction to the physician to choose the best available evidence. The MTUS Methodology for Evaluating Medical Evidence will only be formally applied by reviewing physicians as set forth in section 9792.25.1 when competing recommendations are cited.</p> <p>Reject: Section 9792.25.1(a) clearly states, “This methodology provides a process to evaluate studies, not guidelines. Therefore, the</p>	<p>recommendation applicable to the injured worker’s medical condition or injury.”</p> <p>None.</p> <p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>reviewed materials that would be entirely inappropriate, such as in vitro studies or animal studies.</p> <p>Commenter opines that it is exceptionally likely that judicial review of the application of this rating system will conclude that any materials not listed as having an evidence level are not acceptable as evidence. If so, then any peer-reviewed publication will “trump” any guideline, as there is no evidence level in the draft for a guideline derived from an academic consensus process after consideration of a systematic search of the literature.</p>		<p>reviewing physician shall evaluate the underlying study or studies used to support a recommendation found in a guideline.</p> <p>Reject: This process is part of the evaluation process that will be used by Utilization Review physicians and Independent Medical Review physicians to determine the reasonableness and necessity of medical treatment. Therefore, the scope of judicial review is very limited. Also, see previous response.</p>	None.
9792.21(f)(2) 9792.21(f)(3) 9792.21(g)	<p>Commenter states that the second unintended consequence of these proposed regulations is as follows:</p> <p>Implementation of the proposed MTUS is predicted to result in a significant increase in expedited hearings at the WCAB; and a significant percentage of the expedited hearings will result in technical invalidation of UR and IMR determinations, even if the UR or IMR</p>	Robert Ward Clinical Director CID Management August 29, 2014 Written Comment	Reject: In light of <i>Dubon v. World Restoration, Inc.</i> , 79 Cal. Comp. Cases 1298 (Appeals Board en banc opinion)(Dubon II) where the Appeals Board held that a UR decision is invalid and not subject to IMR only if it is untimely; and in light of the statutorily limited avenues to judicially appeal an IMR decision, we do not believe our	None.



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	<p>MTUS. In fact, the process described in subsection (g) will be mandatory even if the citation that the provider includes is from the MTUS.</p> <p>Commenter opines that reviews that do not include documentation of having followed the process described in subsection (g) will be vulnerable to judicial reversal. UR physicians would not be reasonably expected to follow and document that process if a citation were buried in a section of irrelevant boilerplate language; and/or if the citation were from the MTUS. It is already common for some providers to place extensive, and often irrelevant, bibliographies in their medical reporting.</p> <p>Commenter states that there will also be hearings convened even if the process has been followed perfectly, based on allegations that the UR or IMR physician rated evidence improperly. This will result in attorneys who know nothing about rating scientific evidence arguing for a decision on the issue from a WCAB judge who likewise knows nothing</p>		<p>physician correctly cites the MTUS, there will be no need for the reviewing physician to conduct a medical evidence search because there will be no dispute.</p> <p>Reject: Although our proposed regulations set forth a mandatory medical evidence search sequence, there is no required documentation to show that the sequence has been followed. The medical evidence search sequence merely sets forth the sequence in which a physician shall conduct his or her search for medical evidence.</p> <p>Commenter's concerns relate to the process that Utilization Review or Independent Medical Review physicians are mandated to follow when evaluating medical evidence. As previously stated, we do not believe our proposed regulations will lead to a significant increase in expedited hearings at the</p>	None.

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>about rating evidence. Commenter opines that this is inevitable that this will occur, as the process described in 9792.25.1 offers no suggestion or process as to what occurs if the treating physician and the UR and/or IMR physician have divergent assessments of the level of evidence of the citations that are being compared.</p>		<p>WCAB (see previous response). These proposed regulations provide a transparent, systematic process to evaluate medical evidence. However, physicians will still be using their medical judgment when applying the MTUS methodology for evaluating medical evidence.</p>	
9792.25.1	<p>Commenter states that the third unintended consequence of these proposed regulations is as follows:</p> <p>The resource requirements of UR and IMR will increase sufficiently as to drive employers/insurers to abandon them; and will distort the integrity of the review process via unintended financial rewards to reviewing physicians in exchange for authorization.</p> <p>Commenter states that in cases where providers appended significant bibliographies to their documentation, the time invested by UR physicians and IMR physicians to comply with the mandatory evidence rating and</p>	<p>Robert Ward Clinical Director CID Management August 29, 2014 Written Comment</p>	<p>Reject: This process already exists and is clearly set forth in section 9792.25(c)(1). These proposed regulations merely clarifies the process while at the same time proposing a more comprehensive and efficient methodology to evaluate medical evidence.</p> <p>Accept: In light of <i>Dubon v. World Restoration, Inc.</i>, 79 Cal. Comp. Cases 1298 (Appeals Board en banc opinion)(Dubon II) where the Appeals Board held that a UR decision is invalid and not subject to IMR only if it is untimely, DWC is taking into</p>	<p>None.</p> <p>Section 9792.21.1 is added to provide specific instructions to treating physicians and reviewing physicians after conducting the medical evidence search in the sequence set forth in section 9792.21.1(a). Any citation provided in the RFA, Utilization Review decision or Independent Medical Review decision</p>

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	<p>documentation process will be significant; often greater than the time required for all other elements of their review combined. In instances where reviewing physicians are paid a flat rate per review, this will create a significant financial bias to authorize care rather than to rate evidence. This is contrary to the interests of injured workers, as authorization of inappropriate care leads to real harm, just as surely as delay of appropriate care does.</p> <p>Commenter states that for UR programs that compensate reviewing physicians according to their time on task, the increase in cost to conduct UR will increase immediately. For UR programs on a flat rate and the present IMR program (also on a flat rate), fees for these services will have to increase fairly rapidly. Otherwise, there will be a fairly rapid economic selection process that will drive thorough physicians out of these systems; selecting in favor of those who are willing to sacrifice quality for volume.</p> <p>In addition to the significant increase</p>		<p>consideration the tight time constrains necessary to complete a Utilization Review decision. Therefore, section 9792.21.1(b) is added to clarify the documentary requirements that must be provided by the treating physicians, especially when he or she is attempting to rebut the MTUS' presumption of correctness, the Utilization Review physicians and the Independent Medical Review physicians. In addition, details are provided for the citation format that must be used.</p> <p>Reject: Again, this process already exists and is clearly set forth in section 9792.25(c)(1). These proposed regulations clarifies the process while at the same time proposing a more comprehensive and efficient methodology to evaluate medical evidence.</p> <p>Accept: Sections 9792.21.1(b)(1)(A)1. and 2. in</p>	<p>“shall be the primary source relied upon which he or she believes contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury” However, if more than one citation is provided, “then a narrative shall be included... explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury but is not</p>

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	<p>in physician time that will be required to complete UR within the requirements of the described process, commenter opines that it will not be possible to complete the mandated process of evaluating the evidence without expending significant financial resources to obtain full-text publications, which range from \$10 to over \$100 per article, depending on the source journal.</p> <p>Commenter states that details of the study population (subsection (a)(1)) are rarely found in abstracts. Factors introducing bias into a study (subsection (a)(2)) are almost never found in abstracts. The study design (subsection (a)(3)) is usually not apparent from non-structured abstracts. The extent to which a study addresses the truly excellent questions posed in subsection (a)(4) is often not possible to assess from an abstract.</p> <p>Commenter states that since only the abstracts are free for most publications (and in some cases, not even the abstract is available free), it will be necessary to purchase the full text</p>		<p>addition to 9792.21.1(b)(1)(B)1. and 2. to provide details that need to be provided by the treating physician. Our proposed regulations require the citation of the primary source relied upon and if more than one citation is provided than a narrative shall be provided explaining how each guideline or study cited provides additional information that is not addressed by the primary source cited.</p> <p>Reject: DWC is requiring the entire study or relevant portion of the guideline that contains the recommendation the physician believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury be reviewed and not just the abstract.</p> <p>Reject: In light of <i>Dubon v.</i></p>	<p>addressed by the primary source cited.”</p> <p>Sections 9792.21.1(b)(1)(A)1. and 2. in addition to 9792.21.1(b)(1)(B)1. and 2. are added to make clear that the citation provided by the treating physician be the primary source relied upon and if more than one citation is provided then a narrative shall be included explaining how each guideline or study cited provides additional information that is not addressed by the primary source cited.</p> <p>None.</p> <p>None.</p>

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	<p>publications in order to complete the rating; no matter how irrelevant to the services under consideration.</p> <p>Commenter opines that the small minority of treating physicians who actively seek financial gain from the workers' compensation system without regard to the other parties involved will, without question, begin loading their documentation with bibliographies in order to extort authorizations of unnecessary services.</p> <p>Commenter states that employers and insurers will see a very rapid rise in dispute resolution costs, arising from the increase in WCAB hearings, as predicted above. Commenter opines that these factors combined will pressure claims administrators to make decisions as to whether to conduct review primarily on actuarial considerations, rather than on the welfare of injured workers.</p>		<p><i>World Restoration, Inc.</i>, 79 Cal. Comp. Cases 1298 (Appeals Board en banc opinion)(Dubon II) where the Appeals Board held that a UR decision is invalid and not subject to IMR only if it is untimely; and in light of the statutorily limited avenues to judicially appeal an IMR decision, we do not believe our proposed regulations will lead to a significant increase in expedited hearings at the WCAB. DWC is taking into consideration the tight time constrains necessary to complete a Utilization Review decision. Therefore, section 9792.21.1(b) is added to clarify the documentary requirements that must be provided by the treating physicians, especially when he or she is attempting to rebut the MTUS' presumption of correctness, the Utilization Review physicians and the Independent Medical Review physicians. In addition, details</p>	

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			are provided for the citation format that must be used.	
9792.21(j)	<p>Commenter states that the forth unintended consequence of these proposed regulations is as follows:</p> <p>Only employers may authorize medical treatment beyond that recommended by the MTUS, based on unique patient presentations. Such authorizations may not be made by the claims administrator, UR physicians or IMR physicians.</p> <p>Commenter states that this subsection makes an explicit statement that employers may approve medical treatment beyond what is covered in the MTUS or best available evidence to account for unique medical circumstances. The specific naming of the employer for this purpose implies that only the employer may do so. Commenter opines that this effectively removes this option from claims administrators, UR physicians and IMR physicians. In an instance where a reviewing physician or the claims administrator has made such an</p>	Robert Ward Clinical Director CID Management August 29, 2014 Written Comment	Accept. Section 9792.21(j) is re-numbered and re-lettered to 9792.21.1(e) and will be clarified to add "...and their representatives."	Section 9792.21(j) is re-numbered and re-lettered to 9792.21.1(e) and states, "Employers and their representatives..."

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	<p>authorization for a portion of a course of treatment but not all, a successful challenge can be made at the WCAB to invalidate the entire determination of medical necessity on the course of care. Those who have directly experienced the workings of a WCAB hearing will know that this is not an unlikely hypothetical.</p>			
9792.21(j)	<p>Commenter states that the fifth unintended consequence of these proposed regulations is as follows:</p> <p>Determinations of medical necessity will be constrained to comply only with the MTUS; even when high-quality evidence arising from the specific patient’s response to medical treatment would make such determination grossly inconsistent with standards of care.</p> <p>Commenter notes that the authors of the proposed MTUS have omitted the patient’s response to care as a source of evidence. This is actually inconsistent with the principles of evidence-based care.</p> <p>Commenter states that because this</p>	<p>Robert Ward Clinical Director CID Management August 29, 2014 Written Comment</p>	<p>Reject in part. Accept in part. Reject: The proposed definition of Evidence-Based Medicine allows the integration of the best available research evidence with clinical expertise and patient values. The consideration of outcomes of prior care for the specific patient falls under the categories of clinical expertise and patient values. Therefore, for patients who do not technically meet guideline criteria but have a history of the same treatment with excellent outcome’s section 9792.21(j) could apply. Additionally, “functional improvement” has been</p>	<p>None.</p> <p>Section 9792.21(j) is</p>

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	<p>subsection explicitly permits variance from scientific evidence based on the specific patient only by the employer; and only for authorizations; there is a strong legal argument to be made that no one but the employer can vary from scientific evidence based on the unique patient; and that there can be no variance from scientific evidence except to reach an authorization.</p> <p>Commenter states that this means that under proposed 9792.21(j), a patient who has previously received a form of treatment that is not supported by science, and for whom there is excellent evidence of objective clinical benefit, cannot have such service authorized by anyone but the employer.</p> <p>Commenter states that under proposed 9792.21(j), a patient who meets guideline criteria for a procedure; and who has had the procedure repeatedly with either no benefit or with actual adverse effects; must receive continuing authorization from a reviewing physician. □</p>		<p>defined to incorporate patient response to treatment.</p> <p>Accept: Section 9792.21(j) is re-numbered and re-lettered to 9792.21.1(e) and will be clarified to add "...and their representatives."</p>	<p>re-numbered and re-lettered to 9792.21.1(e) and states, "Employers and their representatives..."</p>
9792.25.1	Commenter states that the sixth	Robert Ward		

<b>Medical Treatment Utilization Schedule</b>	<b>RULEMAKING COMMENTS 15 DAY COMMENT PERIOD</b>	<b>NAME OF PERSON/ AFFILIATION</b>	<b>RESPONSE</b>	<b>ACTION</b>
	<p>unintended consequence of these proposed regulations is as follows:</p> <p>Experimental and proprietary forms of treatment will nearly always be authorized.</p> <p>Commenter opines that for experimental treatments for which there is only very preliminary evidence, while there would be inadequate evidence to establish that the treatment is safe or effective, the limited evidence available would by default be the strongest. Application of the proposed MTUS would result in these being authorized, effectively converting injured workers into unknowing and non-consenting human subjects.</p> <p>Commenter states that for propriety treatment modalities, it is typical to find a very small body of poor-quality publication that was produced by individuals with financial interest in the propriety treatment. These publications are traditionally supportive of the procedure, as any self-produced studies that have</p>	<p>Clinical Director CID Management August 29, 2014 Written Comment</p>	<p>Reject in part. Accept in part. Reject: Section 9792.25 instructs a reviewing physician to consider applicability and bias and then determine the strength of the evidence. Factors that must be considered when determining the strength of evidence include but are not limited to the study design, efficacy of the treatment, and treatment harms.</p> <p>Accept: Clarification to section 9792.25 is made to make clear that a reviewing physician can end his or her evaluation of medical evidence if there are issues with applicability or bias.</p>	<p>None.</p> <p>Section 9792.25(a)(2)(A) is added that states, "The evaluation of medical evidence can end after this step if a citation to a guideline or a study contains a recommendation supported by inapplicable studies and the other citation contains a recommendation that is supported by</p>

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	<p>negative outcomes are typically withheld from publication. In addition, for these types of treatments, it is rare that individuals without a financial interest have studied the treatment, so it is also typical to find that there is no other published evidence. Commenter opines that the application of the proposed MTUS would result in such treatment being authorized. Use of such modalities is very popular among a small minority of treating physicians; apparently because these can be billed using undefined CPT codes, allowing escape from the bill review process.</p> <p>As an example, commenter states that there is at this time a form of supervised electrical stimulation falling into this category that is being routinely billed at a bit over \$2,000 per session by physicians employing it (localized intensive neurostimulation therapy). While the ODG recommends against it, commenter states that the use of this modality would be consistently approved using the proposed MTUS, based on case studies produced by the equipment</p>			<p>studies applicable to the injured worker’s medical condition or injury.”</p> <p>Section 9792.25(a)(3)(A) is added that states, “The evaluation of medical evidence can end after this step if a citation to a guideline or a study contains a recommendation supported by studies determined to be of poor quality due to the presence of bias and the other citation contains a recommendation that is supported by studies determined to be of good quality due to the absence of bias.”</p>

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9792.21(j) 9792.25.1	<p>manufacturer.</p> <p>Commenter states that in order that the principles of evidence-based medicine be effectively introduced into the MTUS, he recommends that there be the ability to consider unique patient presentations on a reasoned basis for both authorizations and adverse determinations; and that there be no restriction of such consideration to employers only. [accomplished via revision of 9792.21(j)]</p> <p>Commenter opines that in order to provide a mechanism by which competing forms of evidence can be rated to settle a dispute of this type, without creating the unintended consequences described above, the rating process should be:</p> <p>* Explicitly bypassed when the UR physician or IMR physician is utilizing the current ACOEM Guidelines, ODG or materials from the National Guideline Clearinghouse.</p> <p>* Conducted by someone other than the UR or IMR physician (see below)</p>	Robert Ward Clinical Director CID Management August 29, 2014 Written Comment	<p>Accept: Section 9792.21(j) is re-numbered and re-lettered to 9792.21.1(e) and will be clarified to add "...and their representatives."</p> <p>Reject: Merely citing the current ACOEM, ODG or materials from the National Guideline Clearinghouse may not be the best available evidence. Although both ACOEM and ODG are well respected, if there is a new study that contains a recommendation supported by better evidence than the ACOEM or ODG recommendations then that recommendations should guide medical care.</p> <p>Reject: The reasonableness and</p>	<p>Section 9792.21(j) is re-numbered and re-lettered to 9792.21.1(e) and states, "Employers and their representatives..."</p> <p>None.</p> <p>None.</p>

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	<ul style="list-style-type: none"> <li>* Cost neutral</li> <li>* Explored only after UR and /or IMR have been completed (to prevent delays in care; specifically, other elements of the treatment plan not involved in a dispute over evidence.)</li> <li>* Engineered to create a centralized and public source of rating results, such that a body of rating is collected over time that prevents the need to rate a particular source of evidence de novo each time it is cited; and to prevent unnecessary hearings at the WCAB regarding which source is superior.</li> <li>* Amended to indicate the process by which disagreements over competing evidence rating are to be settled.</li> </ul> <p>Commenter recommends that some group established by the DWC (perhaps members, or subcommittees, of the Medical Evidence Evaluation Advisory Committee) should provide evidence ratings. Materials could be rated on an ad hoc basis as disputes arise, with results added to a growing database, such that over time many materials in a dispute would have</p>		<p>necessity of a treatment request are determined by UR and, if there is a dispute, by IMR determinations. Therefore, rating disputes must be done during UR and/or IMR not after it is completed.</p> <p>Reject: Although commenter's suggestion of a public source of rating results is well received, it will not prompt any regulatory changes that mandates DWC to do this, although it may be considered by others on a voluntary basis.</p> <p>Reject: This is unnecessary because evidence rating is something that UR and IMR reviewers are already required to do. Currently, section 9792.25(c)(1) provides a much more complicated and time consuming methodology for rating evidence. These proposed regulations are more comprehensive and takes less steps to apply. Decisions regarding the reasonableness</p>	<p>None.</p> <p>None.</p>

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	<p>already been rated. Such ratings could then be appropriately considered by legal professionals during the dispute resolution process at the WCAB.</p> <p>If the DWC cannot craft an evidence rating process that does not impose the process conflicts, unintended consequences and costs described above, commenter recommends that the DWC not make any evidence rating process mandatory.</p> <p>In the event that the DWC chooses not to heed his recommendations and proceeds with a mandatory rating process, commenter recommends that the Division do the following:</p> <p>* The MTUS, ACOEM Guidelines, ODG and materials from the National Guideline Clearinghouse be rated according to their own internal evidence ratings, if given; and that there be a default rating provided by the DWC in cases where there is no such internal rating. This would also require that there be some form of equivalence rating for materials that use a</p>		<p>and necessity of a treatment request are to be determined by UR and IMR physicians and not by legal professional at the WCAB.</p> <p>Reject: These proposed regulations do not impose the process conflicts, unintended consequences and costs described by commenter, because the requirement to rate evidence is already required in section 9792.25(c)(1) and these proposed regulations merely clarifies the process, allows for the evaluation and rating of non-randomized trials and is more efficient.</p> <p>Moreover, a rating system is necessary because of Labor Code section 4604.5. Without the ability to evaluate the evidence supporting competing recommendations, there would be no way to determine which recommendation to apply if the MTUS is silent or if the MTUS is being rebutted.</p>	None.

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	<p>different rating scale than does 9792.25 (e.g., A, B, C or D rating)</p> <p>* It is recommended that the regulations be amended to require that the treating physician specifically indicate that they are providing a citation to challenge the correctness of the MTUS; and that in the event that the treating physician provides multiple citations for a medical good or service, that the treating physician must indicate which of their citations they feel is the strongest evidence to support their request. It is also recommended that the process mandated in subsections (f)(2) and (f)(3) only be required of UR or IMR physicians when the treating physician has made these indications; and is only required to complete the evidence evaluation/rating process for the citation that the provider has indicated is the strongest.</p> <p>* The factors or criteria which are to be considered for each peer-reviewed publication be amended to include only those that can be typically determined based on an</p>		<p>Accept: Sections 9792.21.1(b)(1)(A)1. and 2. in addition to 9792.21.1(b)(1)(B)1. and 2. to provide details that need to be provided by the treating physician. Our proposed regulations require the citation of the primary source relied upon and if more than one citation is provided than a narrative shall be provided explaining how each guideline or study cited provides additional information that is not addressed by the primary source cited.</p> <p>Reject: Reasonable and necessary medical care should not be denied because a UR or IMR reviewer needs to be able to make a determination by merely reviewing an abstract. The rating process should</p>	<p>Sections 9792.21.1(b)(1)(A)1. and 2. in addition to 9792.21.1(b)(1)(B)1. and 2. are added to make clear that the citation provided by the treating physician be the primary source relied upon and if more than one citation is provided then a narrative shall be included explaining how each guideline or study cited provides additional information that is not addressed by the primary source cited.</p> <p>None.</p>

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	<p>abstract.</p> <p>* That there be some indication as to how the rating process should proceed in the event that the information is not in the abstract or when there is no free abstract available. [Suggestion: Such materials should be deemed non-ratable and excluded]</p> <p>* That only peer-reviewed publications at the level of controlled clinical trial or better be considered as scientific evidence sufficient to make a determination of medical necessity.</p>		<p>proceed and costs will be incurred by the physician who has read and is relying upon the recommendation cited to guide the requested treatment.</p> <p>Reject: Although the commenter is correct that peer-reviewed publications at the level of controlled clinical trial or better is more trustworthy, these regulations have provided a hierarchy of external evidence to assist in evaluating medical evidence.</p>	None.
9792.20(d)	<p>Commenter recommends the following revised language:</p> <p>(d) “Evidence-Based Medicine (EBM)” means a systematic approach to making clinical decisions <del>which allows the integration of</del> <u>based on</u> the best available research evidence <del>with clinical expertise and patient values.</del></p> <p>Commenter states that the</p>	<p>Brenda Ramirez Claims &amp; Medical Director California Workers’ Compensation Institute (CWCI) August 30, 2014 Written Comment</p>	<p>Reject: Goes beyond the scope of the first 15-day comment period because no changes were made to section 9792.20(d) from the 45-day comment period.</p>	None.

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	<p>administrative director has not eliminated the use of clinical expertise and patient values, even though there is no definition of these factors in the proposed regulations and no possible useful definition in any scientific literature. Commenter opines that the these subjective assessments are diametrically opposed to the statutory standards. Section 5703.27 requires the adoption of a treatment schedule that shall incorporate evidence-based, peer-reviewed, nationally recognized standards of care. Evidence-based medicine does not merely allow the integration of the best available research evidence, it requires it.</p> <p>Commenter states that the proposed regulations are replete with requirements to ascertain the strongest medical evidence that the proposed treatment is based on scientific medical evidence. Commenter opines that including the terms “clinical expertise and patient values” contradicts the language in section 9792.21(c) which states: “EBM is a method of improving the quality of care by encouraging practices that</p>			

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	<p>work, and discouraging those that are ineffective or harmful. EBM asserts that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for making clinical decisions.” The AD has defined scientifically based and the strength of evidence in terms of a body of scientific medical literature used to support the recommended treatment. Commenter states that clinical expertise and patient values are not reflected in the statute and cannot be imposed by regulation. <i>Mendoza v WCAB</i> (2010) En Banc Opinion 75 CCC 634.</p> <p>Commenter states that the MTUS has to be definitive in order to establish useful, clear, and scientific treatment guidelines as the statutes direct. The treatment schedule is not used exclusively by treating physicians. Rather, the Legislature requires that the treatment schedule be used by injured workers and physicians who treat them, claims administrators, utilization review physicians, IMR, employers, applicants’ attorneys, defense attorneys, judges and the</p>			

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	<p>WCAB and the reviewing courts.</p> <p>Commenter opines that the workers compensation community must have a treatment schedule that is as straightforward as modern medical science can make it. Section 4610 charges utilization review physicians with the obligation to determine the appropriateness of requested treatment within very tight time frames. Treatment guidelines that provide clear direction, are well supported by scientific medical evidence, and are based on graded peer reviews are essential for the utilization review system to function as intended. Conversely, a treatment schedule that allows “clinical expertise and patient values” to influence the evaluation of treatment is in conflict with what the Legislature provided by statute.</p> <p>Commenter states that the Legislature not only defined the elements of the treatment schedule, it also provided that the guidelines set forth in the schedule “shall be presumptively correct on the issue of extent and scope of medical treatment” (section</p>			

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	<p>4604.5). This statutory presumption provides additional legal authority and is intended to limit disputes over which course of care is medically appropriate. When disputes have to be resolved, the WCALJ should be able to rely on the clarity of the recommendations, the weight of the supporting medical evidence, and the strength of evidence within the MTUS. Similarly, when the WCAB is required to determine disputed medical care, the MTUS and the presumption will direct that decision to the extent the scientific evidence allows. “Clinical expertise and patient values” are not scientific medical evidence. The inclusion of “clinical expertise and patient values” will only create ambiguity and confusion, when the statutory standard is evidence-based, peer-reviewed, nationally recognized standards of care.</p> <p>Commenter recommends eliminating the subjective, unscientific elements. Alternatively commenter suggests using the definition of Evidence-Based Medicine (EBM) that the Institute of Medicine (IOM) adopted</p>			

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	<p>in 2009:</p> <p>“EBM is the framework for methodologically analyzing best evidence so that the care provided to each patient delivers the most value. The benefits of EBM will be to reduce discrepancies in care of patients and improve value of the healthcare delivered. (IOM, Evidence-Based Medicine, 2009.)”</p>			
9792.21(e)	<p>Commenter recommends the following revised language:</p> <p>(e) When the MTUS’s presumption of correctness is <del>challenged</del> <u>successfully rebutted by a preponderance of the scientific medical evidence</u> pursuant to Labor Code section 4604.5 <del>or when there is a topical gap and a medical treatment or a diagnostic test is not addressed by the recommended guidelines set forth in the MTUS,</del> medical care shall be in accordance with <u>other scientifically- and evidence-based nationally recognized medical treatment guidelines</u> <del>the best available medical evidence found in scientifically and evidenced based medical treatment guidelines or peer-</del></p>	<p>Brenda Ramirez Claims &amp; Medical Director California Workers’ Compensation Institute (CWCI) August 30, 2014 Written Comment</p>	<p>Reject in part. Accept in part. Reject: Commenter’s suggested language will not be adopted. Accept in part. Section 9792.21(e) is deleted and clarification is made that the MTUS’ presumption of correctness stands unless it is successfully challenged.</p>	<p>Section 9792.21(e) is deleted and replaced with section 9792.21.1(d), (1) and (2) which states, “(d) ...There are two limited situations that may warrant treatment based on recommendations found outside of the MTUS.” Section (d)(1) states, “First if a medical condition or injury is not addressed by the MTUS, medical care shall be in accordance with</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>reviewed published studies that are nationally recognized by the medical community.</p> <p>Commenter notes that 4600(b) says "...<b>notwithstanding any other law</b>, medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment that is based upon the guidelines adopted by the administrative director pursuant to Section 5307.27," (emphasis added) and Labor Code section 4604.5 says the guidelines "shall constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions."</p> <p>Commenter states that the MTUS is presumptively correct unless the injury is not covered by the MTUS. The presumption of correctness of the MTUS stands until it is successfully rebutted, not just until it is challenged or when there is a "topical gap" and a medical treatment or a diagnostic test is not addressed by the recommended guidelines set forth in the MTUS. Labor Code 4604.5 states that the</p>			<p>other medical treatment guidelines or peer-reviewed studies..." Section (d)(2) states, "Second, if the MTUS' presumption is successfully challenged. The recommended guidelines set forth in the MTUS are presumptively correct on the issue of extent and scope of medical treatment. The presumption is rebuttable and may be controverted by a preponderance of scientific medical evidence establishing that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of his or her injury. The presumption created</p>

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	<p>“presumption may be rebutted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of this or her injury,” and as the presumption is “one affecting the burden of proof,” the guidelines must be proved to be incorrect.</p> <p>Commenter notes that if the presumption is successfully rebutted by a preponderance of the scientific medical evidence, the MTUS does not apply. Labor Code section 4604.5(d) specifies that authorized medical care for injuries not covered by the MTUS must be in accordance with other evidence-based medical treatment guidelines that are nationally recognized and scientifically based.</p>			<p>is one affecting the burden of proof. Therefore, the treating physician who seeks treatment outside of the MTUS bears the burden of rebutting the MTUS’ presumption of correctness by a preponderance of scientific medical evidence.”</p>
9792.21(f)(2) and 9792.21(f)(3)	<p>Commenter recommends the following revised language:</p> <p>(2) Utilization Review physicians <del>shall</del> <u>may</u> apply the medical literature search sequence set forth in subdivision 9792.21(g) if the requesting treating physician cited a</p>	<p>Brenda Ramirez Claims &amp; Medical Director California Workers’ Compensation Institute (CWCI) August 30, 2014 Written Comment</p>	<p>Reject: The medical evidence search sequence remains mandatory for Utilization Review physicians. In fact, changes are made to the medical evidence search sequence to clarify it is mandatory for all physicians.</p>	<p>Section 9792.21.1(a) mandates the search to always begin with the MTUS, then in the limited situation where a medical condition or injury is not addressed by the</p>

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	<p>recommendation in the chart notes or Request for Authorization and the requested treatment or diagnostic service is being denied;</p> <p>(3) Independent Medical Review physicians shall apply the medical literature search sequence set forth in subdivision 9792.21(g) to <u>determine whether the presumption of correctness of the MTUS was successfully rebutted and if so to ensure that medical care is in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed studies that are nationally recognized by the medical community other scientifically- and evidence-based nationally recognized medical treatment guidelines.</u></p> <p><b>Discussion</b>  Committer strongly recommends replacing “shall” with “may” in (2) so it is clear that a literature search is optional. Commenter states that there is no statutory basis or necessity for requiring the utilization reviewer to conduct a literature search, although</p>		<p>Section 9792.21 is broken up into two sections and new section 9792.21.1 is added. Section 9792.21 will solely discuss the role of the MTUS and describe the two limited situations that may warrant treatment based on recommendations found outside of the MTUS. 9792.21.1(a) is the Medical Evidence Search Sequence and requires treating physicians and reviewing physicians apply this search sequence whenever they search for medical evidence. Although 9792.21.1(a)(2)(A) – (C) references the MTUS Methodology for Evaluating Medical Evidence, no formal application of section 9792.25.1 is required when applying the medical evidence search sequence. The reference to section 9792.25.1 in sections 9792.21.1(a)(2)(A), (B), and (C) is provided as instruction to the physician to choose the best available</p>	<p>MTUS or if the MTUS’ presumption of correctness is being challenged, then the sequence mandates a search of the most current ACOEM or ODG. Next the sequence mandates a search of the most current version of other evidence-based medical treatment guidelines, and finally, the sequence mandates a search for current studies that are scientifically-based, peer-reviewed, and published in journals that are nationally recognized by the medical community.</p>

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	<p>he or she may choose to do so. It is inappropriate to require Utilization Review physicians to perform medical literature searches. Literature searches are time consuming and cannot reasonably be accomplished within the very tight UR timelines. Commenter opines that to require UR physicians to perform literature searches whenever treating physicians cite recommendations that may be unsupported by the MTUS in chart notes or RFAs, is totally unreasonable. Commenter states that if this proposed requirement is retained, it will significantly increase the cost of utilization review, add fertile grounds for yet more disputes and more unnecessary expedited hearings, and result in ineffective or deleterious medical care and unnecessary treatment delays for injured employees. Intended or not, this will further undermine the legislative intent for effective, timely Utilization Review.</p> <p>Commenter notes that the Independent Medical Review physician must determine whether the presumption of</p>		<p>evidence. The MTUS Methodology for Evaluating Medical Evidence will only be formally applied by reviewing physicians as set forth in section 9792.25.1 when competing recommendations are cited.</p>	

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	<p>correctness of the MTUS has been successfully rebutted. If the presumption is successfully rebutted by a preponderance of the scientific medical evidence, the MTUS does not apply. Labor Code section 4604.5(d) specifies that authorized medical care for injuries not covered by the MTUS must be in accordance with other evidence-based medical treatment guidelines that are nationally recognized and scientifically based.</p> <p>Commenter references comments made regarding 9792.21(e).</p>			
9792.21(g)(2) 9792.21(g)(3)	<p>Commenter recommends the following revised language:</p> <p>(2) Search the most current version of other evidence-based medical treatment guidelines that are recognized by the national medical community and are scientifically based to find a recommendation applicable to the injured worker's specific medical condition. <del>Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section</del></p>	Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) August 30, 2014 Written Comment	Reject: See above response. Although no action was prompted by commenter's suggestions, the action set forth above was included to show the organizational changes made to section 9792.21 and the addition of new section 9792.21.1.	None.

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	<p>9792.25.1.—Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: <a href="http://www.guideline.gov/">www.guideline.gov/</a>. If the current version of the medical treatment guideline is more than five years old, or if no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then</p> <p>(3) Search for current studies, that are scientifically based, peer-reviewed, and published in journals that are nationally recognized by the medical community to <del>find</del> <u>determine whether a preponderance of scientific medical evidence rebuts the MTUS’s presumption of correctness recommendation applicable to the injured worker’s specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section</u> 9792.25.1.—A search for peer-</p>			

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	<p>reviewed published studies may be conducted by accessing the U.S. National Library of Medicine's database of biomedical citations and abstracts that is searchable at the following website: www.ncbi.nlm.nih.gov/pubmed. Other searchable databases may also be used.</p> <p>Commenter states that it is inappropriate to require medical reviewers to do a literature search. Commenter opines that it is even less appropriate to require medical reviewers to identify the recommendations in guidelines, journals or studies that are supported by the highest level of evidence according to the strength of evidence methodology in 9792.25.1, which is per the AGREE II methodology. AGREE II is a tool designed primarily designed for use by guideline developers and requires extensive training and time to properly apply. It is impossible to correctly assess levels of evidence within the current UR timeframes and budgets. Commenter strongly recommends the deletions</p>		<p>Reject: Currently, medical reviewers are supposed to support their decisions with medical evidence. These proposed regulations provide a search sequence to finding medical evidence that shall be followed by treating physicians and medical reviewer to ensure consistency and efficiency.</p> <p>Reject: Section 9792.25(a)(1) does not mandate the use of AGREE II. The systematic methodology for evaluating medical evidence set forth in section 9792.25(a)(1) was developed from information obtained from the Cochrane Group and the Oxford Centre</p>	<p>None.</p> <p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>indicated, or alternatively this modification in (2):</p> <p><u>The independent medical reviewer shall determine</u> <del>Choose</del> the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1.</p> <p>and this modification in (3):</p> <p><u>The Independent Medical Reviewer shall</u> <del>Choose the recommendation that is supported with the highest level of evidence according to</del> <u>determine</u> the strength of evidence <u>according to the</u> methodology set forth in section 9792.25.1.</p> <p>Commenter states that the MTUS is presumptively correct unless the injury is not covered by the MTUS. The presumption of correctness of the MTUS stands until it is successfully rebutted, not just until it is challenged or when there is a “topical gap” and a medical treatment or a diagnostic test is not addressed by the recommended</p>		<p>for Evidence-based Medicine (see Initial Statement of Reasons, under the heading “Technical, Theoretical, or Empirical Studies, Reports or Documents,” items (4) and (8). Medical and/or legal actions and costs will not be driven up because a similar systematic approach is already required pursuant to current section 9792.25(c)(1) which was adopted from ACOEM.</p> <p>Reject: See previous response.</p>	<p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>guidelines set forth in the MTUS. Labor Code 4604.5 states that the “presumption may be rebutted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of this or her injury.”</p>			
9792.21(h)	<p>Commenter recommends the following revised language:</p> <p>(h) After applying the medical literature search sequence set forth in section 9792.21(g), <del>Utilization Review decisions and Independent Medical Review decisions</del> shall contain the citation of the medical treatment guideline <u>recommendation</u>, or peer-reviewed published studies <u>with the recommendation supported with the highest level of evidence</u>. Treating physicians and utilization reviewers may cite the <u>supporting medical treatment guideline or peer-reviewed published study that contains the recommendation supported with the highest level of evidence in the chart notes or Request for Authorization, particularly if barriers to getting</u></p>	<p>Brenda Ramirez Claims &amp; Medical Director California Workers’ Compensation Institute (CWCI) August 30, 2014 Written Comment</p>	<p>Reject: See previous response.</p>	<p>None.</p>



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	<p>whether or not literature searches and strength of evidence analyses were required, and whether they were properly, completely, and timely performed. Under Dubon, any of these issues will shift the case from a prompt evaluation of the best medical care to litigation at the Board as to whether the UR decision contains “material procedural defects that undermine the integrity of the UR decision.” This will simply become a new way to divert decisions by medical professionals, flood the Board with questionable disputes, and increase the cost of utilization reviews.</p> <p>Commenter states that chart notes are not required and are rarely submitted. Commenter states that the last two phrases in (h) are both unnecessary and confusing.</p>		<p>untimely; and in light of the statutorily limited avenues to judicially appeal an IMR decision, we do not believe our proposed regulations will lead to a significant increase in expedited hearings at the WCAB.</p> <p>Accept: Section 9792.21(h) is deleted and all references to “chart notes” have been removed.</p>	<p>Section 9792.21(h) is deleted and replaced with section 9792.21.1.(b) with no mention of “chart notes”.</p>
9792.21(i)	<p>Commenter recommends the following revised language:</p> <p>(i) <del>Finally, if there is a discrepancy between the recommendations cited, the underlying medical evidence supporting the differing</del></p>	<p>Brenda Ramirez Claims &amp; Medical Director California Workers’ Compensation Institute (CWCI) August 30, 2014</p>	<p>Reject: Section 9792.21(i) is deleted because organizational changes are made to section 9792.21 and new section 9792.21.1 is added. Section 9792.21.1(c) replaces section 9792.21(i). Commenter’s</p>	<p>None.</p>

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	<p>recommendations shall be evaluated according to the MTUS Hierarchy of Evidence for Different Clinical Questions set forth in section 9792.25.1 to determine which recommendation is supported with the highest level of evidence.</p> <p>(1) Utilization Review physicians shall apply the MTUS Hierarchy of Evidence for Different Clinical Questions if the treating physician cited a recommendation in the chart notes or Request for Authorization and the requested treatment or diagnostic service is being denied. In these situations, Utilization Review decisions shall clearly document the levels of evidence as set forth in the MTUS Hierarchy of Evidence for Different Clinical Questions (e.g. 1a, 1b, 2, etc.) between the recommendation cited by the treating physician and the recommendation used to deny the treatment or diagnostic service request.</p> <p>(2) Independent Medical Review physicians shall apply the MTUS Hierarchy of Evidence for Different</p>	Written Comment	suggested changes are not adopted. Section 9792.21.1 requires the IMR reviewer to apply the MTUS Methodology for Evaluating Medical Evidence if there is dispute as to which recommendation is applicable to the injured worker's medical condition or injury to determine which recommendation is supported by the best available evidence.	

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	<p><del>Clinical Questions if to determine whether the presumption of correctness of the MTUS has been rebutted where there is a dispute over the between the recommendations cited by the treatment requested by the treating physician, and the Utilization Review physician or if the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed studies that are nationally recognized by the medical community was not cited by either the treating physician or the Utilization Review physician and the IMR reviewer is able to cite a recommendation supported with stronger medical evidence. In these situations, tThe Independent Medical Review decisions shall clearly document the levels of evidence as set forth in the MTUS Hierarchy of Evidence for Different Clinical Questions (e.g. 1a, 1b, 2, etc.) for all recommendations cited including any recommendations cited by the Independent Medical Review physician. The Independent Medical Review decision shall contain the recommendation supported be</del></p>			

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	<p><u>based on the MTUS if applicable; or on other scientifically- and evidence-based nationally recognized medical treatment guidelines for injuries not covered by the MTUS or if the MTUS presumption of correctness has been rebutted by a preponderance of the scientific medical evidence, with the best available medical evidence which determines medical care that is reasonably necessary to cure or relieve the injured worker from the effects of his or her injury.</u></p> <p>Commenter states that the Independent Medical Review process is a process for resolving medical necessity disputes over the denial or modification of treatment requested by the treating physician. Commenter opines that there is no statutory authority for the Independent Medical Review Physician interjecting and ruling on his or her own treatment recommendation.</p> <p>Commenter notes that Labor Code section 4604.5(d) requires:</p> <p>“For all injuries not covered by the</p>		Accept: Agree.	None.

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	official utilization schedule adopted pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence-based medical treatment guidelines that are recognized by the national medical community and scientifically based.”			
9792.21(j)	<p>Commenter recommends that this sub section be deleted.</p> <p>Commenter states that the claims administrator has the authority and responsibility for approving medical treatment. Insured employers do not have that authority.</p> <p>Commenter opines that even if “employers” is replaced by “claims administrators,” the language may arguably conflict with Labor Code sections 4600 (a) and (b) that define treatment reasonably required to cure the injured worker from the effects of the injury as treatment based on the MTUS.</p> <p>Commenter opines that since (j) is problematic and is not necessary, it is best deleted.</p>	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) August 30, 2014 Written Comment	Reject: Section 9792.21(j) is re-numbered and re-lettered to section 9792.21.1(e) and will remain but amended to include, “...and their representatives...”	Section 9792.21(j) is re-numbered and re-lettered to section 9792.21.1(e) and is amended to state, “Employers and their representatives...”
9792.25(a)(1)	Commenter recommends the	Brenda Ramirez	Reject: Goes beyond the scope	None.

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	<p>following revised language:</p> <p><del>(a) For purposes of sections 9792.25-9792.26, the following definitions shall apply:</del></p> <p>(4) “Appraisal of Guidelines for Research &amp; Evaluation II (AGREE II) Instrument” means a tool designed primarily to help guideline developers and users assess the methodological rigor and transparency in which a guideline is developed. The Administrative Director adopts and incorporates by reference the Appraisal of Guidelines for Research &amp; Evaluation II (AGREE II) Instrument, May 2009 into the MTUS from the following website: <a href="http://www.agreetrust.org">www.agreetrust.org</a>. A copy of the Appraisal of Guidelines for Research &amp; Evaluation II (AGREE II) Instrument, May 2009 version may be obtained from the Medical Unit, Division of Workers’ Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <a href="http://www.dwc.ca.gov">http://www.dwc.ca.gov</a>.</p> <p>Commenter recommends retaining the</p>	<p>Claims &amp; Medical Director California Workers’ Compensation Institute (CWCI) August 30, 2014 Written Comment</p>	<p>of the first 15-day comment period because no changes were made to section 9792.25(a)(1) from the 45-day comment period version.</p>	

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	<p>current methodology for evaluating criteria and determining strength of evidence. Commenter opines that using AGREE II protocols will not limit MTUS recommendations to those supported by peer-reviewed, and nationally recognized scientific medical evidence as Sections 4604.5 and 5307.27 require. Extensive training is necessary for all those who will use the protocols. Applying the protocols is much more time consuming than the existing standards.</p> <p>As stated in (a), The AGREE II Instrument is “a tool designed primarily to help guideline developers and users <b>assess the methodological rigor and transparency in which a guideline is developed</b>” (emphasis added). Commenter opines that the appraisal guidelines may be appropriate to assist MEEAC with its duties; however, the instrument is not appropriate or intended for use by treating physicians or utilization reviewers.</p>			
9792.25(a)(2) through (a)(29)	Commenter recommends that these subsections be deleted.	Brenda Ramirez Claims & Medical Director	Reject: Goes beyond the scope of the first 15-day comment period because no changes	None.

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	<p>Commenter notes that the Administrative Director intends to adopt the AGREE II protocols, and provides the AGREE II web site address. Commenter opines that if the Administrative Director adopts the AGREE II methodology, including details such as definitions (2) through (29) in this section does not appear necessary since the AGREE II Instrument and AGREE II Training Tools and related resources are available on that web site. Commenter opines that including these details also adds complexity that is not necessary and which will lead to additional disputes and confusion.</p> <p><b>Commenter would like to note:</b></p> <p>AGREE II protocols are complex and time-consuming. Correctly applying the AGREE II tool will require thorough training. If the Administrative Director adopts the AGREE II tool, commenter strongly recommends that the Administrative Director not require their use by treating physicians and utilization reviewers, and require that:</p>	<p>California Workers' Compensation Institute (CWCI) August 30, 2014 Written Comment</p>	<p>were made to sections 9792.25(a)(2) through (a)(29) from the 45-day comment period version.</p>	

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	<p>1) MEEAC members and IMR reviewers are thoroughly trained on applying the AGREE II tool before the effective date of these regulations.</p> <p>2) The MTUS include the strength of evidence for each recommendation.</p>			
9792.25.1	<p>Commenter recommends deleting this section.</p> <p>Commenter continues to recommend retaining the current methodology for evaluating criteria and determining strength of evidence. Refer to her comment regarding 9792.25(a).</p>	<p>Brenda Ramirez Claims &amp; Medical Director California Workers' Compensation Institute (CWCI) August 30, 2014 Written Comment</p>		
9792.20(a) 9792.20(b) 9792.20(d) 9792.20(g)	<p>Commenter strongly supports the revision of the definition of ACOEM Guides by deleting the reference to the 2004 second edition. The ACOEM Guides have undergone multiple revisions since the 2004 edition. Commenter states that this will allow providers, reviewers and payors to reference the most current version of ACOEM Guides. Commenter is also supportive of the revision of the definition of "chronic pain" by adding a three month timeframe from the</p>	<p>Bernyce Peplowski, DO, MS, FACOEM Senior Vice President US Health Works August 29, 2014 Written Comment</p>	Accept.	None.

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	initial onset of pain, which we believe is consistent with nationally recognized evidence-based medical guidelines. Commenter concurs with the clarification that medical care be rendered in accordance with the best available medical evidence when there is a topical gap or where a medical treatment or diagnostic test is not addressed by the MTUS.			
9792.21(i)(1)	<p>Commenter strongly supports the application of Hierarchy of Evidence when determining care pathways for injured workers. Commenter is concerned that requiring a utilization reviewer to rank by hierarchy each submitted reference with a Request for Authorization (RF A) could potentially delay decisions and substantially increase UR costs. Commenter states that in order to rank an obscure article, it could require obtaining the full reference (which may have an associated cost) as well as substantial additional time for the utilization reviewer.</p> <p>Commenter is concerned that some providers (hoping to trigger a missed time frame) could deliberately submit</p>	Bernyce Peplowski, DO, MS, FACOEM Senior Vice President US Health Works August 29, 2014 Written Comment	Accept: Sections 9792.21.1(b)(1)(A)1. and 2. in addition to 9792.21.1(b)(1)(B)1. and 2. replaces section 9792.21(i) and gives the details that need to be provided by the treating physician. Our proposed regulations require the citation of the primary source relied upon and if more than one citation is provided than a narrative shall be provided explaining how each guideline or study cited provides additional information that is not addressed by the primary source cited.	Sections 9792.21.1(b)(1)(A)1. and 2. in addition to 9792.21.1(b)(1)(B)1. and 2. are added to make clear that the citation provided by the treating physician be the primary source relied upon and if more than one citation is provided then a narrative shall be included explaining how each guideline or study cited provides additional information that is not addressed by the



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	<p>the foundation for any further proposed modifications to the MTUS to insure that injured workers have access to the highest quality and most effective medical treatment for their injury.</p> <p>Commenter states that the practice guidelines of the American College of Occupational and Environmental Medicine (ACOEM) are also consistent with this proposed definition. ACOEM states in its practice guidelines that "decisions to adopt particular courses of actions must be made by trained practitioners on the basis of the available resources and the particular circumstances presented by the individual patient."</p>		Accept. Agree.	None.
9792.21(e)	<p>Commenter opines that the proposed language conflicts with Labor Code section 4604.5(a) because it establishes a different standard for rebuttal than is authorized by statute. Section 4604.5(a) provides, in part, that:</p> <p>"The presumption is rebuttable and may be controverted by a preponderance of the scientific</p>	Diane Worley California Applicants' Attorneys Association (CAAA) August 29, 2014 Written Comment	Reject: Commenter's suggested language is not adopted. However, clarifying changes are made to make clear there are two limited situations that may warrant treatment based on recommendations found outside the MTUS.	Section 9792.21(e) is deleted and replaced with section 9792.21.1(d), (1) and (2) which states, "(d) ... There are two limited situations that may warrant treatment based on recommendations found outside of the

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	<p>medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of his or her injury."</p> <p>Commenter recommends that proposed §9792.21(e) be amended to read:</p> <p>"(e) When the MTUS's presumption of correctness is challenged pursuant to Labor Code section 4604.5 or when there is a topical gap and a medical treatment or a diagnostic test is not addressed by the recommended guidelines set forth in the MTUS, medical care shall be based on a preponderance of the scientific medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of his or her injury."</p> <p>Commenter previously proposed the following language for §9792.21(e):</p> <p>" The MTUS's presumption of correctness may be rebutted if medical</p>			<p>MTUS." Section (d)(1) states, "First if a medical condition or injury is not addressed by the MTUS, medical care shall be in accordance with other medical treatment guidelines or peer-reviewed studies..." Section (d)(2) states, "Second, if the MTUS' presumption is successfully challenged. The recommended guidelines set forth in the MTUS are presumptively correct on the issue of extent and scope of medical treatment. The presumption is rebuttable and may be controverted by a preponderance of scientific medical evidence establishing</p>

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	<p>evidence is cited that contains a recommendation applicable to the specific medical condition or diagnostic test requested by the injured worker and the recommendation is the same level of evidence as the medical evidence used to support the MTUS's recommendation and the requesting physician documents the clinical justification for the treatment for this patient."</p> <p>Commenter believes that amending §9792.21(e) with this suggested language will provide needed clarity in the MTUS on how the presumption of correctness may be rebutted.</p>			<p>that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of his or her injury. The presumption created is one affecting the burden of proof. Therefore, the treating physician who seeks treatment outside of the MTUS bears the burden of rebutting the MTUS' presumption of correctness by a preponderance of scientific medical evidence."</p>
9792.21(g)	<p>Commenter notes that this section defines how a medical literature search is to be conducted "to find the best available medical evidence." As proposed, physicians are directed to first "search the most current version of ACOEM or ODG...." From a practical standpoint commenter does not believe it is appropriate under</p>	<p>Diane Worley California Applicants' Attorneys Association (CAAA) August 29, 2014 Written Comment</p>	<p>Accept in part. Reject in part. Accept: Section 9792.21(g) is deleted and replaced with section 9792.21.1(a). This re-organizational change is to clarify the medical evidence search sequence begins with the MTUS.</p>	<p>Section 9792.21.1(a) mandates the search to always begin with the MTUS, then in the limited situation where a medical condition or injury is not addressed by the MTUS or if the</p>

<b>Medical Treatment Utilization Schedule</b>	<b>RULEMAKING COMMENTS 15 DAY COMMENT PERIOD</b>	<b>NAME OF PERSON/ AFFILIATION</b>	<b>RESPONSE</b>	<b>ACTION</b>
	<p>these circumstances to instruct physicians to first look to ACOEM since a large portion of the MTUS already incorporates ACOEM guidelines.</p> <p>Commenter believes there is no statutory authority for this provision. The effect of this provision is to establish an additional hierarchy of evidence within the statutory hierarchy established under Labor Code section 4610.5, subdivision (b), paragraph (2).</p> <p>In order to eliminate what she opines is an inappropriate "hierarchy within a hierarchy," commenter recommends that Proposed §9792.21(g) be amended to delete "then" and add "or" at the end of paragraphs (1), and (2). Commenter opines that providing that the physician may use either paragraphs (1), (2), or (3) will allow review of any "peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service" as permitted by statute.</p>		<p>Reject: Section 9792.21.1(a) sets forth a medical evidence search sequence providing details of the way in which a search for medical evidence should be conducted. It is not a hierarchy of evidence, but rather, it mandates the search source order that must be followed when conducting a search for medical evidence. Although section 9792.25.1 references sections 9792.21.1(a)(2)(A), (B), and (C), it is provided as instruction to the physician to choose the best available evidence that they find when conducting their search for evidence. However, the MTUS Methodology for Evaluating Medical Evidence will only be formally applied by reviewing physicians as set forth in</p>	<p>MTUS' presumption of correctness is being challenged, then the sequence mandates a search of the most current ACOEM or ODG. Next the sequence mandates a search of the most current version of other evidence-based medical treatment guidelines, and finally, the sequence mandates a search for current studies that are scientifically-based, peer-reviewed, and published in journals that are nationally recognized by the medical community.</p>

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			section 9792.25.1 when competing recommendations are cited	
9792.21(i)	Commenter supports the proposed revision to this subdivision that requires Utilization Review(UR) and Independent Medical Review(IMR) Physicians to clearly document the level of evidence being applied to deny the treatment or diagnostic services being requested ,using the MTUS Hierarchy of Evidence for Different Clinical Questions as set forth in § 9792.25.1. Commenter opines that adding this requirement should allow all parties to easily determine the "highest level of evidence" applied to the treatment request, which will eliminate potential disputes. The result will be to speed up the final determination where there are competing recommendations between the treating physician and UR and IMR Physicians.	Diane Worley California Applicants’ Attorneys Association (CAAA) August 29, 2014 Written Comment	Agree. Accept. Although section 9792.21(i) is deleted and replaced with section 9792.21.1(b). This re-organizational change is to clarify the requirements necessary for treating physicians when making a Request for Authorization (RFA), the requirements necessary for Utilization Reviewers when modifying, delaying or denying an RFA, and the requirements necessary for Independent Medical Reviewers in the IMR decisions.	None.
9792.21(j)	Commenter supports the addition of this subsection, which reminds employers that they may approve “medical treatment beyond what is covered in the MTUS or supported by the best available medical evidence in	Diane Worley California Applicants’ Attorneys Association (CAAA) August 29, 2014	Accept. Agree. For organizational purposes section 9792.21(j) is replaced with 9792.21.1(e).	None.



<b>Medical Treatment Utilization Schedule</b>	<b>RULEMAKING COMMENTS 15 DAY COMMENT PERIOD</b>	<b>NAME OF PERSON/ AFFILIATION</b>	<b>RESPONSE</b>	<b>ACTION</b>
9792.21 9792.25.1	<p>Commenter is supportive of the changes that describe EBM as a systematic approach which allows the integration of the best available research evidence with clinical expertise to making clinical decisions by applying an explicit systematic methodology to focus the evaluation of medical evidence (i.e., Subdivision (e)(1) where rebuttal can be performed with a higher level of evidence than that used to support the MTUS' recommendation).</p> <p>Related to this, Subdivision (g) requires a medical literature search be conducted by medical reviewers and enjoins the requesting provider to find the highest level of applicable evidence specific to the injured workers' medical condition when the MTUS is silent on a particular medical condition or diagnostic test (Subdivision (f)).</p> <p>Commenter is concerned that the process of rebuttal and search by the practitioner is unworkably burdensome and thereby will threaten routine conservative and effective</p>	<p>Dean Gean, MD Bernyce Peplowski, DO Robert Blink, MD Steven Feinberg, MD Steven Levitt, MD Occupational &amp; Environmental Medicine (OEM) Physicians August 30, 2014 Written Comment</p>	<p>Accept: Although commenter did not include the phrase "patient values."</p> <p>Reject: Section 9792.21(g) is deleted and replaced with section 9792.21.1(a). Section 9792.21.1(a) sets forth a medical evidence search sequence providing details of the way in which a search for medical evidence should be conducted. It is not a hierarchy of evidence, but rather, it mandates the search source order that must be followed when conducting a search for medical evidence. Although section 9792.25.1 references sections 9792.21.1(a)(2)(A),</p>	<p>None.</p> <p>None.</p>

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	<p>care. Even with common work injuries, application of EBM to reasonable and necessary treatment plans is not always straightforward (e.g., due to patient-specific issues such as co-morbidities, age, psychosocial issues, cultural setting, religious background, genetics, etc.). Physician judgment should not replace proven and applicable evidence; but when such evidence is lacking, or only marginally applicable, there should be latitude to allow a physician to explain why a course of action is needed and to have such explanations given serious consideration.</p> <p>Commenter recommends that the DWC implement some process of supporting physicians' latitude in decision-making when it is supported by disciplined physician rationale done in accordance with accepted standards of practice. Commenter recommends that if a therapy or diagnostic test is denied despite a coherent presentation of a logical basis of clinical judgment, that in addition to following Subdivision (j) mandate to cite guidelines or EBM citations,</p>		<p>(B), and (C), it is provided as instruction to the physician to choose the best available evidence that they find when conducting their search for evidence. However, the MTUS Methodology for Evaluating Medical Evidence will only be formally applied by reviewing physicians as set forth in section 9792.25.1 when competing recommendations are cited.</p> <p>Reject: <del>Section 9792.21(j) is re-numbered and re-lettered to section 9792.21.1(e) should sufficiently cover commenter's concerns without regulatorily requiring reviewing physicians to provide a narrative response to a request made by treating physicians which may be interpreted as a requirement to provide a point by point narrative response. It appears commenter was referring to section 9792.21(h) rather than</del></p>	None.

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	<p>the DWC should require reviewers to specifically address a requesting physician’s explanation (which reasonably should articulate why a course of action is needed) and specifically address and give serious consideration to, in a logical analysis, the requesting physician’s rationale for treatment.</p> <p>Commenter has a related concern regards the application of Hierarchy of Evidence when determining care pathways for injured workers. Commenter is concerned that requiring a UR reviewer to rank by the hierarchy each reference submitted with an RFA could potentially delay decisions and substantially increase UR costs. Commenter opines that to properly rank a scientific article could require obtaining the full reference (with likely associated cost) and could well increase the time needed for a UR reviewer to complete a review. Commenter is concerned about providers who could submit voluminous, difficult to obtain references, slowing down the process and risking the reviewer missing a</p>		<p><u>9792.21(j) and was likely looking at the 45 day comment period version of the proposed regulations rather than the First 15 day version. Section 9792.21(h) is re-numbered and re-lettered to section 9792.21.1(b) to provide more detailed guidance of the process that must be followed after conducting a medical evidence search. However, commenter’s suggestion will not be adopted because it is couched in language that is overly broad. Commenter fails to define the phrase “accepted standards of practice”. Therefore, a reasonably articulated course of action may not be supported by medical evidence and may not comport with the statutory mandates of Labor Code sections 5307.27 and 4604.5(d), namely that authorized treatment shall be guided and in accordance with evidence-based standards of care.</u></p>	

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	<p>time limit.</p> <p>Commenter recommends that if the requesting provider relies on references not found in MTUS, ACOEM or ODG, that the articles referenced) or their abstracts if adequate to show the article’s place in the hierarchy of evidence) be submitted along with the providers’ request or appeal.</p>		<p>Accept: DWC is taking into consideration the tight time constrains necessary to complete a Utilization Review decision. Therefore, section 9792.21.1(b) is added to clarify the documentary requirements that must be provided by the treating physicians, especially when he or she is attempting to rebut the MTUS’ presumption of correctness, the Utilization Review physicians and the Independent Medical Review physicians. In addition, details are provided for the citation format that must be used.</p> <p>Reject: Requiring the treating physician to provide a copy of the full article may be overly burdensome.</p>	<p>Section 9792.21.1 is added to provide specific instructions to treating physicians and reviewing physicians after conducting the medical evidence search in the sequence set forth in section 9792.21.1(a). Any citation provided in the RFA, Utilization Review decision or Independent Medical Review decision “shall be the primary source relied upon which he or she believes contains the recommendation that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
				<p>injury” However, if more than one citation is provided, “then a narrative shall be included... explaining how each guideline or study cited provides additional information that guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury but is not addressed by the primary source cited.”</p> <p>None.</p>

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9792.25 9792.25.1	<p>Commenter states that access to actual full-text articles rather than abstracts can be expensive, and as a practical matter, at times, it can be impossible to review every bit of literature before making a time-sensitive decision on an individual case.</p> <p>Commenter states that the National Clearinghouse contains many divergent guidelines, most of which are not workers' compensation-related and many of which even contradict each other, even though all of the guidelines contained therein have passed the Appraisal of Guidelines for Research and Evaluation (<b>AGREE</b>).</p>	<p>Lisa Anne Forsythe Senior Consultant Coventry Workers' Compensation Services August 30, 2014 Written Comment</p>	<p>Accept: See previous response.</p> <p>Accept: Agree.</p>	<p>See previous response.</p> <p>None.</p>
Initial Statement of Reasons	<p>Commenter questions whether the statement of economic impact in the Initial Statement of Reasons (ISOR) remains valid given the likely significant increased costs associated with the amended regulations. Commenter assumes that Paragraph 5 of the ISOR refers to the requirements</p>	<p>Mark E. Webb Vice President General Counsel Pacific Comp August 30, 2014 Written Comment</p>	<p>Reject in part. Accept in part. Reject: The Initial Statement of Reasons remains valid. We disagree that the proposed regulations will significantly increase costs within the State of California.</p> <p>Accept: Item #5 and Item #6</p>	<p>None.</p> <p>None.</p>

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	<p>in Government Code §11346.2(b)(5)(A) and that Paragraph 6 of the ISOR refers to Government Code §11346.3(b)(1)(A-D) and not the statutory references that actually appear in the ISOR.</p> <p>With that assumption, commenter notes that the ISOR states, under Paragraph 5:</p> <p>“Although there may be minor costs to disseminate the amended criteria to serve as reference material in the medical decision making process, those costs will likely be offset by the savings from avoidance of inappropriate medical treatment, the delivery of state-of-the-art treatment when appropriate for the patient, improved health outcomes, and reduced overall costs of caring for chronic conditions.”</p> <p>Commenter notes that there is no reference to any study or other supporting information for this conclusion. In fact, however, there is evidence to the contrary:</p>		<p>contains incorrect citations and should be Government Code §11346.2(b)(5)(A) and §11346.3(b)(1)(A-D) respectively.</p> <p>Reject: Commenter cites the <i>WCIRB January 1, 2015 Pure Premium Rate Filing</i>, but it merely shows that the estimated frictional costs savings of approximately \$200 million resulting from the IMR provisions of SB 863 are not reflected. The ISOR’s Economic Impact Analysis is an assessment of the economic impact of these proposed regulations. DWC maintains its position in the ISOR which states, “The proposed regulations will explain and clarify the scientific process by which clinical decisions are made for injured workers. The</p>	None.

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	<p>“The WCIRB’s estimated frictional cost savings related to IMR were predicated on replacing higher cost medical treatment dispute resolution mechanisms such as medical liens and the qualified medical evaluator (QME) and expedited hearing processes with lower cost IMRs. However, Division of Workers’ Compensation (DWC) data on IMR suggests the volume of IMRs is two to four times higher than that contemplated in the initial cost estimates. Also, while at a reduced volume, medical treatment on a lien basis is still occurring. Finally, while qualified medical evaluations are generally not being conducted on medical necessity issues, many claims, partially in response to the Dubon decision, are having expedited hearings on utilization review issues. For all these reasons, the WCIRB’s updated cost projections reflected in the proposed January 1, 2015 pure premium rates do not reflect the estimated frictional cost savings of approximately \$200 million resulting from the IMR provisions of SB 863 that were reflected in earlier WCIRB evaluations of SB 863.”</p>		<p>MTUS Hierarchy of Evidence for Different Clinical Questions will replace the strength of evidence methodology that was limited in scope and will provide clearer guidance for medical decision-makers and treating physicians.”</p>	



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	<p>imposed on all claims administrators require that, "...policies and procedures shall ensure that decisions based on the medical necessity to cure and relieve of proposed medical treatment services are consistent with the schedule for medical treatment utilization adopted pursuant to Section 5307.27." [Labor Code § 4610(c)] Finally, the MTUS is the framework by which independent reviewers must assess whether a decision by a claims administrator that does not approve a request for authorization (RFA) for medical treatment was appropriate. [Labor Code § 4610.5(c)(2)]</p>			
<p>9792.21(e) 9792.21(f)(2) 9792.21(g)-(i)</p>	<p>Commenter notes that the Division has adopted significant regulations regarding the UR process. 8 CCR § 9792.7(a)(3) states that a utilization review plan must contain:</p> <p>“A description of the specific criteria utilized routinely in the review and throughout the decision-making process, including treatment protocols or standards used in the process. The treatment protocols or standards governing the utilization review</p>	<p>Mark E. Webb Vice President General Counsel Pacific Comp August 30, 2014 Written Comment</p>		

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	<p>process shall be consistent with the Medical Treatment Utilization Schedule adopted by the Administrative Director pursuant to Labor Code section 5307.27.”</p> <p>Proposed 8 CCR § 9792.21(f)(2), states:</p> <p>“Utilization Review physicians shall apply the medical literature search sequence set forth in subdivision 9792.21(g) if the requesting treating physician cited a recommendation in the chart notes or Request for Authorization and the requested treatment or diagnostic service is being denied;”</p> <p>Commenter opines that the proposed language would seem to require significant additional activities by UR physicians when denying treatment. [See also: proposed 8 CCR § 9792.21(g) – (i)] This is a cost. Commenter states that while it may be implied that this process is applied only when there is a question of whether the recommended treatment in the MTUS is rebutted by the</p>		<p>Reject: Disagree. Utilization Review decisions and Independent Medical Review decisions are required to be consistent with the Medical Treatment Utilization Schedule. The MTUS consist of section 9792.20 through section 9792.26. Currently, the MTUS requires the application of a strength of evidence rating</p>	<p>None.</p>

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	<p>documentation appended to an RFA or existing within chart notes somewhere, or when the MTUS is silent on the condition for which treatment is sought, as noted <i>post</i> the plain language of the regulation does not limit the medical literature search to such circumstances.</p> <p>Commenter states that even assuming this paragraph applies only in circumstances described in proposed subdivision (e) of 8 CCR § 9792.21, the potential cost must be measured not just by the additional expense of conducting such a search but also the potential frictional costs of proving such a search did in fact take place. <i>Dubon v. World Restoration, Inc.</i> (2014) 79 Cal. Comp. Cases 566 stands, at least for the moment, for the proposition that adhering to the rules and regulations governing the UR process is a legal question and that if a violation of a certain gravity is proved the workers' compensation judge may then put back on his or her stethoscope and make a medical necessity decision based on the requesting physician's documentation. Regardless of the</p>		<p>methodology set forth in section 9792.25(c)(1) if there are competing recommendations. These proposed regulations revise the current strength of evidence rating methodology by providing a more comprehensive and less burdensome process to evaluate medical evidence when there are competing recommendations. The reason for the inclusion of a medical evidence search sequence set forth in section 9792.21.1(a), replacing 9792.21(g), is to ensure consistency and efficiency. We are providing physician's in the worker's compensation system guidance in how to search for medical evidence. Conducting a medical literature search is costly and time consuming. These proposed regulations provide an abridged search sequence, instructing providers to first look at the MTUS, then ACOEM or ODG, then other</p>	

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	<p>wisdom of the Dubon decision (presently under reconsideration) it is the law. Commenter opines that adding more requirements and complexity to the UR process, as noted by the WCIRB, also likely adds litigation costs to the system.</p>		<p>medical treatment guidelines because a medical literature search has already been conducted by these guideline makers. However, the search sequence also allows a physician to search for current studies that are scientifically-based, peer-reviewed, and published in journals that are nationally recognized by the medical community to account for, in particular, new evidence that may not yet be included in a guideline.</p> <p>Reject: In light of <i>Dubon v. World Restoration, Inc.</i>, 79 Cal. Comp. Cases 1298 (Appeals Board en banc opinion)(Dubon II) where the Appeals Board held that a UR decision is invalid and not subject to IMR only if it is untimely; and in light of the statutorily limited avenues to judicially appeal an IMR decision, we do not believe our proposed regulations will lead to a significant increase in</p>	<p>None.</p>

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			expedited hearings at the WCAB.	
9792.21(f)(3) 9792.21(i)(2)	<p>Commenter opines that given that the definition of “medical treatment guidelines” in proposed 8 CCR § 9792.20(g) would appear to have the consequence that all currently existing specific guidelines are now outdated, it is not unreasonable to assume that paragraph (3) of subdivision (f) of proposed 8 CCR § 9792.21 applies to <i>all</i> independent reviews.</p> <p>Commenter states that given that the method of conducting reviews was not specified in the RFP for independent review services (DIR DWC RFP#14-001), which required only that the successful independent review organization (IRO) demonstrate, “Experience and familiarity with evidence-based medical treatment and guidelines, and understanding of the workers’ compensation Medical Treatment Utilization Schedule (MTUS) in the State of California,” it is not unreasonable to assume that imposing the requirements of the literature search in subdivision (g) of</p>	Mark E. Webb Vice President General Counsel Pacific Comp August 30, 2014 Written Comment	Reject in part. Accept in part. Reject: The definition for “Medical Treatment Guidelines” set forth in section 9792.20(g) will continue to contain the phrase “reviewed and updated within the last five years” because it is important that the most current versions of the guidelines are relied upon when a treatment request is made that is based on recommendations found outside of the MTUS or when MEEAC reviews guidelines to update the MTUS. The five year time period is necessary to give the phrase “most current version” context. However, if a guideline or study is older than five years old, it may be outdated, but by no means is it considered invalid if it contains seminal scientific studies that are still the basis of unchanged recommendations.	None.

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	<p>this proposed regulation would significantly add to the costs if the IMR process. [See also: proposed 8 CCR § 9792.21(h) – (i)]</p> <p>Commenter states that IMR was intended to reduce overall workers’ compensation costs by \$300M. Commenter states that none of these estimated savings has been achieved. Total medical cost containment expenses for insurers alone were \$446M during calendar year 2013. (WCIRB (2014), <i>Report on 2013 California Workers’ Compensation Losses and Expenses</i>) Commenter has seen a very large universe of IMR requests starting in August of 2013. In May of this year alone, there were over 19,000 IMR requests. (WCIRB Claims Working Group Meeting of July 31, 2014, citing DWC statistics) Commenter states that the costs of 2014 IMR have not worked their way into the data, but will by necessity further increase the medical cost containment expenses in the system.</p> <p>Commenter opines that the proposed</p>		<p>Accept: Individual studies described in section 9792.20(g)(3), replaced by section 9792.21.1(a)(2)(C), should be no older than 5 years old to be considered up-to-date.</p> <p>Reject: Disagree. As commenter’s quote from the RFP states, “...understanding of the workers’ compensation Medical Treatment Utilization Schedule...” Again, the MTUS consist of section 9792.20 through section 9792.26. Currently, the MTUS requires the application of a strength of evidence rating methodology set forth in section 9792.25(c)(1) if there are competing recommendations. (See previous response).</p> <p>Reject: See previous response.</p>	<p>None.</p> <p>None.</p> <p>None.</p>

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	<p>regulations also call into question whether new and costly challenges to IMR will be created. 8 CCR §9792.10.6(d) states:</p> <p>“The determination issued by the medical reviewer shall state whether the disputed medical treatment is medically necessary. The determination shall include the employee’s medical condition, a list of the documents reviewed, a statement of the disputed medical treatment, references to the specific medical and scientific evidence utilized and the clinical reasons regarding medical necessity.”</p> <p>Commenter opines that the proposed regulations establish somewhat elaborate requirements upon the IMR reviewer which can be assumed would need to be documented in the determination sent to the Administrative Director in accordance with the aforementioned regulation. [See: Proposed 8 CCR § 9792.21(f)(3) and (i)(2)] Commenter wonders if this would mean that if there was a dispute over whether this search process was</p>		<p>Reject: Although our proposed regulations set forth a mandatory medical evidence search sequence, there is no required documentation to show that the sequence has been followed. The medical evidence search sequence merely sets forth the order in which a physician shall conduct his or her search for medical evidence. The medical evidence search sequence is set forth in these proposed regulations in the interest of consistency and efficiency. We provided guidance to the physician to simplify the medical evidence search process. From a substantive standpoint, however, there is no difference if a physician found what he or she believes to be the best available evidence in the MTUS or an</p>	<p>None.</p>

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	<p>properly performed a determination by the Administrative Director could be overturned because, “(t)he administrative director acted without or in excess of the administrative director’s powers by approving a determination that didn’t correctly follow the search requirement?</p> <p>From what commenter has observed as numerous assaults on UR and IMR, the scope of challenge is basically limited only by the creativity of attorneys to see what may stick when thrust aggressively upon the wall of the WCAB.</p> <p>Commenter states that this too involves costs.</p> <p>Commenter states that the purpose of this review is not to attempt to assign a specific cost increase number to these proposed regulations. Instead, the purpose is to show that these regulatory initiatives are not without cost, and that the rule making proceeding has not reflected the necessary studies and analysis required by the Government Code to</p>		<p>individual study. The issue will be how the reviewing physician evaluates medical evidence supporting the competing recommendations. These proposed regulations provide a comprehensive, transparent, systematic process to evaluate medical evidence in section 9792.25.1.</p> <p>Reject: Clarifying this requirement is necessary as evidenced by comments similar to this that fails to acknowledge this process is already required pursuant to current section 9792.25(c)(1).</p> <p>Reject: Again, the requirement to evaluate competing recommendations already exist. In addition, although the medical evidence search sequence is introduced with these proposed regulations, by implication, the requirement to search for medical evidence already exists. For example, if</p>	<p>None.</p> <p>None.</p>

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	<p>assess and, where possible, quantify these costs.</p> <p>Commenter opines that a relative modest increase in costs to the UR/IMR processes, especially in the post- Dubon environment, can lead to significant system-wide costs. Commenter states that by the time these regulations are adopted, an approximate estimate of only a 10 percent increase in medical cost containment expenses, using likely 2014 costs, would place the economic impact of these regulations in excess of the \$50M threshold that would require the Division to acknowledge these rules are major regulations, as defined in Government Code § 11342.548 and thus requiring the analysis set forth in Government Code § 11346.3(c)(1) as set forth in 1 CCR §§ 2000 et seq.</p> <p>Commenter opines that regardless of whether these regulations constitute major regulations, however, the cost impact has not been measured and as such this proceeding is defective.</p>		<p>a medical condition or injury is not addressed by the MTUS and the Utilization Review decision modifies, delays or denies the treating physician's Request for Authorization, the decision must be supported by medical evidence and a citation provided. It is implied, that the UR physician had to search for the medical evidence in order to come up with the citation. These proposed regulations merely provide guidance to a process that is already required.</p>	
General Comment	Commenter states that there are	Mark E. Webb	Reject in part. Accept in part.	Section 9792.21(f)(2)

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	<p>provisions that are potentially in conflict with existing law and regulations. [See: Government Code § 11349(d)] Commenter states that Proposed 8 CCR § 9792.21(f)(2) appears to place new requirements on UR plans regulated under 8 CCR § 9792.7(a)(3), <i>supra</i>, at least for denials.</p> <p>Commenter notes that it appears that delays or modifications to an RFA would follow a different procedure. Labor Code § 4610(e) states: “(n)o person other than a licensed physician who is competent to evaluate the specific clinical issues involved in the medical treatment services, and where these services are within the scope of the physician’s practice, requested by the physician may modify, delay, or deny requests for authorization of medical treatment for reasons of medical necessity to cure and relieve.”</p> <p>Commenter states that the proposed regulation apparently requires a different UR process for delays and modifications that it does for denials. This is not a distinction made in the</p>	<p>Vice President General Counsel Pacific Comp August 30, 2014 Written Comment</p>	<p>Reject: Disagree that these proposed regulations are in potential conflict with existing laws and regulations. Accept in part: Section 9792.21(f)(2) is re-numbered and re-lettered to section 9792.21.1(b)(2)(A) and the words “modified” and “delayed” are added to comport with the language used in Labor Code section 4610.</p> <p>Reject: This was not the DWC’s intent. Also, see previous response regarding the revisions made.</p>	<p>is re-numbered and re-lettered to section 9792.21.1(b)(2)(A) and states, “...if the RFA is being modified, delayed or denied.”</p> <p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>regulations adopted by the Division specifically addressing the UR process. See: 8 CCR § 9792.7(b). Consistency as defined in Government Code § 11349(d) means; "...being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law."</p> <p>Commenter states that the recent Appeals Board decision in <i>Hernandez v. Geneva Staffing, Inc.</i> (2014) Case No: ADJ7995806 calls into question the interpretation of this proposed regulation and its reference to "chart notes or Request for Authorization". The Board, by its embracing Business &amp; Professions Code § 4040, would seem to have imposed a broader definition of what may trigger UR, at least for a "prescription" for purposes of home health care. Following the Board's logic, it would seem that <i>Hernandez</i> would be applicable to all circumstances where something is "prescribed" and the proposed regulation is inconsistent with that holding.</p>		<p>Reject: Disagree with commenter's interpretation of <i>Hernandez</i> that a prescription "may trigger UR" for purposes of home health care. <i>Hernandez</i> states, "This prescription requirement is a limit on the employer's duty to provide medical treatment". A prescription puts the employer/claims adjuster on notice for payment of home health care services. However, a prescription alone does not obviate the need for a physician to submit an RFA. <i>Hernandez</i> goes on to state, "But, by itself, a prescription is not 'proof' of what are reasonable and necessary home</p>	<p>None.</p>

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	<p>The ISOR states, in regards to 8 CCR § 9792.21 in general:</p> <p>“However, since the MTUS cannot address every conceivable medical condition or if there is evidence to rebut the MTUS, these proposed amendments specify the procedure to evaluate medical evidence in order to determine the best available medical evidence. The process begins with a medical literature search sequence that shall be conducted by providers making treatment decisions and should be conducted by treating physicians.”</p> <p>Commenter opines that this explanation certainly makes sense and is implied in subdivision (e) of proposed 8 CCR § 9792.21. The difficulty, however, is that proposed subdivision (f) doesn’t expressly apply only to such circumstances. It would appear to apply to <i>all</i> denials. Commenter states that if the Division intends to state that the requirements of subdivision (f) apply only to those situations described in subdivision (e) and the ISOR of this</p>		<p>health care services. Injured workers bear the burden to prove that the services are reasonably required. Injured workers and their physicians are required to comply with the applicable rules and statutes when seeking services.”</p> <p>Section 9792.6.1(t) requires a RFA.</p> <p>Accept in part. Reject in part. Accept: Clarification is made to section 9792.21 breaking it up into two sections, 9792.21 and 9792.21.1. Section 9792.21 discusses the role of the MTUS. Section 9792.21.1 will separately set forth the Medical Evidence Search Sequence and then provide clear instructions to physicians after they’ve conducted a medical evidence search. Every search for medical evidence begins with the MTUS and likely ends there, unless, the treatment request falls under the limited situation where a medical condition or</p>	<p>Section 9792.21 is broken up into two sections, 9792.21 and 9792.21.1. Section 9792.21.1(a) “Treating physicians and medical reviewers shall conduct the following medical evidence search sequence for the evaluation and treatment of injured workers.” (a)(1) states, “Search the recommended guidelines set forth in the current MTUS to find a recommendation applicable to the injured worker’s medical condition or injury.” (a)(2) states,</p>

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	<p>proposed regulation, then it needs to say so.</p> <p>Commenter states that the scope of subdivision (f) is in conflict with the ISOR and, more importantly, with 1 CCR § 16(a)(2), which provides that a regulation is presumed to violate the clarity standard in Government Code § 11349 if, "...the language of the regulation conflicts with the agency's description of the effect of the regulation." See also: <i>Sims v. Department of Corrections &amp; Rehabilitation</i> (2013), 216 Cal. App. 4th 1059; 157 Cal. Rptr. 3d 409.</p> <p>Commenter requests that rather than going through the many conflicts the proposed regulations create with existing regulations governing UR and IMR, that the Division consider a broader question. In order for there to be a rebuttal to the MTUS there needs to be a specific guideline to rebut. As was indicated previously, "Medical treatment guidelines":</p> <p>"...means the most current version of written recommendations which are</p>		<p>injury is not addressed by the MTUS or if the MTUS' presumption of correctness is being challenged.</p> <p>Reject: Whenever there are competing recommendations, then reviewing physicians shall evaluate the different recommendations pursuant to the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1.</p>	<p>"In the limited situation where a medical condition or injury is not addressed by the MTUS or if the MTUS' presumption of correctness is being challenged then:" What follows is the Medical Evidence Search Sequence. Section 9792.21.1(b) provides detailed instructions to treating physicians, utilization review physicians and Independent Medical review physicians after conducting the medical evidence search in the sequence provided. Section 9792.21.1(c) states, "If the treating physician and/or the Utilization Review physician and/or the</p>

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	<p>systematically developed by a multidisciplinary process through a comprehensive literature search to assist in decision-making about the appropriate medical treatment for specific clinical circumstances reviewed <i>and updated within the last five years.</i>” [Proposed 8 CCR 9792.20(g)]</p> <p>Commenter opines that this would, in essence, repeal by implication all the specific guidelines in 8 CCR § 9792.23.1 through 8 CCR § 9792.24.3, as all of these specific guidelines are now over 5 years old and, by definition are not “guidelines” were this definition to be adopted.</p> <p>Commenter opines that it appears that what the Division is attempting to do is fundamentally alter Labor Code § 5307.27 to say that the Division is going to adopt a set of guidelines on how to evaluate other guidelines but not expressly to adopt a MTUS, “...that shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly</p>		<p>Reject: Disagree. There is no attempt by the DWC to fundamentally alter Labor Code section 5307.27. The MTUS constitutes the standard of care for the provision of medical care in accordance with Labor Code section 4600. The MTUS remains valid even</p>	<p>Independent Medical Review physician cited different guidelines or studies containing recommendations that are at variance with one another, the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1 shall be applied by the reviewing physician to determine which one of the recommendations is supported by the best available evidence.”</p> <p>None.</p>

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	<p>performed in workers' compensation cases.”</p> <p>The product of this process of literature review and application of hierarchy of evidence would then produce a decision that would, apparently <i>ad hoc</i>, have attached to it a presumption of correctness. Labor Code § 4604.5(a) states:</p> <p>“The recommended guidelines set forth in the medical treatment utilization schedule adopted by the administrative director pursuant to Section 5307.27 shall be presumptively correct on the issue of extent and scope of medical treatment. The presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of his or her injury. The presumption created is one affecting the burden of proof.”</p> <p>A presumption affecting the burden of</p>		<p>if it has not been updated in the last five years. Guidelines that have not been updated or reviewed within the last five years may not be up-to-date, but they are by no means expired or invalid. The phrase that guidelines be “reviewed and updated within the last five years” will remain because it is important that the most current versions of the guidelines are relied upon when MEEAC reviews guidelines to update the MTUS or when a treatment request is made that is based on recommendations found outside of the MTUS. However, there may be seminal scientific studies that support recommendations in a medical guideline that have not been updated in the past 5 years or that may have carried over to updated versions of the medical guideline because it is still the best available medical evidence and the recommendations remain unchanged.</p>	

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	<p>proof is a presumption established to implement some public policy other than to facilitate the determination of the particular action in which the presumption is applied, such as the policy in favor of establishment of a parent and child relationship, the validity of marriage, the stability of titles to property, or the security of those who entrust themselves or their property to the administration of others. (Evidence Code § 605)</p> <p>Further, the Appeals Board may take into evidence, “The medical treatment utilization schedule in effect pursuant to Section 5307.27 or the guidelines in effect pursuant to Section 4604.5.”</p> <p>As stated in Government Code § 11342.2, “Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of</p>			

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	<p>the statute.”</p> <p>Commenter states that the proposed MTUS regulations are indeed in conflict with the statutes that authorize it.</p> <p>Commenter, during the course of this rule making proceeding, has stated that there needs to be a reexamination of the wisdom of having specific medical treatment guidelines as opposed to a process whereby a peer to peer discussion can be facilitated to provide the best and most effective treatment to injured workers. Doing that within the statutory constraints of the MTUS is difficult at best.</p> <p>Commenter opines that the Division needs to focus far less on the legal aspects of the MTUS and far more on the clinical ones. States across the country with similar legislative authority have provided relatively easy to use guidelines that support evidence based medicine and can nevertheless promote a positive dialogue between providers and payers. Commenter states that this</p>		<p>Reject: Disagree, see previous response.</p> <p>Reject: Peer to peer discussions are always encouraged. There is nothing in these proposed regulations that preclude or discourages peer to peer discussions. However, it is important that a transparent, systematic process is in place to evaluate medical evidence if there is a dispute between which recommendation determines the injured worker’s medical care.</p>	<p>None.</p> <p>None.</p>

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	<p>does not require building up further the evidentiary foundation for any possible course of treatment in order to be worthy of a legal presumption that no longer has a place in resolving disputes over medical necessity.</p> <p>Commenter opines that the Division should use this elaborate mechanism to identify the existing body of evidence based guidelines and send a clear message to providers and payers alike as to what is expected when treating someone who has suffered an occupational injury or illness.</p>		<p>Reject: Labor Code section 4604.5 is still in effect and clearly states the MTUS “shall be presumptively correct on the issue of extent and scope of medical treatment. The presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of his or her injury. The presumption created is one affecting the burden of proof.” These proposed regulations make it clear that the MTUS constitutes the standard of care for the provision of medical care in accordance with Labor Code section 4600. It provides a transparent, systematic,</p>	<p>None.</p>

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			methodology to evaluate medical evidence when there are competing recommendations.	