

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
General Comment	<p>Commenter opines that the new guidelines seem to be directed towards limiting treatment to the injured worker needs and is leaving it up to the carrier to decide what is necessary. Commenter recommends the following.</p> <p>1. Functional Improvement should also mean maintenance of ADL's. Some patient's pain is so severe, that they need regular medical treatment just to be able to survive day to day even in PNS state. Don't forget the law states "cure or relieve" effects of industrial injury. If the pain is not treated, we are not following "relieve" part of the law.</p> <p>2. If a source of Guidelines discussing treatment in question within the last 5 years is not available, one should be able to cite the latest available.</p> <p>3. Commenter fails to see how it is a fair situation for an injured worker, when a third party, who is not directly involved in day-to-day care and who never examined the patient, has the last say in what treatment the IW is to</p>	<p>Michael Bazel, MD November 28, 2014 Written Comment</p>	<p>Reject: Disagree. Evidence-based medicine will dictate what reasonable and necessary medical treatment is.</p> <p>Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.</p> <p>Reject: Our proposed regulations require that the most current version of the guideline be cited.</p> <p>Reject: Labor Code section 4604.5 is clear that the MTUS and all treatment not covered by the MTUS shall be evidenced-based. The definition of evidenced-based</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>

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	<p>get. The treating physician already has an uphill battle in trying to prove his treatment plan. Medicine is not black and white. Medical Doctor who has gone through years of Medical School and Residency and gained years of experience and has examined his patient and has developed relationship with his patient should be able to decide what is good for his patient, not some bureaucrat sitting in the office, who is conducting a paperwork review for \$85 per hour. Currently proposed guidelines place no importance on Medical Doctor's experience.</p> <p>Commenter opines how ridiculous is it to say that employer and their representative, "at their discretion," may approve the treatment. Commenter wonders how often this would happen. May be ... never? Commenter states that the goal of insurance company is very different from its responsibility. By law, they are required to provide medically necessary treatment, but their goal is to deny as much as possible, so they can save money for the next</p>		<p>medicine allows for the integration of the best available research evidence with clinical expertise and patient values.</p> <p>Reject: Section 9797.21(j) is re-numbered and re-lettered to section 9792.21.l(e) and is provided for patients who do not technically meet guideline criteria or their clinical diagnostic and therapeutic situations are not covered by evidence-based medicine. Disagree that employers or their representatives will “never” approve especially when the medical records</p>	None.

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	<p>stockholders report. Commenter opines that if the DWC does not provide an incentive for insurance companies to provide timely care, the injured worker will be at even more disadvantage he is now.</p> <p>Commenter questions if the people who opted to give the last say to the insurance company regarding treatment decisions would actually want to be treated under such a system.</p>		<p>show objective clinical benefit from previous treatment that do not technically meet guideline criteria.</p> <p>Reject: Goes beyond the scope of this rulemaking.</p>	None.
General Comment	<p>Commenter opines that the most recent proposed revision of the California MTUS, while somewhat improved relative to the original proposal, still suffers from significant flaws.</p> <p>In addition to being in some ways fundamentally inconsistent with the principles of evidence-based medicine, commenter states that the adoption of the current proposal would create a significant deterioration of the workers compensation system in California. The most significant problems associated with the current proposed MTUS are listed below;</p>	Robert Ward December 8, 2014 Written Comment	Reject: Disagree that these proposed regulations are fundamentally inconsistent with the principles of evidence-based medicine. It is consistent with the definition provided by David Sackett who is widely regarded as one of the pioneers of evidence-based medicine. "Evidence-Based Medicine means a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient values."	None.

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	<p>followed by a more detailed discussion of each problem noted; and finally by suggestions for amendment.</p> <p>Significant issues with the proposed MTUS:</p> <ol style="list-style-type: none"> 1) Inconsistent with, and violates, California Labor Code 4604.5(a) 2) Internally inconsistent, and inconsistent with the principles of evidence-based medicine 3) Highly probable to result in very significant cost increases to California employers 4) Highly probable to result in significant increases in delays of delivery of medical treatment 5) Creates new, unanticipated and potentially serious risks of significant harm to injured workers 6) Creates an overly-laborious, broadly applied solution to address a potential problem of entirely unknown scope and impact. <p>1) Inconsistent with, and violates, California Labor Code 4604.5(a)</p> <p>LC4604.5(a) (cited below for convenience) explicitly establishes:</p>		<p>Reject: Commenter’s interpretation that the UR or IMR physician“...is required to immediately abandon the recommendation of the</p>	<p>None.</p>

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	<p>(1) that the MTUS has a rebuttable presumption of correctness on issues of medical necessity; and (2) that the burden of proof for overcoming this presumption lies with the party seeking to rebut the presumption. The current MTUS proposal patently sets aside both of these requirements.</p> <p>Commenter states that under the currently proposed process, in any instance where the requesting physician cites any reference material of any type (even if that citation is the MTUS), the UR physician or IMR physician is required to immediately abandon the recommendation of the MTUS; and to instead seek evidence as per proposed 9792.25.1, and rely on the recommendations therein. This is not a process for rebuttal of the presumption of correctness; but is actually an a priori abandonment of the presumption prior to any assessment of the evidence provided by the requesting physician.</p> <p>Commenter states that under the currently proposed process in 9792.25.1, the burden of proof is not</p>		<p>MTUS” whenever a treating physician provides a citation is incorrect. The UR or IMR physician is required to apply the MTUS Methodology for Evaluating Medical Evidence only when there are competing recommendations. A fundamental concept of evidence-based medicine is that the best available evidence is used to guide clinical decisions. Therefore, a system must be in place to evaluate medical evidence in order to determine the quality and strength of evidence used to support the recommendations for a medical condition or injury.</p> <p>Reject: Section 9792.21 clearly states “the treating physician who seeks treatment outside of</p>	<p>None.</p>

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	<p>placed on the party seeking to rebut the presumption of correctness. Rather, the burden of proof defaults to the reviewing physician.</p> <p>Commenter opines that unless and until these deficiencies are corrected, it is doubtful that the proposed process would withstand judicial scrutiny.</p> <p>4604.5. (a) 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>2) Internally inconsistent, and inconsistent with the principles of</p>		<p>the MTUS bears the burden of rebutting the MTUS' presumption of correctness by a preponderance of scientific medical evidence." In addition, section 9792.21.1(b)(1)(B) requires the treating physician to provide a citation in the RFA or attachment to the RFA of the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment.</p> <p>Reject: Commenter's statement that these regulations</p>	<p>None.</p>

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	<p>evidence-based medicine</p> <p>It is the intention of the authors of the proposed MTUS that physicians would seek evidence in the following order of preference, and make determinations consistent with the recommendations (applicable to the injured worker's condition and the medical treatment under consideration), consistent with the following ordered source hierarchy:</p> <ol style="list-style-type: none"> 1) MTUS 2) Most recent version of ACOEM or ODG 3) Most recent version of other nationally recognized evidence-based medical treatment guidelines 4) Current peer-reviewed, scientifically-based publications <p>This intention of the authors is codified in proposed 9792.21(d)(1).</p> <p>Unfortunately, the proposed process as described in 9792.21.1 and 9792.25.1 does not operate in this manner. The proposed process actually makes it entirely impossible for any reviewing physician to rely on an applicable</p>		<p>“requires that the reviewing physician abandon the guideline recommendation in favor of a single publication from the guideline bibliography” is incorrect. The MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1(a) states, “This methodology provides a process to evaluate studies, not guidelines” is misinterpreted by commenter. This same section goes on to state, “Therefore, the reviewing physician shall evaluate the underlying study or studies used to support a recommendation found in a guideline.” The guideline recommendation is not abandoned as commenter suggests, rather, the reviewer is required to evaluate the medical evidence supporting the recommendation. This is an example of the comprehensiveness of our proposed methodology which</p>	

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	<p>recommendation from any guideline not adopted into the MTUS. This is because, upon finding an applicable recommendation in such a guideline, the reviewing physician is mandated to apply the process described in 9792.25.1; which in turn requires that the reviewing physician abandon the guideline recommendation in favor of a single publication from the guideline bibliography.</p> <p>In addition to being procedurally inconsistent, the current process proposal is also inconsistent with the statement that the MTUS is consistent with the principles of evidence-base medicine, as found in proposed 9792.21(b). The procedurally forced abandonment of a high-quality, consensus-based recommendation derived from a wide literature base in favor of a recommendation from a single publication is both unsupportable and antithetical to the principles of evidence-based medicine.</p> <p>3) Highly probable to result in very significant cost increases to California</p>		<p>allows a reviewing physician to evaluate the medical evidence supporting guideline recommendations with the medical evidence supporting a single study.</p> <p>Reject: See previous response.</p> <p>Reject: Disagree that these proposed regulations will</p>	<p>None.</p> <p>None.</p>

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	<p>employers</p> <p>The proposed process is very resource intensive. To search out, obtain, evaluate and document evaluation of evidence as described in the proposed process would take a significant amount of time for each recommendation. For evaluation of treatment plans containing multiple services without MTUS recommendations; and/or instances where the treating physician has cited multiple references; this process can potentially add many hours of reviewer time to each utilization review and each independent medical review.</p> <p>Commenter states that most physicians are more entrepreneurial than altruistic, in that few will work for free. This means that UR physicians will need to be compensated for their time. As the cost of UR physician time increases, the overall cost of UR will increase to insurers/employers.</p> <p>As the cost of UR increases, there will</p>		<p>result in very significant cost increases to California employers. Costs to California employers will not significantly increase because a similar systematic approach is already required pursuant to current section 9792.25(c)(1) which was adopted from ACOEM. These proposed regulations clarify this requirement and sets forth in detail the process that needs to be followed when there are competing recommendations. Although the medical evidence search sequence is introduced with these proposed regulations, by implication, the requirement to search for medical evidence already exists as well. For example, if 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</p>	

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	<p>be an increase in the number of treatment plans that will not be sent to UR, even if the claims administrator believes the treatment likely to be unnecessary. This is because there will be an actuarial determination that the probable cost of care is less than or equal to the more costly UR process. This type of decision-making will result in increases in medical treatment costs.</p> <p>Insurers and employers will face a meaningful increase in overall costs. They will have to choose whether to bear those additional costs in UR; or in additional unnecessary medical treatment.</p> <p>Additionally, in the evaluation of treatment plans for which multiple cycles of the proposed MTUS process will be necessary to review the treatment plan, timely completion of a decision may be unachievable. As any late review determination is invalid at the WCAB, it is predicted that it will become increasingly common for treating physicians to use the proposed process to prevent timely UR as a</p>		<p>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> <p>Reject: See previous response.</p> <p>Reject: See previous response.</p>	<p>None.</p> <p>None.</p>

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	<p>The implementation of the proposed MTUS process drives up the cost of UR and also medical treatment costs, insurers and employers will naturally be attracted to the use of other mechanisms to limit costs.</p> <p>It is predicted that disputes of liability will become more commonplace. In some instances, such an increase may be appropriate. However, it is also predicted that this will become more common in inappropriate instances; particularly with regard to the treatment of iatrogenic effects of treatment for the original industrial condition(s).</p> <p>Many insurers are at this time readily accepting requests for authorization, even if the requesting provider has not utilized Form RFA; has utilized an outdated Form RFA; or has committed some error in the completion and submission of the request for authorization. As the proposed MTUS process drives medical and review costs upward, insurers and employers will likely engage in efforts to cease accepting treatment plans in instances</p>		<p>Reject: Treatment harms is one of the factors considered when applying the MTUS Methodology for Evaluating Medical Evidence.</p> <p>Reject: See previous response regarding commenter's predictions of increased costs and the response provided.</p>	<p>None.</p> <p>None.</p>

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	<p>where the intent is clear, but the execution of the paperwork is flawed. This is a nearly cost-free alternative to actually rendering a decision on medical necessity, and in many instances will serve only to delay or prevent appropriate care.</p> <p>In the event of an adverse determination via the UR process, if the same treatment is requested by the same provider within 12 months, and the documentation does not contain evidence of a material change in the case relevant to the reasons for the prior adverse determination, the insurer/employer is not required to take any "further action". Many insurers are not currently making use of this provision of LC4610. Among those that are, correspondence to the treating physician explaining why their request for authorization is not being reviewed is provided as a courtesy is common. As the proposed MTUS drives costs upward, the use of this process to make treatment unavailable to the injured worker for a period of 12 months will increase; and the frequency of communicating this</p>		<p>Reject: See previous response regarding commenter's predictions of increased costs and the response provided.</p>	<p>None.</p>

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	<p>outcome to injured workers and providers will decrease.</p> <p>Everyone who works in the California work comp system is aware of the many months of delays in determination and treatment arising from problems in the IMR system during 2013 and 2014. In the event that Maximus attempts to comply with the MTUS proposal, it is very likely that they will be unable to keep pace with IMR volume, both from the combined effects of the additional time required for completion and the attrition of their reviewer panel (as physicians reach the conclusion that the increased work load is not worth their time for the modest, fixed compensation offered).</p> <p>5) Creates new, unanticipated and potentially serious risks of significant harm to injured workers</p> <p>In the event that a treating physician requests any experimental form of medical service, there will be no evidence other than the initial case studies or pilot studies. If the results of</p>		<p>Reject: These proposed regulations clarify a process that already exists. A systematic approach is already required pursuant to current section 9792.25(c)(1) which was adopted from ACOEM. These proposed regulations sets forth in detail the process that needs to be followed when competing recommendations are cited. Although the medical evidence search sequence is introduced with these proposed regulations, by implication, the requirement to search for medical evidence already exists as well. For example, if 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,</p>	<p>None.</p>

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	<p>these studies are promising, then under the proposed process, reviewing physicians would be required to deem the service as medically necessary; even in the absence of any meaningful safety data; and even in the absence of FDA approval. Reviewing physicians could be placed in a situation where compliance with the MTUS requires authorizing services that would potentially be deemed unacceptable for the enrollment of human subjects by an Institutional Review Board.</p> <p>The practice of medicine is populated with many examples of widely accepted treatment, for which no guidelines or scientific evidence exists. Consider, for example, a simple request of a shower chair to enable a patient to safely bathe following total knee replacement. Any reasonable reviewing physician would recognize this as reasonably necessary for the cure and relief of industrial injury. However, under the proposed MTUS, reviewing physicians would be required to deny any request for which there is neither a MTUS recommendation; nor applicable</p>		<p>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> <p>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>Reject: Disagree. A physician’s clinical expertise and medical judgment is not precluded by these proposed regulations. As commenter states, “Any reasonable reviewing physician would recognize this as reasonably necessary for the cure and</p>	<p>None.</p> <p>None.</p>

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	<p>scientific evidence.</p> <p>An insurer or employer who desires to reduce costs by denying appropriate medical care may succeed in doing so under this proposal via well-reasoned but excessively narrow or biased consideration of the applicability of the evidence to the patient demographic or condition; and to the issue of bias itself. Similarly, physicians who desire to increase their accounts receivable via inappropriate service may do likewise; or may simply provide so many competing references that timely review becomes effectively impossible.</p> <p>6) Creates an overly-laborious, broadly applied solution to address a potential problem of entirely unknown scope and impact.</p> <p>The intended purpose of the proposed MTUS changes appears to be to provide a process framework for physicians to challenge the correctness of the MTUS. The need for such a process is essentially unknown. There is at this time no information on</p>		<p>relieve of industrial injury.” Moreover, section 9792.21.1(e) can always be asserted.</p> <p>Reject: Although commenter is correct in suggesting there will always be folks who will attempt to abuse any set of regulations, this process of citing recommendations and evaluating competing recommendations are already in place as set forth in section 9792.25(c)(1) and timely reviews are still occurring.</p> <p>Reject: The process framework to evaluate medical evidence is required pursuant to Labor Code section 4604.5. Again, a similar regulatory process is already in place as set forth in section 9792.25(c)(1).</p>	<p>None.</p> <p>None.</p>

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	<p>whether this has been reported to be a hurdle for treating physicians; and if so, what the magnitude and frequency of this of the problem may be. There is no known factual basis for asserting that there are common problems or difficulties in this regard.</p> <p>The current proposal is not limited to this unknown problem; but instead creates a solution that is to be applied broadly to every instance in which the MTUS is challenged; or in which the MTUS is silent.</p> <p>As has been discussed above, the current proposal entails multiple and significant risks of harm to all stakeholders within the workers compensation system; with the singular exception of abusive treating physicians seeking to make review of their treatment plans impractical and/or prohibitively expensive.</p> <p>The application of a potentially hazardous, impractical, slow, expensive and labor-intensive solution to a problem of unknown import does not appear to be prudent.</p>		<p>Reject: See previous response. In addition, when there are competing recommendations a process must be in place in order to evaluate the medical evidence that supports the competing recommendations.</p> <p>Reject: Disagree. See previous responses.</p> <p>Reject: See previous responses.</p> <p>Reject: A process for assessing/weighing of</p>	<p>None.</p> <p>None.</p> <p>None.</p> <p>None.</p>

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	<p>Commenter offers the following suggestions for amendment of the MTUS proposal</p> <p>1) In instances where the correctness of the MTUS is being challenged, the burden of proof must be placed upon the party so challenging, as mandated by LC4604.5(a). As such, a process for assessment/weighing of evidence in such instances should be reserved to only those instances where a party is actually issuing such a challenge.</p> <p>2) In every instance where the treating physician is the party seeking to rebut the presumption of correctness, the treating physician should be required to:</p> <p>A) Clearly document their intention to rebut on DWC Form RFA (form should be amended to so indicate for each requested medical service)</p> <p>B) Document the reasoning for the assertion that the MTUS is not correct in the specific case under review; and/or that their alternative evidence is superior.</p> <p>C) Provide the citation for the</p>		<p>evidence needs to be applied even in situations where the MTUS's presumption is not being challenged. For example, if the treating physician requests a medical treatment not addressed by the MTUS and provides a citation to a guideline that contains a recommendation, but the UR reviewer believes a competing recommendation should guide the injured worker's medical treatment, a transparent process must be in place so the public understands how the medical evidence is being evaluated by the reviewer.</p> <p>Accept in part. Reject in part: Accept: A and C. Section 9792.21.1(b)(1)(B) is revised to include commenter's suggestion. C is accepted but no action is being taken because it is already proposed. Reject: B and D. With regards to B, although commenter's suggestion is well received, the DWC does not want to switch</p>	<p>Section 9792.21.1(b)(1)(B) will include the phrase, "...a clear and concise statement that the MTUS' presumption of correctness is being challenged..."</p> <p>None.</p>

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	<p>alternative evidence that they wish to use; in sufficient detail as to enable another party to easily retrieve and locate the evidence for consideration (as has been described in the MTUS proposal).</p> <p>D) Document that they have undertaken the search for, and assessment of, evidence as described in proposed 9792.25.1</p> <p>3) The DWC is strongly urged to develop and mandate use of a form for this purpose, both to facilitate challenges by physicians and to facilitate evaluation of those challenges by reviewing physicians.</p> <p>4) In instances where the MTUS is silent on a medical service; and there is a recommendation in the most recent version of ACOEM, ODG or other nationally recognized evidence-based guideline; UR physicians and IMT physicians must be able to utilize those recommendations without having to engage in the evaluation methodology found in 9792.25.1.</p> <p>5) In instances where a UR physician</p>		<p>the burden of evaluating medical evidence onto the treating physician because it should remain with the reviewing physicians. With regards to D, no formal documentation will be required on any physician that the search for medical evidence was conducted in the sequence set forth in section 9792.21.1(a).</p> <p>Reject: Treating physicians are required to use the RFA form, UR physicians and IMR physicians are required to use their respective decision letters.</p> <p>Reject: Competing recommendations can exist in the guidelines commenter mentions. If this occurs, then which recommendation should prevail and guide the injured worker's treatment? Hence, evaluating medical evidence is necessary.</p>	<p>None.</p> <p>None.</p>

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	<p>or IMR physician wishes to rebut the presumption of correctness of the MTUS in order to issue and authorization; and the rebuttal is based on more recent evidence than that used to create the MTUS recommendation(s) in the form of ACOEM; ODG; or applicable, non-biased peer-reviewed publications of controlled clinical trial or better; the reviewing physician should be able to rebut without engaging in the evaluation process described in 9792.9.1. The reasoning for this is that otherwise, the uncompensated labor required of reviewing physicians to authorize when the MTUS recommends otherwise creates a significant bias against the interests of the injured worker.</p> <p>6) In instances where there is limited data on clinical efficacy and no data on safety, reviewing physicians should not be required to authorize. While evidence-based medicine clearly favors evidence in place of private empiricism, it does not embrace blind adherence to insufficient evidence. In such circumstances, clinical</p>		<p>Reject: If a UR physician is approving an RFA, there is no reason to engage in the evaluation process because there will be no competing recommendations to evaluate. Commenter's hypothetical does not make sense when applied to UR physicians. However, if the UR physician modifies, delays or denies an RFA, then the IMR physician is required to engage in the evaluation process set forth in section 9792.25.1.</p> <p>Accept: Agree. These proposed regulations do not embrace blind adherence to insufficient evidence. Section 9792.25.1 provides a transparent, systematic methodology to evaluate medical evidence. Physicians will be exercising clinical</p>	<p>None.</p> <p>None.</p>

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	<p>professionals should be allowed to exercise clinical judgment.</p> <p>7) In instances where there is no applicable or unbiased evidence whatsoever, reviewing physicians should be free to exercise clinical judgment in the form of reasoned opinions regarding medical necessity (e.g., probable benefits vs. probable risks).</p>		<p>judgment.</p> <p>Accept: Section 9792.21.1(e) covers this.</p>	None.
9792.20(d)	<p>Commenter would like to emphasize her strong support of the proposed definition of EBM contained in §9792.20(d): "'Evidence-Based Medicine (EBM)' means a systematic</p>	<p>Diane Worley California Applicants' Attorneys Association (CAAA)</p>	<p>Reject: Although we agree with the commenter, it goes beyond the scope of the Second 15-day comment period because no changes</p>	None.

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	<p>approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient values."</p> <p>Commenter states that this definition allows the integration of three things, best available research evidence, clinical expertise and patient values. It recognizes that determining the proper treatment for every patient and condition is not simply a matter of applying a cookie cutter approach to finding the treatment option supported by the highest level of medical evidence. An individualized approach is still sought to obtain the most effective and accurate treatment plan for each individual patient. A healthy twenty five year old worker with a back injury and no history of other medical problems is not going to need the same treatment as a sixty two year old worker with a back injury, and diabetes, obesity, and a smoking history.</p> <p>Commenter states that in medicine, comorbidity, described as the effect all</p>	<p>December 9, 2014 Written Comment</p>	<p>were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.</p> <p>Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.</p> <p>Reject: Goes beyond the scope of the Second 15-day comment period because no changes</p>	<p>None.</p> <p>None.</p>

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	<p>other diseases may have on an individual patient other than the primary medical condition, is a necessary evaluation tool. Comorbidity affects prognosis and the delivery of medical care. The presence of comorbid disorders increases disability, hinders rehabilitation, increases the number of complications after surgical procedures and enhances the chances of decline in aged people. It is well established in medicine that the presence of comorbidity must be taken into account when selecting a diagnosis and treatment plan for any given injury, disease, or medical condition.</p> <p>After reviewing the proposed modifications to the current draft of the MTUS regulations, commenter believes that “clinical expertise and patient values” are for the most part ignored in the Medical Evidence Search Sequence and MTUS Methodology for Evaluating Medical Evidence sections. Further, the application of the MTUS guidelines is set forth in a vacuum and fails to be integrated with the basic foundations</p>		<p>were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.</p> <p>Reject: Clinical expertise will be applied and the consideration of the patient’s values will be factored in when a treating physician makes a judgment call on what medical treatment to request. Physician reviewers will use the MTUS to assist in the provision of medical treatment because it offers an analytical framework for the evaluation and</p>	None.

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	<p>of the practice of medicine, including how diagnoses and medical treatment plans are regularly formulated for patients based on individual factors. Commenter believes that EBM can co-exist with these principles. Commenter also believes that treatment guidelines should be applied in the same manner to work injuries, as they are to medical conditions in Group Health, and Medicare, as an example.</p> <p>By analogy, physicians have experience applying “guidelines” integrating their clinical judgment in another context for work injuries which can be applied here. When evaluating permanent disability under the AMA guidelines, Labor Code section 4660 permits reliance on the entire AMA Guides to the Evaluation of Permanent Impairment, including the instructions on the use of clinical judgment, in deriving an impairment rating in a particular case. In the <i>Guzman III</i> case, the DCA said on pages 14 -15, “...the <i>Guides</i> must be applied "as intended" and "as written," but we take a broader view of both its text and the statutory mandate. Section</p>		<p>treatment of injured workers and helps them understand what treatment has been proven effective in providing the best medical outcomes to those workers. If a treatment request is made and the recommendation is outside of the MTUS, then physician reviewers will use those recommendations as guidance instead of the MTUS. In either case, clinical expertise and patient values are not ignored.</p> <p>Reject: See previous response.</p>	<p>None.</p>

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	<p>EBM , clinical expertise and patient values, will have the same result here, i.e. evidence based decisions that are useless, diagnostic reasoning that is inadequate , and treatment decisions that are inaccurate and inconsistent. As in <i>Guzman III</i>, treating physicians should be allowed to utilize independent analysis to promote consistency in treatment decisions.</p> <p>Commenter requests that “the integration of the best available research evidence with clinical expertise and patient values" must be the foundation for any further proposed modifications to the MTUS regulations to insure that injured workers have access to the highest quality and most effective medical treatment for their injury. Like impairment rating guidelines, treatment guidelines should also be applied to achieve treatment accuracy and to promote consistency in treatment decisions.</p>		Reject: See previous response.	None.
9792.21.1(a)	Commenter notes that this subdivision establishes a mandatory medical evidence search sequence (a hierarchy) to be used by the treating, Utilization	Diane Worley California Applicants’ Attorneys	Reject: Treating physicians are not required to formally apply the MTUS Methodology for Evaluating Medical Evidence	None.

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	<p>Review (UR), and Independent Medical Review (IMR) physicians. However, there is no authority in statute for establishing a mandatory hierarchy that is applicable to the treating physician. Thus, this subdivision must be significantly amended.</p>	<p>Association (CAAA) December 9, 2014 Written Comment</p>	<p>set forth in 9792.25.1 nor the Hierarchy of Evidence for Different Clinical Questions. Only UR and or IMR physicians are required to apply section 9792.25.1. Section 9792.21.1(a) establishes the sequence in which one shall conduct a medical evidence search it does not establish a medical evidence hierarchy as commenter states. Labor Code section 4604.5(d) states, “treatment not covered by the MTUS shall be in accordance with other evidence-based medical treatment guidelines that are recognized generally by the national medical community.” Therefore, the requirement to conduct a search for medical evidence is implied in Labor Code section 4604.5(d). The phrase, “Choose the recommendation that is supported with the best available evidence according to the MTUS Methodology for Evaluating Medical Evidence</p>	

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	<p>Labor Code §4610.5(c)(2) defines "medically necessary" and "medical necessity" based on a defined ranking of standards, starting with the MTUS. However, as set forth in Labor Code §4610.5(c) that definition applies only "for the purposes of this section and Section 4610.6." Labor Code §§ 4610.5 and 4610.6 set forth the rules and procedures to be followed in</p>		<p><u>set forth in section 9792.25.1” is used because the goal of the medical evidence search sequence is to assist physicians search for the best available evidence. Section 9792.21.1(a) does not require any physician to show how he or she formally applied the MTUS Methodology for Evaluating Medical Evidence. Formal application of the MTUS Methodology for Evaluating Medical Evidence is set forth in section 9792.25.1 and it explicitly states UR and IMR physicians are the only one’s required to show how it was formally applied.</u></p>	<p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2 ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>making UR determinations of disputed medical treatment requests. Commenter states that the definition of "medically necessary" and "medical necessity," and the hierarchy of standards established under §4610.5(c)(2), apply <u>only</u> to the UR process.</p> <p>Commenter states that the treating physician is not conducting UR, and therefore the hierarchy established under Labor Code §4610.5(c)(2) is <u>not</u> applicable when the treating physician makes a treatment recommendation rebutting the MTUS. Instead, based on the statutory language in Labor Code §4604.5 the treating physician can rebut the MTUS 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 states that in order to bring subdivision (a) into compliance with these governing statutes, all</p>		<p>Reject: On top of Labor Code §4610.5(c)(2)'s hierarchy is the MTUS which is precisely the subject of this rulemaking.</p> <p>Reject: Agree with commenter's statement; however, if a treating</p>	<p>None.</p> <p>None.</p>

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	<p>references to the "treating physician" must be deleted. The statutory rule governing rebuttal of the MTUS by the treating physician as set forth under Labor Code §4604.5 is already incorporated in these draft regulations (§9792.21(c)(2)) and therefore, any reference to the treating physician in subdivision (a) is both inappropriate and would only lead to unnecessary disputes and higher costs.</p> <p>Commenter states that the provisions applicable to UR and IMR physicians in subdivision (a) must be amended. As noted, Labor Code §4610.5(c)(2) does include a hierarchy of standards to be applied in determining medical necessity in the UR process. However, the search sequence established in subdivision (a) goes far beyond that statutory hierarchy.</p> <p>Paragraph (a)(2) requires that "where a medical condition or injury is not addressed by the MTUS or if the MTUS' presumption of correctness is being challenged" the UR or IMR physician must first review "the most current version of ACOEM or ODG."</p>		<p>physician is attempting to rebut the MTUS, a transparent, systematic, methodology for evaluating medical evidence is required to determine if the MTUS has been rebutted by "a preponderance of the scientific medical evidence". Otherwise, how would one know if that standard has been met? Again, these proposed regulations are improving a process that already exists in current regulations set forth in section 9792.25(c)(1).</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</p>	None.

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	<p>The governing statute, Labor Code §4610.5(c)(2), however, provides only that where the MTUS is inapplicable the reviewer shall rely upon "peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service." Limiting the reviewing physician to two specific guidelines does not conform to this statute because it impermissibly restricts the ability of the reviewing physician to utilize any other "peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed treatment."</p> <p>Commenter recommends that the provisions in subdivision (a) applicable to UR and IMR physicians be amended to conform to the hierarchy as set forth in Labor Code §4610.5(c)(2). Alternatively, commenter opines that this section could be brought into compliance with the governing statute by changing the search sequence for UR and IMR physicians to a recommended sequence, rather than a mandated sequence.</p>		<p>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: See previous response. In addition, nothing in these proposed regulations limits a reviewing physician to two specific guidelines. Section 9792.21.1(a) sets forth the sequence in which a medical evidence search should be conducted. A medical evidence search 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 MTUS' presumption of correctness is being challenged, then the sequence mandates a search of the most current ACOEM or ODG.</p>	None.

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			<p>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> <p>Reject: See previous response.</p>	
9792.21.1(b)	<p>Commenter states that the introductory sentence should be amended to delete the requirement that the treating physician must follow a specific hierarchy of standards.</p> <p>Commenter states that this subdivision sets forth very detailed requirements for the treating, UR, and IMR physicians as to what must be cited to support the recommendation for the treatment, or rationale for modifying, delaying, or denying the treatment.</p> <p>Commenter supports the proposed amendments that require UR and IMR</p>	<p>Diane Worley California Applicants' Attorneys Association (CAAA) December 9, 2014 Written Comment</p>	<p>Reject: Section 9792.21.1(a) does not state "the treating physician must follow a specific hierarchy of standards" it does, however, state that they shall "conduct the following medical evidence search sequence..."</p> <p>Accept: Agree.</p>	<p>None</p> <p>None.</p>

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	<p>physicians to clearly document the level of evidence being applied to deny the treatment or diagnostic services being requested. Commenter opines that adding this requirement will 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.</p> <p>Commenter is concerned that placing further mandates on treating physicians to provide specific documentation with their RFAs places an additional burden that may have serious impacts on the system. Under the current fee schedule treating physicians are not paid for doing this work. Further, physicians don't have to provide this level of documentation when requesting medical treatment for their patients under Medicare, Kaiser, or Blue Cross Health Plans. Placing added burdens on treating physicians, without providing</p>		<p>Reject: Labor Code section 4604.5 makes it clear that the MTUS is presumptively correct and that the presumption of correctness may be rebutted by a preponderance of the scientific medical evidence establishing that a variance from the MTUS is reasonably required to cure or relieve the injured worker. The presumption created is one affecting the burden of proof. Therefore, if a treating physician is claiming that the</p>	<p>None.</p>

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	<p>reasonable reimbursement, will place a burden on MPN doctors in an already strained MPN process and may drive doctors out of the Workers' Compensation System. Commenters' organization's members report that a number of physicians have already stopped accepting new workers' compensation patients. Commenter recommends that the Division consider, at the earliest possible time, recommended amendments to the physician fee schedule to provide a reasonable payment for preparation of the RFA and supporting documentation. Although commenter recognizes that this would cause a slight increase in paid fees, she believes that the net impact would be a savings for the system as it will facilitate compliance with the requirements of this new section. With an increase in properly supported RFAs it would reduce the number of treatment requests that go through the dispute resolution process. Commenter opines that one explanation for the high rate of UR denials and IMR appeals in the system is in part due to the extra burdens</p>		<p>MTUS should be rebutted because there is better scientific medical evidence, then the treating physician should be required to provide a citation to the guideline or study that he or she is relying upon to rebut the MTUS.</p>	

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	placed upon physicians with the use of the MTUS guidelines, and the requirement to support their RFAs with additional documentation.			
9792.21.1(c)	<p>Commenter notes that Labor Code §4610.6(e) requires that if the medical professionals reviewing the case are evenly split on whether the disputed medical treatment should be provided, the decision shall be in favor of providing the services. In order to implement this statutory provision, commenter recommends that §9792.21.1 (c) be amended to add the following language:</p> <p><u>If the medical professionals reviewing the case are evenly split on whether the disputed medical treatment should be provided, the decision shall be in favor of providing the services.</u></p>	Diane Worley California Applicants' Attorneys Association (CAAA) December 9, 2014 Written Comment	Reject: Section 4610.6(e) pertains to a situation where there is more than one Independent Medical Reviewer and if they are evenly split, then the decision shall be in favor of providing services. Labor Code section 4604.5, on the other hand, sets the standard for rebutting the MTUS at "a preponderance of the scientific medical evidence."	None.
9792.21.1(e)	Commenter supports the addition of this subdivision 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 order to account for unique medical circumstances warranting an exception."	Diane Worley California Applicants' Attorneys Association (CAAA) December 9, 2014 Written Comment	Agree. Accept.	None.

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	<p>Commenter recommends that the second sentence of this subdivision, which reads: "The treating physician should provide clear documentation of the clinical rationale focusing on expected objective functional gains afforded by the requested treatment and impact upon prognosis," be deleted. Commenter opines that this sentence does not conform to the "cure or relieve" standard of care which is to be used to determine what is reasonable and medically necessary treatment. Commenter opines that the MTUS focuses too much on "cure," but says little about medical treatment that will "relieve" the injured worker of the effects of the injury.</p> <p>Labor Code Section 4600(b) states:</p> <p>"As used in this division and notwithstanding any other provision of law, 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</p>		<p>Reject: Disagree. These proposed regulations do not ignore that standard to cure or relieve. If the objective functional gain is pain relief so that the injured worker can return to work, that falls under the "relieve" category.</p>	<p>None.</p>

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	<p>pursuant to Section 5307.27." (Emphasis added)</p> <p>Labor Code Section 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." [Emphasis added.]</p> <p>Commenter opines that it is clear upon a review of these statutes that the standard of care for California's injured workers remains a two pronged test as to what is reasonable and medically necessary. That is an injured worker has the right to</p>		Reject: See previous response.	None.

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	<p>medical care that either will cure OR relieve the effects of the injury.</p> <p>Commenter states that the MTUS is replete with the phrase "functional improvement," as a prerequisite to approving the treatment request, which is analogous to treatment that leads to a cure of the injury or illness. Commenter states that this is an incorrect standard of review for determining if a treatment request is reasonable and medically necessary based on the statutes cited above.</p> <p>The Workers' Compensation Appeals Board has overturned the application of this incorrect standard (see <u>Loynachan v. Co. of Los Angeles</u>, Case No. ADJ7144283). Commenter opines that forcing workers through the dispute process by ignoring the statutory standard, and requiring "functional improvement" is wasteful and harmful to both employers and workers. Commenter recommends that the Division not only amend this subdivision to conform to the proper "cure or relieve" standard, but to also revise other sections of the MTUS to</p>		<p>Reject: Disagree. These proposed regulations do not ignore that standard to cure or relieve. If the objective functional gain is pain relief so that the injured worker can return to work, that falls under the "relieve" category.</p>	<p>None.</p>

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	incorporate this statutory standard.			
9792.25.1(3)(A) 9792.25.1(4)	<p>Commenter notes that the modifications to section 9792.25.1 provide a methodology for reviewers to evaluate studies including the "quality" of studies. While determining if the study supports the treatment recommendation is appropriate, this section also allows the UR and IMR reviewer to conduct an evaluation of whether there was "bias" in the study including factors such as financial interests, academic interests, and industry influence.</p> <p>Commenter opines that this section introduces a subjective analysis to an otherwise objective evidence based system. It gives authority to the UR and IMR reviewer to weigh evidence way beyond the statutory authority given them to determine only issues of medical necessity applying the MTUS guidelines. Further, if the UR or IMR reviewer is incorrect in determining there is bias in a study, there is no remedy for the injured worker in the current regulatory and statutory scheme.</p>	Diane Worley California Applicants' Attorneys Association (CAAA) December 9, 2014 Written Comment	Reject: The systematic methodology for evaluating medical evidence set forth in section 9792.25.1 was developed from information obtained from the Cochrane Group and the Oxford Centre for Evidence-based Medicine (see Initial Statement of Reasons, under the heading "Technical, Theoretical, or Empirical Studies, Reports or Documents," items (4) and (8). Bias is a factor that is considered when evaluating the quality of evidence.	None.

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	<p>Commenter recommends that section 9792.25.1, subdivision (3), and subparagraph (A), be deleted in its' entirety, as it exceeds statutory authority, and is not within the purview of the regulatory process. Commenter recommends that subdivision (4) be renumbered to (3), and that it be amended as follows:</p> <p>(3 4)–If the guidelines or studies cited contain recommendations supported by studies applicable to the worker and his or her medical condition or injury and if the recommendations are supported by studies that are determined to be of good quality due to the absence of bias, then the reviewing physician shall determine the strength of evidence used to support the differing recommendations by applying the Hierarchy of Evidence for Different Clinical Questions set forth in 9792.25.1(b). <u>If the studies are of equal strength after applying the questions in 9792.25.1(b) , the decision shall be in favor of providing the services. To apply the</u></p>		<p>Reject: See previous response. In addition, Labor Code section 4605.4(a) states the MTUS' "presumption of correctness 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 creates is one affecting the burden of proof." Therefore, to overcome the MTUS' presumption there must be stronger evidence, not equal evidence.</p>	<p>None.</p>

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	Hierarchy of Evidence for Different Clinical Questions, the following steps shall be taken:			
General Comment	<p>Commenter is concerned that these proposed regulations do not adequately account for the need to recognize that EBM is not simply a process of looking up the “best available medical evidence” and blindly following that guideline or study. EBM requires that the best available evidence be integrated with the clinical expertise of the treating physician and with patient and community values. Commenter notes that The Center for Evidence Based Medicine states on its’ website that “even excellent external evidence may be inapplicable to or inappropriate for an individual patient.” The goal of all parties should be to get the most appropriate treatment to the worker as quickly as possible. Commenter opines that this goal will be reached only if the regulations establish a process that truly "allows the integration of the best available research evidence with clinical expertise and patient values.”</p>	<p>Diane Worley California Applicants’ Attorneys Association (CAAA) December 9, 2014 Written Comment</p>	<p>“Evidence-Based Medicine” was adopted from information from Sackett DL, Rosenberg WM, Gray JA, Haynes RB, and Richardson WS, “Evidence based medicine: what it is and what it isn’t” <i>BMJ</i>, 1996; January 13, Volume 312, 71-72 see Initial Statement of Reasons, under the heading “Technical, Theoretical, or Empirical Studies, Reports or Documents,” item (9). Sackett’s article states, “Evidence based medicine is not ‘cookbook’ medicine...any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient’s clinical state, predicament, and preferences...” Under these proposed regulations, physicians will continue to use his/her judgment and it will be</p>	None.

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			integrated with the best available medical evidence.	
9792.21.1(b)(1)(A)	Commenter recommends replacing the term “may” in the definition with the term “shall.”	<p>Jeremy Merz California Chamber of Commerce</p> <p>Jason Schmelzer California Coalition on Workers’ Compensation December 9, 2014 Written Comment</p>	Reject: Labor Code section 4604.5 only places the burden of proof on the treating physician if he/she is attempting to rebut the MTUS’ presumption of correctness. A similar burden is not place on the treating physician if he/she is seeking treatment not addressed by the MTUS.	None.
9792.25(a)(1)	<p>Commenter opines that the intent of this section of the MTUS is intended to help guide the MEEAC in its deliberations relative to MTUS guideline updates. To ensure this intent and that the AGREE II is not used as an instrument by physicians for alternative medical treatment of an injured worker outside of existing guidelines, commenter requests that the section include a reference to the MEEAC.</p> <p>Recommendation: With respect to the definition in this subsection, commenter recommends that the AGREE II Instrument be more clearly defined as a tool for the MEEAC’s use</p>	<p>Jeremy Merz California Chamber of Commerce</p> <p>Jason Schmelzer California Coalition on Workers’ Compensation December 9, 2014 Written Comment</p>	Reject: The AGREE II instrument can be used by all guideline developers, not just MEEAC. Commenter’s suggestion is unnecessary because section 9792.26(e) states, “To assess the quality and methodological rigors used to develop a medical treatment guideline, members of MEEAC shall use a modified version of the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, May 2009.”	None.

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	<p>and consideration when revising the MTUS guidelines.</p> <p>(a) For purposes of sections 9792.25-9792.26, the following definitions shall apply:</p> <p>(1) “Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument” means a tool designed primarily to help the MEEAC, guideline developers and users assess the methodological rigor and transparency in which a guideline is developed.</p>		<p>Reject: See response above. AGREE II was not designed primarily to help the MEEAC.</p>	<p>None.</p>
<p>9792.21.1(b)(1)(A)</p>	<p>Commenter notes that this subsection suggests treating physicians <i>may</i> provide in the Request for Authorization (RFA) or in an attachment to the RFA a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker’s medical condition or injury, if the medical condition or injury is not addressed by the MTUS.</p> <p>Commenter recommends that “<i>may</i></p>	<p>Peggy Thill Claims Operations Manager</p> <p>Dinesh Govindarao, MD, MPH Chief Medical Officer December 9, 2014</p>	<p>Reject: Labor Code section 4604.5 only places the burden of proof on the treating physician if he/she is attempting to rebut the MTUS’ presumption of correctness. A similar burden is not place on the treating physician if he/she is seeking treatment not addressed by the MTUS. Hence, the word “may” is appropriate here.</p>	<p>None.</p>

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	provide” be changed to “ shall provide ”. Commenter opines that the burden of proof should be on the treating physician.			
General Comment	<p>Commenter’s primary concern is related to pricing considerations. Commenter opines that while consideration of medical necessity and other factors assist with eliminating unnecessary expense related to procedures that are not medically necessary, there is little in either MTUS or the medical necessity process that addresses similar or like therapies that are equivalent in treatment of a medical condition. The HMO and PPO world has addressed these issues through plan designs and the utilization review process which allows the carrier to approve an equivalent treatment that is less costly than a more costly treatment that produces the same or similar outcome. So for example if outpatient treatment of substance abuse is equally effective as inpatient treatment for a specified disorder, the less expensive outpatient treatment should be tried first. Commenter opines that if the two treatments for a specific condition are</p>	<p>Sharon L. Hulbert Assistant General Counsel Zenith Insurance Company December 9, 2014 Written Comment</p>	<p>Reject: Goes beyond the scope of this rulemaking. Although commenter’s suggestions are reasonable, the MTUS’ authorizing statutes, Labor Code sections 5307.27, 4600 and 4604.5 specifically address standards of care from an evidence-based medicine perspective but do not mention cost considerations as a factor when determining the medical necessity of a treatment request.</p>	<p>None.</p>

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	<p>equally effective, then the carrier should be permitted to approve the less expensive alternative.</p> <p>In workers' compensation, carriers are required to address whether the treatment will cure or relieve the injury and guidance is needed when there are two equally effective ways of doing so at a great cost difference. This will become more critical as new technologies and treatments are developed.</p> <p>Commenter references an article from CostHelperHealth.com that demonstrates the need for such tools in its review of the cost of a prosthetic leg and provides an example of how health plans address the cost issue through application of guidelines:</p> <ul style="list-style-type: none"> • “For patients with health insurance, out-of-pocket costs typically consist of doctor visit copays and coinsurance of 10%-50%. All types of prosthetic legs typically are covered by health insurance, but the particular leg that will 			

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	<p>be covered usually depends on the individual patient's amputation level, condition and needs. For example, The BlueCross BlueShield of North Carolina policy for lower-limb prostheses states that myoelectric, or computer-controlled, prosthetic legs would be covered for patients who have the physical strength and demonstrated need to move for long distances at variable rates of speed or over uneven terrain. A basic prosthetic leg might be covered for a homebound individual who needs to move around the house.</p> <ul style="list-style-type: none"> • For patients without health insurance, a prosthetic leg typically costs less than \$10,000 for a basic prosthetic leg up to \$70,000 or more for a more advanced computerized prosthetic leg controlled by muscle movements. Costs depend on the type of leg and the level of amputation. • For example, according to a 			

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	<p>white paper from the Bioengineering Institute Center for Neuroprosthetics, at the Worcester Polytechnic Institute, a basic below-the-knee prosthetic that would allow a patient to walk on flat ground costs \$5,000-\$7,000, while one that would allow the patient to walk on stairs and bumpy ground could cost \$10,000. For a device that would allow a patient to walk and run as well as a non-amputee, the cost could go up to \$15,000. Prosthetics with special hydraulic or mechanical systems that allow for movement control can cost more than \$15,000. And a computer-assisted prosthetic leg costs \$20,000 or more. According to Brown University, the C-Leg computerized prosthetic leg by Otto-Bock, for above-the-knee amputees, can cost as much as \$50,000, or up to \$70,000 or more, including the prosthetic foot.</p>			

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	<ul style="list-style-type: none"> • A prosthetic leg likely will need to be replaced several times during a patient's lifetime, and patients need ongoing adjustments. A Department of Veterans Affairs study showed the average lifetime cost for prosthetics and medical care for loss of a single leg for a veteran of the Iraq or Afghanistan wars was more than \$1.4 million.” • <p>Source: http://health.costhelper.com/prosthetic-legs.html (footnotes omitted)</p> <p>Commenter encourages the DWC to utilize cost factors and review processes as part of MTUS to allow cost considerations to be included in the medical necessity review when equal treatments of equal efficacy are available. Commenter states that if a provider believes a more costly treatment alternative is medically necessary, the provider can submit documentation to show why that treatment is the medically appropriate</p>			

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	treatment based on the individual patient's circumstances.			
General Comment	<p>Commenter states that the proposed changes add greater rigor and specificity to the application of evidence based medicine (EBM) to the MTUS.</p> <p>As part of this increase in rigor and specificity, commenter would like to address the larger picture and bring up the issue of the balance between the rigor of the guidelines and the impact this can have on physician decision-making and practice.</p> <p>Commenter opines that some of the aspects of the proposed changes, including the requirements to factor in details of evidence strength, if applied to community practitioners, may be an unworkable administrative burden and brings a serious risk of delaying good medical care. It is the commenters understanding that the need to note the strength of evidence is intended to only apply to utilization review (UR) and Independent Medical Review (IMR), yet for community practitioners this will likely be the</p>	<p>Robert C. Blink, MD, MPH, FOCEOM</p> <p>Steven D. Feinberg, MD, MPH</p> <p>Constantine J. Gean, MD, MBA, MS, FACOEM</p> <p>Stephen Levit, MD</p> <p>Bernyce Peplowski, DO, MS, FACOEM</p> <p>Troy Ross, MD, MPH December 8, 2014 Written Comment</p>	<p>Reject in part. Accept in part. Reject: These proposed regulations do not add greater rigor because the process to evaluate the strength of evidence is already in place as set forth current section 9792.25(c)(1). Accept: Agree, these proposed regulations provide specificity to a process that already exists.</p> <p>Reject: Labor Code section 4604.5 has not been recently amended. The burden of proof to rebut the MTUS has remained with the treating physician long before these proposed regulatory changes. As commenters correctly points out, "the need to note the strength of evidence is intended to only apply to utilization review (UR) and Independent Medical Review (IMR)", not to treating</p>	<p>None.</p> <p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>standard they must meet in order to obtain utilization review approvals. Commenter states that OEM physicians support EBM, but are aware of its limitation. Commenter notes that preventing and resolving disputes over costly or risky procedures appears to be one target of the proposed reforms; unfortunately they seem to be written broadly enough that they threaten to burden routine conservative and effective care as well. Even with common work injuries, commenter states that the application of EBM to reasonable and necessary treatment plans is not always straightforward, due to patient-specific issues such as co-morbidities, age, psychosocial issues, cultural setting, religious background, genetics, etc.</p> <p>Commenters concerns can be summarized in three ways. First is that the UR regulations, taken as a whole, may be a burden on small practices, which are generally of high quality and are precisely the practices least able to afford increased time and research on documentation beyond</p>		<p>physicians. These proposed regulations provide specificity to the process that must be followed to evaluate medical evidence. Treating physicians will have a clearer understanding of what treatment requests will be approved and or denied. As commenter’s also point out, applying EMB principals is “not always straightforward” and these proposed regulations allow for the integration of the best available research evidence with clinical expertise and patient values.</p> <p>Reject: Goes beyond the scope of these regulations because it is a general comment regarding the UR regulations.</p>	None.

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	<p>what is already needed. Of course, this issue is also relevant for large practices.</p> <p>Commenter's second concern is that there is a serious risk of forcing high-quality practitioners out of the workers' compensation system, especially if they are in small practices. This is particularly worrisome for non-procedure-oriented specialties where the economic realities of these practices may not allow increases in the time and resources needed to comply with the proposed MTUS changes. A strategy of waiting to watch for that to happen may create serious permanent damage to the pool of quality providers available and we would propose that proactive analysis and preventive action is needed to prevent this.</p> <p>Commenter's third concern is the additional burden of the practitioner having to purchase reference resources such as ODG or ACOEM Guidelines as the MTUS refers to these.</p>		<p>Reject: Disagree there is a serious risk of forcing high quality practitioners out of the workers' compensation system because the process to evaluate the strength of evidence is already in place as set forth current section 9792.25(c)(1).</p> <p>Reject: Currently the MTUS consist of many chapters that are adopted from ACOEM that requires a practitioner to purchase this reference resource. The MTUS' adoption of ODG is available on DWC's</p>	<p>None.</p> <p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2 ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>review. One possible remedy to this problem would be to limit the number of citations that could be submitted on any particular Request for Authorization (RFA)/Independent Medical Review (IMR) appeal. If there are several studies on the issue, medical providers should be asked to select the research that are of the highest quality.</p> <p>Commenter states that the flowchart will be a helpful tool in the Medical Evidence Search Sequence.</p>		<p>rebutted and/or the reasonableness and necessity of his/her treatment request within the limits already provided for in these proposed regulations.</p> <p>Agree: Accept.</p>	None.
General comment	<p>Commenter represents and is part of the Working Group¹ and opines that, as drafted, proposed MTUS regulations violate Section 4604.5 of the Labor Code. Section 4604.5 provides in part that the “...recommended guidelines set forth in the medical treatment utilization schedule adopted by the administrative director ... shall be</p>	<p>Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment</p>	<p>Reject: Disagree that these proposed regulations violate Labor Code section 4604.5. Substantively, nothing has changed from the existing regulations except these proposed regulations provide specificity to a process that was already implied but not expressly stated in the current</p>	None.

¹ The members of the Medical Disability Management working group include: **Dr. Bernyce Peplowski**, SVP, Innovation & Nat Medical Strategy, US Health Works; **Dr. Kurt Hegmann**, Professor & Director, Occ Safety & Health Univ of Utah; Chair & Editor in Chief ACOEM Guidelines (via telecon); **Dr. Laurence Miller**, Medical Director, Anthem Workers’ Compensation; **Dr. Ravi Prasad**, Assistant Chief, Division of Pain Medicine, Clinical Associate Professor, Stanford University Medical Center; **Dr. Steve Wiesner**, Chief, Occupational Health Department, Assistant Physician-In-Chief, Kaiser Permanente East Bay Medical Center; **Dr. Melvin Belsky**, Corporate Medical Director, WC, Safeway Inc.; **Mr. Mark Pew**, Senior Vice President, PRIUM and **Ms. Lori Kammerer**.

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	<p>presumptively correct on the issue of extent and scope of medical treatment.” The proposed regulations undermine the MTUS presumption of correctness by allowing a treating physician to challenge MTUS simply by suggesting a course of treatment that differs from the MTUS, at which point the burden of rebutting the presumption of MTUS correctness effectively shifts from the treating physician to the reviewers.</p> <p>For example, the draft regulations allow a treating physician to submit a single document or medical literature citation, at which point it becomes the obligation of the reviewer to review the citation and essentially prove to the requesting physician that the MTUS is correct and applicable to the patient treatment plan – not the submitted citation or study.</p> <p>Commenter states that once a citation is submitted in the request for authorization (RFA), the reviewer must compare and assess the validity of the citation and essentially prove that the MTUS is in fact valid. Given</p>		<p>regulations. Currently, if a treating physician is attempting to rebut the MTUS, he or she can do so by a preponderance of scientific medical evidence establishing that a variance from the MUST is reasonably required. These proposed regulations clarify that a citation needs to be provided, which is already implied.</p> <p>Reject: Disagree that the reviewing physicians are required to “essentially prove to the requesting physician that the MTUS is correct.” Reviewing physicians need to evaluate the medical evidence supporting competing recommendations.</p> <p>Reject: Disagree that these proposed regulations will “result in nearly automatic approvals of any RFA as long as the requesting physician has submitted any citation that</p>	<p>None.</p> <p>None.</p>

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	<p>the short time frames for reviewing treatment requests there is no reasonable opportunity for a particularized review of the literature cited in the RFA. This will necessarily result in nearly automatic approvals of any RFA as long as the requesting physician has submitted any citation that departs from the MTUS guidelines.</p> <p>Commenter proposes to cure these and other fatal defects in the regulations she has submitted in a mock-up. Commenter opines that if the changes suggested in the mockup are adopted by the Division of Worker's Compensation, the regulations will preserve the presumption of correctness, and will continue to keep the burden of proof for rebutting the statutory presumption of correctness with the requesting party.</p> <p>Without adoption of the amendments suggested in the mockup, commenter believes very strongly that the draft regulations violate both Labor Code Section 4604.5 and the applicable standards of review by the Office of</p>		<p>departs from the MTUS" 5 days is enough time for a UR physician to evaluate the evidence supporting competing recommendations.</p> <p>Reject: See previous responses.</p> <p>Reject: See previous responses.</p>	<p>None.</p> <p>None.</p>

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	<p>Administrative Law set forth in Government Code 11349 and 11349.1 relating to “necessity,” “authority,” “clarity,” “consistency,” “reference,” and “non-duplication.”</p> <p>Commenter requests that the Division cancel any proposed plans to submit the existing draft regulations for OAL approval, and that the DWC adopt the changes to the regulations that she has recommended in the mockup.</p>		Reject: See previous responses.	None.
9792.20(a)	Commenter recommends removal of the phrase “Published by the Reed Group.”	Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment	Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.	None.
9792.20(d)	<p>Commenter recommends the following revised language:</p> <p>ed) “Evidence-based Evidence-Based Medicine (EBM)” means based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE; a <u>ed) “Evidence-Based Evidence-Based Medicine (EBM)” means based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE; a systematic approach to making</u></p>	Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment	Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.	None.

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	<p>clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient values, <u>relies primarily on the highest level of research evidence that complies with the Standards for Developing Trustworthy Clinical Practice Guidelines, released by the Institute of Medicine (IOM) on March 23, 2011. It may also include integration of clinical expertise, patient values, and weighting of risk versus benefit.</u></p>			
9792.20(e)	<p>Commenter recommends the following revised language:</p> <p>(fe) “Functional improvement” means either a clinically significant improvement in <u>work function,</u> activities of daily living, <u>decreasing or eliminating work restrictions,</u> or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to sections 9789.10-9789.111 <u>medical evaluation and</u></p>	Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment	Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.	None.

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	treatment , and a reduction in the dependency on continued medical treatment.			
9792.20 – proposed new subsection	<p>Commenter recommends the following new language:</p> <p><i><u>(f) “IOM” means the Institute of Medicine, an independent, nonprofit organization that is the health division of the National Academies, which comprises the National Academy of Sciences, the National Academy of Engineering, the National Research Council, and the IOM.</u></i>²</p>	Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment	Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.	None.
9792.20(g)	<p>Commenter recommends the following revised language:</p> <p><i><u>(hg) “Medical treatment guidelines” means the most current version of peer-reviewed, written recommendations used to assist in decision-making about the appropriate medical treatment for specific clinical circumstances revised within the last five years</u></i></p>	Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment	Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.	None.

² The IOM list of standards is available on the web at <http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx> and the book of guidelines is available at http://books.nap.edu/openbook.php?record_id=13058

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	<p>which are <u>These are</u> systematically developed by a multidisciplinary process through a comprehensive literature search <u>and are to assist in decision-making about the appropriate medical treatment for specific clinical circumstances</u> reviewed and updated within the last <u>five years</u>.</p>			
9792.20(h)	<p>Commenter recommends the following revised language:</p> <p>(h) “Nationally recognized” means published in a peer-reviewed medical journal; or developed, endorsed and disseminated by a national organization with affiliates based in two or more U.S. states; or currently adopted for use by one or more U.S. state governments or by the U.S. federal government; <u>or currently adopted for use by one or more U.S. state governments or by the U.S. federal government</u> and is the most current version.</p>	Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment	Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.	None.
9792.20(j)	<p>Commenter recommends the following revised language:</p> <p>(k) “Peer reviewed” means that a medical study’s content, methodology</p>	Lori Kammerer Kammerer & Company Medical Disability Management	Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version	None.

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	<p>and results have been evaluated and approved prior to publication by an editorial board of qualified experts. a peer-reviewed journal that has submitted its published articles for review by experts who are not part of the editorial staff. The numbers and kinds of manuscripts sent for review, the number of reviewers, the reviewing procedures and the use made of the reviewers' opinions may vary, and therefore each journal should publicly disclose its policies in the Instructions to Authors for the benefit of readers and potential authors." (International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals, 2001)</p>	<p>Working Group December 9, 2014 Written Comment</p>	<p>that had not already been posted and reviewed during the previous comment periods.</p>	
9792.20(k)	<p>Commenter recommends that this subsection be removed.</p>	<p>Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment</p>	<p>Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period version that had not already been posted and reviewed during the previous comment periods.</p>	<p>None.</p>
9792.21(b)	<p>Commenter recommends the</p>	<p>Lori Kammerer</p>	<p>Reject: Commenter's</p>	<p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2 ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>following revised language:</p> <p>(b) The MTUS is intended to assist in the provision of medical treatment by offering an analytical framework for the evaluation and treatment of injured workers and to help those who make decisions regarding the medical treatment of injured workers understand what treatment has been proven effective in providing the best medical outcomes to those workers, in accordance with section 4600 of the Labor Code. <u>The MTUS provides a framework for the most effective treatment of work-related illness or injury to achieve functional improvement, return to work, and disability prevention. The MTUS is based on the principals of Evidenced-Based Medicine (EBM).</u></p> <p><u>EBM is a systematic approach to making clinical decisions which allows the integration of the best available evidence with clinical expertise and patient values. EBM is a method of improving the quality of care by encouraging practices that work, and discouraging those that</u></p>	<p>Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment</p>	<p>suggested changes deletes proposed revisions that although are not instructive, the DWC believes are informative and necessary because it helps members of the public understand Evidence-Based Medicine.</p>	

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	<p>are ineffective or harmful. EBM asserts that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for making clinical decisions. Instead, EBM requires the evaluation of medical evidence by applying an explicit systematic methodology to determine the quality and strength of evidence used to support the recommendations for a medical condition or injury. The best available evidence is then used to guide clinical decision making.</p>			
9792.21.1(a)	<p>Commenter recommends the following revised language:</p> <p><u>(a) When searching medical evidence pursuant to Section 9792.21(d)(1) or (2), treating physicians and medical reviewers shall conduct the following medical evidence search sequence for the evaluation and treatment of injured workers.</u></p>	Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment	Reject: When searching for medical evidence, physicians shall begin with the MTUS. This is an important clarification we made from the 45 day and First 15-day iterations of these proposed regulations.	None.
9792.21.1(a)(2)(B) 9792.21.1(a)(2)(C)	<p>Commenter recommends the following revised language:</p> <p>(B) Search the most current version of other evidence based medical treatment guidelines that are</p>	Lori Kammerer Kammerer & Company Medical Disability Management Working Group	Reject: Commenter's suggested deletions make the medical evidence search sequence vague and ambiguous. The provisions will remain because they	None.

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	<p><u>recognized by the national medical community and are scientifically based to find a recommendation applicable to the injured worker's medical condition or injury. Choose the recommendation that is supported with the best available evidence according to the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1. Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: www.guideline.gov/. If no applicable recommendation is found, or if the treating physician or reviewing physician believes there is another recommendation supported by a higher quality and strength of evidence, then</u></p> <p><u>(C) Search for current studies that are scientifically based, peer-reviewed, and published in journals that are nationally recognized by the medical community to find a recommendation applicable to the injured worker's medical condition</u></p>	<p>December 9, 2014 Written Comment</p>	<p>provide necessary instruction and information to members of the public. Moreover, the term “medical literature search” is a term of art and means doing a comprehensive search of the current medical literature. Requiring workers’ compensation physicians to conduct a medical literature search is impractical and overly burdensome. Therefore, these proposed regulations provide a medical evidence search sequence for efficiency and consistency reasons because it is an abridged literature search that instructs physicians to first search for medical evidence in guidelines that we can assume has already conducted a medical literature search.</p>	
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	<p>or injury. Choose the recommendation that is supported with the best available evidence according to the MTUS Methodology for Evaluating Medical Evidence set forth in section 9792.25.1. A search for peer-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><u><i>(B) Search the most current version of other evidence-based medical treatment guidelines that are consistent with EBM principles set forth in Section 9792.20(d).</i></u></p> <p><u><i>(C) Perform a systematic review of the literature that is clearly applicable to the patient, and that is consistent with EBM as set forth in 9792.20(d). Case studies, case series, and case-cohorts reporting of treatment results without controls,</i></u></p>			
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	<p><u>and/or studies without high statistical power, shall not be considered adequate proof of effect. In addition, possible iatrogenic adverse effects due to a treatment are the responsibility of the requesting treating physician. In addition to providing the relevant citation, the requesting treating physician shall also submit the actual evidence-based supporting literature when medical justification is not identified in nationally recognized guidelines or MTUS.</u></p>			
<p>9792.21.1(b)(1)(A) 9792.21.1(b)(1)(B)</p>	<p>Commenter recommends the following revised language:</p> <p><u>(A) may provide in the Request for Authorization (RFA) or in an attachment to the RFA a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury, if the medical condition or injury is not addressed by the MTUS.</u></p> <p><u>1. The citation provided by the</u></p>	<p>Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment</p>	<p>Reject in part. Accept in part. Reject: Commenter's recommended changes for Section 9792.21.1(b)(1)(A) and (b)(1)(B) will not be adopted because it only provides regulatory guidance when a treating physician is attempting to rebut the MTUS' presumption of correctness. Commenter's suggested revisions fail to provide regulatory guidance if a medical condition or injury is not addressed by the MTUS. In addition, commenter's</p>	<p>None as a result of this comment but the DWC has revised section 9792.21.1(b)(1)(A) on its own initiative by moving the last part of the sentence to the beginning for clarification. The phrase "if the medical condition or injury is not addressed by the MTUS" is moved from the end of the</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2 ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>treating physician 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.</p> <p>2. If the treating physician provides more than one citation, then a narrative shall be included by the treating physician in the RFA or in an attachment to the RFA 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>(B) shall provide in the RFA or in an attachment to the RFA a citation to the guideline or study containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured</p>		<p>suggested language does not fully address the potential for treating physicians to inundate their RFA's with citations and copies of articles that have nothing to do with determining the reasonableness and necessity of a treatment request. Commenter's suggestion that treating physicians shall submit "All medical citations and documentation submitted in support of the treatment request" lacks specificity and may be too broadly interpreted. will not prompt changes. However, the DWC has revised section 9792.21.1(b)(1)(A) on its own initiative by moving the last part of the sentence to the beginning for clarification.</p> <p>Accept: Some of commenter's recommended changes will be accepted for changes to section 9792.21.1(b)(1)(B). The requirement that treating physicians provide a "clear and</p>	<p>sentence to the beginning of the sentence.</p> <p>Section 9792.21.1(b)(1)(B) is revised to state, "If the medical condition or injury is addressed by the MTUS but the treating physician is attempting to rebut the MTUS' presumption of correctness, then the treating physician shall provide in the RFA or in an attachment to the RFA the following: a clear and concise statement that the MTUS' presumption of correctness is being challenged; a citation to the guideline or study containing the recommendation he or she believes</p>

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	<p><u>worker's medical condition or injury, if the medical condition or injury is addressed by the MTUS but the treating physician is attempting to rebut the MTUS' presumption of correctness.</u></p> <p><u>1. The citation provided by the treating physician 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.</u></p> <p><u>2. If the treating physician provides more than one citation, then a narrative shall be included by the treating physician in the RFA or in an attachment to the RFA 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.</u></p>		<p>concise statement that the MTUS' presumption of correctness is being challenged" is added and the requirement that treating physicians provide "a copy of the entire study or the relevant sections of the guideline containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury" is added.</p>	<p>guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury; and a copy of the entire study or the relevant sections of the guideline containing the recommendation he or she believes guides the reasonableness and necessity of the requested treatment that is applicable to the injured worker's medical condition or injury"</p>

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	<p><u>(A) A treating physician shall provide in the Request for Authorization (RFA) all of the following:</u></p> <p><u>(1) A clear and concise statement that the treating physician is challenging the presumption of correctness afforded the MTUS.</u></p> <p><u>(2) All medical citations and documentation submitted in support of the treatment request, which shall include the full text of any articles cited in the RFA.</u></p>			
<p>9792.21.1(b)(2) 9792.21.1(b)(3) 9792.21.1(c) 9792.21.1(d) 9792.21.1(e)</p>	<p>Commenter recommends that these sections be removed in their entirety.</p>	<p>Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment</p>	<p>Reject: If commenters' recommended changes are accepted, Utilization Review and Independent Medical Review physicians will not have any substantive regulatory requirement to perform. Commenter recommends UR and IMR physicians perform their search for medical evidence according to the sequence they suggest, but delete all other requirements.</p>	<p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2 ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.25 9792.25.1	Commenter recommends that these sections be removed in their entirety.	Lori Kammerer Kammerer & Company Medical Disability Management Working Group December 9, 2014 Written Comment	Reject: If commenters' recommended changes are accepted, Utilization Review and Independent Medical Review physicians will not have any substantive regulatory requirement to perform. Commenter recommends UR and IMR physicians perform their search for medical evidence according to the sequence they suggest, but delete all other requirements. <u>In addition, the deletion of section 9792.21.1(e) removes an important clarifying provision. Employers and their representatives should be allowed to approve medical treatment requests at their discretion. There could be many reasons for approving a treatment request not covered by the MTUS or supported by the best available medical evidence and removing this provision blurs the ability to do so.</u>	None.
General Comment	Commenter is very appreciative of the	Brenda Ramirez		

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	<p>revisions and clarifications incorporated by the administrative director (AD) in the current proposed regulations. Commenter opines that these changes are clearly aimed at creating a more efficient and effective process for identifying and providing proven, high-quality medical care to injured workers as promptly as possible. Commenter notes that the medical treatment guidelines will be used not just by treating physicians, but by the entire workers compensation community to determine the best medical care available. Commenter states that the revisions to the proposed regulations are very helpful for all those individuals using the MTUS.</p> <p>Commenter states that the statutory scheme adopted by the Legislature in 2004 made fundamental changes to the provision of medical care to injured employees. Amendments to the Labor Code in sections 4600, 4604.5 and 5307.27 defined the employer's liability to provide all medical care "reasonably required to cure or relieve the injured worker from the effects of his or her injury."</p>	<p>Claims & Medical Director California Workers' Compensation Institute (CWCI) December 9, 2014 Written Comment</p>		

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	<p>Section 4600 now states: (b) As used in this division and notwithstanding any other provision of law, medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury <i>means</i> treatment that is based upon the guidelines adopted by the administrative director pursuant to Section 5307.27. (Emphasis added)</p> <p>Section 5307.27, defines medical care as follows: On or before December 1, 2004, the administrative director shall adopt ... a medical treatment utilization schedule, that shall incorporate <i>the evidence-based, peer-reviewed, nationally recognized standards of care</i> recommended by the commission pursuant to Section 77.5, and that shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all</p>			

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	<p>treatment procedures and modalities commonly performed in workers' compensation cases. (Emphasis added)</p> <p>Section 4604.5 specifies: The recommended guidelines set forth in the schedule adopted pursuant to subdivision (a) shall reflect practices that are evidence and scientifically based, nationally recognized, and peer reviewed. (Emphasis added)</p> <p>The Supreme Court affirmed that determination in <u>SCIF v WCAB</u> (Sandhagen) (2008) 73 CCC 981, stating, in essence, that reasonable and necessary medical care under section 4600 is treatment provided in accordance with the medical treatment utilization schedule (MTUS). To the extent that the proposed Medical Utilization Treatment Schedule (MTUS) regulations include references to “best available research evidence with clinical expertise and</p>		<p>Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period to section 9792.20(d) definition for “Evidence-Based Medicine” that had not already been posted and reviewed during the previous comment periods.</p>	<p>None.</p>

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	<p>patient values,” they violate the statutory mandate established by the Legislature.</p> <p>Commenter opines that the decision to approve a treatment or diagnostic test should not be based solely on whether there is evidence to support that request, as cost effectiveness is also an important component of the analysis. Incorporation of cost effectiveness has been the standard practice for groups such as the US Preventative Services Task Force. Cost-effectiveness analysis includes not only the expected benefits and harms, but also the costs of alternative strategies.</p> <p>Commenter notes that the American College of Cardiology and the American Heart Association announced in March 2014 that they will begin to include value assessments when developing guidelines. A study published in JAMA Internal Medicine (2013: 173(12):1091-1097) showed that when formulating clinical guidance documents, 57% of physician societies explicitly integrated cost, 13%</p>		<p>Reject: See previous response to commenter Sharon Hulbert. Goes beyond the scope of this rulemaking. Although commenter’s suggestions are reasonable, the MTUS’ authorizing statutes, Labor Code sections 5307.27, 4600 and 4604.5 specifically address standards of care from an evidence-based medicine perspective but do not mention cost considerations as a factor when determining the medical necessity of a treatment request.</p>	<p>None.</p>

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	<p>implicitly considered costs, and only 10% intentionally excluded costs.</p> <p>Commenter opines that considering the cost of the therapy and approving a less expensive but equally effective treatment will help address and manage the rising costs of medical treatment. This has essentially been done with respect to brand versus generic drugs, and that concept should be expanded to all treatment requests. If a requesting provider believes a more expensive treatment will offer benefits not provided by a less expensive efficacious treatment, he or she can document why the more expensive treatment is needed at the time of request.</p> <p>Commenter opines that a treatment guideline that fails to include an assessment of cost vs benefit will unnecessarily increase expenses in the system.</p>			
9792.20(d) 9792.21(b)	<p>Commenter recommends the following revised language: Evidence-Based Medicine (EBM)”</p>	Brenda Ramirez Claims & Medical Director California Workers’	Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-	None.

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2 ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>means a systematic approach to making clinical decisions which allows the integration of <u>based on the</u> best available research evidence with clinical expertise and patient values.</p> <p>Commenter states that the 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 these subjective assessments are diametrically opposed to the statutory standards and the specific declaration within the proposed regulations that the MTUS is based on the principals of evidence-based medicine. 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</p>	<p>Compensation Institute (CWCI) December 9, 2014 Written Comment</p>	<p>day comment period to section 9792.20(d) definition for “Evidence-Based Medicine” that had not already been posted and reviewed during the previous comment periods.</p> <p>Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period to section</p>	<p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>medical evidence. Commenter opines that including the terms “clinical expertise and patient values” contradicts the language in section 9792.21(b) which states: “EBM is a method of improving the quality of care by encouraging practices that 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. Clinical expertise and patient values are contrary to these statutory standards and cannot be imposed by regulation. <u>Mendoza v WCAB</u> (2010) En Banc Opinion 75 CCC 634.</p> <p>Commenter opines that because the treatment schedule is used by injured workers, treating physicians, claims administrators, utilization review physicians, IMR, employers, applicants’ attorneys, defense</p>		9792.21(b) that had not already been posted and reviewed during the previous comment periods.	

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	<p>attorneys, judges, the WCAB and the reviewing courts, the treatment guidelines must be as straightforward as modern medical science can make them. 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. Commenter recommends eliminating these subjective, unscientific elements.</p> <p>Commenter supports the additional revisions and clarifications to § 9792.21.</p>			
9792.20(b)	<p>Commenter recommends the following revised language:</p> <p>(<u>eb</u>) “Chronic pain” means any pain lasting three or more months from the initial onset of pain of more than 3 month's duration from the initial onset that persists beyond the expected date</p>	<p>Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) December 9, 2014 Written Comment</p>	<p>Reject: Goes beyond the scope of the Second 15-day comment period because no changes were made in the Second 15-day comment period to section 9792.20(b) definition for “Chronic Pain” that had not already been posted and</p>	<p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>of healing.</p> <p>Commenter states that during the course of the development of these regulations, the division and the community have debated the pros and cons of a definition based on a 3 month duration or pain beyond the expected period for healing. The definition of chronic pain must match the medical evidence. Most medical research (on which guidelines for chronic pain must be based), use a three month duration to define chronic pain. But some guidelines use the latter definition and both definitions have advantages and deficits.</p> <p>Commenter opines that the use of a specific period of time will eliminate potential litigation over what constitutes “the anticipated time of healing.” Including the expected period for healing as a modifier of the 3 month standard will clarify that chronic pain extends beyond what the medical evidence suggests.</p> <p>Commenter notes that pain that exists beyond 3 months but within the expected period for healing would not</p>		<p>reviewed during the previous comment periods.</p>	

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	be considered ‘chronic pain’ under this definition.			
9792.21.1(b)(1)(A)	<p>Commenter recommends the following revised language:</p> <p>(b)(1)(A) may shall <u>provide in the Request for Authorization (RFA) ...</u></p> <p>Commenter supports subdivision (b)(1) as modified except that if the treating physician believes the medical condition or injury is not addressed by the MTUS, commenter recommends requiring in (b)(1)(A) that the treating physician provide the citation to the other guideline or study containing the recommendation he or she believes establishes the reasonableness and necessity of the requested treatment.</p>	Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) December 9, 2014 Written Comment	<p>Reject: Commenter’s recommended changes for <u>Section 9792.21.1(b)(1)(A) will not prompt changes.</u> Pursuant to Labor Code section 4600, an employer is <u>obligated to provide reasonable and necessary medical treatment to cure or relieve the injured worker from the effects of his or her injury.</u> Here, the <u>commenter’s recommended change shifts the burden onto the treating physician to prove that a treatment request not covered by the MTUS is reasonable and necessary.</u> This is <u>unlike the situation where the treating physician is attempting to rebut the MTUS’ presumption of correctness.</u> In that situation, the burden of proof shifts to the treating physician pursuant to Labor Code section 4604.5(a) because the treating physician is attempting to rebut the <u>MTUS’ recommendation that</u></p>	None as a result of this comment but the DWC has revised section 9792.21.1(b)(1)(A) on its own initiative by moving the last part of the sentence to the beginning for clarification. The phrase “if the medical condition or injury is not addressed by the MTUS” is moved from the end of the sentence to the beginning of the sentence.

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			is applicable to the injured worker. However, the DWC has revised section 9792.21.1(b)(1)(A) on its own initiative by moving the last part of the sentence to the beginning for clarification.	
9792.21.1(d)(1)(A)	<p>Commenter recommends the following revised language:</p> <p><u>(d)(1)(A) Indicate the current version of the MTUS is being cited and the effective year of the guideline;</u></p> <p>Commenter opines that this clarification is necessary because it is not necessary to cite the effective year of a recommendation or set of recommendations as long as they are included in the currently adopted MTUS. Commenter states that the most current version of the MTUS should always apply when determining the most appropriate treatment.</p>	Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) December 9, 2014 Written Comment	Reject: "The effective year of the guideline" refers to the effective year that particular guideline was adopted into the MTUS.	None.
9792.21.1(e)	<p>Commenter recommends that this subdivision be eliminated.</p> <p>Commenter opines that this subdivision is unnecessary.</p>	Brenda Ramirez Claims & Medical Director California Workers' Compensation	Reject: An employer and his or her representatives can always approve a medical treatment request. The proposed regulations provide some	None.

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	<p>Commenter states that if the Division believes exception language should remain, the language must be modified to allow not only for approving medical treatment beyond what is covered in the MTUS, but also for not allowing medical treatment that is covered in the MTUS to account for medical circumstances warranting an exception.</p> <p>Commenter opines that the language contradicts language in other sections, is confusing, may be misunderstood and will likely result in unintended consequences. For example, disputes may arise over whether an insured employer may override the claims administrator or its utilization review decision. Commenter states that removing the language will eliminate this problem and allow exceptions to continue unfettered where warranted by the medical circumstances.</p>	<p>Institute (CWCI) December 9, 2014 Written Comment</p>	<p>guidance to treating physicians that exceptions can be made and the documentation that should be provided.</p> <p>Reject: Commenter states that exceptions are currently allowed where warranted by the medical circumstances, these proposed regulations are no different.</p>	<p>None.</p>
9792.23(b)	<p>Commenter supports the proposed general approach taken in section 9792.23 to identify the most effective medical treatment. Specific recommendations are offered to improve its execution and results.</p>	<p>Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI)</p>	<p>Reject: Changes to section 9792.23(b) are not substantive in nature but are reference changes that need to be made as a result of changes being made in this rulemaking.</p>	<p>None.</p>

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	<p>Commenter recommends the following revised language:</p> <p>(b) For all conditions or injuries not addressed in the MTUS, the authorized treatment and diagnostic services in the initial management and subsequent treatment for presenting complaints shall be in accordance with other scientifically and evidence-based medical treatment guidelines that are nationally recognized <u>generally</u> by the <u>national</u> medical community pursuant to section 9792.21(d)(12).</p> <p>Commenter states that the recommended language change more closely conforms to the language and its meaning in Labor Code section 4604.5(d) which states:</p> <p>“For all injuries not covered by the 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 generally by the national medical community and scientifically</p>	<p>December 9, 2014 Written Comment</p>	<p>Reject: Section 9792.21(d)(1) is the correct reference not section 9792.21(d)(2) which pertains to situations where the MTUS is presumption of correctness is being rebutted.</p>	<p>None.</p>

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	<p>based.”</p> <p>As in the Labor Code section 4604.5(d) language, commenter opines that it will be clear under the recommended language that national standards prevail, and not local “community standards” that differ from generally accepted national standards or that are accepted only by a minority in the national medical community.</p> <p>Commenter notes that the recommended change to the section number corrects what appears to be an inadvertent typographical error, as it is section 9792.21(d)(2) that pertains to treatment guidelines other than the MTUS.</p>			
9792.25.1(a)	<p>Commenter recommends the following revised language:</p> <p><u>(a) When necessary to evaluate the quality and strength of evidence used to support a contested recommendation pursuant to section 9792.21.1, treating physicians, Utilization Review and Independent Medical Review physicians shall</u></p>	<p>Brenda Ramirez Claims & Medical Director California Workers’ Compensation Institute (CWCI) December 9, 2014 Written Comment</p>	<p>Reject in part. Accept in part. Reject: Commenter’s recommended language will not be adopted. <u>Although we agree with commenter that the language can be clarified, her recommended language will not be adopted because the phrase “When necessary” is vague and ambiguous and is</u></p>	<p>Section 9792.25.1(a) is revised to state, “When competing recommendations are cited to guide medical care, Utilization Review and Independent Medical Review physicians shall</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2 ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>apply the MTUS Methodology for Evaluating Medical Evidence.</p> <p>Commenter states that the recommended change clarifies that it is only necessary for physicians and reviewers to evaluate the quality and strength of evidence when section 9792.21.1 indicates that it is necessary to do so. This is a clarification that may eliminate unnecessary disputes over when medical reviewers must evaluate the quality and strength of evidence of recommendations.</p>		<p><u>not as specific as the amended language chosen. In addition, commenter requires treating physicians to apply the MTUS Methodology for Evaluating Medical Evidence which opens the door to denials of RFA's by reviewing physicians because of a procedural defect without substantively evaluating if the treatment is reasonably necessary.</u></p> <p>Accept: Agree with commenter that the language can be clarified to make it clear the MTUS Methodology for Evaluating Medical Evidence shall be applied by UR and IMR physicians when competing recommendations are cited.</p>	<p>apply the MTUS Methodology for Evaluating Medical Evidence to evaluate the quality and strength of evidence used to support the recommendations that are at variance with one another. The MTUS Methodology for Evaluating Medical Evidence provides a process to evaluate studies, not guidelines.”</p>
9792.25.1(b)	<p>Commenter strongly supports the proposed general approach to determining the quality and strength of evidence. Commenter suggests retaining the existing methodology for determining the strength of evidence. The ACOEM Treatment Guidelines underlie the bulk of the MTUS and ACOEM provides a strength-of-</p>	<p>Brenda Ramirez Claims & Medical Director California Workers' Compensation Institute (CWCI) December 9, 2014 Written Comment</p>	<p>Reject: Commenter recommends retaining the current methodology for evaluating medical evidence adopted from ACOEM. The existing standard is currently set forth in section 9792.25(c)(1) and is an eleven step evaluation process. The</p>	<p>None.</p>

Medical Treatment Utilization Schedule	RULEMAKING COMMENTS 2ND 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	<p>evidence rating for each of its individual recommendations. If ACOEM's strength-of-evidence standards are retained in the regulations, physicians and reviewers need only compare the strength of evidence supporting non-ACOEM recommendations. Commenter opines that this will significantly reduce the number of disagreements and the time and resources needed to identify recommendations supported by the strongest evidence. If the Administrative Director decides not to retain the current methodology, commenter recommends instead that the MTUS include the strength of evidence underlying each recommendation in the MTUS as evaluated under the new methodology.</p>		<p>proposed methodology is just a five step process and is much more comprehensive because evidence supported by non-randomized controlled trials can be evaluated.</p>	