

Response No. 1

Adoption by Incorporation by Reference an Existing Document and Any Future Updates

The adoption by incorporation by reference of a document and its future updates or amendments promulgated by a private organization is not recommended as it raises a serious concern of the unconstitutional delegation of legislative power to nongovernmental bodies.

1. Background:

The purpose of proposed medical treatment utilization schedule regulations is to implement, interpret, and make specific the following Labor Code sections that the Division of Workers' Compensation is responsible for administering.

Labor Code section 77.5 requires the Commission on Health and Safety and Workers' Compensation (hereinafter CHSWC) to conduct a survey and evaluation of evidence-based, peer-reviewed, nationally recognized standards of care, and to report its findings and recommendations to the Administrative Director for purposes of the adoption of a medical treatment utilization schedule. The survey shall be updated periodically.

Labor Code section 5307.27 requires the Administrative Director, in consultation with CHSWC, to adopt, after public hearings, a medical treatment utilization schedule to address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases.

Labor Code section 4604.5(a) provides that the recommended guidelines set forth in the medical treatment utilization schedule pursuant to Labor Code section 5307.27 are presumptively correct on the issue of extent and scope of medical treatment. The presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines is reasonably required to cure or relieve the injured worker from the effects of his or her injury. The presumption created is one affecting the burden of proof.

Labor Code section 4604.5(b) provides that the recommended guidelines set forth in the adopted schedule shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed. The guidelines shall be designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and shall constitute care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions.

Labor Code section 4605.5(c) provides that three months after the publication date of the updated American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines, and continuing until the effective date of a medical treatment utilization schedule, pursuant to section 5307.27, the recommended guidelines

set forth in the American College of Occupational and Environmental Medicine's Occupational Medicine practice Guidelines shall be presumptively correct on the issue of extent and scope of medical treatment regardless of date of injury.

Labor Code section 4604.5(e) provides that for all injuries not covered by the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines (ACOEM Practice Guidelines) or official utilization schedule after adoption pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence based medical treatment guidelines generally recognized by the national medical community and that are scientifically based.

Labor Code section 4600 provides, in pertinent part, that medical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that are reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer. In the case of his or her neglect or refusal reasonably to do so, the employer is liable for the reasonable expense incurred by or on behalf of the employee in providing treatment. Also pertinent to these proposed regulations is subdivision (b) of Labor Code section 4600. This subdivision provides that, 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 pursuant to Labor Code section 5307.27, or prior to the adoption of those guidelines, the updated American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines.

2. A regulation can adopt a document by incorporation by reference:

Labor Code section 77.5 requires the Commission on Health and Safety and Workers' Compensation (hereinafter CHSWC) to conduct a survey and evaluation of evidence-based, peer-reviewed, nationally recognized standards of care, and to report its findings and recommendations to the Administrative Director for purposes of the adoption of a medical treatment utilization schedule. By its statutory language, it is clear that the legislature contemplated the Administrative Director to adopt a medical treatment utilization schedule based upon pre-existing medical treatment guidelines developed and published by private organizations such as the ACOEM Practice Guidelines.

The court in *Int'l Ass'n of Plumbing Etc. Officials v. Cal. Bldg. Stds. Com.*, 55 Cal. App. 4th 245, 249-250 (Cal. Ct. App. 1997), recognized that publications such as the above medical treatment guidelines are typically subject to the copyright of the private organization that drafts and publishes them, and therefore, the court held that a regulation can adopt by incorporation by reference such publications with appropriate deletions and additions. The court held:

“The process of adopting building standards into a centralized code is facilitated by the use of model codes. Model codes are drafted and

published by private organizations such as ICBO and IAPMO. (§ 18916.) Model codes are typically subject to the copyright of the private organizations that draft and publish them and the state cannot reproduce the text of the model codes without reaching an agreement with the copyright holders. Consequently, unless the Commission and an organization that publishes a model code first enter into a written agreement concerning publication, a state building standard can adopt a provision of a model code only by reference, with appropriate additions or deletions. (§ 18928.1.) As a result, a person planning a project must have access to the applicable model code or codes as well as the California Building Standards Code in order to determine the standards that apply to the project. By reference to the adoption tables of the California Building Standards Code the user can determine whether a particular model standard has been adopted by an agency or agencies with jurisdiction over a project, and the appropriate part of the California Building Standards Code will provide additions or deletions to the model standard that have been made by an adopting agency.”

The court in *Kings Rehabilitation Center, Inc. v. Premo*, 69 Cal. App. 4th 215, 218 (Cal. Ct. App. 1999) held the following:

“Where a regulation which incorporates a document by reference is approved by OAL and filed with the Secretary of State, the document so incorporated shall be deemed to be a regulation subject to all provisions of the APA.” (Cal. Code Regs., tit. 1, § 20, subd. (e).)

The OAL regulation is not a statute, but it is a regulation approving the practice of incorporation by reference and it was promulgated by the very agency which regulates regulations. It is entitled to deference. (*Whitcomb Hotel, Inc. v. Cal. Emp. Com.* (1944) 24 Cal. 2d 753, 756-757 [151 P.2d 233, 155 A.L.R. 405].)

The fact that no statute explicitly authorizes the practice of incorporation by reference does not mean it is illegal; no statute specifically forbids the practice, either. Further, at least one statute assumes the practice is lawful. Government Code section 11344.6 provides in relevant part that: “The courts shall take judicial notice of the contents of each regulation which is printed or which is incorporated by appropriate reference into the California Code of Regulations as compiled by the office.” There is no reason to judicially notice illegal regulations, therefore we assume the Legislature has agreed with OAL's determination that incorporation by reference can, in some cases, further the purposes of the APA.”

Title 1, California Code of Regulations section 20 (1 CCR §20) provides for the circumstances of when and how a regulation may incorporate a document by reference. 1 CCR §20 states in pertinent part:

“(a) "Incorporation by reference" means the method whereby a regulation printed in the California Code of Regulations makes provisions of another document part of that regulation by reference to the other document.

(b) Material proposed for ‘incorporation by reference’ shall be reviewed in accordance with procedures and standards for a regulation published in the California Code of Regulations. Except as otherwise specified in section 11 of these regulations, OAL shall not review material proposed for ‘incorporation by reference’ for compliance with the applicable standards of Government Code section 11349.1 when a California statute or other applicable law specifically requires the adoption or enforcement of the incorporated material by the rulemaking agency.”

3. The Division of Workers' Compensation may incorporate an existing document by reference. However, if the regulation also adopts future updates or amendments to the document, the constitutional validity of the regulation is subject to challenge.

As stated earlier, 1 CCR §20, sets forth the circumstances when a regulation may incorporate another document by reference. In particular, 1 CCR §20(c)(4) states, “An agency may “incorporate by reference” only if the following conditions are met...(4) The regulation text states that the document is incorporated by reference and identifies the document by title and **date of publication or issuance**. Where an authorizing California statute or other applicable law requires the adoption or enforcement of the incorporated provisions of the document as well as subsequent amendments thereto, no specific date is required.” (Emphasis added.)

After review of the authorizing statutes discussed above, no statute evidences such a requirement. In particular, no statute requires the Administrative Director to adopt a particular document or any subsequent amendments thereto. Rather, the statutes (Labor Code section 77.5) require CHSWC to conduct a survey and evaluation of evidence-based, peer-reviewed, nationally recognized standards of care, and to report its findings and recommendations to the Administrative Director for purposes of the adoption of a medical treatment utilization schedule.

Thus, in this case, a regulation may only incorporate an existing document by reference which is identified by title and date of publication or issuance.

The question of whether the constitutional validity of a regulation can be challenged if it incorporates by reference medical treatment guidelines or portions thereof and its subsequent updates or amendments, which is promulgated by a private association, is discussed below.

Article IV, section 1 of the California Constitution provides that “[t]he legislative power of this State is vested in the California Legislature which consists of the Senate and Assembly, but the people reserve to themselves the powers of initiative and referendum.”

(*Cal Const, Art. IV § 1*)

In addition to the constitutional provision, the common law doctrine also prohibits delegation of legislative power. The court in *Kugler v. Yocum*, 69 Cal. 2d 371, 375-377 (Cal. 1968), held, “[t]he power . . . to change a law of the state is necessarily legislative in character, and is vested exclusively in the legislature and cannot be delegated by it This doctrine rests upon the premise that the legislative body must itself effectively resolve the truly fundamental issues. It cannot escape responsibility by explicitly delegating that function to others or by failing to establish an effective mechanism to assure the proper implementation of its policy decisions.” (Also see *Plastic Pipe & Fittings Assn. v. California Building Standards Com.*, 124 Cal. App. 4th 1390 (Cal. Ct. App. 2004).)

Case law has also determined there is “no distinction between direct legislative adoptions and those made by state administrative agencies pursuant to statutory authority. See, e.g., *Seale v. McKennon*, supra....[D]elegation of **prospective** rule making power constitutes an unlawful delegation of legislative authority...Needless to say, if the Legislature may not take such action itself, it may not authorize an administrative agency to do so.” (emphasis added) (1980 Cal. AG LEXIS 57, 35-36 (Cal. AG 1980)).

As a result, attempts to adopt by reference existing medical treatment guidelines or portions thereof, together with any future amendments or updates that are promulgated by private associations, raise serious constitutional issues. It is well settled that the California courts support regulations which incorporate by reference documents in existence at the time the regulation is adopted. If, however, a regulation attempts to adopt future amendments or updates of the incorporated document, the courts have cast considerable doubt as to the validity of adopting documents **prospectively**. Such an act may be viewed as an invalid delegation of legislative power.

In *Plastic Pipe & Fittings Assn. v. California Building Standards Com.*, 124 Cal. App. 4th 1390 (Cal. Ct. App. 2004), the California Building Standards Commission received proposed building standards from state agencies for consideration in an annual code adoption cycle. The building standards ordinarily are based on model codes with any amendments deemed appropriate. The model codes are often published by private organizations or associations. The court in *Plastic Pipe & Fittings Assn.* at page 1410 held the following:

“The legislative power of the state is vested in the Legislature. (*Cal. Const.*, art. IV, § 1.) An unconstitutional delegation of legislative authority occurs if a statute authorizes another person or group to make a fundamental policy decision or fails to provide adequate direction for the implementation of a fundamental policy determined by the Legislature. (*Carson Mobilehome Park Owners' Assn. v. City of Carson* (1983) 35 Cal.3d 184, 190 [197 Cal. Rptr. 284, 672 P.2d 1297]; *Kugler v. Yocum* (1968) 69 Cal.2d 371, 376-377 [71 Cal. Rptr. 687, 445 P.2d 303].) For the Legislature to grant a private association such as the International

Association of Plumbing and Mechanical Officials the power to make law with no direction from the Legislature and no review by a state agency would be unconstitutional. (*International Association of Plumbing etc. Officials v. California Building Stds Com.*, *supra*, 55 Cal.App.4th at p. 253.)”

In *Bakersfield v. Miller*, 64 Cal. 2d 93, 97-98 (Cal. 1966) the court held, “[t]he Uniform Building Code has been enacted by many cities throughout the state. The authority of local agencies to adopt such uniform codes by reference is specifically provided by Government Code sections 50022.1- 50022.8, and the practice of adoption by reference has been judicially approved. In *Agnew v. City of Culver City* (1956) 147 Cal.App.2d 144, 153-157 [304 P.2d 788] the court criticized the practice of adopting codes promulgated by private associations if the intent is to adopt in advance changes which the association might choose to make at some future time.” (Citations omitted.) Also see *Westminster Mobile Home Park Owners' Ass'n v. City of Westminster*, 167 Cal. App. 3d 610 (Cal. Ct. App. 1985)

Insofar as future editions of medical treatment guidelines are concerned, there is no rational basis for predicting what future provisions will be considered appropriate by each private association that will be promulgating the future update. If future updates are automatically incorporated by reference into the regulation, which have the full force and effect of law, then the Administrative Director has delegated her power to make regulatory law in California to a private association with no limitation whatsoever and with no rational basis for determining what policy will be implemented. If the medical treatment guidelines updates automatically go into effect upon its publication, this regulation can be viewed as a violation of both article IV, section 1, of the California Constitution and of the common law doctrine prohibiting the delegation of legislative power.

Thus, based upon the above discussion, it is not appropriate that the medical treatment utilization schedule regulations adopt future updates or editions of documents adopted by incorporation by reference.

Response No. 2—Definition of term “Evidence-Based.”

In the Initial Statement of Reasons, the following justification was set forth for the definition of the term “evidence-based:”

As used in these regulations, the term “evidence-based” is defined to mean “based at a minimum on a systematic review of literature published in medical journals included in MEDLINE.”

Labor Code section 77.5 mandates that CHSWC conduct “a survey and evaluation of *evidence-based*, peer-reviewed, nationally recognized standards of care, including existing medical treatment utilization standards, including independent medical review, as used in other states, at the national level, and in other medical benefit systems.” (Emphasis added.) Labor Code section 77.5 further mandates that CHSWC “issue a report of its findings and recommendations to the administrative director for purposes of the adoption of a medical treatment utilization schedule.”

Labor Code section 5307.27 requires, in relevant part, that the Administrative Director, in consultation with CHSWC, adopt “a medical treatment utilization schedule, that shall incorporate the *evidence-based*, peer-reviewed, nationally recognized standards of care recommended by CHSWC pursuant to [Labor Code] section 77.5.” (Emphasis added.) Labor Code section 4604.5(b) provides that “[t]he recommended guidelines set forth in the schedule adopted ... shall reflect practices that are *evidence* and scientifically *based*, nationally recognized, and peer-reviewed.” (Emphasis added.)

For the reasons set forth below, section 9792.20(f) defines the term “evidence-based” as “based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE.”

Evidence-based medicine is a formal method of clinical decision-making based on knowledge of application of medical literature underlying each clinical decision rather than reliance on anecdote or personal experience. (*Evidence-Based Medicine & The California Workers’ Compensation System*, California Workers’ Compensation Institute, Harris, Swedlow, February 2004, p. 1.) This approach has been described as a paradigm shift for medical practice because Evidence-Based Medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. (*Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*, JAMA, November 4, 1992-Vol 268, No. 17 at p. 2420.)

In keeping with this goal, a number of major medical journals use a more informative structured abstract format, which incorporates issues of methods and design into the portion of an article the reader sees first. Textbooks that provide a

rigorous review of available evidence, including a methods section describing both the methodological criteria used to systematically evaluate the validity of the clinical evidence and the quantitative techniques used for summarizing the evidence, have begun to appear. Practice guidelines based on rigorous methodological review of the available evidence are increasingly common. (*Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*, JAMA, November 4, 1992-Vol 268, No. 17 at p. 2421.) The evidence-based medicine concept, therefore, is widely accepted within the medical community as the approach to guideline development that is most likely to provide the best information to physicians and the best possible care to patients. (*Evidence-Based Medicine: The Organizing Principle Behind the Development of ACOEM's Occupational Medicine Practice Guidelines*, ACOEM Practice Guidelines, ACOEM APG Insights, OEM Press, Fall 2004, p. 1.)

Evidence-based medicine began to develop as a methodology in the early 1970's when studies demonstrated wide, unexplained, variation in the use of resources for treatment of similar health problems. During that time, increased focus was placed on "the use of subjective or random treatments creating random outcomes" that "compromised quality of care and increased costs to the individual and overall health care system." One of the evidence-based medicine's early proponents, D. L. Sackett, M.D., described evidence-based medicine as the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." This approach requires "integrating individual clinical expertise with the best available clinical evidence from systematic research." Other definitions are similar, describing evidence-based medicine as "the concept of formalizing the scientific approach to the practice of medicine for identification of 'evidence' to support ... clinical decisions," the "ability to track down, critically appraise, and incorporate evidence into clinical practice," (*Evidence-Based Medicine: The Organizing Principle Behind the Development of ACOEM's Occupational Medicine Practice Guidelines*, ACOEM Practice Guidelines, ACOEM APG Insights, OEM Press, Fall 2004, at p. 1.)

Implicit in the various definitions of evidence-based medicine generally described above, is the understanding that while evaluation of the scientific evidence is a necessary component of evidence-based medicine, it must occur in the context of current clinical practice standards. In this regard, the appendix of the ACOEM Practice Guidelines states "it is possible to develop guidelines or conclusions regarding treatment and causation that are truly based on the scientific evidence" only "to the extent that the literature has adequate high quality studies of a given topic." (*Evidence-Based Medicine: The Organizing Principle Behind the Development of ACOEM's Occupational Medicine Practice Guidelines*, ACOEM Practice Guidelines, ACOEM APG Insights, p. 1, OEM Press, Fall 2004.) The objective of evidence-based medicine has been defined as "minimizing the effects of bias in determining an optional course of care" (Cohen, Stavri, and Hersh, 2004)." (*2005 RAND Report*, at p. xiv.)

As used in these regulations, the term “evidence-based” is defined to mean “based at a minimum on a systematic review of literature published in medical journals included in MEDLINE.” This definition is derived from the 2005 RAND Report, at p. 21, wherein RAND states that based on the requirements set forth in Labor Code section 5307.27 (i.e, evidence-based, peer reviewed, nationally recognized standards of care), it developed “generous definitions for these requirements in order to be inclusive.” RAND defined the terms “evidence-based” and “peer reviewed” together to mean “based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE.” MEDLINE (commonly known as PubMed) is the search engine for the National Library of Medicine.

At the outset, it is noted that Section 9792.20(f) has been re-lettered Section 9792.20(d). With regard to comments not addressed in the Initial Statement of Reasons, it is noted that various commenters have recommended a variation to the definition of the term “evidence-based.” The recommended definition stating “based on a systematic review of rigorous, scientific medical studies to guide effective medical decision-making and ensure the consistent use of proven medical practices” is not necessary. This comment combines two concepts: the concept of evidence-based and the concept of medical treatment guidelines. In order to distinguish these two concepts, ACOEM’s new hierarchy (see, Response No. 12—ACOEM’s Criteria Used to Rate Randomized Controlled Trials and Strength of Evidence Ratings) separates these two concepts to avoid confusion. We agree that MEDLINE contains medical articles for various purposes. That is the reason that a systematic review is performed on the articles to determine which ones are relevant for the development of evidence-based guidelines. The approach is not to simply tally how many articles support the use of a proposed treatment but rather to analyze the rigor of each article separately to determine the ultimate recommendation. The proposed regulations require the use of MEDLINE so that the entire body of literature is examined rather than just one medical article that supports the proposed treatment. With regard to the proposed definition requiring that the published medical journal be “for national sale and distribution,” we note that some journals of high quality are distributed for free to members of organizations or in the internet. We do not want to discourage use of these journals. Moreover, one must review the whole body of literature regardless of whether an article is for sale or not.

Response No. 3—Definition of term “medical treatment.”

Agree in part. At the outset, Section 9792.20(h), now re-lettered Section 9792.20(g), has been corrected for clerical error. Section 9792.20(g) now states that “Medical treatment” is care which is reasonably required to cure or relieve the employee from the effects of the industrial injury consistent with the requirements of sections 9792.20-9792.23,” and not 9792.20-9722.23

With regard to the comments presented, the term “medical treatment” has been defined in the context of the medical treatment utilization schedule set forth in the proposed regulations. Labor Code section 4600 provides, in pertinent part, that medical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer. In the case of his or her neglect or refusal reasonably to do so, the employer is liable for the reasonable expense incurred by or on behalf of the employee in providing treatment.

As pertinent to this proposed definition, Senate Bill 899 amended the Labor Code by adding subdivision (b) to Labor Code section 4600. This subdivision provides that, “[a]s 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 pursuant to Labor Code section 5307.27.”

The definition of “medical treatment” in the proposed regulations clarify that pursuant to the statute, the long standing definition of “medical treatment” (i.e., treatment “reasonably required to cure or relieve the injured worker from the effects of his or her injury”) has been modified to state that the treatment must also be “based upon the guidelines adopted by the administrative director pursuant to Labor Code section 5307.27.” These guidelines are set forth in the proposed regulations at sections 9792.20-9792.23. Thus, for purposes of these regulations, “medical treatment” is defined as “care which is reasonably required to cure or relieve the employee from the effects of the industrial injury consistent with the requirements of sections 9792.20-9722.23.”

If the definition proposed by commenters is adopted, the definition would take medical treatment for injured workers outside of the requirements of Labor Code section 4600 and outside of the medical treatment utilization schedule, which is comprised of sections 9792.20-9792.23.

Response No. 4—Definition of term “medical treatment guidelines.”

In the Initial Statement of Reasons (ISOR), the following justification was set for the definition of the term “medical treatment guidelines at pp. 12-14:”

Labor Code section 4604.5(a) provides that “[u]pon adoption by the administrative director of a medical treatment utilization schedule pursuant to Section 5307.27, the recommended guidelines set forth in the schedule shall be presumptively correct on the issue of extent and scope of medical treatment.” This section further provides that the “presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines is reasonably required to cure or relieve the injured worker from the effects of his or her injury.”

Labor Code section 4604.5(e) provides, that “[f]or all injuries not covered by the ... official utilization schedule after adoption pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence based medical treatment guidelines generally recognized by the national medical community and that are scientifically based.”

Pursuant to Labor Code section 4604.5(a), the ACOEM Practice Guidelines are presumptively correct but this presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence. Section 4604.5(e) further states that if an injury is not covered by the ACOEM Practice Guidelines, then treatment shall be in accordance with other evidence based medical treatment guidelines. Therefore, the scientific medical evidence sufficient to overcome the presumption of correctness attributed to the ACOEM Practice Guidelines or the recommended treatment for a condition or a specific injury not addressed in the ACOEM Practice Guidelines may be presented based on another evidence-based medical treatment guideline.

The proposed regulations defined the term “medical treatment guidelines” to mean “written recommendations systematically developed through a comprehensive literature search to assist in decision-making about the appropriate health care for specific clinical circumstances.”

Evidence-based medicine focuses on the need for health care providers to rely on a critical appraisal of available scientific evidence rather than clinical opinion or anecdotal reports in reaching decisions regarding diagnosis, treatment, causation, and other aspects of health care decision making. This mandates that information regarding health outcomes in study populations or experimental groups be extracted from the medical literature, after which it can be analyzed, synthesized, and applied to individual patients. (ACOEM Practice Guidelines, at p. 491.) The definition of the term “medical treatment guidelines” set forth in the proposed regulations is based on a definition for this term contained in the publication

Crossing the Quality Chasm, which states at page 145: “Many efforts to develop clinical practice guidelines, defined as ‘systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances,’ flourished during the 1980s and early 1990s (Institute of Medicine, 1992).” Guidelines build on syntheses of the evidence, but go one step further to provide formal conclusions or recommendations about appropriate and necessary care for specific types of patients. (Lohr et al.,1998.) Thus, to the extent that the literature has adequate high-quality studies of a given topic, it is possible to develop guidelines or conclusions regarding treatment and causation that are truly based on scientific evidence. (ACOEM Practice Guidelines, at p. 491.)

“Medical treatment guidelines are an important tool for implementing evidence-based medicine.” (2005 RAND Report, at p. xiv.) A high-quality guideline can help curtail the effects of bias in formulating a treatment plan.” (2005 RAND Report, at p. xiv.) Guidelines have many applications; one of the most common applications is to provide a structured literature review that distills the most current scientific evidence into recommendations for physicians. (2005 RAND Report, at p. xiv.) As the quality of research varies significantly, use of guidelines in the workers’ compensation system should reduce reliance on individual physicians’ opinions which could lead to wide variations in treatment for the same industrial injuries. Use of guidelines should further promote quality health care for the injured worker. (See *Crossing the Quality Chasm* at p. 77, which states in pertinent part: “The availability of systematic reviews and the resulting clinical guidelines for practicing clinicians is an essential adjunct to practice. A growing body of evidence demonstrates that the use of clinical practice guidelines with other supportive tools, such as reminder systems, can improve patient care” [Citations omitted].)

As stated above, the definition of the term “medical treatment guidelines” is based on the definition set forth in the publication “*Crossing the Quality Chasm*.” This definition, however, has been modified for purposes of the proposed regulations to mean “written recommendations systematically developed through a comprehensive literature search to assist in decision-making about the appropriate health care for specific circumstances.” The phrase “written recommendations” was added to the definition to avoid any use of oral guidelines. The phrase “systematically developed through a comprehensive literature search” was used to assure that the guidelines used are evidence-based as required by the statute. Further, it takes 17 years on the average for “new knowledge generated by randomized controlled trials to be incorporated into practice.” (*Crossing the Quality Chasm*, at pp. 13, 145.) This lag time, between when a new advance is recognized and when it actually benefits patients, can be reduced if physicians use well developed guidelines.¹ Thus, the phrase “to assist in decision-making about

¹ Guidelines vary greatly in the degree to which they are derived from and consistent with the evidence base. First, there is much variability in the quality of systemic reviews which are the foundation for guidelines. Second, guideline development generally relies on expert panels to arrive at specific clinical

the appropriate health care for specific clinical circumstances” in the definition is used to signify that the guidelines should help physicians assimilate evidence and tailor it to the treatment of individual patients.

Thus, the proposed MTUS regulations define the term “medical treatment guidelines” as “written recommendations systematically developed through a comprehensive literature search to assist in decision-making about the appropriate health care for specific clinical circumstances.”

Commenters [in the pre-rule making period] argue that the draft regulations include an inappropriate definition of “medical treatment guidelines” because the definition should make it clear that the term refers to the entire MTUS, and not ACOEM alone. Commenters believe that pursuant to Labor Code section 5307.27 and Labor Code section 4600, the logical conclusion which may be drawn is that the word guidelines in 4600 is meant to be the entire set of regulations as adopted by the Administrative Director, rather than any one set of guidelines found within those regulations

As indicated above, Labor Code section 4604.5(a) provides that “[u]pon adoption by the administrative director of a medical treatment utilization schedule pursuant to Section 5307.27, the recommended guidelines set forth in the schedule shall be presumptively correct on the issue of extent and scope of medical treatment.” Moreover, Labor Code section 4604.5(e) provides, that “[f]or all injuries not covered by the ... official utilization schedule after adoption pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence based medical treatment guidelines generally recognized by the national medical community and that are scientifically based.” Thus, it is clear that the statute requires the adoption of the medical treatment utilization schedule by way of regulations (i.e., Sections 9792.20-9792.23), that the statute envisioned incorporation of medical treatment guidelines as part of the schedule, and that the statute further envisioned usage of other medical treatment guidelines to address gaps in the schedule. Therefore, the definition of the term “medical treatment guidelines” based on the requirements of the statute is appropriate.

With regard to the comments not addressed in the ISOR, the definition of the term “medical treatment guidelines” has been amended for clarification purposes. Some commenters indicated that the definition should limit the effective date of the treatment guideline in order to insure currency. We agree this is important to prevent the use of outdated guidelines to guide the provision of medical treatment. We amended the definition of the term “medical treatment guidelines” to require that the guidelines be the most current version and also be revised within the last five years. We used the requirement of 5 years based on the National Guideline Clearinghouse (NGC)’s inclusion

conclusions. Judgment must be exercised in this process because the evidence base is sometimes weak or conflicting, or lacking in the specificity needed to develop recommendations useful for making decisions about individual patients in particular settings. (See, *Crossing the Quality Chasm* at p. 151.)

criteria at <http://www.guideline.gov/about/inclusion.aspx>. This document will be added to the rulemaking file under documents relied upon. Other commenters objected to the use of the phrase “appropriate health care” in the definition on the basis that the term “medical treatment” was more appropriate as the regulations already contained a proposed definition to that term. We agree that the phrase “appropriate health care” should be replaced with the phrase “medical treatment” for clarity purposes because the proposed regulations as pointed out by the commenters already contain a definition of the term medical treatment. Finally, some commenters suggested in connection with the definition of the term “nationally recognized,” that the phrase “multidisciplinary clinical panel” be added to the definition of that term as that phrase reflects the findings of several studies showing that such panels are an important component of guideline quality. We agree with the recommendation that multidisciplinary clinical panels should be involved in the development of the guidelines, however, DWC believes that this requirement relates more appropriately to the definition of “medical treatment guidelines.” Thus, the definition of the term “medical treatment guidelines” has been amended to include the requirement that the guidelines be developed by a multidisciplinary process. The justification for this requirement is set forth in the ISOR at p. 20, and in the 2005 RAND Report at p. xviii. Based on the comments accepted as set forth above, the definition of the term “medical treatment guidelines,” has been amended to mean “the most current version of written recommendations revised within the last five years which are systematically developed by a multidisciplinary process through a comprehensive literature search to assist in decision-making about the appropriate medical treatment for specific clinical circumstances.”

With regard to the remaining comments submitted, it appears that some commenters are confusing the use of the term “medical treatment guidelines,” as used in a general sense with the term “Medical Treatment Utilization Schedule,” which refers to the medical treatment utilization schedule adopted in the proposed regulations pursuant to the statute. (Lab. Code, § 5307.27.) Although the Medical Treatment Utilization Schedule contains as of now two medical treatment guidelines, i.e., the ACOEM Practice Guidelines and the Acupuncture Practice Guidelines, it will in the future contain other medical treatment guidelines as the MTUS continues to be updated. The proposed regulations at Section 9792.21(c) refer to the term “medical treatment guidelines,” when addressing other medical treatment guidelines which are not part of the MTUS. Thus it is necessary to define that term in the proposed regulations. However, we agree that the proposed regulations, as written, are confusing. In order to clarify the confusion, we have amended Section 9792.21(a), (b), (c), and Section 9792.22(a) and (b) to insert the term “Medical Treatment Utilization Schedule” instead of the term “ACOEM Practice Guidelines.” With this change, it is clear that the MTUS is the schedule adopted by the Administrative Director; that the ACOEM Practice Guidelines is one guideline incorporated into the MTUS; and the Acupuncture Medical Treatment Guidelines is another guideline incorporated into the schedule.

Response No. 5

“Generally recognized by the national medical community” language and definition of term “nationally recognized.”

Labor Code section 77.5 required the Commission on Health and Safety and Workers’ Compensation (CHSWC) to “conduct a survey and evaluation of evidence-based, peer-reviewed, *nationally recognized* standards of care, including existing medical treatment utilization standards, including independent medical review, as used in other states, at the national level, and in other medical benefit systems,” and to “report ... its findings and recommendations to the administrative director for purposes of the adoption of a medical treatment utilization schedule.” (Emphasis added.)

Labor Code section 5307.27 requires, in relevant part, the “administrative director ... [to] adopt ... a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, *nationally recognized* standards of care ...” (Emphasis added.)

Labor Code section 4604.5(b) requires, in pertinent part, that “[t]he recommended guidelines set forth in the schedule adopted ... shall reflect practices that are evidence and scientifically based, *nationally recognized*, and peer-reviewed.” (Emphasis added.)

Labor Code section 4604.5(e) provides, on the other hand, that for “all injuries not covered by the ... official utilization schedule after adoption ..., authorized treatment shall be in accordance with other evidence based medical treatment guidelines *generally recognized by the national medical community* and that are scientifically based. (Emphasis added.)

While Labor Code sections 77.5, 5307.27 and 4604.5(b) consistently refer to “nationally recognized” by the medical community when referring to medical treatment guidelines, section 4604.5(e) uses the term “generally recognized by the national medical community.” After review of the Labor Code sections as set forth above, the Administrative Director determines that both terms have essentially the same meaning, and in order to implement, interpret, and make specific Labor Code section 4604.5(e), it is necessary to harmonize this section with the remaining statutes (Lab. Code, §§ 77.5, 5307.27, and 4604.5(b).) In this regard, the Administrative Director determines that it is appropriate to use the term “nationally recognized” throughout the regulations as this term is used consistently in Labor Code sections 77.5, 5307.27 and 4604.5(b), and it is already defined in the proposed regulations. Accordingly, the language “generally recognized by the national medical community” contained in Sections 9792.21(c) and 9792.22(b) will be substituted with the language “nationally recognized.”

Further, as pertinent to the definition of “nationally recognized,” we stated in the Initial Statement of Reasons (ISOR), at pp. 14-16 as follows:

Labor Code section 77.5 mandates that CHSWC conduct “a survey and evaluation of evidence-based, peer-reviewed, nationally recognized standards of care,

including existing medical treatment utilization standards, including independent medical review, as used in other states, at the national level, and in other medical benefit systems.” Labor Code section 77.5 further mandates that CHSWC “issue a report of its findings and recommendations to the administrative director for purposes of the adoption of a medical treatment utilization schedule.”

Labor Code section 5307.27 requires, in relevant part, that the Administrative Director, in consultation with CHSWC, adopt "a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by the commission pursuant to [Labor Code] section 77.5.” Labor Code section 4604.5(b) provides that “[t]he recommended guidelines set forth in the schedule adopted ... shall reflect practices that are evidence and *scientifically based*, nationally recognized, and peer-reviewed.” (Emphasis added.)

For the reasons set forth below the term “scientifically based” has been defined to mean “based on scientific literature, wherein the literature is identified through performance of a literature search, the identified literature is graded, and then used as the basis for the guideline.”

Evidence-based medicine focuses on the need for health care providers to rely on a critical appraisal of available scientific evidence rather than clinical opinion or anecdotal reports in reaching decisions regarding diagnosis, treatment, causation, and other aspects of health care decision making. To the extent that the literature has adequate high-quality studies of a given topic, it is possible to develop guidelines or conclusions regarding treatment and causation that are truly based on scientific evidence. (ACOEM Practice Guidelines, at p. 491.)

The foundation of the practice of medicine that is evidence and scientifically based lies in developments in clinical research over the last 30 years. In 1960, the randomized clinical trial was an oddity, it is now accepted that virtually no drug can enter clinical practice without a demonstration of its efficacy in clinical trials. (*Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*. JAMA 268(17):2420-5, 1992, at p. 2420, cited in *Crossing the Quality Chasm* at p. 222.) Additionally, the same randomized trial method is increasingly being applied to surgical therapies and diagnostic tests. (*Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*. JAMA 268(17):2420, 1992.) A new philosophy of medical practice and teaching has followed these methodological advances and practice guidelines based on rigorous methodological review of the available evidence are increasingly common. (*Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*. JAMA 268(17):2420, 1992.)

Thus, evidence based medicine involves the skill of defining a patient problem, searching, evaluating, and then applying original medical literature. (*Evidence-*

Based Medicine: A New Approach to Teaching the Practice of Medicine. JAMA 268(17):2422, 1992.) Because of this requirement, it is important to look at all relevant articles on a given topic as results between different experiments might vary. A thorough literature review should be done before a conclusion is drawn. Because not all of the evidence is of equal quality, the evidence must be analyzed critically or graded to determine the validity of any recommendation.

Because of an awareness of the limitations of traditional determinants of clinical decisions, evidence based medicine allows for conclusions regarding treatment that are truly based on scientific evidence. (*Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine.* JAMA 268(17):2424, 1992.) Thus, it is necessary to define the term “scientifically based” to mean “based on scientific literature, wherein the literature is identified through performance of a literature search, the identified literature is graded, and then used as the basis for the guideline.”

At the outset, it is noted that Section 9792.20(l) setting forth the definition of the term “nationally recognized,” has been re-lettered Section 9792.20(i). In connection with the definition of the term “nationally recognized,” some commenters have raised questions as to whether their organization meets the definition of “nationally recognized” under the proposed definition requiring that the national organization be “based in two or more U.S. states.” In order to be inclusive, the definition of the term “nationally recognized” will be amended to state “disseminated by a national organization *with affiliates* based in two or more states.” Moreover, some commenters argue that the adoption of a guideline by one or more U.S. state governments fails to satisfy the requirement that a guideline be “nationally” recognized and/or fails to require proper screening. This definition is also amended to require that the adopted guideline not only be adopted by one or more U.S. state governments, but also be in use by one or more U.S. state governments. This will satisfy the requirement that the guideline has gone through proper screening by the rulemaking process of the state using it, and that it be in actual use as opposed to just be adopted but not in use. With regard to comments that the definition is too broad, DWC notes that the definition is intended to be inclusive, not restrictive. (See 2005 RAND report at p. xvi.) Thus the term “nationally recognized” has been amended to mean “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; and is the most current version.”

Response No. 6

ACOEM Meets the Requirements of Labor Code section 5307.27

Agree in part. “Workers experience a broad range of injuries of the muscles, bones, and joints, as well as a wide variety of other medical problems. These often require diagnostic tests, such as X-rays and magnetic resonance imaging (MRI). In California, common therapies include medication, physical therapy, chiropractic manipulation, joint and soft-tissue injections, and surgical procedures.” (2005 RAND Report, at p. xv.)

In its 2005 report, RAND concentrated its analysis “on diagnostic tests and therapies that are performed frequently and that contribute substantially to costs within the California workers’ compensation system.” (*Id.*, at p. xv.) RAND “identified several such tests and therapies and considered them to be priority topic areas that the guidelines should cover: MRI of the spine, spinal injections, spinal surgeries, physical therapy, chiropractic manipulation, surgery for carpal tunnel and other nerve-compression syndromes, shoulder surgery, and knee surgery.” (*Id.*, at p. xv.) RAND indicates that “taken together, these procedures account for 44 percent of the payments for professional services provided to California injured workers. In addition the surgeries account for about 40% of payments for inpatient hospital services.” (*Id.*, at p. xv.) RAND evaluated ACOEM’s guidelines and ascertained that these guidelines did satisfy the requirement to address the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases.

We disagree with the comment that ACOEM does not meet the requirements of Labor Code section 5307.27. For example, Chapter 12. Low Back Complaints, commencing at page 287, satisfies this requirement as illustrated below. As stated by RAND, in California common therapies include medication, physical therapy, chiropractic manipulation, joint and soft-tissue injections, and surgical procedures.” (2005 RAND Report, at p. xv.) The ACOEM Practice Guidelines discusses these very same subjects: Medications are discussed at pages 287, 298, 299, and 308. Physical therapy is discussed at pages 298, 299, and 308. Chiropractic manipulation is discussed at pages 298-300 and 308. Joint and soft-tissue injections are discussed at pages 300 and 309. Surgical Procedures are discussed at pages 305-307, and 310.

Thus, although ACOEM Practice Guidelines met the minimum requirement, these guidelines do not cover every treatment procedures and modalities commonly performed in workers’ compensation in California. These subjects will be evaluated by the Medical Evidence Evaluation Advisory Committee (advisory committee). This advisory committee will be created by way of these proposed regulations to review the medical literature in these areas to determine if new evidence should be used to supplement the ACOEM Practice Guidelines as adopted in the medical treatment utilization schedule. Representatives from the orthopedic field, chiropractic field, occupational medicine field, acupuncture medicine field, physical therapy field, psychology field, pain specialty field, occupational therapy field, psychiatry field, neurosurgery field, family physician field, neurology field, internal medicine field, physical medicine and rehabilitation field, and podiatrist field will be represented in the advisory committee.

Response No. 7
Adoption of Supplemental Guidelines

Commenters representing various non-surgical treatment providers argue that the ACOEM Practice Guidelines should be supplemented with their respective specialty guidelines. In its April 6, 2006 Updated and Revised CHSWC Recommendations to DWC on Workers' Compensation Medical Treatment Guidelines, CHSWC states at p. 2:

CHSWC recommends the ACOEM guidelines as the primary basis for the medical treatment utilization schedule because their flexibility allows medical decisions to take into consideration the full range of valid considerations and thus to provide optimal care for individual patients.

CHSWC, however, continues at page 2: "Numerous gaps and weaknesses in the ACOEM or any other existing set of guidelines will have to be filled by reliance on other guidelines." CHSWC indicates, in relevant part at p. 3, that "[t]he comprehensive guideline sets evaluated by RAND are generally weak regarding physical modalities such as chiropractic and physical therapy. In addition, stakeholder input indicates ACOEM is weak for occupational therapy, acupuncture and biofeedback." CHSWC then states:

Recognizing that general guidelines are subject to abuse by both excessive treatment and unwarranted denials, CHSWC recommends that specific guidelines be established for these therapies. *The quality of the guidelines developed by specialty organizations in these fields has not been independently evaluated, so CHSWC cannot recommend those guidelines.*

In the Initial Statement of Reasons (ISOR), the following justification was set forth, in part, for not adopting multiple contradictory guidelines as recommended by the CHSWC. The Initial Statement of Reasons states commencing at page 33 as follows:

[An] ... example of an inconsistency between guidelines that were submitted to the Administrator Director for consideration is found in section 4F of the *Guide to Physical Therapist Practice*, which addresses impairments of the spinal region such as lumbago, low back pain and sciatica. The text of the guideline states at page 221 that "80% of patients/clients who are classified into this pattern will achieve the anticipated goals and expected outcomes with 8 to 24 visits during a single continuous episode of care." In contrast, the ACOEM Practice Guidelines recommend only one to two visits for education, counseling, and evaluation of home exercise for range of motion and strengthening. (ACOEM Practice Guidelines, at p. 299.)

A further inconsistency is found in the section on low back in the guideline submitted by the Biofeedback Society of California. This guideline states at page 17 that biofeedback may be given up to 1 to 3 times per week for low back problems and that the time to produce an

initial effect is 4 to 6 sessions with the maximum duration of 12 to 16 sessions without documentation of need. (*Biofeedback Draft Medical Treatment Guidelines, Biofeedback Society of California, 2005.*) ACOEM states that biofeedback is not recommended for the low back problems. (ACOEM Practice Guidelines, at p. 300.)

The discrepancies found in the guidelines that were submitted to the Administrative Director for consideration extend beyond treatment recommendations into diagnostic modalities. The aforementioned *Guidelines for Chiropractic Quality Assurance and Practice Parameters* states with “proper patient selection and technical detail, full spine radiography is safe and effective.” The test is appropriate for such situations as evaluation of complex biomechanical or postural disorder, and the evaluation of multi-level spinal complaints as a result of biomechanical compensations. It is not acceptable for routine evaluation or screening of patients or for re-evaluation of biomechanical or postural disorders other than scoliosis. (*Guidelines for Chiropractic Quality Assurance and Practice Parameters* at pp. 18-19.) ACOEM, however, states “[f]or most patients presenting with true neck or upper back problems, special studies are not needed unless a three or four week period of conservative care and observation fails to improve symptoms.” (ACOEM Practice Guidelines, at p. 177.) The criteria for ordering tests include the emergence of a red flag, physiologic evidence of tissue insult or neurologic dysfunction, failure to progress in a strengthening program intended to avoid surgery, and clarification of the anatomy prior to an invasive procedure. For the low back, ACOEM states: “Lumbar spine x-rays should not be recommended in patients with low back pain in the absence of red flags for serious spinal pathology, even if the pain has persisted for at least six weeks. However, it may be appropriate when the physician believes it would aid patient management.” (ACOEM Practice Guidelines, at p. 303.) These examples demonstrate that the indications in the chiropractic guideline are more expansive than those found in the ACOEM Practice Guidelines.

With regard to CHSWC’s recommendation that the Administrative Director consider adopting an interim guideline in the podiatry field, it should be noted that, in a letter dated December 9, 2004, Jon Hultman, the Executive Director of the California Podiatric Medical Association, states that his organization “has identified specific services requiring guideline development and has previously submitted them to the RAND Group.” He supports the use of practice guidelines, but has not identified any specific guidelines that his organization would like to have included in the utilization schedule.

The fact that the Administrative Director is not including the above-discussed guidelines in the medical treatment utilization schedule at this

time, however, does not mean that the Administrative Director intends to rely solely on the ACOEM Practice Guidelines in the future. In this regard, the Medical Director proposes to create by way of these regulations a medical evidence evaluation advisory committee to provide recommendations to the Administrative Director on matters concerning the medical treatment utilization schedule. (For further explanation, see necessity statement regarding section 9792.23(a)(1).)

Because of inconsistencies between the above-referenced guidelines and the ACOEM Practice Guidelines in terms of recommendations and the system of scientific review used in the development of these guidelines, the Administrative Director determined that adopting multiple contradictory guidelines at this time as recommended by CHSWC would result in disputes and negate the presumption of correctness. (Labor Code section 4604.5(a).) These guidelines will be examined in the future by the medical evidence evaluation advisory committee, and after proper evaluation, recommendations will be provided to the Administrative Director.

As reflected in the draft of the regulations, the goal of DWC is to create the Medical Evidence Evaluation Advisory Committee (advisory committee) pursuant to Section 9792.23, and to have the advisory committee conduct its own scientific evidence review and provide recommendations to the Medical Director on matters concerning the MTUS, including those areas that needed supplementation. With the exception of the acupuncture modality (see Response No. 14—Acupuncture Medical Treatment Guidelines), these modalities will be addressed by the advisory committee and the MTUS will be supplemented as necessary. The advisory committee can also help insure that any supplemental guidelines adopted avoid any contradictions to the MTUS in order to prevent conflict with the presumption of correctness.

Response No. 8
CHSWC's Recommendations on Physical Modalities

In its “Updated and Revised CHSWC Recommendations to DWC on Workers’ Compensation Medical Treatment Guidelines,” dated April 6, 2006, CHSWC stated that stakeholder input indicates ACOEM is weak for occupational therapy, acupuncture and biofeedback (at p. 3). CHSWC recognized that general guidelines were subject to abuse by both excessive treatment and unwarranted denials. CHSWC further indicated that it had not independently evaluated the quality of the guidelines developed by specialty organizations in these fields and could not recommend those specialty guidelines (at p. 3). Instead, CHSWC recommended that the Administrative Director consider adopting interim guidelines for specified therapies, including chiropractic, physical therapy, occupational therapy, acupuncture, and biofeedback, consisting of a prior authorization process in which the indications for treatment and the expected progress shall be documented, and documentation of actual functional progress shall be required at specified intervals as a condition of continued authorization for the specified modalities (at p. 1). In this regard, it is noted that of these therapies, only chiropractic treatment and acupuncture are specified in Labor Code section 4600.

CHSWC further recommended using National Institutes of Health consensus statements and other states’ established guidelines, such as Colorado, to compose guidelines containing: a list of conditions for which each modality may be appropriate, a documentation process to justify the initiation of a treatment plan, a documentation process to justify continuation of a treatment plan by demonstrating functional improvement at specified intervals, and a maximum number of visits and duration of course of treatment (at p. 3). CHSWC opined that the documentation process should assure that a physician is accountable for a prolonged course of physical modalities without discouraging brief trials of inexpensive therapies in cases where those therapies have arguable merit. The primary criteria for authorizing and continuing such therapies should be the restoration of the injured employee’s level of function and, where feasible, an early and sustained return to work (at p. 3).

With regard to the comments that the proposed MTUS regulations should be drafted to incorporate CHSWC’s recommendations, and except for the Acupuncture Medical Treatment Guidelines (see Response No. 14—Acupuncture Medical Treatment Guidelines), the Administrative Director does not intend to rely solely on the ACOEM Practice Guidelines in the future. Although the ACOEM Practice Guidelines met the minimum requirements, these guidelines do not cover every treatment procedures and modalities commonly performed in workers’ compensation in California. These subjects will be evaluated by the Medical Evidence Evaluation Advisory Committee (advisory committee) that will be created by way of the proposed regulations. (See, proposed Section 9792.23.) The advisory committee will review the medical literature in these areas to determine if new evidence should be used to supplement the ACOEM Practice Guidelines as adopted. Representatives from the orthopedic field, chiropractic field, occupational medicine field, acupuncture medicine field, physical therapy field, psychology field, pain specialty field, occupational therapy field, psychiatry field,

neurosurgery field, family physician field, neurology field, internal medicine field, physical medicine and rehabilitation field, and podiatrist field will be included in the advisory committee to provide their expertise to the Medical Director in evaluating these subjects.

The Administrative Director is adopting the ACOEM Practice Guideline as this guideline was thoroughly evaluated by RAND and was found to be suitable for California's workers' compensation system and to be consistent with Labor Code section 5307.27. ACOEM remains the foundation for the MTUS, and any supplemental guidelines including the Acupuncture Medical Treatment Guidelines, must be fitted to ACOEM. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a).

Moreover, it is noted that the ACOEM Guidelines support the use of therapies that lead to functional improvement. "Patient and clinician should remain focused on the ultimate goal of rehabilitation leading to optimal functional recovery, decreased healthcare utilization, and maximal self-actualization." (ACOEM Practice Guidelines, at p. 106). The advisory committee will continue with the goal of providing care that promotes functional improvement pursuant to the statute.

Response No. 9
Incorporation of ACOEM into the MTUS

In the Initial Statement of Reasons (ISOR), the following justification was set forth for adopting the ACOEM Practice Guidelines into the Medical Treatment Utilization Schedule, at pp. 18-23:

Labor Code section 77.5 mandates that CHSWC conduct “a survey and evaluation of evidence-based, peer-reviewed, nationally recognized standards of care, including existing medical treatment utilization standards, including independent medical review, as used in other states, at the national level, and in other medical benefit systems. The survey shall be updated periodically.” Labor Code section 77.5 further mandates that CHSWC “issue a report of its findings and recommendations to the administrative director for purposes of the adoption of a medical treatment utilization schedule.”

Labor Code section 5307.27 requires, in relevant part, that the Administrative Director, in consultation with CHSWC, adopt, after public hearings, "a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by [CHSWC] pursuant to [Labor Code] section 77.5, and that shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases.” Labor Code section 4604.5(b) provides that “[t]he recommended guidelines set forth in the schedule adopted ... shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed.”

Pursuant to Labor Code section 77.5, CHSWC and the Division of Workers’ Compensation contracted with the RAND Institute for Civil Justice and RAND Health (hereinafter RAND) to conduct a study of medical treatment utilization guidelines. The “Working Paper” for the study was issued by RAND in November 2004. The “Working Paper” was later published in a report entitled: “*Evaluating Medical Treatment Guideline Sets for Injured Workers in California*,” (RAND, 2005). Pursuant to that study, CHSWC recommended, in pertinent part, that the Administrative Director:

- I. Consider adopting an interim utilization schedule based on the ACOEM Guidelines;¹

¹ CHSWC further stated in this regard: “CHSWC recommends consideration of the ACOEM guidelines as the primary basis for the medical treatment utilization schedule because their flexibility allows medical decisions to take into consideration the full range of valid considerations and thus to provide optimal care for individual patients. The effectiveness of care to mitigate disability should prevail over administrative efficiency of the UR tool, although efficiency of administration is an undeniable asset to effectiveness of care. It is contemplated that the ACOEM criteria may be translated into a step-by-step automated process. Once that is done, it will ameliorate the drawbacks of the ACOEM guidelines.” (http://www.dir.ca.gov/chswc/CHSWC_Med%20Treat_Nov2004.pdf)

- II. Consider replacing the ACOEM Guidelines with respect to spinal surgery by the American Academy of Orthopedic Surgery (AAOS) guidelines; and
- III. Consider adopting interim guidelines for specified therapies, including podiatry, chiropractic, physical therapy, occupational therapy, acupuncture, and biofeedback.²

The Administrator Director decided to adopt the ACOEM Practice Guidelines as the medical treatment utilization schedule, and not to replace the ACOEM Practice Guidelines with respect to spinal surgery by AAOS or to adopt interim guidelines for specified therapies as recommended by CHSWC. The following is an explanation for this decision.

Adoption of the ACOEM Practice Guidelines as the Medical Treatment Utilization Schedule.

In its evaluation of the medical treatment guidelines study, RAND's approach was to identify guidelines addressing work-related injuries, screen those guidelines using multiple criteria, and evaluate the guidelines that met their criteria. Table 4.1 at page 21 of the study identifies the screening criteria based on Labor Code section 5307.27 as defined by RAND. These criteria included the following elements:

- (1) evidence-based, peer-reviewed,
- (2) nationally recognized,
address common and costly tests and therapies for injuries of spine, arm, and leg,
- (3) reviewed or updated at least every three years,
- (4) developed by a multidisciplinary clinical team,
- (5) cost less than \$500 per individual user in California. (*Id.*, at p. 21.)

The first two criteria were required by the statute. (Lab. Code, §§ 77.5, 5307.27.) RAND indicates it "developed generous definitions for these requirements in order to be inclusive at this stage." (2005 RAND Report, at p. 21.) RAND indicates that together these two terms "were taken to mean based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE." (2005 RAND Report, at p. 21.) The remaining criteria were developed in conjunction with CHSWC and DWC. (2005 RAND Report, at pp. xiv-xvii.)

² CHSWC's full recommendation is stated as follows: "CHSWC recommends that the AD consider adopting interim guidelines for specified therapies, including podiatry, chiropractic, physical therapy, occupational therapy, acupuncture, and biofeedback, consisting of a prior authorization process in which the indications for treatment and the expected progress shall be documented, and documentation of actual functional progress shall be required at specified intervals as a condition of continued authorization for the specified modalities. (http://www.dir.ca.gov/chswc/CHSWC_Med%20Treat_Nov2004.pdf)

RAND applied the selection criteria in three phases:

- The first phase required guidelines to be current (developed or at least reviewed during the past three years), to be nationally recognized, and to address at least two different types of tests and therapies for injuries of the spine, arm and leg.
- The second phase required the guidelines to be evidence-based and peer-reviewed, to be developed by a multidisciplinary panel, to be kept up-to-date in the future, and to be available for less than about \$500 per individual use in California.
- The third phase determined whether the guidelines addressed most of the cost-driver topics. (*2005 RAND Report*, at pp. 25-26.)

To apply the first phase of the selection criteria, RAND:

“used information obtained during the search process to determine whether a guideline was nationally recognized. [RAND] judged whether a guideline was current from dates provided in its content or introductory materials. [RAND] determined whether a guideline addressed at least two different types of tests and therapies for injuries of the spine, arm, and leg by examining its content. In making comprehensiveness decisions, [RAND] included only sections of each guideline that were reviewed or updated during the past three years.” (*2005 RAND Report*, at p. 26.)

To apply the second phase of the selection criteria, RAND:

“used information included in the guideline content and introductory materials and also contacted the guideline developers for details and corroborating evidence. To verify that systematic literature reviews were performed during the development process, [RAND] asked the developers to describe the process and provide [them] search terms, data bases searched, and other corroborating materials. To verify that there was a multidisciplinary development process, [RAND] asked the developers [them] with materials convincingly demonstrating that at least three different types of specialists treating injured workers were involved. To be considered up-to-date in the future, guideline developers had to document their intention to at least review a guideline every three years. ... To meet the cost criterion, developers had to document their intention to make the guideline available to Californians at \$500 or less per individual use.” (*2005 RAND Report*, at p. 26.)

The fifth criterion, as contained in the second phase of the selecting criteria, i.e., that multidisciplinary clinical panels had to be involved in developing the guidelines, is of import. In its 2005 report, RAND discusses a report issued by the Institute of Medicine (IOM) as follows: “A 1990 IOM report on clinical practice guidelines considered a multidisciplinary development process to be an important

component of guideline quality. The report asserted that use of a multidisciplinary team increases the likelihood that (1) all relevant scientific evidence will be considered, (2) practical problems with using the guidelines will be identified and addressed, and (3) affecting [provider] groups will see the guidelines as credible and will cooperate in implementing them [citation omitted].” (2005 RAND Report, at p. xviii.)

To apply the third phase of the selection criteria, RAND:

“determined whether the guidelines addressed most of [its] cost-driver topics: MRI of the spine, spinal injections, spinal surgery, physical therapy, chiropractic manipulation, surgery for carpal tunnel and related conditions, shoulder surgery, and knee surgery.” (2005 RAND Report, at p. 26.)

After applying the screening criteria to the guidelines examined, five comprehensive guideline sets met the screening criteria developed by RAND and remained eligible for further evaluation.³ These Guidelines are listed at Table 4.2 of the study at page 27:

- (1) AAOS—Clinical Guidelines by the American Academy of Orthopedic Surgeons
- (2) ACOEM—American College of Occupational and Environmental Medicine Occupational Medicine Practice Guidelines
- (3) Intracorp—Optimal Treatment Guidelines, part of Intracorp Clinical Guidelines Tool®

³ As reflected in the 2005 RAND Report, ACOEM met the screening criteria requiring the guidelines to be evidence-based. In its ACOEM APG Insights of Fall 2004, ACOEM indicates that the ACOEM Practice Guidelines "were developed using the principles of evidence-based medicine (EBM). The College chose EBM as the organizing methodology for its Practice Guidelines because this concept is widely accepted within the medical community as the approach to guideline development that is most likely to provide the best information to physicians and the best possible care to patients." ACOEM further noted that "implicit" in the concept of EBM "is the understanding that while evaluation of the scientific evidence is a necessary component of EBM, it must occur within the context of current clinical practice standards." Accordingly, the appendix of the ACOEM Guidelines explicitly states "it is possible to develop guidelines or conclusions regarding treatment and causation that are truly based on the scientific evidence' only 'to the extent that the literature has adequate high-quality studies of a given topic [footnote omitted].' In the absence of high-grade evidence, available scientific information must be analyzed in the context of current clinical practice in order to determine the 'value' of accepting a given intervention or causal hypothesis." ACOEM further states (in Insights), that "the assessment of 'value' is inherent in any set of evidence-based guidelines, including those developed by ACOEM. Value may be determined by generally considering the current standards regarding treatments or tests, and more specifically based upon an analysis of the benefit or potential benefit of an intervention, weighed against the cost." The appendix then performs the last step in clarifying the relationship between the evidence, assessment of value, and final guidelines development by stating "[w]hile most clinical practice guidelines cite the literature on which they are based, the final decision regarding the implications of the studies involved is the consensus opinion of those who develop the guidelines. It is critical that those opinions reflect a commitment to the use of the high-quality scientific evidence." (*Evidence-Based Medicine: The Organizing Principle Behind the Development of ACOEM's Occupational Medicine Practice Guidelines*, ACOEM Practice Guidelines, ACOEM APG Insights, p. 1, OEM Press, Fall 2004; ACOEM Practice Guidelines, at p. 491.)

- (4) McKesson—McKesson/InterQual Care Management Criteria and Clinical Evidence Summaries
- (5) ODG—Official Disability Guidelines: Treatment in Workers’ Comp, by Work-Loss Data Institute

After identification of the five sets of guidelines which met the selection criteria, RAND convened a multidisciplinary panel of expert clinicians to evaluate the comprehensiveness and validity of the guideline content. (2005 RAND Report, at pp. 35, 80.) The ACOEM Practice Guidelines was ranked first in comprehensiveness and validity of the guideline content. (2005 RAND Report, at pp. 48, 81.)

RAND concluded in its report at page 82 that “the results of the clinical content evaluation indicate that there is no reason for the state to choose another guideline set to replace the ACOEM at this time.”⁴ RAND proceeded to set forth in its study short term, intermediate term and longer term recommendations to the State. (2005 RAND Report, at pp. 85-88.)

Based on the 2005 RAND study, CHSWC recommended, in pertinent part, that the Administrative Director consider adopting an interim utilization schedule based on the ACOEM Practice Guidelines.⁵ Based on the 2005 RAND study as set forth above, and pursuant to CHSWC’s recommendation, the Administrative Director has determined that the ACOEM Practice Guidelines meet the standard in Labor Code section 4604.5(b), that guidelines set forth in the medical treatment utilization schedule pursuant to section 5307.27 “shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed.” (See also, *Evidence-Based Medicine & The California Workers’ Compensation System*, California Workers’ Compensation Institute, Harris, Swedlow, February 2004, p. 2.)

With regard to the comments not addressed by the ISOR, it is noted that the Medical Evidence Evaluation Advisory Committee (advisory committee) is being formed to supplement the ACOEM Practice Guidelines. Labor Code section 5307.27 requires that

⁴ In its general findings and observations, the Bickmore report, states: “The provision of utilization review services in conjunction with evidence based medicine guidelines, notably those of the American College of Occupational and Environmental Medicine (ACOEM), has helped the insurance community effectively manage the cost of medical treatment in a manner that is also generally responsive to the treatment needs of the injured workers.” (*A Study of the Effects of Legislative Reforms on California Workers’ Compensation Insurance Rates*, State of California, Department of Industrial Relations, Division of Workers’ Compensation, Bickmore Risk Services (BRS), January 2006, at p. III-9.)

⁵ The CHSWC also recommended that the ACOEM Practice Guidelines be replaced with respect to spinal surgery by the American Academy of Orthopedic Surgery (AAOS) guidelines. This recommendation will be addressed below.

the MTUS addresses “at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases.” The advisory committee will be composed of various experts from specified specialty fields who will aid the Medical Director in continuous study of the medical treatment utilization schedule. The Medical Director will advise the Administrative Director regarding revisions and/or supplementation of the schedule as necessary in order to comply with the requirements of Labor Code section 5307.27.

Response No. 10

“Medical Treatment” Not Addressed in the Medical Treatment Utilization Schedule as Opposed to “Condition or Injury” not Addressed in the Medical Treatment Utilization Schedule

Labor Code section 4600 provides, in pertinent part, that “[m]edical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer. In the case of his or her neglect or refusal reasonably to do so, the employer is liable for the reasonable expense incurred by or on behalf of the employee in providing treatment.”

Senate Bill (SB) 899 (Chapter 34, stats. of 2004, effective April 19, 2004) amended the Labor Code by adding subdivision (b) to Labor Code section 4600. This subdivision provides that, “[a]s 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 pursuant to Labor Code section 5307.27.”

Labor Code section 4610 requires employers to establish and maintain a utilization review process consistent with the utilization schedule developed by the Administrative Director pursuant to section 5307.27, and prior to the adoption of that schedule, consistent with the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines (ACOEM Practice Guidelines). The utilization review (UR) regulations implement the utilization review process pursuant to Labor Code section 4610. Consistent with Labor Code section 4610, section 9792.8(a)(1) of the UR regulations provide that the criteria used in the utilization review process “shall be consistent with the schedule for medical treatment utilization adopted pursuant to Labor Code section 5307.27... [and p]rior to [the] adoption of the schedule ... consistent with the ... ACOEM Practice Guidelines.”

Labor Code section 5307.27 (SB 228, Chapter 639, stats. of 2003, effective January 1, 2004) requires that the Administrative Director adopt a medical treatment utilization schedule that addresses, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. Labor Code section 4604.5 (SB 228, Chapter 639, stats. of 2003, effective January 1, 2004, later amended by SB 899 (Chapter 34, stats. of 2004, effective April 19, 2004)) provides that the recommended guidelines set forth in the adopted schedule shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed. The proposed medical treatment utilization schedule (MTUS) regulations adopt the medical treatment utilization schedule. Two significant elements of the MTUS regulations is the adoption and incorporation of the ACOEM Practice Guidelines into the schedule, and the creation of the Acupuncture Medical Treatment Guidelines.

Labor Code section 4604.5 (SB 228, Chapter 639, stats. of 2003, effective January 1, 2004, amended by SB 899 (Chapter 34, stats. of 2004, effective April 19, 2004)) provides that for all injuries not covered by the ACOEM Practice Guidelines or official utilization schedule after adoption pursuant to Section 5307.27, authorized treatment shall be in accordance with other evidence-based medical treatment guidelines generally recognized by the national medical community and that are scientifically based.

Labor Code section 4604.5 also provides that the ACOEM Practice Guidelines, and continuing until the effective date of the medical treatment utilization schedule adopted pursuant to Labor Code section 5307.27, are presumptively correct on the issue of extent and scope of medical treatment. The presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines is reasonably required to cure or relieve the injured worker from the effects of his or her injury, in accordance with Labor Code section 4600. The presumption created is one affecting the burden of proof.

Some commenters have requested that Sections 9792.21(c) and 9792.22(c)(1) be amended to state that treatment may not be denied on the “sole basis that the treatment is not addressed” by the ACOEM Practice Guidelines as opposed to on the “sole basis that the condition or injury is not addressed” in the ACOEM Practice Guidelines. For clarification purposes, this comment will be review as stating that the “treatment” or “injury or condition” is not addressed in the MTUS as the MTUS is the schedule, and the ACOEM Practice Guidelines, 2nd Edition, is one component of the schedule although considered to be the framework of the schedule.

As previously indicated and pursuant to Labor Code section 4600, the injured worker is entitled to medical treatment “to cure or relieve the injured worker from the effects of his or her injury.” In workers’ compensation, the term “injury” encompasses the terms “medical condition” and “illness.” When treating a patient, the physician starts with the determination of the diagnoses or condition. Upon making the diagnosis, the physician looks for the best treatment for that condition. The medical treatment utilization schedule performs that function for the physician by providing evidence-based guidelines that are presumptively correct.

If a condition is covered by the MTUS and a course of treatment is provided for that condition, then that course of treatment has the Labor Code section 4604.5 presumption when a question arises as to whether a treatment should be authorized. If the provider wants to pursue a treatment for a condition addressed in the MTUS that is not part of the course of treatment provided by the MTUS, the provider must overcome the presumption afforded to that course of treatment described in the MTUS. This presumption may be rebutted by a “preponderance of the scientific medical evidence establishing that a variance from the guidelines is reasonably required to cure or relieve the injured worker from the effects of his or injury.” (Lab. Code, § 4604.5(a), Cal. Code Regs., tit.8, § 9792.8(a)(1).) For example, a course of treatment is set forth in the ACOEM Practice

Guidelines for the low back. If the physician wants to use an alternate treatment such as Botulinum Toxin (Botox), which is not mentioned in Chapter 12-Low Back Complaints, commencing on page 286, that physician must overcome the presumption afforded to the course of treatment as provided in the MTUS. The presumption may be overcome by submission of scientific evidence that supports that treatment. This approach is consistent with the requirements of the statute that the treatment be “evidence-based.” (Lab. Code, § 5307.27.)

Another consequence with using the word “treatment” rather than “condition,” in the above-referenced sections is the situation where there is no evidence about a proposed treatment. In this situation, the burden of proof would be shifted to the claims administrator to prove the lack of value of the proposed medical treatment in order to deny the request. This shift of burden of proof is not consistent with the statute.

Response No. 11
Chronic Conditions

In the Initial Statement of Reasons (ISOR), the following justification was set forth for the determination that ACOEM applies to chronic conditions:

The argument that the ACOEM Practice Guidelines do not apply to chronic cases and, therefore, are not appropriate guidelines for the treatment of industrial injuries at the chronic stage is based on the belief that the ACOEM Practice Guidelines only apply to the first 90 days following the industrial injury and consequently only apply to the acute stage of the medical condition. This is a mistaken interpretation of the ACOEM Practice Guidelines. “The Guidelines apply to any point following a health complaint, illness, or injury that the principles [sic] it espouses, or the information it includes, is applicable to the care of an injured worker.” (ACOEM’s letter to the Administrative Director, dated September 28, 2004, at p. 4.)

ACOEM “mostly focuses on the first 90 days following a workplace injury because 90 percent” of industrial injuries are resolved in the first 90 days. Generally, “in the absence of complicating factors, most common occupational health problems resolve in less than 30 days.” (APG Insights, ACOEM, Fall 2004 at p. 5.) [“APG Insights” refers to ACOEM’s Practice Guidelines Insights. APG Insights is “an educational publication intended to provide information and opinion as one source of guidance for health professionals.” The editors state that “APG Insights should always be considered in connection with the relevant part of said Guidelines.” (APG Insights, Fall 2004 at p. 5.)]

With regard to the scientific evidence available to support recommendations, “[s]cientific studies tend to address the presence or absence of tissue pathology during the first 90 days.” (APG Insights, ACOEM, Fall 2005, at p. 5.) The ACOEM Practice Guidelines “*initially* focus on the first 90 days following a workplace health problem, since the natural history of the problem discussed is that approximately 90 percent resolve in this time period. In addition, more high-grade scientific studies have addressed the diagnosis and treatment of acute health problems than chronic conditions. (Emphasis added, ACOEM’s letter to the Administrative Director, dated September 28, 2004, at p. 4.)

As to diagnostic testing and treatment, the criteria for surgery and imaging depend on the entire clinical picture rather than the time elapsed since the injury. Because injured workers are most likely to return to health and function if they receive proper care as soon after the injury as possible, applying the principles in ACOEM should markedly reduce the number of cases that remain under treatment past the expected resolution date. (ACOEM’s letter to the Administrative Director, dated September 28, 2004, at p. 4.)

Moreover, there are examples in the ACOEM Practice Guidelines which further contradict the belief that the ACOEM Practice Guidelines only applies to acute conditions. “Chapter 6 deals extensively with chronic pain.” By definition, “chronic pain occurs in cases that are more than 90 days from the date of injury.” Regarding pain, ACOEM states that the distinction between acute and chronic pain is arbitrary and chronicity may be reached from one to six months post-injury. The International Association for the Study of Pain has stated that three months is the definitional time frame, while the American Psychiatric Association uses a six-month limit. (ACOEM Practice Guidelines, at p. 108; Chapter 6.) Similarly, the ACOEM Practice Guidelines address issues of stress in Chapter 15. These issues “often arise in cases that do not involve physical injury and often relate to long-standing conditions.” (ACOEM Practice Guidelines, at Chapter 15; ACOEM’s letter to the Administrative Director, dated September 28, 2004, at p. 4.)

Further, the ACOEM Practice Guidelines has many references to treatment or diagnostic studies that are only appropriate later in the course of injuries. For instance, the chapter on shoulder complaints states that conservative care should be done for impingement syndrome for 3 to 6 months before surgery should be considered. (See ACOEM Practice Guidelines, Chapter 9 Shoulder Complaints, at p. 211.) In addition, many of the diagnostic or treatment recommendations in ACOEM are pertinent for acute or chronic conditions. As an example, the indications for an x-ray for the lumbar area are the same at the 89th day or at one year from the injury. The basic tenets found in the first seven chapters, [the first seven chapters of the ACOEM Practice Guidelines are listed under the heading “Foundations of Occupational Medicine Practice.” These chapters are the following: (1) Prevention, (2) General Approach to Initial Assessment and Documentation, (3) Initial Approaches to Treatment, (4) Work-Relatedness, (5) Cornerstones of Disability Prevention and Management, (6) Pain, Suffering, and the Restoration of Function, and (7) Independent Medical Examinations and Consultations] such as the assessment of an injury, are applicable at all phases of an injury be it acute or chronic. Thus, it is clear that the ACOEM Practice Guidelines are applicable for both acute and chronic medical conditions.

With regard to comments not specifically addressed by the justification set forth in the Initial Statement of Reasons, it is noted that although the Initial Statement of Reasons provides the justification for the definitions of the terms “acute” and “chronic,” DWC agrees that the distinction between an acute stage and a chronic stage of a condition is a clinical one. Because the intent of the regulations is to state that the MTUS applies to all conditions for the duration of the medical condition, the definitions of “acute” (Section 9792.20(a)), and “chronic” (Section 9792.20(d)) will be removed from the regulations. Because these terms have been removed from the proposed regulations, the first sentence of Section 9792.22(a) will be amended to read as follows:

- (a) The Medical Treatment Utilization Schedule is presumptively correct on the issue of extent and scope of medical treatment and diagnostic

services addressed in the Medical Treatment Utilization Schedule for the duration of the medical condition.

Some commenters argue that a statement in the ACOEM Practice Guidelines support the argument that the guidelines do not apply to chronic conditions. Commenters reference Chapter 12-Low Back, page 287, paragraph 2, wherein ACOEM states: “Recommendations on assessing and treating adults with potentially work-related low back problems (i.e. activity limitations due to symptoms in the low back of less than three months duration) are presented in this clinical practice guideline.”

Other commenters argue ACOEM does not apply to chronic conditions and reference the algorithm entitled: “Further Management of Occupational Knee Complaints,” contained in Chapter 13, Knee Complaints, at page 352. Commenters state that “the entry-level circumstance for use of the algorithm is stated as, “[w]orkers with knee-related activity limitations > (greater than) 4-6 weeks, but < (less than) 3 months duration,” and argue that this supports their contention that ACOEM does not apply to chronic conditions.

A review of the ACOEM Practice Guidelines Chapters reflect that the approach of the guidelines in general follow a specific method in treating the specific body part, beginning with:

- (1) The initial assessment and diagnosis of patients.
- (2) The identification of red flags that may indicate the presence of a serious underlying medical condition; initial management.
- (3) The diagnostic considerations and special studies for identifying clinical pathology, work-relatedness, return to work, modified duty and activity.
- (4) Further management considerations, including the management of delayed recovery.

Chapter 8-Neck and Upper Back Complaints addresses injuries to the neck and upper back. The general approach set forth in this chapter is presented as follows:

“Recommendations on assessing and treating adults with potentially work-related neck and upper back complaints are presented in this chapter. Topics include the initial assessment and diagnosis of patients; identification of red flags that may indicate the presence of a serious underlying medical condition; initial management; diagnostic considerations and special studies for identifying clinical pathology, work-relatedness, return to work, modified duty and activity; and further management considerations, **including the management of delayed recovery.**” (At p. 165.)

Chapter 9-Shoulder Complaints addresses injuries to the shoulder. The general approach set forth in this chapter is presented as follows:

“This clinical practice guideline presents recommendations on assessing and treating adults with potentially work-related shoulder complaints are presented in this chapter. Topics include the initial assessment and diagnosis of patients with acute and sub-acute shoulder complaints that are potentially work-related, identification of red flags that may indicate the presence of a serious underlying medical condition, initial management, diagnostic considerations, and special studies for identifying clinical pathology, work-relatedness, return to work, modified duty and activity, and further management considerations, **including the management of delayed recovery.**” (At p. 195.)

Chapter 10-Elbow Complaints addresses injuries to the elbow. The general approach set forth in this chapter is presented as follows:

“This chapter presents recommendations on assessing and treating adults with elbow complaints that may be work-related. Topics include the initial assessment and diagnosis of patients with acute and sub-acute elbow complaints; identifying red flags that may indicate the presence of a serious underlying medical condition; initial management; diagnostic considerations; and special studies for identifying clinical pathology, work-relatedness, return to work, modified duty and activity; and further management considerations, **including the management of delayed recovery.**” (At p. 227.)

Chapter 11-Forearm, Wrist, and Hand Complaints addresses injuries to the forearm, wrist and hand. The general approach set forth in this chapter is presented as follows:

“Recommendations on assessing and treating adults with potentially work-related forearm, wrist, or hand complaints are presented in this clinical practice guideline. Topics include the initial assessment and diagnosis of patients with acute and sub-acute forearm, wrist, or hand complaints that may be work-related, identification of red flags that may indicate the presence of a serious underlying medical condition, initial management, diagnostic considerations and special studies for identifying clinical pathology, work-relatedness, modified duty and activity; and return to work, as well as further management considerations, **including the management of delayed recovery.**” (At p. 253.)

Chapter 12-Low Back Complaints addresses injuries to the low back. The general approach set forth in this chapter is presented as follows:

“Recommendations on assessing and treating adults with potentially work-related low back complaints (i.e., activity limitations due to symptoms in the low back of less than three months duration) are presented in this clinical practice guideline. Topics include the initial assessment and diagnosis of patients with acute and sub-acute low back complaints that

are potentially work-related, identification of red flags that may indicate the presence of a serious underlying medical condition, initial management, diagnostic considerations and special studies for identifying clinical pathology, work-relatedness, modified duty and activity; and return to work, as well as further management considerations, **including the management of delayed recovery.**” (At p. 287.)

Chapter 13-Knee Complaints addresses injuries to the knee. The general approach set forth in this chapter is presented as follows:

“Recommendations on assessing and treating adults with potentially work-related knee problems are presented in this clinical practice guideline. Topics include the initial assessment and diagnosis of patients with acute and sub-acute knee complaints that are potentially work-related; identification of red flags that may indicate the presence of a serious underlying medical condition; initial management; diagnostic considerations and special studies for identifying clinical pathology; work-relatedness; modified duty and activity; and return to work; and further management considerations, **including the management of delayed recovery.**” (At p. 329.)

Chapter 14-Ankle and Foot Complaints addresses injuries to the ankle and foot. The general approach set forth in this chapter is presented as follows:

“Recommendations on assessing and treating adults with potentially work-related ankle and foot problems are presented in this clinical practice guideline. Topics include the initial assessment and diagnosis of patients with acute and sub-acute ankle or foot complaints that may be work-related, identification of red flags that may indicate the presence of a serious underlying medical condition, initial management, diagnostic considerations and special studies for identifying clinical pathology, work-relatedness, modified duty and activity, return to work; and further management considerations, **including the management of delayed recovery.**” (At p. 361.)

All of these chapters include a statement regarding the management of delayed recovery. In recognizing delayed recovery, the chapters share a common recommendation to the physician to assess patients for non-physical factors such as psychosocial, workplace, or socioeconomic problems which may be investigated and addressed in cases of delayed recovery or return to work. (See, e.g., pp. 166, 196, 228, 254, 288, 330, 362.) Upon recognition of delayed recovery by the physician, principles of properly addressing this situation would refer the physician to Chapter 5-Cornerstones of Disability Prevention and Management. In further assessing delayed recovery, consideration of additional risk factors include “[t]he existence of chronic pain or other medical complications.” Following the identification of these additional risks, the clinical guidelines would be covered by Chapter 6-Pain, Suffering, and the Restoration of Function.

Moreover, Chapter 16-Eye, also addresses identification of delayed recovery. (See, ACOEM Practice Guidelines at p. 417.) Chapter 15-Stress-related Conditions address acute stress-related conditions of relatively short duration. However, chronic behavioral and stress issues are partially addressed in Chapters 5 (at p. 91) and 6, and provide clear indications for referrals to specialists (at p. 92).

To further substantiate that ACOEM addresses chronic conditions, it is clear, for example, from reviewing the entire Low Back chapter that the intention of ACOEM is to address the continuum of care required in managing low back pain. Reference is also made to Chapter 6-Pain, Suffering and the Restoration of Function, page 105, wherein ACOEM states at page 108: “The distinction between acute and chronic pain is somewhat arbitrary. Chronicity may be reached from one to six months postinjury.”

Some commenters submit that ACOEM states that imaging (i.e. MRI) and other tests are not usually helpful during the first four to six weeks of low back symptoms (See p. 313.) Commenters argue that under the proposed regulations this could be interpreted to mean that via application of the ACOEM guidelines to chronic as well as acute conditions, an injured worker with a low back injury with a duration of 6 months, would never be able to get an MRI because ACOEM does not recommend such a procedure during the first three months of care. Commenters conclude that it is inappropriate, within the confines of these regulations, to provide for blanket applicability of the ACOEM Practice Guidelines for chronic conditions.

Commenters’ interpretation of the ACOEM Practice Guidelines is incorrect. At the very outset of planning treatment, the first issue is to assess for red flags which would automatically indicate immediate diagnostic studies. (See, Algorithm 12-1, at page 311.) “In the absence of red flags, diagnostic testing is not helpful in the first 4-6 weeks.” (ACOEM at p. 311.) After four weeks, ACOEM directs the treater to Algorithm 12-3. Evaluation of Slow-to-Recover Patients with Occupational Low Back Complaints (Symptoms >4 weeks) at page 313, where indications for further testing is described when there are no red flags. Moreover, ACOEM is clear that when red flags appear, imaging is appropriate. See, Table 12-8, page 309 of the guidelines. This table addresses the recommended indications for Imaging (CT or MRI). The Chart in Table 12-8 sets forth the recommended indications for Imaging as when: cauda equina syndrome, tumor, infection, or fracture are strongly suspected and plain film radiographs are negative; and it states that MRI is the test of choice for patients with prior back surgery. The ACOEM Practice Guidelines do not limit these tests to any time period, and it is clear that the clinical indications for a test are often the same regardless of the stage of the condition.

Moreover, a commenter argues the issue that ACOEM does not apply to chronic conditions is settled by case law. As reflected by the analysis above, the issue of whether or not a condition has reached a chronic stage is a clinical determination, not a legal determination.

In *Hamilton v. Goodwill Industries*, 2004 Cal. Wrk. Comp. P.D. LEXIS 87, the Applicant sustained an admitted specific injury on 2/13/2003, involving her back, neck, shoulders, bilateral arms, bilateral hands, bilateral legs, and bilateral knees. Benefits were provided, and the issue of a gym membership as part of her medical treatment subsequently arose. In a Findings and Award (F&A) dated 7/12/2004, the Workers' Compensation Judge (WCJ) found that the applicant was entitled to the gym membership as part of her medical treatment. Defendant sought reconsideration from the Workers' Compensation Appeals Board (WCAB), contending in relevant part, that Applicant was required to carry an affirmative burden of proving that the proposed treatment was supported by a "preponderance of the scientific medical evidence," in order to rebut the presumption of correctness attributed to the ACOEM Practice Guidelines pursuant to Labor Code § 4604.5.

The WCJ recommended that reconsideration be denied. In his Report and Recommendation on Petition for Reconsideration (Report), the WCJ stated that the statute required "scientific medical evidence" only to rebut the presumption of correctness of the ACOEM Guidelines, whereas that presumption of correctness was inapplicable to the present case because the Guidelines themselves were inapplicable. The WCJ said the ACOEM Practice Guidelines applied to "acute" injuries only, which the WCJ interpreted as the first 90 days following the injury. Because the Guidelines were inapplicable, Applicant had no burden to rebut the presumption of their correctness by a "preponderance of the scientific medical evidence," pursuant to Labor Code § 4604.5. The WCAB panel denied reconsideration by adopting and incorporating the reasons set forth in the WCJ's Report.

In *Gee v. Workers' Comp. Appeals Bd.* (2002) 96 Cal.App.4th 1418, 1425, fn. 6 [67 Cal.Comp.Cases 236], the Court said: "Unlike a three-member panel WCAB decision, an en banc WCAB decision binds all WCJ's, just as a published appellate opinion does." (Emphasis added.) Also, Board Rule 10341 (Cal. Code Regs., tit. 8, § 10341) provides that Appeals Board en banc decisions are binding on Appeals Board panels and WCJs, which implicitly suggests that panel decisions are not binding. A review of published decisions reflects that no en banc WCAB decision or published appellate opinion has determined that the ACOEM Practice Guidelines do not apply to "chronic conditions," or that they only apply to the first 90 days following the injury.

Response No. 12

ACOEM's Criteria Used to Rate Randomized Controlled Trials and Strength of Evidence Ratings

In the proposed draft of the Medical Treatment Utilization Schedule (MTUS) regulations of July 2006, Section 9792.22(c)(1) set forth the hierarchy of evidence required to determine the appropriate treatment. The Initial Statement of Reasons provided the following pertinent justification for the hierarchy of evidence, at pp. 44-45, as follows:

It is noted that there are various formats which have been created to evaluate the relative strengths of evidence. (ACOEM Practice Guidelines, at p. 501.) The hierarchy of evidence set forth in this section is based on the hierarchy to grade evidence referenced in the ACOEM Practice Guidelines at page 501, and used by the Cochrane Review, an internationally respected guideline developer. (ACOEM Practice Guidelines, at p. 501.) The hierarchy referenced in the ACOEM Practice Guidelines at page 501 is as follows:

Level A. Strong research-based evidence provided by generally consistent findings in multiple (more than one) high quality randomized control studies (RCTs).

Level B. Moderate research-based evidence provided by generally consistent findings in one high-quality RCT and one or more low quality RCTs, or generally consistent findings in multiple low quality RCTs.

Level C. Limited research based evidence provided by one RCT (either high or low quality) or inconsistent or contradictory evidence findings in multiple RCTs.

Level D. No research-based evidence, no RCTs.

The hierarchy of evidence in proposed section 9792.22(c) is based on the hierarchy of evidence referenced in the ACOEM Practice Guidelines at page 501 as set forth above with the exception that “**Level D.** No research-based evidence, no RCTs” has not been included in the hierarchy. The reason for not including this level into the hierarchy of scientific evidence in this section is that this category does not contain the level of medical evidence required by the statute.

Thus, it is necessary to set forth a hierarchy of scientifically based evidence published in peer-reviewed, nationally recognized journals to determine the effectiveness of different medical treatment and diagnostic services (1) where the medical treatment or diagnostic services provided are not addressed or are at variance with the provisions of section 9792.22(a) referring to medical treatment or diagnostic services that are addressed by the ACOEM Practice Guidelines; (2) where the medical treatment or diagnostic services provided are not addressed or are at

variance with the provisions of section 9792.22(b) referring to medical treatment or diagnostic services that are addressed by other medical treatment guidelines that are “scientifically and evidence-based” and are “generally recognized by the national medical community[;]” and (3) where the medical treatment or diagnostic services provided are in conflict as between two guidelines that are “scientifically and evidence-based” and are “generally recognized by the national medical community.” This is consistent with the requirements of Labor Code section 5307.27.

During the 45-day comment period, ACOEM notified DWC that it would adopt a new methodology to evaluate the scientific evidence for its updates of the ACOEM Practice Guidelines, 2nd Edition. ACOEM has now completed the updated methodology, and has provided DWC the following justification:

Methodology Advances for Occupational Medicine Practice Guidelines, 2nd Edition

The methodology that the American College of Occupational and Environmental Medicine (ACOEM) has adopted for updates to its *Occupational Medicine Practice Guidelines, 2nd Edition*, is designed to produce the most rigorous, reproducible, and transparent occupational health guidelines available. There are several advances with this methodology, including improvements in: 1) criteria to grade articles; 2) strength of evidence ratings; and 3) evidence-based recommendation categories. Each of these advances is briefly described below as are the reasons for these improvements.

To rate the articles, ACOEM used an adapted 11 variable (or attribute) system (see Table 1), established explicit criteria for each of the 11 variables and then scored each attribute using a scale of 0, 0.5 or 1.0. This approach results in a numerical rating of each individual article, ranging 0 to 11.0. Those numerical article ratings are then mapped to the study quality range ratings of: low quality (3.5 or less); intermediate quality (4-7.5); and high quality (8-11).

These study quality ratings are then used to determine the Strength of Evidence Ratings for the evidence base for a particular topic (see Table 2). There are 3 levels of such evidence: Strong (A), Moderate (B), and Limited (C) Evidence Bases. There is a fourth category of “I” Insufficient Evidence. All are clearly defined and are linked to ratings of the articles.

The Strength of Evidence Ratings is then utilized to develop the Evidence-Based Recommendations (see Table 3). ACOEM has developed 9 recommendation categories that parallel the strength of evidence categories. There are also 3 categories for “insufficient evidence”, including 1 category for recommendations that would include very low-

cost, low-risk interventions (such as the use of acetaminophen) that are unlikely to be subject to randomized controlled trials (RCTs).

There are several reasons for these changes. The underlying reason for all of the changes is a desire to improve clarity, transparency, reproducibility, and communication. The criteria to rate articles are purposefully more detailed than in other previously available guidelines. By providing these explicit ratings and ultimately mapping them to “strength of the evidence”, the entire system and process becomes more reproducible. It also becomes possible for others to critique the process, analyses, recommendations, and thereby resulting in continual quality improvement.

The Strength of Evidence Ratings changes include the elimination of the “D” rating. This recognizes that the former “D” level evidence included either a lack of evidence or a consensus of experts and is not evidence based. Thus, it was replaced with “I” (Insufficient), rather than implying it was the next lower level below “C.” The recommendations are developed from those improvements in the strength of evidence by making them parallel. For example, there are 2 levels of “A” recommendations, one in favor and one against. At each step in this process, there are explicit criteria with definitions to make a process that is as reproducible as possible.

Because ACOEM has updated its methodology, and in light of the fact that we have adopted ACOEM into the MTUS, we have amended Section 9792.22(c)(1) to reflect ACOEM’s updated methodology. ACOEM remains the foundation for the MTUS, and the adoption of the updated methodology allows the MTUS to remain consistent with ACOEM’s current methodology to evaluate evidence-based medical treatment guidelines. Just as new evidence emerges that will change treatment recommendations over time, the instrument used to evaluate the evidence will also evolve over time. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a). For the same reasons, the term “hierarchy of evidence” as previously defined in section 9792.20(g) has been moved to section 9792.20(l), and re-named “strength of evidence.” The definition as noticed remains the same.

Comments were received that the level “D” should be included in DWC’s hierarchy. DWC agrees with ACOEM’s change from level “D” to level “I” as this new terminology clarifies that this level of evidence is insufficient. For this reason, DWC will now include level “I” in its hierarchy.

Given that ACOEM has established a new strength of evidence rating system, with grading criteria for levels A, B, C, and I, the term “hierarchy of evidence” in the original proposed regulation will now be replaced by the term “strength of evidence” into the MTUS.

“Strength of Evidence” is a better term to describe the ACOEM evidence based review process and it will be used to evaluate scientific evidence for specific treatment recommendations in the course of treatment of an injured worker when such requested treatments fall outside the presumption afforded by the MTUS.

The criteria used to rate randomized controlled trials and the strength of evidence ratings is included in proposed Section 9792.22. The additional section (Table 3) from ACOEM’s justification as reflected on the document relied upon provided to DWC by ACOEM was not included in the proposed regulations because that table is for creation of treatment guidelines which falls outside of the scope of this regulation.

We disagree with the hierarchy suggested by the California Labor Federation, AFL-CIO and various unions. The proposed hierarchy fails to comply with the requirement of the statute that treatment pursuant to Labor Code section 4600 be based on guidelines that “reflect practices that are evidence and scientifically based, nationally recognized, and peer reviewed.” (Lab. Code, § 4604.5(b).) Moreover, the use of “best clinical judgment” when no scientific evidence exists to guide a physician’s treatment determination under the updated ACOEM methodology would be considered insufficient evidence, and thus not consistent with the MTUS. For example, a recent NY Times article, dated November 15, 2006, entitled *Study Questions Angioplasty Use In Some Patients*, states that the common practice of opening a blocked artery with balloons and stents can be lifesaving in the early hours after a heart attack, but a new study concludes that it often does no good if the heart attack occurred three or more days before the seeking treatment. www.nytimes.com/2006/11/15/health/15heart.html It should be noted that a common practice by physicians has been to open up arteries three or more days after the heart attack with balloons and stents. Thus, the practice of physicians employing “best clinical judgment” on a presumptive basis in the absence of evidence-based guidelines may not necessarily produce the best outcomes when scientific evidence becomes available.

Some commenters request that the hierarchy of scientifically based-evidence include case reports and/or clinical examples in the determination of effective treatment. The updated ACOEM Practice Guidelines methodology provides a more reliable set of criteria in which to determine strength of evidence, the application of which might better distinguish the difference between limited evidence-base versus insufficient evidence-base. Regardless, the statute requires evidence-based treatment recommendations (Lab. Code, § 5307.27) as set forth in the proposed MTUS regulations.

Other commenters request that an additional level of evidence should be included in the Hierarchy of Scientific Based Evidence. They request that a level should be included pursuant to C.F.R. Title 21 – Food and Drugs. Commenters believe that U.S. federal government approval to market a medical device as safe and effective provides prima facie evidence that the device is appropriate when prescribed for the indications for use. Commenters opine that FDA approval for medical devices clearly meets the standard in Senate Bill 228 as nationally recognized, scientifically based, medical evidence and therefore should be highly ranked in the hierarchy of evidence described in §9792.22. We disagree. Guidelines adopted by the DWC will be evidence-based. FDA approval

may not necessarily be evidence-based treatment. See Journal of the American Board of Family Medicine (JABFM) article entitled: Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice: JABFP March-April 2004, Vol. 17, No. 2, pp 142-149. (<http://www.jabfm.org/cgi/content/full/17/2/142>)

Moreover, even with FDA approval, post-marketing data might lead to further evidence that puts into question the safety, efficacy, and usefulness of any drug or device, and therefore it is important to continuously review best practices for any given condition. For example in the article entitled: *Safety of Neck Stents Debated*, dated October 25, 2006, states that despite the FDA approval of stents for carotid artery disease, the safety efficacy and usefulness is currently being debated given post-approval scientific evidence. (<http://www.nytimes.com/2006/10/25/business/25cnd-stent.html>)

Therefore, it is DWC's responsibility to adopt and/or create guidelines that reflect updated systematic review of current evidence as this is the intent of the statute. (See Lab. Code, §5307.27.)

Other commenters object to the hierarchy of evidence as including consensus-based recommendations, arguing that ACOEM by its own admission is consensus based. We disagree. In the ACOEM Practice Guidelines, at pages 491-492, ACOEM states:

Guidelines can be evidence based only to the extent that there is appropriate scientific literature on which they can be based. That a particular intervention or hypothesis has not been “proved” to be valid does not necessarily mean that it is invalid or not useful—only that we have not yet devised a study that conclusively supports or refutes it. Unfortunately, guideline development most often requires reaching a consensus regarding “best practice” in areas in which there is not definitive literature. Guideline developers must then base their recommendations on something other than science. Frequently, recommendations are premised on the apparent reasonableness of the intervention in question, the degree to which it puts a patient at risk for harm, and the apparent cost-effectiveness of the intervention.

Despite the lack of high-quality studies on a number of topics, it remains desirable for clinical practice guidelines to be as evidence based as is currently possible. This requires a comprehensive review and critical evaluation of the available literature. The goal of such a review is to ascertain whether the design, result/outcomes, and statistical power of individual studies warrant their use as a basis for treatment or other health care decisions.

As reflected from the quotation above, it is incorrect to state that the ACOEM Practice Guidelines is consensus-based. To the contrary, ACOEM's intention is to require a comprehensive review and critical evaluation of the available literature. If consensus is applied at all, it is applied to the scientific evidence reviewed. Moreover, the ACOEM's

updated methodology makes clear that the evidence is reviewed to support a recommendation.

Response No. 13

Composition of Medical Evidence Evaluation Advisory Committee

In the Initial Statement of Reasons, at pages 48-52, the following justification was set forth for the composition of the medical evidence evaluation advisory committee:

Labor Code section 4600(a) provides that "... [m]edical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer..." Labor Code section 4600(b) provides that "... medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment that is based upon the guidelines adopted by the administrative director pursuant to Section 5307.27...."

Labor Code section 5307.27 requires that the medical treatment utilization schedule adopted by the Administrative Director "incorporate ... evidence-based, peer-reviewed, nationally recognized standards of care ... that shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases." (Emphasis added.)

"Workers experience a broad range of injuries of the muscles, bones, and joints, as well as a wide variety of other medical problems. These often require diagnostic tests, such as X-rays and magnetic resonance imaging (MRI). In California, common therapies include medication, physical therapy, chiropractic manipulation, joint and soft-tissue injections, and surgical procedures." (2005 RAND Report, at p. xv.)

In its 2005 report, RAND concentrated its analysis "on diagnostic tests and therapies that are performed frequently and that contribute substantially to costs within the California workers' compensation system." (*Id.*, at p. xv.) RAND "identified several such tests and therapies and consider them to be priority topic areas that the guidelines should cover: MRI of the spine, spinal injections, spinal surgeries, physical therapy, chiropractic manipulation, surgery for carpal tunnel and other nerve-compression syndromes, shoulder surgery, and knee surgery." (*Id.*, at p. xv.) RAND indicates that "taken together, these procedures account for 44 percent of the payments for professional services provided to California injured workers. In addition the surgeries account for about 40% of payments for inpatient hospital services." (*Id.*, at p. xv.)

As stated by RAND in its report, injured workers "experience a broad range of injuries of the muscles, bones, and joints." (*Id.*, at p. xv; see also, ICIS Data

compiled by CWCI and reported in *Evidence-Based Medicine & The California Workers' Compensation System: A Report to the Industry*, California Workers' Compensation Institute, Harris, Swedlow, February, 2004, at pp. 2-5.) For example, in the California workers' compensation system, low back complaints—soft tissue complaints or nerve involvement—“account for almost 18 percent of all claims and 22 percent of total benefits.” (*Evidence-Based Medicine & The California Workers' Compensation System: A Report to the Industry*, California Workers' Compensation Institute, Harris, Swedlow, February, 2004, at p. 5.) Orthopedists specialize in musculoskeletal injuries. It is therefore, necessary to have orthopedist in medical evaluation advisory committee to represent this specialized field.

Further in its 2005 report, RAND identified diagnostic tests and therapies that are performed frequently and that contribute substantially to costs within the California workers' compensation system, including, but not limited to, physical therapy, and chiropractic manipulation. (*2005 RAND Report*, at p. xv.) The utilization of both chiropractic treatment and physical therapy modalities were much higher than in other states prior to the recent reforms. “The number of chiropractor visits was twice that of the median state for the claims with an average of 12 months' maturity and was 3.5 times that of the median state at 36 months.” (*The Anatomy of Workers' Compensation Medical Costs and Utilization in California*, 5th Edition, Workers' Compensation Research Institute, Eccleston, Zhao, November 2005, at p. x.) “The increase in visits per claim to chiropractors was coupled with a steady increase in the proportion of resource-intensive services.” (*Id.*, at p. xi) “Payments per claim for physical medicine increased very rapidly over the period and nearly 18 percent in the most recent period. Again, the change was the result of increases in utilization rather than prices.” (*Id.*, at p. 18.) “Physical medicine constitutes more than one-third of all outpatient medical care costs in California workers' compensation.” (*Evidence-Based Medicine & The California Workers' Compensation System: A Report to the Industry*, California Workers' Compensation Institute, Harris, Swedlow, February, 2004, p. 6; see also, California Workers' Compensation Institute, *Bulletin No. 05-13*, September 23, 2005, p. 1.) The ACOEM Practice Guidelines, on the other hand, do not recommend high levels of utilization in physical therapy or chiropractic manipulation. (*Evidence-Based Medicine & The California Workers' Compensation System: A Report to the Industry*, California Workers' Compensation Institute, Harris, Swedlow, February, 2004, pp. 6-7; ACOEM Practice Guidelines, at pp. 298-301.) In certain musculoskeletal disorders, chiropractic treatment is considered an “optional” treatment by ACOEM. (ACOEM Practice Guidelines, at p. 173.) The medical evidence evaluation advisory committee will review the medical literature in these areas to determine if new evidence should be used to supplement the ACOEM Practice Guidelines as adopted as the medical treatment utilization schedule on these subjects. Thus, it is necessary to have a representative of the chiropractic field on the medical evidence evaluation advisory committee.

Further, many therapies used by both occupational and physical therapist are similar, therefore, depending on the expertise in evidence review and guideline development, a candidate from either group may be selected.

Occupational medicine is the branch of medicine that deals with the prevention and treatment of diseases and injuries occurring at work or in specific occupations (<http://www.answers.com/occupational+medicine&r=67#Medical>). The ACOEM Practice Guidelines, which have been adopted as the medical treatment utilization schedule, was developed by the Practice Guidelines Committee of the American College of Occupational and Environmental Medicine, an organization that represents more than 6,000 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM) (<http://www.acoem.org/general/>). It is necessary to have an occupational medicine physician included in this committee to provide the expertise in this field.

As previously indicated, Labor Code section 4600(a) provides for acupuncture treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury. The treatment, however, must be based upon the medical treatment utilization schedule as adopted by the Administrative Director consistent with Labor Code section 5307.27 (Lab. Code, §4600(b).)

The Administrative Director has adopted the ACOEM Practice Guidelines as California's medical treatment utilization schedule. In addition, the Administrative Director has adopted an Acupuncture Medical Treatment Guideline into the MTUS. (See, Response No. 14-Acupuncture Medical Treatment Guidelines.) Nevertheless an acupuncturist has been added to the committee in order to have a multidisciplinary committee.

Many injured workers have a psychological component to their injury either because the injury was primarily psychological in nature or as sequelae to another type of injury. Studies have shown that workers who are absent from work for six months only have a 50% chance of successfully returning to work, one of the ultimate goals of the treatment of injured workers. Reasons for delayed recovery might be either psychological or employment factors. (ACOEM Practice Guidelines, at p. 84.) Thus, it is important to include either a psychologist or psychiatrist in the medical evidence evaluation advisory committee. Depending on the expertise in evidence review and guideline development of the individual candidates, a specialist in either field will be considered.

A pain specialist was added to the committee because almost all injuries involve a component of pain and because the approach to treating pain has changed over the last decade. (ACOEM Practice Guidelines, at p. 105.) Instead of treating patients to try to rid them of all pain with such things as

narcotics, many physicians believe that the focus for pain treatment should be on helping the patient obtain as much functional recovery as possible. (ACOEM Practice Guidelines, at pp. 106-107.) Any revisions to the medical treatment utilization schedule promulgated by the Administrative Director will benefit from the expertise of a pain specialist to incorporate this new evidence into the schedule. In sum, the committee membership was constituted so that there is a balance of different occupations representing common procedures in workers' compensation. If those occupations use similar modalities, then it is appropriate to elect one member from those occupations.

Further, it is necessary for the Medical Director to appoint an additional three (3) members to the medical evidence evaluation advisory committee. These members will participate on the medical evidence evaluation advisory committee as subject matter experts for any given topic being reviewed in connection with the medical treatment utilization schedule.

With regard to comments not addressed by the justification set forth in the Initial Statement of Reasons, many commenters have suggested that the Medical Evidence Evaluation Advisory committee be augmented in recognition of the role and contribution of other specialties in the treatment of workplace injuries. We agree in part. We have expanded the number disciplines included in the advisory committee to better address "the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases" as required by the statute. (Lab. Code, § 5307.27.) Moreover, we have amended Section 9792.23 (a)(1) and 9792.23(f) to clarify that the committee will be advising the Medical Director on issues relating to MTUS, not the Administrative Director. Thus, Section 9792.23(a)(1) now states:

(a)(1) The Medical Director shall create a medical evidence evaluation advisory committee to provide recommendations to the Medical Director on matters concerning the medical treatment utilization schedule. The recommendations are advisory only and shall not constitute scientifically based evidence.

Section 9792.23(f) has been amended as follows:

(f) The Administrative Director, in consultation with the Medical Director may revise, update, and supplement the medical treatment utilization schedule as necessary.

The advisory committee has been increased from 10 members to 17 members, and the following disciplines are now represented as set forth in Section 9792.23(2)(A)-(O):

(2) The members of the medical evidence evaluation advisory committee shall be appointed by the Medical Director, or his or her designee, and shall consist of 17 members of the medical

community, holding a Medical Doctor (M.D.), Doctor of Osteopathy (D.O.), who are board certified by an American Board of Medical Specialties (ABMS) or American Osteopathic Association approved specialty boards (AOA) respectively, Doctor of Chiropractic (D.C.), Physical Therapy (P.T.), Occupational Therapy (O.T.), Acupuncture (L.Ac.), and Psychology (PhD.) licenses, and representing the following specialty fields:

- (A) One member shall be from the orthopedic field;
- (B) One member shall be from the chiropractic field;
- (C) One member shall be from the occupational medicine field;
- (D) One member shall be from the acupuncture medicine field;
- (E) One member shall be from the physical therapy field;
- (F) One member shall be from the psychology field;
- (G) One member shall be from the pain specialty field;
- (H) One member shall be from the occupational therapy field;
- (I) One member shall be from the psychiatry field;
- (J) One member shall be from the neurosurgery field;
- (K) One member shall be from the family physician field;
- (L) One member shall be from the neurology field;
- (M) One member shall be from the internal medicine field;
- (N) One member shall be from the physical medicine and rehabilitation field;
- (O) One member shall be from the podiatrist field;

Because the he advisory committee has been increased from 10 members to 17 members, the number subject matter experts has been reduced from three (3) to two (2).

Response No. 14
Acupuncture Medical Treatment Guidelines

The Initial Statement of Reasons (ISOR) sets forth the Division of Workers' Compensation's justification for not adopting an acupuncture medical treatment guideline in the proposed MTUS, as recommended by RAND and CHSWC. With respect to the Acupuncture and Electroacupuncture Evidence-Based Treatment Guidelines, First Edition, December 2004, the ISOR specifically notes at page 35:

[An] ... example demonstrating guideline recommendation variation relates to the acupuncture treatment guidelines. Chapter Eleven of the ACOEM Practice Guidelines addressing forearm, wrist and hand complaints, such as carpal tunnel syndrome, de Quervain's tenosynovitis and trigger finger, states: "Most invasive techniques, such as needle acupuncture and injection procedures, have insufficient high quality evidence to support their use." (ACOEM Practice Guidelines, at 265) The *Acupuncture and Electroacupuncture: Evidence-Based Treatment Guidelines* written in 2004, however, state at page 63: "The use of acupuncture and electroacupuncture is appropriate for, but not limited to, the following types of forearm, hand, and wrist conditions: Forearm sprain/strain, deQuervains Syndrome, wrist/finger sprain/strain, arthritis, carpal tunnel syndrome, trigger finger, and tendonitis of forearm/wrist." Thus, ACOEM instructs physicians that evidence does not support the use of acupuncture for these areas of the body, while the guideline written by acupuncturists supports its use.

The Initial Statement of Reasons concluded at page 36:

Because of inconsistencies between the above-referenced guidelines and the ACOEM Practice Guidelines in terms of recommendations and the system of scientific review used in the development of these guidelines, the Administrative Director determined that adopting multiple contradictory guidelines at this time as recommended by CHSWC would result in disputes and negate the presumption of correctness. (Labor Code section 4604.5(a).) These guidelines will be examined in the future by the medical evidence evaluation advisory committee, and after proper evaluation, recommendations will be provided to the Administrative Director.

Labor Code section 4600(a) provides that "[m]edical, surgical, chiropractic, *acupuncture*, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer....".

Labor Code section 4600(b) provides that "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 pursuant to Section*

5307.27 or, prior to the adoption of those guidelines, the updated American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines.

Labor Code section 5307.27 provides that "... the administrative director ... shall adopt ... a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care ..., and that *shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases.*"

DWC has re-evaluated the 2005 RAND Study in light of the multiple comments received on acupuncture during the 45-day comment period. In its evaluation of the medical treatment guidelines study, RAND's approach was to identify guidelines addressing work-related injuries, screen those guidelines using multiple criteria, and evaluate the guidelines that met their criteria. (RAND Report, at p. 21.) RAND applied the selection criteria in three phases. (RAND Report at pp. 25-26.) To apply the third phase of the selection criteria, RAND:

"determined whether the guidelines addressed most of [its] cost-driver topics: MRI of the spine, spinal injections, spinal surgery, physical therapy, chiropractic manipulation, surgery for carpal tunnel and related conditions, shoulder surgery, and knee surgery." (2005 RAND Report, at p. 26.)

In reviewing the addressed topics, it is noted that RAND did not evaluate acupuncture as a topic.

Moreover, in its 2005 RAND Report, at page 85, RAND stated: "[o]ur findings questioned the validity of the ACOEM Guideline for the physical modalities and the residual content, but our evaluation methods appeared to have important limitations for these areas; therefore, we are not confident that the ACOEM Guideline is valid for nonsurgical topics." RAND goes on to state that they "recommend that to identify high-quality guidelines for the nonsurgical topics, the State proceed with the intermediate-term solutions described" In its intermediate-term recommendations, RAND states, in relevant part, at page 86, that "[i]f the State wishes to develop a patchwork of existing guidelines addressing work related injuries, [their] research suggests the following priority topic areas: physical therapy of the spine and extremities, chiropractic manipulation of the spine and extremities, spinal and paraspinal injection procedures, magnetic resonance imaging (MRI) of the spine, chronic pain, occupational therapy, devices and new technologies, and *acupuncture.*" (Emphasis added.)

In its April 6, 2006 Updated and Revised CHSWC Recommendations to DWC on Workers' Compensation Medical Treatment Guidelines, CHSWC states at p. 2:

CHSWC recommends the ACOEM guidelines as the primary basis for the medical treatment utilization schedule because their flexibility allows medical decisions to take into consideration the full range of valid considerations and thus to provide optimal care for individual patients.

CHSWC, however, continues at page 2: “Numerous gaps and weaknesses in the ACOEM or any other existing set of guidelines will have to be filled by reliance on other guidelines.” CHSWC indicates, in relevant part, that “stakeholder input indicates ACOEM is weak for ... acupuncture” CHSWC then states:

Recognizing that general guidelines are subject to abuse by both excessive treatment and unwarranted denials, CHSWC recommends that specific guidelines be established for these therapies. *The quality of the guidelines developed by specialty organizations in these fields has not been independently evaluated, so CHSWC cannot recommend those guidelines.* Instead, CHSWC recommends using National Institutes of Health consensus statements and other states’ established guidelines, such as Colorado, to compose guidelines containing:

- A list of conditions for which each modality may be appropriate,
- A documentation process to justify the initiation of a treatment plan,
- A documentation process to justify continuation of a treatment plan by demonstrating functional improvement at specified intervals, and
- A maximum number of visits and duration of course of treatment.

In sum, CHSWC recommends that:

[T]he AD consider adopting interim guidelines for specified therapies, including ... acupuncture ... consisting of a prior authorization process in which the indications for treatment and the expected progress shall be documented, and documentation of actual functional progress shall be required at specified intervals as a condition of continued authorization for the specified modalities (At page 1.)

Chapter 3—Initial Approach to Treatment of the ACOEM Practice Guidelines, at page 43, sets forth the recommended initial approach to treatment of industrial injuries. In addressing nonsurgical management of industrial injuries, ACOEM presents options on pages 46-50, which include discussions on physical methods. These physical methods include chiropractic and physical therapy but do not include acupuncture. Page 50 of Chapter 3 does refer to “other methods and modalities,” but refers the reader to Chapters 8-16.

A review of these chapters reflects that the ACOEM Practice Guidelines, Second Edition, references acupuncture treatment as follows: Acupuncture treatment is addressed in the guidelines at pages 174, 204, 235, 300, 339. In Chapter 10. Elbow Complaints, page 235, the guidelines indicate: “The efficacy of needle acupuncture is not yet clearly supported by quality medical evidence.” In Chapter 13. Knee Complaints, page 339, the guidelines indicate: “Some studies have shown that transcutaneous electrical neurostimulation

(TENS) and acupuncture may be beneficial in patients with chronic knee pain, but there is insufficient evidence of benefit in acute knee problems.” In Chapter 12. Low Back Complaints, page 300, the guidelines state: “Acupuncture has not been found effective in the management of pain based on several high-quality studies, but there is anecdotal evidence of its success.” In Chapter 8. Neck and Upper Back Complaints, page 174, the guidelines state: “Invasive techniques (e.g., needle acupuncture and injection procedures such as injection of trigger points, facet joints, or corticosteroids, lidocaine, or opioids in the epidural space) have no proven benefits in treating acute neck and upper back symptoms.” In Chapter 9. Shoulder Complaints, page 204, the guidelines state: “Some small studies have supported using acupuncture, but referral is dependent on the availability of experienced providers with consistently good outcomes.”

In its article entitled *Acupuncture-Medical Literature Analysis and Recommendations*, published in the APG Insights, Winter 2005 (which has been added to the documents relied upon in the formal rulemaking file), at p. 2, ACOEM performs an interim review of the scientific literature on acupuncture, and updates its position on the reasonableness of acupuncture treatment. ACOEM concludes in that article that:

It would consequently seem most reasonable for acupuncture to be classified, as stated in the initial second edition of the guidelines, as an optional intervention; with indications for its use, and discontinuation, as stated in this article.

The comments received argue that the ACOEM Practice Guidelines do not address acupuncture properly, and requesting that we adopt the Acupuncture and Electroacupuncture Evidence-Based Treatment Guidelines, First Edition, December, 2004. We agree in part. We have determined that it is necessary to address the acupuncture modality in our medical treatment utilization schedule as our first priority in supplementing the schedule. This is based on the fact that RAND did not evaluate acupuncture treatment, our own review of the ACOEM Practice Guidelines as set forth above, and the determination that among all nonsurgical treatment options, acupuncture is not covered as well as the other modalities in the ACOEM Practice Guidelines. Indeed ACOEM’s own publication, the APG Insights as reflected above, states that Acupuncture should be regarded as an optional intervention. A recommendation that is different from the ACOEM Practice Guidelines, Second Edition.

In recognizing that Labor Code section 4600 provides that the injured worker is entitled to acupuncture as reasonably required medical treatment to cure or relief the effects of the industrial injury, and because Labor Code section 5307.27 requires that the medical treatment utilization schedule *address, at a minimum*, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases, it is necessary to address the acupuncture modality in our medical treatment utilization schedule as our first priority in supplementing the schedule. Accordingly, Section 9792.21(a)(2) has been added to the proposed regulations setting forth the Acupuncture Medical Treatment Guidelines.

The Acupuncture Medical Treatment Guidelines have been written pursuant to RAND's and CHSWC's recommendations as set forth above. Both RAND and CHSWC suggested adoption of ACOEM supplemented with specific guidelines addressing gaps. As indicated above, it was determined that the acupuncture guideline was a priority because acupuncture is the treatment that is not covered as well in the ACOEM Practice Guidelines yet access to acupuncture is required by Labor Code section 4600. Although CHSWC recommended that we adopt a guideline such as the National Institutes of Health consensus statements, it was determined that these statements were non-specific and would not satisfy the requirements that the guideline "shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases." (Lab. Code, § 5307.27.) CHSWC also recommended that a guideline such as the guideline on acupuncture from the State of Colorado be examined. Upon review of Colorado's guidelines on acupuncture it was determined that these guidelines were more on point with the requirements of Labor Code section 5307.27. The Colorado guideline has gone through multidisciplinary review and formal rulemaking prior to its adoption as a state regulation. This process is also consistent with that proposed by these regulations. Thus, the Acupuncture Medical Treatment Guideline has been crafted based on the Colorado Acupuncture Guidelines, and taking into consideration ACOEM's APG Insights, wherein ACOEM has revised the medical literature and has updated its position on the reasonableness of acupuncture treatment as an optional intervention.

As reflected in the Acupuncture Medical Treatment Guidelines, we have crafted the guidelines based on the Colorado Guidelines but have not adopted their guidelines in their entirety to avoid conflict. ACOEM remains the foundation for the MTUS, and any supplemental guidelines including the Acupuncture Medical Treatment Guidelines, must be fitted to ACOEM as it provides the framework for the MTUS appropriate for those conditions covered by ACOEM. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a). The language contained in the proposed regulations at Section 9792.21(a)(2)(D) stating that "[a]cupuncture treatments may be extended if objective functional improvement is documented," has been crafted to be more consistent with the philosophy of functional restoration as a goal of medical treatment in the ACOEM Practice Guidelines. The ACOEM Practice Guidelines provide that the "[p]atient and clinician should remain focused on the ultimate goal of rehabilitation leading to optimal functional recovery, decreased healthcare utilization, and maximal self-actualization. (ACOEM, at p. 106.) In order to objectify functional improvement, the AMA Guides can offer a systematic approach to track improvement. For example, the ACOEM Practice Guidelines, state at page 89, that "[t]he first step in managing delayed recovery is to document the patient's current state of functional ability (including activities of daily living) and the recovery trajectory to date as a timeline." Assessing activities of daily living is a component of the AMA Guides in addition to other objective methods. Moreover, we are not including the Colorado acupuncture guideline's section on "other acupuncture modalities" as these adjunctive acupuncture modalities discussed in the section are not specific to acupuncture.

As reflected in Section 9792.21(a)(2), we specify in the regulations that the Acupuncture Medical Treatment Guidelines supersede the ACOEM Practice Guidelines chapters of Neck and Upper Back Complaints, Elbow Complaints, Forearm, Wrist, and Hand Complaints, Low Back Complaints, Knee Complaints, Ankle and Foot Complaints, and Pain, Suffering, and the Restoration of Function. The Colorado Medical Guidelines were used to the extent that it supplemented ACOEM in the area of acupuncture. The Chapter Shoulder Complaints was not included because the Colorado Guidelines did not specifically identify acupuncture as a treatment for this shoulder conditions. However, the ACOEM Practice Guidelines does discuss acupuncture in this chapter. The Advisory Committee will provide recommendations to the Medical Director concerning further development of consistent Acupuncture Medical Treatment Guidelines as needed.

The Acupuncture Medical Treatment Guidelines contain three definitions. One definition is for the term “acupuncture,” and the second definition is for the term “acupuncture with electrical stimulation.” These definitions were obtained from the Colorado Medical Treatment Guidelines (7 CCR 1101-3-Rule 17 Medical Treatment Guidelines). Moreover, the Acupuncture Medical Treatment Guidelines contain a third definition for the term “chronic pain for purposes of acupuncture.” This definition was obtained from Exhibit 9 to the Colorado Medical Treatment Guidelines (7 CCR 1101-3-Rule 17 Medical Treatment Guidelines).

Moreover, a definition to the term “functional improvement,” has been added to the regulations at Section 9792.20(e). The term is defined to mean:

“[E]ither a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam performed and documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to Sections 9789.10-9789.111; and a reduction in the dependency on continued medical treatment.”

This definition is adapted from the medical treatment philosophy that is incorporated in the ACOEM Practice Guidelines. For example, the ACOEM Practice Guidelines state at page 77 as follows:

In order for an injured worker to stay at or return successfully to work, he or she must be physically able to perform some necessary job duties. This does not necessarily mean that the worker has fully recovered from the injury, or is pain-free: it means that the worker has sufficient capacity to safely perform some job duties. Known as functional recovery, this concept defines the point at which the worker has regained specific physical functions necessary for reemployment. (See, ACOEM Practice Guidelines, at p. 77.)

Another example is contained at ACOEM Practice Guidelines, page 106, which states as follows:

Pain in today's work place presents a challenge to the occupational physician. Although mistreating or undertreating pain is of concern, and even greater risk for the physician is overtreating the chronic pain patient, especially with opioids and other medications. Overtreatment often results in irreparable harm to the patient's socioeconomic status, home life, personal relationships, and quality of life in general. However, because opioids are "easy" and represent a path of little resistance, they may prevent the patient, the physician, or both from vesting in a difficult and uncomfortable rehabilitation course. A physician's choice to palliate and not rehabilitate is a profound clinical, ethical, and medico-economic decision not to be taken lightly or be based on unfounded dogma. A patient's complaints of pain should be acknowledged. Patient and clinician should remain focused on the ultimate goal of rehabilitation leading to optimal functional recovery, decreased healthcare utilization, and maximal self-actualization. (See, ACOEM Practice Guidelines, at p. 106.)

The ACOEM's APG Insights, Winter 2005, at page 10, states "[t]he literature does not provide guidance regarding what number of treatments would ultimately be appropriate, but if patients have demonstrated evidence of ongoing improvement by the sixth treatment, completion of another six treatments would appear reasonable." Based on ACOEM's recent systematic review of acupuncture scientific evidence as reflected in the 2005 Winter APG Insights, and adapting it for the purposes of the medical treatment utilization schedule, it is necessary to clarify what ACOEM refers to as "demonstrated evidence of ongoing improvement." To this end, a definition of the term functional improvement has been added to the proposed regulations. The approach is to document improvement in activities of daily living and/or to document a reduction work restrictions, with the requirement that there would also be a documented reduction in the dependency on continued medical treatment. (See, Labor Code section 4660, see also, Guides to the Evaluation of Permanent Impairment, Fifth Edition, pp. 2, 8.). Moreover, the definition requires that the improvement be apparent enough that no special testing such as functional capacity evaluation should be required.

We agree with CHSWC guidelines must be evaluated before recommendations on their quality can be presented. (See, Updated and Revised CHSWC Recommendations to DWC on Workers' Compensation Medical Treatment Guidelines, April 6, 2006, at page 2.) We did not adopt the Acupuncture and Electroacupuncture Evidence-Based Treatment Guidelines, First Edition, December, 2004 because the guideline was not vetted through a process such as RAND's or our committee. We disagree with comments indicating that the Acupuncture and Oriental Medicine Organization was instructed by the Administrative Director to develop evidence-based guidelines and to confer with RAND and submit the guidelines to the Administrative Director by December, 2004. This organization, as many other organizations, inquired as how acupuncture could be represented in the guideline review conducted by RAND. They were advised, as other organizations were advised, to submit their guidelines to RAND for review in their study. Any deadline imposed on them was imposed by RAND.

With regard to comments citing one controlled study, it is noted that one citation of one study does not constitute systematic review.

Moreover, opposition to the workers' compensation reform legislation is a matter to be brought before the legislature. In view of the Acupuncture Medical Treatment Guidelines, the Economic and Fiscal Impact Statement will be updated and submitted to appropriate reviewing entities.

Response No. 15

Meetings of the Medical Evidence Evaluation Committee are not Subject to the Open Meeting Requirements of the Bagley-Keene Open Meeting Act

The meetings of the Medical Evidence Evaluation Advisory Committee (“advisory committee”) are not subject to the open meeting requirements of the Bagley-Keene Open Meeting Act (Government Code §§11120, et seq.), because this Act is not applicable to an advisory committee created by the Medical Director.

Background: The proposed 8 CCR §9792.23 directs the Medical Director to create an advisory committee to provide recommendations to the Medical Director on matters concerning the medical treatment utilization schedule (MTUS). The recommendations are advisory only and shall not constitute scientifically based evidence. The proposed regulation also sets forth the composition of the committee, the appointing authority, organizational structure of the advisory committee, term of each appointment, frequency of meetings, and the functional responsibilities of the committee. The proposed 8 CCR §9792.23 states the following:

(a)(1) The Medical Director shall create a medical evidence evaluation advisory committee to provide recommendations to the Medical Director on matters concerning the medical treatment utilization schedule. The recommendations are advisory only and shall not constitute scientifically based evidence.

(A) If the Medical Director position becomes vacant, the Administrative Director shall appoint a competent person to temporarily assume the authority and duties of the Medical Director as set forth in this section, until such time that the Medical Director position is filled.

(2) The members of the medical evidence evaluation advisory committee shall be appointed by the Medical Director, or his or her designee, and shall consist of 17 members of the medical community, holding a Medical Doctor (M.D.), Doctor of Osteopathy (D.O.), who are board certified by an American Board of Medical Specialties (ABMS) or American Osteopathic Association approved specialty boards (AOA) respectively, Doctor of Chiropractic (D.C.), Physical Therapy (P.T.), Occupational Therapy (O.T.), Acupuncture (L.Ac.), and Psychology (PhD.) licenses, and representing the following specialty fields:

- (A) One member shall be from the orthopedic field;
- (B) One member shall be from the chiropractic field;
- (C) One member shall be from the occupational medicine field;
- (D) One member shall be from the acupuncture medicine field;
- (E) One member shall be from the physical therapy field;
- (F) One member shall be from the psychology field;

- (G) One member shall be from the pain specialty field;
- (H) One member shall be from the occupational therapy field;
- (I) One member shall be from the psychiatry field;
- (J) One member shall be from the neurosurgery field;
- (K) One member shall be from the family physician field;
- (L) One member shall be from the neurology field;
- (M) One member shall be from the internal medicine field;
- (N) One member shall be from the physical medicine and rehabilitation field;
- (O) One member shall be from the podiatrist field;
- (P) Two additional members shall be appointed at the discretion of the Medical Director or his or her designee.

(3) In addition to the seventeen members of the medical evidence evaluation advisory committee appointed under subdivision (a)(2) above, the Medical Director, or his or her designee, may appoint an additional two members to the medical evidence evaluation advisory committee as subject matter experts for any given topic.

(b) The Medical Director, or his or her designee, shall serve as the chairperson of the medical evidence evaluation advisory committee.

(c) The members of the medical evidence evaluation advisory committee shall use the hierarchy of evidence set forth in subdivision (c)(1) of section 9792.22 to evaluate evidence when making recommendations to revise, update or supplement the medical treatment utilization schedule.

(d) The members of the medical evidence evaluation advisory committee, except for the three subject matter experts, shall serve a term of two year period, but shall remain in that position until a successor is selected. The subject matter experts shall serve as members of the medical evidence evaluation advisory committee until the evaluation of the subject matter guideline is completed. The members of the committee shall meet as necessary, but no less than four (4) times a year.

(f) The Administrative Director, in consultation with the Medical Director, may revise, update, and supplement the medical treatment utilization schedule as necessary.

The division received a public comment to the proposed regulation, wherein the commenter stated the meetings of the advisory committee should be open to the public.

Analysis:

1. Bagley-Keene Open Meeting Act

The Bagley-Keene Open Meeting Act. ("Act") requires "state bodies" to hold their meetings open to the public unless specifically exempted in the Act. There are other special open meeting laws that are applicable to other public entities such as the Grunsky-Burton Open Meeting Act which is applicable to the Legislature, and the Ralph M. Brown Act which is applicable to local agencies.

The Act, which was originally enacted in 1967, is contained in sections 11120 et seq. of the Government Code. The Act is modeled after the Ralph M. Brown Act (§54950 et seq., enacted in 1953) which, as stated above, is the open meeting act for local agencies.¹

The legislative intent of the Act can be found at Gov. Code §11120, which states the following:

“It is the public policy of this state that public agencies exist to aid in the conduct of the people's business and the proceedings of public agencies be conducted openly so that the public may remain informed.

“In enacting this article the Legislature finds and declares that it is the intent of the law that actions of state agencies be taken openly and that their deliberation be conducted openly.

“The people of this state do not yield their sovereignty to the agencies which serve them. The people, in delegating authority, do not give their public servants the right to decide what is good for the people to know and what is not good for them to know. The people insist on remaining informed so that they may retain control over the instruments they have created.”

The Attorney General's publication, “*A Handy Guide to the Bagley-Keene Open Meeting Act 2004*,” explains the purpose of the Act as follows:

“The Bagley-Keene Open Meeting Act (“the Act” or the “Bagley-Keene Act”), set forth in Government Code section 11120-11132 [footnote], covers all state boards and commissions...

If efficiency were the top priority, the Legislature would create a department and then permit the department head to make decisions. However, when the Legislature creates a multimember board, it makes a

¹ 65 Op. Atty. Gen. Cal. 638; 68 Op. Atty. Gen. Cal. 34 (1985)

different value judgment. Rather than striving strictly for efficiency, it concludes that there is a higher value to having a group of individuals with a variety of experiences, backgrounds and viewpoints come together to develop a consensus. Consensus is developed through debate, deliberation and give and take. This process can sometimes take a long time and is very different in character than the individual-decision-maker model.

Although some individual decision-makers follow a consensus-building model in the way they make decisions, they're not required to do so. When the Legislature creates a multimember body, it is mandating that the government go through this consensus building process."

The Supreme Court has held, "[w]hile the Attorney General's views do not bind us [citations], they are entitled to considerable weight [citations]."² In addition, the Attorney General's parallel publication pertaining to the Ralph M. Brown Act was given "great weight" by the Court of Appeal in *Henderson v. Board of Education*.³

3. Government Code §11121 – definition of "state body" and applicability of this Act to "state bodies".

This Act is only applicable to "state bodies" as defined in Gov. Code §11121.⁴ Gov. Code §11127 states, "[e]ach provision of this article shall apply to every state body unless the body is specifically excepted from that provision by law or is covered by any other conflicting provision of law."

If it is found the medical evidence evaluation advisory committee is a "state body" as defined by Gov. Code §11121, then the advisory committee will be subject to this Act.

Gov. Code §11121 states the following:

"As used in this article, "state body" means each of the following:

"(a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order.

"(b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body.

² *Freedom Newspapers, Inc. v. Orange County Employees Retirement System Board of Directors* (1993) 6 Cal.4th 821, 829; Also see *Joiner v. City of Sebastopol* (1981) 125 Cal.App.3rd 799, 804-805

³ (1978) 78 Cal.App.3rd 875, 882-883

⁴ 75 Op. Atty. Gen. Cal. 263 (1992)

“(c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body, and if the advisory body so created consists of three or more persons.

“(d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.”

4. The advisory committee does not meet the definition of “state body” as set forth in Gov. Code §11121, and therefore is not subject to the Act

The Administrative Director is proposing to adopt a regulation which directs the Medical Director to create an advisory committee to provide recommendations to the Medical Director on matters concerning the medical treatment utilization schedule (MTUS). The advisory committee is not subject to the Act because it is not a “state body” under any of the subdivisions of Section 11121:

Subdivision (a) of Gov. Code §11121

(a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order.

The advisory committee will be a multi-member committee, but it is not “a multimember body of the state”. First, the advisory committee is not created by statute, nor is it created by executive order. Second, it is not “a multimember body of the state required by law to conduct official meetings”.

The Administrative Director is required by Labor Code section 5307.27 to adopt and revise a medical treatment utilization schedule. However, there is *no statutory requirement* to establish a committee to provide recommendations; the Administrative Director’s direction to the Medical Director to establish an advisory committee is a discretionary act. The proposed regulation states that the committee will be composed of “seventeen members” of the medical community and potentially two other subject matter experts. The purpose of the committee is to prepare non-binding recommendations regarding the Administrative Director’s utilization schedule. Thus the advisory committee is not established by statute and is not “required by law to conduct official meetings.”

The Attorney General has examined a very similar situation involving the Insurance Commissioner’s use of an advisory committee and concluded that such an advisory

committee is not a “state body.” The Opinion of the Attorney General states in pertinent part: “The question presented for resolution concerns a task force appointed by the [insurance] commissioner to render advice on public policy issues. The task force is comprised of private citizens, operates under the specific direction and timetable of the commissioner, and is provided necessary resources by the Department of Insurance. Are the meetings of the task force required to be open to members of the public? We conclude that they are not.”⁵ The Opinion notes that the insurance commissioner is an individual state officer, not a body, and that the committee he convened was not required by statute to have official meetings. The Opinion summarized the inapplicability of the Bagley-Keene Act as follows:

“In short, an advisory body to a single state officer is outside the scope of the open meeting requirements of the Act. We reached a similar conclusion with respect to an advisory body to a county officer. In *56 Ops.Cal.Atty.Gen. 14* (1973), we concluded that a local admissions committee appointed by and rendering advice to a county superintendent of schools was not subject to the open meeting requirements of the Ralph M. Brown Act. We noted: “It is thus made clear that a local admissions committee is an advisory group, but only to a single county officer . . . [and hence] is only an advisory arm or adjunct to a single county officer.” [Citation.]

Here, the advisory committee in question is being created by the Medical Director at the direction of the Administrative Director, is not created by statute and is not required by law to conduct official meetings.⁶

Subdivision (b) of Gov. Code §11121

(b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body.

Subdivision (b) of Gov. Code §11121 is not applicable to the advisory committee because it is not a multimember body that exercises any authority *delegated to it by* a “state body”. The Administrative Director has the authority to adopt regulations reasonably necessary to enforce the workers’ compensation law.⁷ As stated above, the Administrative Director is proposing to adopt a regulation requiring the Medical Director to create a medical evidence evaluation advisory committee. Both the Administrative Director and Medical Director are individual appointed state officers.⁸ Clearly, then, neither of these individual officers can be characterized as being a state board,

⁵ 75 Op. Atty. Gen. Cal. 263 (1992)

⁶ 75 Op. Atty. Gen. Cal. 263 (1992)

⁷ Labor Code §5307.3

⁸ See Labor Code §§138.1, 122 and 55

commission, or *multimember body*. Therefore, neither the Administrative Director nor the Medical Director comes within any of the definitions of a "state body".

As discussed above, the advisory committee is being created by the Medical Director, who by definition is not a "state body". The purpose of this advisory committee is to advise the Medical Director in formulating her recommendations for submittal to the Administrative Director. The Attorney General stated the following: "The Brown Act applies to the 'legislative bodies' of all local agencies in California as defined by this Act, e.g., councils, boards, commissions and committees. (Citations) The Bagley-Keene Act applies to multi-member state bodies which are required to meet by law or which are created by executive order. (Citations) Neither act applies to individual decision makers who are not members of boards or commissions such as agency or department heads when they meet with advisors, staff, colleagues or anyone else. Similarly, neither act applies to multi-member bodies which are created by an individual decision maker. (56 *Ops.Cal.Atty.Gen. 14, 19 (1973).*) (Citations)"⁹

Since the Administrative Director and Medical Director do not come within any of the definitions of a "state body," an advisory committee appointed by either of them would not constitute a "state body" under the terms of section 11121(b). Specifically, the advisory committee does not come within subdivision (b) because it *has not been delegated authority by a state body*.

Subdivision (c) of Gov. Code §11121

(c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body, and if the advisory body so created consists of three or more persons.

An advisory committee must be created by *formal action* of the "state body or a member of the state body" in order for it to be considered a "state body". As discussed above, neither the Administrative Director nor the Medical Director is a "state body" or a "member of a state body" under the Act. Since the medical evidence evaluation advisory committee is an advisory committee to a single state officer (Medical Director), the advisory committee does not come within the language of Gov. Code §11121(c). (See 75 Op. Atty. Gen. Cal. 263 (1992))

Subdivision (d) of Gov. Code §11121

(d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation.

⁹ 75 Op. Atty. Gen. Cal. 263 (1992)

Finally, the advisory committee does not come within the language of Gov. Code §11121(d) because no one is a member of the advisory committee who is "a member of a body which is a state body . . . [serving] in his or her official capacity as a representative of that state body"

Conclusion:

For the reasons discussed above, the meetings of the medical evidence evaluation advisory committee are not subject to the open meeting requirements of the Bagley-Keene Open Meeting Act (Government Code §§11120, et seq.), because this Act is not applicable to an advisory committee created by the Medical Director.