

**STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF WORKERS' COMPENSATION**

INITIAL STATEMENT OF REASONS

**Subject Matter of Regulations: Workers' Compensation
Medical Treatment Utilization Schedule**

**TITLE 8, CALIFORNIA CODE OF REGULATIONS
SECTIONS 9792.20 – 9792.23**

Section 9792.20	Medical Treatment Utilization Schedule—Definitions
Section 9792.21	Medical Treatment Utilization Schedule
Section 9792.22	Presumption of Correctness, Burden of Proof and Hierarchy of Scientific Based Evidence
Section 9792.23	Medical Evidence Evaluation Advisory Committee

BACKGROUND TO REGULATORY PROCEEDING

“The California workers’ compensation system has been encumbered by rising costs and high utilization of medical care. Medical costs for injured workers grew 111 percent between 1997 and 2002 and now represent more than half of the total costs of workers’ compensation (California Workers’ Compensation Institute, 2004). Medical Care payments were more than twice the national average in 2002 (National Academy of Social Insurance, 2004).” (*Evaluating Medical Treatment Guideline Sets for Injured Workers in California, RAND Institute for Civil Justice and RAND Health, Nuckols, Wynn, et al., 2005, at p. xiii, hereinafter 2005 RAND Report.*) These high medical costs have been attributed primarily to high utilization rather than high prices:

A comparative study across 12 states performed by the Workers’ Compensation Research Institute concluded that California’s higher medical costs resulted primarily from high utilization rather than high prices (Telles, Wang, and Tanabe, 2004). The study found that

- California had more visits per claim—in total and for physicians, chiropractors, and physical/occupational therapists—than any other states studied.
- The average number of visits for more mature claims was 31 percent higher for hospitals, 70 percent higher for physicians, and 150 percent higher for chiropractors than the 12-state median. (*2005 RAND Report, at p. xiii.*)

In response to this State’s widely-acknowledged workers’ compensation crisis, the Legislature passed Senate Bill 228 (Chapter 639, Stats. of 2003, effective January 1,

2004) and Senate Bill 899 (Chapter 34, stats. of 2004, effective April 19, 2004). Senate Bill 228 included Labor Code section 77.5, which required 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. Senate Bill 228 also included Labor Code section 5307.27, requiring the Administrative Director, in consultation with CHSWC, to adopt, after public hearings, a medical treatment utilization schedule. Section 5307.27 requires the 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.

Senate Bill 228 further included Labor Code section 4604.5, which was later amended by Senate Bill 899. Labor Code section 4604.5 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. Labor Code section 4604.5 also 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. The presumption created is one affecting the burden of proof.

Labor Code section 4604.5 further 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 4604.5 further 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 4604.5 provides that for injuries occurring on and after January 1, 2004, an injured worker shall be entitled to no more than 24 chiropractic, 24 occupational therapy, and 24 physical therapy visits per industrial injury.

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 which was added by Senate Bill 899. 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.

The proposed regulations define the terms used in the controlling statutes, set forth the medical treatment utilization schedule, identify the presumption of correctness and burden of proof required pursuant to the statute and set forth the hierarchy of scientific based evidence to be utilized in specified situations. The proposed regulations further set forth the creation, composition, term of service, and purpose of a medical evidence evaluation advisory committee to advise the Administrative Director on matters concerning the medical treatment utilization schedule.

TECHNICAL, THEORETICAL, OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS

The Division relied upon:

- (1) *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.
- (2) *Acupuncture and Electroacupuncture: Evidence-Based Treatment Guidelines*, Council of Acupuncture and Oriental Medicine Associations, Version 1.1, October, 2004.
- (3) Agency for Healthcare Research and Quality (AHRQ), <http://www.ahrq.gov/>
- (4) *American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines*, 2nd Edition (2004), OEM Press
- (5) *American Society of Orthopedic Surgeons Clinical Guideline on Low Back Pain/Sciatica (Acute) (Phase I and II)*, [http://scholar.google.com/scholar?hl=en&lr=&q=cache:gGcx0Cf5BNQJ:www.aaos.org/wordhtml/pdfs_r/guidelin/suprt_06.pdf+AAOS+Clinical+Guideline+on+Low+Back+Pain/Sciatica+\(Acute\)+\(Phases+1+and+11\)+Support+Document](http://scholar.google.com/scholar?hl=en&lr=&q=cache:gGcx0Cf5BNQJ:www.aaos.org/wordhtml/pdfs_r/guidelin/suprt_06.pdf+AAOS+Clinical+Guideline+on+Low+Back+Pain/Sciatica+(Acute)+(Phases+1+and+11)+Support+Document)
- (6) California Workers' Compensation Institute, *Bulletin No. 05-13*, September 26, 2005
- (7) *CHSWC Recommendations to DWC on Workers' Compensation Medical Treatment Guidelines*, Commission on Health and Safety and Workers' Compensation, November 15, 2004
- (8) *Correspondence from the American College of Occupational and Environmental*

Medicine to the Administrative Director, dated September 28, 2004

(9) *Crossing the Quality Chasm: A New Health System for the 21st Century/Committee on Quality of Health Care in America*, Institute of Medicine, National Academy Press, Washington, D.C., Fifth Printing, June 2004

(10) *Current Diagnosis & Treatment in Orthopedics*, Harry B. Skinner, 3rd edition, Lange Medical Books/McGraw-Hill, 2000

(11) *Decreasing Variation in Medical Necessity Decision Making*, Final Report, August 1999, Center for Health Policy, Stanford University, http://chppcor.stanford.edu/publications/decreasing_variation_in_medical_necessity_decision_making/

(12) Definition of Cauda Equina Syndrome
http://orthoinfo.aaos.org/fact/thr_report.cfm?Thread_ID=285&topcategory=Spine

(13) Definition of CT Scan
<http://www.merriam-webster.com/dictionary/ct%20scan>

(14) Definition of meta analysis
www.vichealth.vic.gov.au/cochrane/overview/definitions.htm

(15) Definition of Occupational Medicine
<http://www.answers.com/occupational+medicine&r=67#Medical>.

(16) *Degenerative Spondylolisthesis*, Brown, Lockwood, PubMed, Instr. Course Lect. 1983:32:162-9, PMID: 6546064,
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=6546064&itool=iconabstr&query_hl=3&itool=pubmed_docsum

(17) *Evaluating Medical Treatment Guideline Sets for Injured Workers in California*, RAND Institute for Civil Justice and RAND Health, Nuckols, Wynn, et al., 2005

(18) *Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*, JAMA, November 4, 1992—Vol. 268, No. 17, pp. 2420-2425

(19) *Evidence-Based Medicine & The California Workers' Compensation System: A Report to the Industry*, California Workers' Compensation Institute, Harris, Swedlow, February, 2004.

(20) *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

(21) *Guide to Physical Therapist Practice*, 2nd Edition, American Physical Therapy

Association

(22) *Guideline for Chiropractic Quality Assurance and Practice Parameters*, Proceedings of the Mercy Center Consensus Conference, Jones & Bartlett, 2005

(23) *Guideline of the Biofeedback Society of California*, <http://www.biofeedbackcalifornia.org/WC%20TreatmentGuides.htm>

(24) *Letter from Jon Hultman, Executive Director of the California Podiatric Medical Association*, dated December 9, 2004

(25) *MEDLINE* (commonly known as PubMed), Search engine for the National Library of Medicine, www.pubmed.gov.

(26) Merriam-Webster On Line, <http://www.merriam-webster.com/dictionary>

(27) *National Guideline Clearinghouse*, <http://www.guideline.gov/>, Disclaimer Statement, set forth at <http://www.guideline.gov/about/disclaimer.aspx>.

(28) *Outline: Estimating the Range of Savings from Introduction of Guidelines Including ACOEM (Revised)*, Frank Neuhauser, UC DATA/Survey Research Center, University of California, Berkeley, October 20, 2003: <http://www.dir.ca.gov/CHSWC/allreports.html>.

(29) *Radiculopathy After Cervical Laminectomy*, Dai L., Ni B., Yuan W., Jia L., PubMed, *Zhonghua Wai Ke Za Zhi* 1999 Oct;37(10):605-6, PMID: 11829904, http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=11829904&itool=iconabstr&query_hl=5&itool=pubmed_docsum

(30) *The Anatomy of Workers' Compensation Medical Costs and Utilization in California*, 5th Edition, Workers' Compensation Research Institute, Eccleston, Zhao, November 2005

(31) The Cochrane Collaboration, <http://www.cochrane.org/>

(32) *Utilization Review & the Use of Medical Treatment Guidelines in California Workers' Compensation: A Comparison of ACOEM & AAOS on Medical Testing and Service Utilization for Low Back Injury*, Harris, Ossler, Crane, Swedlow, February 2005

SPECIFIC TECHNOLOGIES OR EQUIPMENT

None of the proposed regulations mandates the use of specific technologies or equipment.

FACTS AGENCY RELIES ON IN SUPPORT OF ITS INITIAL DETERMINATION THAT THE REGULATIONS WILL NOT HAVE A SIGNIFICANT ADVERSE IMPACT ON BUSINESS

The Administrative Director has determined that the proposed regulations will not have a significant adverse effect on business. All California employers are required pursuant to Labor Code section 4600 to provide medical treatment to injured workers that is reasonably required to cure or relieve the effects of the industrial injury. This treatment must be based upon the medical guidelines adopted in these proposed regulations pursuant to Labor Code section 5307.27. Most of these employers have already been providing this type of medical treatment pursuant to the utilization review process and standards as set forth in Labor Code section 4610 and Title 8 of the California Code of Regulations, section 9792.6 et seq., which became effective as emergency regulations on December 13, 2004, and as permanent regulations on September 22, 2005. There will be some small costs related to purchase of the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines (hereinafter ACOEM Practice Guidelines), Second Edition (2004), if not previously purchased at the cost of \$195.00 per book. There may also be some costs related to the purchase of other medical treatment guidelines that are evidence and scientifically based, nationally recognized, and peer-reviewed if these business do not already own these guidelines as part of their ongoing business practices.

Section 9792.20 Utilization Review Standards—Definitions

Specific Purpose of Section 9792.20:

Section 9792.6 lists and defines the terms used in the proposed regulations. The general purpose of these regulations is to adopt, interpret, and make specific the medical treatment utilization schedule required by Labor Code section 5307.27. The specific purpose of section 9792.20 is to define the terms used in the proposed regulations to ensure that the meanings of the terms are clearly understood by the workers' compensation community.

Necessity:

Section 9792.20(a)—Definition of the term "acute."

A chronic medical condition is defined in the publication "*Crossing the Quality Chasm: A New Health System for the 21st Century/Committee on Quality of Health Care in America, Institute of Medicine,*" published by the National Academy Press, Washington, D.C. (hereinafter "*Crossing the Quality Chasm*")¹, at page 27, as "a medical condition

¹ This is the second and final report of the Committee on the Quality of Health Care in America, which was appointed in 1998 to identify strategies of achieving a substantial improvement in the quality of health care delivered to Americans. The committee's first report focused on patient safety, while this second report focuses more broadly on how the health care delivery system can be designed to innovate and improve care. (Preface at p. ix).

lasting 3 months or more.” In order to differentiate an “acute” medical condition from a “chronic” medical condition, and for the purposes of the proposed regulations, the term “acute” has been defined as “a medical condition lasting less than 3 months.” This definition is also supported by the ACOEM Practice Guidelines, at page 108, wherein it is stated, in part, that the “International Association for the Study of Pain has stated that three months is the definitional timeframe” for an “acute” condition.

Section 9792.21(b)—Definition of the term “American College of Occupational and Environmental Medicine (ACOEM)”

The American College of Occupational and Environmental Medicine (ACOEM) is the author of the Occupational Medicine Practice Guidelines adopted and incorporated by the Administrative Director as part of the medical treatment utilization schedule. It is necessary to identify the “American College of Occupational and Environmental Medicine (ACOEM)” as a medical society of physicians and other health care professionals specializing in the field of occupational and environmental medicine, dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education.

Section 9792.20(c)—Definition of the term “ACOEM Practice Guidelines.”

Labor Code section 5307.27 requires the Administrative Director to adopt a medical treatment utilization schedule that incorporate evidence-based, peer-reviewed, nationally recognized standards of care, and that addresses, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases. The Administrative Director has adopted and incorporated the ACOEM Practice Guidelines as part of the medical treatment utilization schedule (section 9792.21(a)). It is necessary to define the “ACOEM Practice Guidelines” as the American College of Occupational and Environmental Medicine’s Occupational Medicine Practice Guidelines, 2nd Edition (2004), published by OEM Press, and to state that a copy may be obtained from OEM Press, 8 West Street, Beverly Farms, Massachusetts 01915 (www.oempress.com).

Section 9792.20(d)—Definition of the term “chronic.”

It is necessary to define the term “chronic” as “a medical condition lasting 3 months or more.” This definition is obtained from the publication “*Crossing the Quality Chasm*,” at page 27, which defines “chronic” as “a medical condition lasting 3 months or more.”

Section 9792.6(e)—Definition of the term “claims administrator.”

It is a fundamental principle of workers’ compensation law in California that it is the employer’s financial responsibility to provide all medical treatment that is reasonably required to “cure or relieve” the injured worker from the effects of the industrial injury. (Lab. Code, §4600) Labor Code section 4600(b) provides that the treatment must be based upon the guidelines adopted by the Administrative Director pursuant to Labor

Code section 5307.27. This responsibility is delegated from the employer to the claims administrator administering the claim. Thus, it is necessary to define the term “claims administrator” as “a self-administered workers' compensation insurer, a self-administered self-insured employer, a self-administered legally uninsured employer, a self-administered joint powers authority, a third-party claims administrator or the California Insurance Guarantee Association.”

Section 9792.20(f)—Definition of the term “evidence-based.”

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(e) 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.

Section 9792.20(g)—Definition of the term “hierarchy of evidence.”

Labor Code section 5307.27 requires the Administrative Director to “... adopt, after public hearings, a medical treatment utilization schedule that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by the commission pursuant to Section 77.5....”

Labor Code section 4604.5(b) provides that the “recommended guidelines set forth in the schedule adopted pursuant to subdivision (a) shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed....”

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 “[t]he 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(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.”

Proposed Section 9792.22(c) sets forth a hierarchy of scientific based evidence to determine the effectiveness of medical treatment and diagnostic services. The term “hierarchy of evidence” is defined in the context of the proposed regulations as “establish[ing] the relative weight that shall be given to scientifically based evidence.” The phrase “relative weight” is used to denote the significance that should be given to different studies. It is necessary to describe a method to systematically review literature prior to starting the review process so that the reviewers’ own biases have less impact on the conclusions of the review. The quality of medical evidence varies because of criteria such as study design and the sophistication of the statistical analysis that is done on the findings. For instance, a large, prospective case-controlled study is likely to give much more significant results than a small, observational study. Thus, the results from different scientifically based studies or evidence should not be given the same consideration or weight when making a recommendation. (ACOEM Practice Guidelines, at p. 502.)

When using medical literature to make recommendations regarding clinical practice, it is necessary to determine the degree of confidence one has in the conclusions that have

been reached. This is especially the case when a previously accepted treatment, test, or hypothesis has been formally evaluated and found to be lacking. (ACOEM Practice Guidelines, at p. 501.) The use of a hierarchy of scientific based evidence in the context of the proposed regulations will be important in situations (1) where the medical treatment or diagnostic service is neither addressed in the ACOEM Practice Guidelines nor in any other medical treatment guidelines that are evidence and scientifically based and are generally recognized by the national community, or (2) when necessary to overcome the presumption of correctness created pursuant to section 4604.5(a). For example, a new scientific study may be published after publication of the ACOEM Practice Guidelines which may address treatment for a condition (e.g., artificial disk replacement). One clearly must be able to assess the quality of studies reviewed in order to determine which level most appropriately conveys the strength of the available evidence. (ACOEM Practice Guidelines, at p. 502.) Accordingly, in order to implement, interpret and make specific the statute, it is necessary to define the term “hierarchy of evidence” as “establish[ing] the relative weight that shall be given to scientifically based evidence.”

Section 9792.20(h)—Definition of the term “medical treatment.”

It is necessary to define the term “medical treatment” 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] 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.”

It is necessary to 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.”

Section 9792.20(i)—Definition of the term “medical treatment guidelines.”

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.² Thus, the phrase “to assist in decision-making about 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, it is necessary to define the term “medical treatment guidelines” as “written recommendations systematically developed through a comprehensive literature search to

² 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 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.)

assist in decision-making about the appropriate health care for specific clinical circumstances.”

Section 9792.20(j)—Definition of the term “medical treatment provider.”

It is necessary to define the term “medical treatment provider” in the context of the medical treatment utilization schedule proposed regulations. During the provision of medical treatment there will not be only physicians involved in the process but there will also be other providers of medical services. Thus, the term is defined to include “a provider of medical services, as well as related services or goods, including but not limited to an individual provider or facility, a health care service plan, a health care organization, a member of a preferred provider organization.” The definition further includes a medical provider network as provided in Labor Code section 4616 as a medical treatment provider.

Section 9792.20(k)—Definition of the term “MEDLINE.”

It is necessary to define the term “MEDLINE” to state that it is commonly known as PubMed, and that it is the search engine for the National Library of Medicine, and to provide its website address. PubMed is a service of the National Library of Medicine that includes citations from MEDLINE and other life science journals for biomedical articles. PubMed includes links to full text articles and other related resources.

Section 9792.20(l)—Definition of the term “nationally recognized.”

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 the commission 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, the term “nationally recognized” has been defined to mean “published in a peer-reviewed medical journal; developed, endorsed and disseminated by a national organization based in two or more US states; or currently adopted by one or more US state governments or by the US federal government, and is the most current version.”

In developing its screening criteria to select guidelines for further evaluation in connection with its medical treatment guidelines study, RAND developed generous definitions of the requirements set forth in Section 5307.27 in order to be inclusive. The term “nationally recognized” was defined “to mean any of the following: accepted by the National Guideline Clearinghouse; published in a peer-reviewed U.S. medical journal; developed, endorsed, or disseminated by an organization based in two or more U.S. states; currently used by one or more U.S. state governments; or in wide use in two or more U.S. states.” (2005 RAND Report, at pp. 21-22.)

Originally, the term “nationally recognized” was defined in the proposed regulations based on RAND’s definition as contained in its medical treatment guidelines study. (*Id.* at p. 22.) However, during the pre-rulemaking process, comments were received from the public objecting to the inclusion of the standard “accepted by the National Guideline Clearinghouse” in the definition of “nationally recognized.” Specifically, the comments indicated that the National Guideline Clearinghouse does not conduct any independent analysis of the validity of a guideline’s evidence base as it merely reports the guideline. The website of the National Guideline Clearinghouse sets forth a disclaimer statement, wherein it is stated at page 2, in relevant part, that it “make[s] no warranties concerning the content or clinical efficacy of the clinical practice guidelines and related materials.” The disclaimer further states that “[i]nclusion of any guideline in NGC does not constitute or imply an endorsement ... of the guidelines or of the sponsor or developer of any such guidelines.” The comments suggested that the use of the term “accepted by the National Guideline Clearinghouse,” in relation to the defined criteria for medical guidelines pursuant to Labor Code section 5307.27 would foster further litigation over the validity of the guideline. Based on these comments, the definition was revised to delete the reference to the National Guideline Clearinghouse.

The definition used by RAND in its study limited it to “published in a peer-reviewed U.S. Journal.” DWC’s definition, however, was crafted to not limit it to just the United States as many other countries are producing quality studies which might be published in journals such as Lancet or the British Medical Journal.

Further, the definition used by RAND in its study required that the guideline be “developed, endorsed, or disseminated by an organization based in two or more U.S. states.” DWC’s definition modified this requirement of the definition to require that the organization developing, endorsing or disseminating the guideline be a “national” organization as opposed to any organization. This is consistent with the requirement of the statute that the guideline be “nationally recognized.” (Lab. Code, § 5307.27.)

Moreover, the definition used by RAND in its study requires the guidelines be “currently used by one or more U.S. state governments; or in wide use in two or more U.S. states.” DWC’s definition modifies this requirement by requiring the guideline be “currently adopted by one or more U.S. state governments.” The term “used” is substituted with the term “adopted” to assure that the guideline is being actively used. Further the phrase “or in wide use in two or more U.S. states” has being deleted as this requirement will confuse

the public because it is difficult to define the term “wide use.” Furthermore, the definition is amended to add another standard requiring that the guideline is considered nationally recognized if it is currently used “by the U.S. federal government” in recognition that the federal government has and continues to produce quality guidelines (e.g., see the Agency for Healthcare Research and Quality (AHRQ)). Lastly, the definition was crafted to require that the guideline be the most current version to avoid use of outdated guidelines.

Therefore, for purposes of the proposed regulations, the term “nationally recognized” has been defined to mean “published in a peer-reviewed medical journal; developed, endorsed and disseminated by a national organization based in two or more US states; or currently adopted by one or more US state governments or by the US federal government, and is the most current version.”

Section 9792.20(m)—Definition of the term “scientifically based.”

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.”

Consideration of Alternatives:

No more effective alternative to any of the definitions, nor equally effective and less burdensome alternative, has been identified by the Administrative Director at this time.

Section 9792.21 Medical Treatment Utilization Schedule

Specific Purpose of Section 9792.21(a)

The purpose of this section is to set forth the medical treatment utilization schedule. The section informs the public that the Administrative Director adopts and incorporates the ACOEM Practice Guidelines into the medical treatment utilization schedule pursuant to Labor Code section 5307.27. The section further informs members of the public where to obtain a copy of the ACOEM Practice Guidelines.

Necessity

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;³
- 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, occupational therapy, acupuncture, and biofeedback.⁴

³ 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)

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.

I. 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
- (3) address common and costly tests and therapies for injuries of spine, arm, and leg
- (4) reviewed or updated at least every three years
- (5) developed by a multidisciplinary clinical team
- (6) 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.)

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

⁴ 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)

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.⁵ 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®
- (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.)

⁵ 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].'¹ 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.)

In terms of comparing ACOEM and AAOS, the panel found that the ACOEM Practice Guidelines “addressed appropriateness well for three of the four surgical topics and one of the six physical modalities.” In the entire content rating, “panelists agreed that [ACOEM] was valid but were uncertain whether it was comprehensive.” (2005 RAND Report, at pp. xxv, 48.) The panel found that AAOS “addressed appropriateness well for two of four surgical topics and none of the six physical modality topics.” In the entire content rating, panelists agreed that “AAOS was valid but were uncertain whether it was comprehensive.” AAOS was ranked last in the comprehensiveness and validity of the guideline content. (2005 RAND Report, at pp. xxv, 47.)

Although “the panelists thought all five guideline sets required substantial improvement,” they preferred the ACOEM Practice Guidelines. (2005 RAND Report, at pp. xxv, 47.) As opposed to the four other alternative guidelines, the panel considered the ACOEM Practice Guidelines valid but not comprehensive in the entire content rating. The ACOEM Practice Guidelines addressed “cost-driver surgical topics and addressed them well for three of the four therapies the panel rated.” Although the ACOEM Practice Guidelines did “not appear to address physical modalities in a comprehensive and valid fashion,” the four other guidelines did little better. “The same is true of the residual content in each guideline.” (2005 RAND Report, Summary, at pp. xxvii-xxviii.)

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.”⁶ 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.⁷ 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*

⁶ 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.)

⁷ 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.

Workers' Compensation System, California Workers' Compensation Institute, Harris, Swedlow, February 2004, p. 2.)

It is important to note that in its recommendations for the intermediate term, RAND stated that “[w]hen guidelines within a patchwork have overlapping content, the state may want to identify and resolve conflicting recommendations before adopting the additional guidelines.” (2005 RAND Report, Summary, at pp. xxx, 86.) Because no satisfactory mechanism has been identified for merging the contradictory recommendations (see discussion below), and in order to implement, interpret and make specific the requirements of the statute, it is reasonable for the Administrative Director to adopt the ACOEM Practice Guidelines as the medical treatment utilization schedule.

II. Recommendation that the Administrative Director consider adopting an interim utilization schedule based on the ACOEM Practice Guidelines replaced with respect to spinal surgery by the American Academy of Orthopedic Surgery (AAOS) guidelines.

As previously indicated, and for the reasons that follow, the Administrative Director has elected not to replace the spinal surgery section in the ACOEM Practice Guidelines with the spinal surgery section of the AAOS guidelines as recommended by CHSWC.

Labor Code section 77.5(a) provides in part that “the commission⁸ shall 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(b) requires that “the commission shall issue a report of its findings and recommendations to the administrative director for purposes of the adoption of a medical treatment utilization schedule.”

Pursuant to Labor Code section 5307.27, in relevant part, “[T]he administrative director, in consultation with Commission on Health and Safety and Workers’ Compensation, shall adopt, after public hearings, a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by the commission pursuant to 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.”

CHSWC held a meeting on November 15, 2004, and the minutes of that meeting reflect that CHSWC presented recommendations to the Administrative Director regarding medical treatment guidelines. (See CHSWC Minutes of Meeting-November 15, 2004, San Francisco, CA.) CHSWC recommended, in relevant part, that the Administrative Director consider adopting an interim utilization schedule based on the ACOEM Practice Guidelines, replaced with respect to spinal surgery by the AAOS guidelines. (See,

⁸ The “commission” refers to the Commission on Health and Safety and Workers’ Compensation or CHSWC.

CHSWC's Recommendations to DWC on Workers' Compensation Medical Treatment Guidelines, November 15, 2004, pp. 1, 3.)

The Administrative Director considered CHSWC's recommendation in addition to two other alternatives to the spinal surgery portion of the medical treatment utilization schedule, and pursuant to the powers delineated to her in the Labor Code⁹ and based upon the discretion afforded to her in case law,¹⁰ determined that use of AAOS for spinal surgery would result in conflicting recommendations that would affect the presumption of correctness on the issue of extent and scope of medical treatment as delineated in Labor Code section 4604.5(a).

Labor Code section 5307.27 requires that the medical treatment utilization schedule adopted address "all treatment procedures and modalities commonly performed in workers' compensation cases." In its 2005 Report, RAND determined that spinal surgery, among other procedures, was a common procedure performed in workers' compensation cases in California. RAND further identified spinal surgery as a common procedure "that contribute[s] substantially to costs in California." (2005 RAND Report, at p. 22.)¹¹

⁹ See Labor Code section 133, entitled Division of Workers' Compensation—Power and Jurisdiction, stating "The Division of Workers' Compensation, including the administrative director, the court administrator, and the appeals board, shall have power and jurisdiction to do all things necessary or convenient in the exercise of any power or jurisdiction conferred upon it under this code." See also section 5307.3, entitled Administrative Director's powers; changing regulations, stating "The Administrative Director may adopt, amend, or repeal any rules and regulations that are reasonably necessary to enforce this division, except where this power is specifically reserved to the appeals board or the court administrator."

¹⁰ Under the principles of administrative law, courts generally will defer to an agency's construction of the statute it is charged with implementing, and to the procedures it adopts for implementing that statute. *Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 12; see also *Styne v. Stevens* (2001) 26 Cal.4th 42, 53 (Administrator's interpretation of a statute he is charged with enforcing deserves substantial weight.) When a case involves an interpretation of an administrative regulation, a court must necessarily look to the administrative construction of the regulation if the meaning of the words used is in doubt. The ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation. *RCJ Medical Services, Inc. v. Diana Bonta* (2001) 91 Cal. App. 4th 986. The interpretations and opinions of an agency administrator, while not controlling upon the courts, constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. *Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal. 4th 1, 14. Because the agency will often be interpreting a statute within its administrative jurisdiction, it may possess special familiarity with satellite legal and regulatory issues. It is this expertise, expressed as an interpretation, that is the source of the presumptive value of the agency's views. *Exxon Mobil Corp. v. County of Santa Barbara* (2001) 92 Cal. App. 4th 1347, 1357.

¹¹ The 2005 RAND Report states at p. 22: "... Wickizer and colleagues in their workers' compensation UR found that ... [s]avings in inpatient treatment were greatest for spinal surgery, a costly and relatively frequently performed surgery in workers' compensation patient populations (Wickizer, Lessler, and Franklin, 1999)." The report further states that RAND relied on "a listing of the top 150 procedure codes paid under the Official Medical Fee Schedule (OMFS) for professional and other nonhospital services between January 1, 2000, and June 2002 that was developed by the California Workers' Compensation Institute (CWCI, 2003)."

RAND clinical panel rated the AAOS guidelines comprehensive and valid on lumbar spinal decompression and lumbar spinal fusion surgeries. The ACOEM Practice Guidelines was evaluated as comprehensive and valid on lumbar spinal decompression surgery, however, its section on lumbar spinal fusion was rated as comprehensive but the validity was determined to be uncertain. (2005 RAND Report, at p. 44-45.)

Based on these determinations, RAND made the following recommendations: 1) “the state can confidently implement the ACOEM guideline for ... lumbar spinal decompression surgery;” and 2) “the state can confidently implement the AAOS guideline for lumbar spinal fusion surgeries and, if convenient, for lumbar spinal decompression surgery.” (2005 RAND Report, at p. 85)

As a result of RAND’s and CHSWC’s recommendations, the Administrative Director considered three alternatives regarding the spinal surgery portion of the medical treatment utilization schedule. The three alternatives considered were: (1) RAND’s recommendation to use The ACOEM Practice Guidelines for lumbar spinal decompression surgery and AAOS guidelines for lumbar spinal fusion surgery; (2) CHSWC’s recommendation of adopting AAOS guidelines for both lumbar spinal decompression and fusion surgeries; and (3) Use the ACOEM Practice Guidelines for both lumbar spinal decompression and fusion surgeries. As discussed above, in accordance with the powers delineated to her in the Labor Code and based upon the discretion afforded to her in case law, and for the reasons discussed below, the Administrative Director has determined that using the ACOEM Practice Guidelines for both lumbar spinal decompression and fusion surgeries is the best alternative available to better meet the intent of Labor Code sections 4604.5(a) and 5307.27.

1) Alternative One: RAND’s recommendation to adopt a utilization schedule based on the ACOEM Practice Guidelines, but use of separate guidelines - ACOEM for spinal decompression surgery and AAOS for spinal fusion surgery – will affect the presumption of correctness on the issue of extent and scope of medical treatment as delineated in Labor Code section 4604.5(a), because spinal decompression surgery is used in conjunction with spinal fusion surgery.

Spinal decompression surgery can be performed in conjunction with spinal fusion surgery. Thus, it is inappropriate to recommend two separate guidelines for surgical procedures that may be performed during the same operative procedure. The use of two different guidelines may result in conflicting recommendations that would affect the presumption of correctness on the issue of extent and scope of medical treatment as delineated in Labor Code section 4604.5(a).

It is especially true in this case because the AAOS and ACOEM guidelines are fundamentally different with respect to how it grades medical evidence, which results in conflicting recommendations as to diagnostic tests, treatment, such as surgery, and the appropriateness of other services.

The following are examples of when it is recommended that decompression surgery be performed in conjunction with a surgical fusion. In its section entitled “Low Back Pain,” *Current Diagnosis & Treatment in Orthopedics* states that “a subgroup of patients who have persistent, disabling axial low back pain of discogenic origin in the absence of other psychological or organic pathologies may benefit from complete discectomy and interbody fusion.” (Harry B. Skinner, *Current Diagnosis & Treatment in Orthopedics*, 3rd edition, Lange Medical Books/McGraw-Hill, 2000, Chapter 5 “Disorders, Diseases & Injuries of the Spine,” at p. 230.)

Additionally, in the section entitled “*Stenosis of the Lumbar Spine*,” it is indicated that after decompressive laminectomy, postoperative instability is reported in 10-15% of patients treated. Late instability can occur when 50% of bilateral facets have been resected, when 100% of one facet joint has been resected and “[i]n these cases, a prophylactic instrumented lateral fusion should be performed.” (Harry B. Skinner, *Current Diagnosis & Treatment in Orthopedics*, 3rd edition, Lange Medical Books/McGraw-Hill, 2000, Chapter 5 “Disorders, Diseases & Injuries of the Spine,” at p. 236.) Thus, this is another example whereby it is recommended that decompression surgery be performed in conjunction with a spinal fusion surgery.

Finally, other instances demonstrating the situation where spinal decompression surgery and spinal fusion surgery are performed concurrently are: (1) in degenerative spondylolisthesis, it was found that spinal fusion should be performed in conjunction with decompression more frequently in patients with degenerative spondylolisthesis despite the fact that the majority of these patients were over 60 years of age (See PubMed, Instr. Course Lect. 1983:32:162-9, PMID: 6546064); and (2) in radiculopathy after cervical laminectomy, it was found that postoperative radiculopathy is complicated with posterior cervical decompression and is associated with a tethering effect upon the nerve root, therefore, a more logical procedure for prevention of postoperative radiculopathy is decompression through an anterior decompressive procedure in conjunction with a spinal fusion. (See PubMed, Zhonghua Wai Ke Za Zhi 1999 Oct:37(10):605-6, PMID: 11829904.)

As stated earlier, ACOEM and AAOS employ fundamentally different approaches in analyzing evidence, which is reflected in their divergent and sometimes contrary treatment guidelines for the same clinical circumstance. The variation in methodology is illustrated below:

The ACOEM Practice Guidelines evidence classification follows that adopted by the Cochrane Review, which is a research and reference center for evidence-based medicine. The ACOEM Practice Guidelines set forth the evidence level from A to D as follows (ACOEM Practice Guidelines, at p. 501):

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

On the other hand, in AAOS, the literature cited in the bibliography were reviewed and evaluated for quality and categorized from Type I to Type V as follows (AAOS at p. 3):

- | | |
|----------|--|
| Type I | Meta-analysis ¹² of multiple, well-designed controlled studies; or high-power randomized, controlled clinical trial. |
| Type II | Well-designed experimental study; or low-power randomized, controlled clinical trial. |
| Type III | Well-designed, non-experimental studies such as nonrandomized controlled single-group, pre-post, cohort, time, or matched case-control series. |
| Type IV | Well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies. |
| Type V | Case report and clinical examples. |

The strength of the guideline recommendations for or against an intervention was then graded from A to D as follows (AAOS at p. 4):

- | | |
|---|--|
| A | Type I evidence or consistent findings from multiple studies of types II, III, or IV |
| B | Types II, III, or IV evidence and findings are generally consistent |
| C | Types II, III, or IV evidence, but findings are inconsistent |
| D | Little or no systematic empirical evidence. |

¹² A meta analysis uses statistical methods to combine the results from a number of previous experiments or studies examining the same question, in an attempt to summarize the totality of evidence relating to a particular issue. Meta analysis includes a qualitative component (applies pre-determined criteria of study quality) and a quantitative component (integration of numerical information).
www.vichealth.vic.gov.au/cochrane/overview/definitions.htm

As expected, the different methodology employed by ACOEM and AAOS to grade evidence has resulted in conflicting recommendations in their treatment guidelines for the same condition. Examples of the contradictory recommendations made in the AAOS and ACOEM guidelines are as follows:

(a) Recommendations regarding use of X-rays – Regarding the use of X-rays, the ACOEM Practice Guidelines state that “lumbar spine X-rays should not be recommended in patients with low back pain in the absence of red flags¹³ for serious spinal pathology, even if pain has persisted for at least 6 weeks.” (ACOEM Practice Guidelines, at p. 303.) “This may be appropriate, however, when the physician believes it would aid in patient management.” (ACOEM Practice Guidelines, at p. 303.) In the AAOS guidelines, however, X-rays are discussed in Phase II (after 4-6 weeks), but the conditions under which they should be used are unclear.¹⁴ (*Utilization Review & the Use of Medical Treatment Guidelines in California Workers’ Compensation: A Comparison of ACOEM & AAOS on Medical Testing and Service Utilization for Low Back Injury*, California Workers’ Compensation Institute, Harris, Ossler, et al., February 2005, at p. 10.)

(b) Recommendations regarding use of CT scans and MRI¹⁵ - CT and MRI tests are limited to red flag assessment in the ACOEM Practice Guidelines. They are recommended if the patient is not responding to treatment and the patient is considering surgery. AAOS guidelines, on the other hand, allow for CT and MRI tests if there is no response at 4-6 weeks. (*Utilization Review & the Use of Medical Treatment Guidelines in California Workers’ Compensation: A Comparison of ACOEM & AAOS on Medical Testing and Service Utilization for Low Back Injury*, California Workers’ Compensation Institute, Harris, Ossler, et al., February 2005, at p. 15, Table 7.)

(c) Recommendations regarding physical medicine - The ACOEM Practice Guidelines recommend “1-2 visits for a home exercise program.” It further contains “[o]ptional recommendation[s] for relaxation techniques, home application of heat/cold, shoe insoles, and corsets at work. Traction, TENS, Biofeedback, Shoe Lifts and Corsets are not recommended.” AAOS guideline, on the other hand, allows “physical therapy but there [are] no limits re[garding] frequency or duration.” (*Utilization Review & the Use of Medical Treatment Guidelines in California Workers’ Compensation: A Comparison of ACOEM & AAOS on Medical Testing and Service Utilization for Low Back Injury*, California Workers’ Compensation Institute, Harris, Ossler, et al., February 2005, at p. 15, Table 7.)

¹³ Red flags include tumor, infection, fracture, dislocation, a history of tumor, infection, abdominal aneurysm, and a medical history that suggests pathology originating somewhere other than in the lumbosacral area. (ACOEM Practice Guidelines, at p. 296.)

¹⁴ “AAOS Clinical Guideline on Low Back Pain/Sciatica (Acute) (Phases I and II), 2002, page 5: ‘If no response at 4 to 6 weeks, then a diagnosis is obtained from diagnostic studies (e.g., X-ray, MRI).’ ”

¹⁵ CT is computerized tomography (<http://www.merriam-webster.com/dictionary/ct%20scan>); MRI is magnetic resonance imaging (<http://www.merriam-webster.com/dictionary/mri>).

(d) Recommendations regarding chiropractic manipulation – These guidelines again contain contrary recommendations as the ACOEM Practice Guidelines “[re]commends manipulation during the first month if no nerve involvement, and indicates that “[m]anipulation for those with radiation is an ‘optional’ treatment.” AAOS, however, allows for “[m]anual therapy in both Phase I and II, but there are no limits re[garding] [the] frequency or duration.” The AAOS guideline further states that “there is little value in [the] Chronic Phase.” (*Utilization Review & the Use of Medical Treatment Guidelines in California Workers’ Compensation: A Comparison of ACOEM & AAOS on Medical Testing and Service Utilization for Low Back Injury*, California Workers’ Compensation Institute, Harris, Ossler, et al., February 2005, at p. 15, Table 7.)

Because no mechanism has been identified for merging the contradictory recommendations in the guidelines, conflicting recommendations such as those illustrated above will be confusing to the provider, employer, or claims administrator who are required to provide requisite services for an industrial injury and who may incur liability for failing to do so according to the statute¹⁶.

2) Alternative Two: CHSWC’s recommendation to adopt an utilization schedule based on the ACOEM Practice Guidelines, replaced with respect to lumbar spinal decompression surgery and lumbar spinal fusion surgery by the AAOS guidelines will create confusion within the schedule and affect the presumption of correctness on the issue of extent and scope of medical treatment as delineated in Labor Code section 4604.5(a), because recommendations for surgery cannot be separated from recommendations for conservative care.

CHSWC recommended adoption of the ACOEM Practice Guidelines, replaced with respect to spinal surgery by the AAOS guidelines. Even though both the ACOEM and the AAOS guidelines were rated favorably for spinal decompression surgery, CHSWC recommended the adoption of the AAOS guidelines for both lumbar spinal decompression and lumbar spinal fusion surgeries. CHSWC indicated that “there should be less confusion if one guideline were applied to all spinal surgery.” (See *CHSWC’s Recommendations to DWC on Workers’ Compensation Medical Treatment Guidelines*, November 15, 2004, p. 3.)

The Administrative Director agrees with CHSWC that there will be less confusion if one guideline is applied to all spinal surgery, but if and only if, such decisions for the treatment of the injured worker are made without consideration of the total care of the injured worker, including but not limited to, pre- and post- surgery care, and patients who have multiple injuries. Treatment decisions, however, need to be determined within the context of the total care to the injured worker, therefore, subjecting the decision process to two disparate guidelines at one time is not advisable. Based on the review of the ACOEM and AAOS guidelines, the Administrative Director is persuaded that there are fundamental differences within these guidelines with respect to diagnostic and treatment recommendations that cannot be easily reconciled. These fundamental differences, if

¹⁶ Lab. Code §§ 4604.5(a), 4600(a)

CHSWC's recommendation were to be followed, would result in contradictory recommendations among the guidelines contained in the same schedule, and would in turn interfere with the presumption of correctness attributed to the ACOEM Practice Guidelines pursuant to Labor Code section 4604.5.

In order to implement, interpret and make specific the requirements of the statute, the Administrative Director reasonably acted within her discretion in deciding to forgo CHSWC's recommendation to adopt an interim utilization schedule based on the ACOEM Practice Guidelines, replaced with respect to spinal surgery by the AAOS guidelines as this will create confusion and conflicting requirements in the schedule, and negatively impact the statutory presumption of correctness afforded to the schedule.

Most patients with low back pain who ultimately have surgery start by having months of conservative care.¹⁷ The ACOEM Practice Guidelines state "within the first three months after onset of acute low back symptoms, surgery is considered only when serious spinal pathology or nerve root dysfunction not responsive to conservative therapy (and obviously due to a herniated disk) is detected." (ACOEM Practice Guidelines, at p. 305.) Referral for surgical consultation is indicated for patients who have the following: (1) severe and disabling lower leg symptoms in a distribution consistent with radiculopathy; (2) activity limitations due to radiating leg pain for more than one month or extreme progression of lower leg symptoms; (3) clear clinical, imaging, and electrophysiologic evidence of a lesion that has been shown to benefit in both the short and long term from surgical repair; and, (4) failure of conservative treatment to resolve disabling radicular symptoms. (ACOEM Practice Guidelines, at p. 305.)

For patients with unremitting lower back pain, the AAOS guidelines state at page 8: "In choosing to pursue consideration of operative treatment in a small number of patients, the treating physician may suspect a symptomatic, anatomic lesion that requires further diagnostic evaluation. Further diagnostic evaluation should only proceed if the treating physician and the patient both feel operative intervention is an option. Because good surgical outcomes remain elusive in unremitting back pain, additional non-operative care could reasonably be recommended at this point."

As reflected, one cannot easily separate the clinical indications for surgery from the diagnostic tests and the treatment that an individual patient has received. Because initial care differs between ACOEM and AAOS as demonstrated in earlier examples, the Administrative Director has determined that the use of the ACOEM Practice Guidelines for initial back care and for surgery is preferable to having the initial care be guided by the ACOEM Practice Guidelines and surgery by a different guideline. Otherwise, the medical treatment utilization schedule would contain contradictory recommendations that would affect the presumption of correctness that is afforded to the medical treatment

¹⁷ One exception is patients who have cauda equina syndrome. "Low back pain is common and usually goes away without surgery. But a rare disorder affecting the bundle of nerve roots (cauda equina) at the lower (lumbar) end of the spinal cord is a surgical emergency."
http://orthoinfo.aaos.org/fact/thr_report.cfm?Thread_ID=285&topcategory=Spine. In fact, failure of conservative therapy is considered a prerequisite for surgery in many cases.

utilization schedule pursuant to Labor Code section 4604.5. Also, the adoption of multiple guidelines for the same condition may lead to reduced use of any guideline. (*Decreasing Variation in Medical Necessity Decision Making*, Final Report, August 1999, Center for Health Policy, Stanford University, http://chppcor.stanford.edu/publications/decreasing_variation_in_medical_necessity_decision_making/, at p. 47.) This consequence would hamper compliance with the statutory mandate to provide medical services and treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury. (See, Lab. Code §§ 5307.27, 4604.5, 4600.)

3) Alternative Three: Adoption of a utilization schedule based on the ACOEM Practice Guidelines, but use the ACOEM Practice Guidelines for both lumbar spinal decompression and fusion surgeries, is the preferable alternative because it will achieve consistency, and eliminate confusion and conflicting requirements in the schedule.

In making her decision, the Administrative Director conducted a balancing test. If the ACOEM Practice Guidelines are adopted as the medical treatment utilization schedule for all treatment procedures and modalities commonly performed in workers' compensation cases, including spinal surgery, the likelihood of confusion and conflicting requirements in the schedule is eliminated. Eliminating confusing and contrary requirements in the schedule is necessary to preserve the presumption of correctness that is afforded to the medical treatment utilization schedule pursuant to Labor Code section 4604.5. This desired benefit far outweighs the benefit of using a slightly better (RAND clinical panel) rated AAOS guideline for one specific clinical circumstance (lumbar spinal fusion surgery). Using AAOS for the spinal surgery portion of the medical treatment utilization schedule will require commingling two disparate guidelines – ACOEM and AAOS – which, by this very fact, make the presumption of correctness of the medical treatment utilization schedule vulnerable to incongruity, confusion, and litigation.

Since the other two alternatives require the commingling of the ACOEM and AAOS guidelines, and are therefore prone to creating conflict and confusion in the schedule discussed above, the Administrative Director is persuaded that adopting the ACOEM Practice Guidelines as the medical treatment utilization schedule for all treatment procedures and modalities commonly performed in workers' compensation cases is the best alternative.

In addition to the reasons discussed above in section I, the remaining issue that needs to be addressed to complete the balancing test is whether the AAOS guideline for lumbar spinal fusion surgery is significantly better or only slightly better than the ACOEM Practice Guidelines.

The RAND study concludes that as to the five guidelines that met all the screening criteria, the ACOEM Practice Guidelines were ranked first and AAOS was ranked last.

(2005 RAND Report at pp. 47-48)¹⁸ As to spinal surgery, however, the RAND clinical panel rated the AAOS guidelines comprehensive and valid on both lumbar spinal decompression and fusion surgeries, whereas the ACOEM Practice Guidelines were rated to be comprehensive and valid on lumbar spinal decompression surgery, but its section on lumbar spinal fusion was rated as comprehensive with the validity uncertain. (2005 RAND Report, at p. 44-45.)

As used by the RAND clinical rating panel, when a guideline is rated as being “comprehensive”, it means “[w]hen referring to a particular type of test or therapy, the guideline addresses most patients who might be considered candidates for that test or therapy. When referring to a guideline set as a whole, the guidelines address the most common and costly types of treatments for work-related injuries.” (2005 RAND Report, at p. xxxvii) When a guideline is rated as being “valid”, it means “[e]vidence-based or, in the absence of conclusive evidence, consistent with expert opinion.” (2005 RAND Report, at p. xxxviii)

In RAND’s analysis, clinical panelists rated comprehensiveness and validity separately on nine-point scales, with 9 as the highest rating. The “ratings were interpreted as follows:

- Comprehensive or valid: a median rating of 7 to 9 without disagreement.
- Not comprehensive or invalid: a median rating of 1 to 3 without disagreement.
- Uncertain comprehensiveness or validity: a median rating of 4 to 6, or any rating with disagreement.” (2005 RAND Report at p. xxii; also discussed at p. 44)

As to lumbar spinal fusion surgery, the RAND clinical panel gave AAOS and ACOEM guidelines the same rating of 7.00 for comprehensiveness (2005 RAND Report, Appendix E at p. 108), and gave AAOS a rating of 8.0 for validity with no disagreement and the

¹⁸ In conducting its evaluation of the clinical content of the selected guidelines, RAND developed an evaluation method by adapting parts of the RAND/UCLA Appropriateness Method (RAM). (2005 RAND Report, at p. 35.) Following the RAM method the clinical panelists rated the guidelines in a two-round process. During the first process, they rated the guidelines individually. During the second process, they met and discussed their ratings and re-rated questions presented. (2005 RAND Report at pp. 42-43.) With regard to the remaining three guidelines, the panelists’ assessment of comprehensiveness and validity was as follows:

“The **Intracorp guideline** addressed appropriateness well for one of the four surgical topics and none of the six physical modalities. Panelists were uncertain whether the residual content was valid. In the entire-content rating, panelists agreed the guideline was not valid or evidence-based. It was ranked third.”

“The **McKesson guideline** addressed appropriateness well for three of the four surgical topics and two of the six physical modalities. In the residual—and entire—content evaluations, panelists were uncertain about whether it was valid or evidence-based. This guideline tied for second.”

“The **ODG guideline** addressed appropriateness well for two of the four surgical topics and two of the six physical modalities. In the residual –and entire—content evaluations, panelists were uncertain about whether it was valid or evidence-based. This guideline tied for second.” (Emphasis added; 2005 RAND Report, at p. 48.)

ACOEM Practice Guidelines a rating of 6.0. (2005 RAND Report, Appendix E at p. 112.) The remaining three screened guidelines received validity rating of 6.0 or less. (2005 RAND Report, Appendix E at p. 112) There is little explanatory discussion in the 2005 RAND Report regarding relativity of the scores other than the following statement, “[c]loser examination of the scores (given in Appendix E) suggests that panelists thought the ACOEM is mostly evidence-based; nine of 11 panelists rated the guideline set at 6 or higher on a scale of 1 to 9, with a median rating of 6. Seven panelists rated it 6 or higher on validity, with a median score of 7.” (2005 RAND Report at p. 50)

By inference, the ACOEM Practice Guidelines median rating of 6 for validity as to lumbar spinal fusion surgery is considered by the RAND clinical panelists to be evidence-based. Therefore, it is the finding of the Administrative Director that the AAOS guideline for lumbar spinal fusion surgery is only slightly better than the ACOEM Practice Guidelines’ and the ACOEM Practice Guidelines for lumbar spinal fusion surgery meet the mandate of Labor Code section 5307.27, which requires the Administrative Director to adopt a medical treatment utilization schedule that incorporates evidence-based, peer-reviewed, and nationally recognized standards of care.

In conclusion, in accordance with the powers delineated to her in the Labor Code and based upon the discretion afforded to her in case law, and for the reasons discussed above, the Administrative Director has determined that using the ACOEM Practice Guidelines for both lumbar spinal decompression and fusion surgeries is the best alternative available to meet the mandate and intent of Labor Code sections 4604.5(a) and 5307.27.

III. Recommendation that the Administrative Director consider adopting interim guidelines for specified therapies, including podiatry, chiropractic, physical therapy, occupational therapy, acupuncture, and biofeedback.

Labor Code section 4604.5(a) provides that upon adoption of a medical treatment utilization schedule by the Administrative Director, the recommended guidelines set forth in the medical treatment utilization schedule are “*presumptively correct on the issue of extent and scope of medical treatment*”. (Emphasis added.)

The system and rigor of scientific review used in the development of evidence-based guidelines varies significantly from one group to another. Should the Administrative Director adopt multiple guidelines, more disputes will arise as the lack of agreement between guidelines would negate the presumption of correctness under some circumstances.

As previously stated, ACOEM used the method that was adopted by the Cochrane Review. They use the following system to analyze research:

Level A. Strong research-based evidence provided by generally consistent findings in multiple (more than one) high-quality randomized control trials (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. (ACOEM Practice Guidelines, at p. 501.)

In contrast, for example, the *Guidelines for Chiropractic Quality Assurance and Practice Parameters*' scientific review varies from that of the ACOEM Practice Guidelines. The Guideline for Chiropractic Quality Assurance and Practice Parameters use the following system to judge the quality of evidence:

Class I: Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, or specificity.

Class II: Evidence provided by one or more well-designed uncontrolled observational clinical studies, such as case-control, cohort studies, etc.; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, specificity; and published in refereed journals.

Class III: Evidence provided by expert opinion, descriptive studies, or case reports. (Guidelines for Chiropractic Quality Assurance and Practice Parameters, at pp. 5-6.)

Thus, while ACOEM does not consider case reports or descriptive studies to be scientific evidence worthy of inclusion, others guidelines do.¹⁹ Partly because of the difference in evidence grading, recommendations in guidelines vary significantly.

¹⁹ While case reports, case series, and similar descriptive studies may assist one in determining that a particular intervention needs to be studied, they are the weakest form of evidence. In this regard the ACOEM Practice Guidelines states in its Appendix at page 493:

"Case reports and case series are examples of descriptive studies. In these, the author simply describes the characteristics of a given disease process or treatment response among a group of individuals, attempting to ascertain what factor the individuals had in common that could explain the outcome. This type of study does not, by definition, include individuals without the treatment or condition. Consequently, while one can look at the affected population and generate hypotheses regarding the relationship(s) between the exposure or treatment and the observed outcome (which then can be tested in future studies), case reports cannot be used as grounds to assert the existence of a causal relationship between the two."

Another 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 eletroacupuncture 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.

A third 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.

Specific Purpose of Section 9792.21(b)

The section informs the public that the ACOEM Practice Guidelines are intended to assist medical treatment providers by offering an analytical framework for the evaluation and treatment of injured workers. The section also informs the public that the ACOEM Practice Guidelines are intended to help those who make medical treatment decisions regarding the care of injured workers understand what treatment, as required by Labor Code section 4600, has been proven effective in providing the best medical outcomes to those workers.

Necessity

Labor Code section 77.5(a) requires 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...." Labor Code section 77.5(b) requires CHSWC to "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 the Administrative Director to "... adopt, after public hearings, a medical treatment utilization schedule that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by the commission pursuant to Section 77.5...." Labor Code section 4604.5(b) provides that "... [t]he guidelines shall be designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and shall constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions."

Labor Code section 4600(a) provides that "... [m]edical ... [treatment] 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...."

Section 9792.21(b) is required by the statute. This section is necessary to clarify that the ACOEM Practice Guidelines, as the selected guidelines for the medical treatment utilization schedule pursuant to Labor Code section 5307.27, are the guidelines designed to assist the providers by offering an analytical framework for the evaluation and treatment of injured workers. Further, it is necessary to inform the public that pursuant to the statute, the ACOEM Practice Guidelines are intended to help the medical treatment providers who treat injured workers understand what treatment has been proven effective in providing the best medical outcomes to those workers consistent with the requirements of Labor Code section 4600.

Specific Purpose of Section 9792.21(c)

The purpose of this section is to address treatment not discussed in the ACOEM Practice Guidelines. The section informs the public that treatment shall not be denied on the sole basis that the condition or injury is not addressed by the ACOEM Practice Guidelines. The section clarifies that under these circumstances, the claims administrator is required to authorize treatment that is in accordance with other scientifically and evidence-based medical treatment guidelines that are generally recognized by the national medical community.

Necessity:

Labor Code section 5307.27 requires the Administrative Director to "... adopt, after public hearings, a medical treatment utilization schedule that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by the commission pursuant to Section 77.5...."

Labor Code section 4604.5(b) provides that the "recommended guidelines set forth in the schedule adopted pursuant to subdivision (a) shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed...."

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."

It is necessary to inform the public, and specifically the medical providers, that not all industrial injuries or conditions are addressed by the ACOEM Practice Guidelines. In this regard, and until the schedule is further amended to include areas not addressed by the ACOEM Practice Guidelines, the claims administrator is required to provide medical treatment pursuant to Labor Code section 4600 as mandated in Labor Code section 4604.5(e). In that regard, the statute itself sets forth the standard for the medical treatment guideline which may be used to provide the required treatment. That guideline must be "evidence-based," "scientifically based," and "generally recognized by the national medical community."

Section 9792.21(c) states that treatment shall not be denied on the sole basis that the condition or injury is not addressed by the ACOEM Practice Guidelines. This requirement was necessitated by many public comments received during the pre-rulemaking period of these proposed regulations, stating that the ACOEM Practice Guidelines were being misapplied in that claims administrators were denying medical treatment on the sole basis that the condition or injury was not addressed by the ACOEM Practice Guidelines. In order to implement, interpret and make specific Labor Code section 4604.5(e) which provides, that "[f]or all injuries not covered by the ... official utilization schedule ... 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," the Administrative Director has determined that it is necessary to require in the proposed regulations that treatment cannot be denied on the sole basis that the condition or injury is not addressed in the ACOEM Practice Guidelines.

Consideration of Alternatives:

No more effective alternative to this section, nor equally effective and less burdensome alternative, has been identified by the Administrative Director at this time.

Section 9792.22 Presumption of Correctness, Burden of Proof and Hierarchy of Scientific Based Evidence

Specific Purpose of Section 9792.22(a):

The purpose of this section is to inform the public that the ACOEM Practice Guidelines are presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in those guidelines for both acute and chronic medical conditions. This is consistent with the requirements of Labor Code section 4604.5(a).

The section also informs the public that the presumption is rebuttable and may be controverted by a preponderance of 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. Further, the section informs the public that the presumption created is one affecting the burden of proof. This is consistent with the requirements of Labor Code section 4604.5(a).

Necessity:

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. The presumption created is one affecting the burden of proof.”

It is necessary to clarify that the ACOEM Practice Guidelines, which have been adopted and incorporated in the proposed regulations as the medical treatment utilization schedule in section 9792.21(a), are presumed to be correct on the issue of extent and scope of medical treatment as required by Labor Code section 4604.5(a).

It is also necessary to clarify in the proposed regulations that the presumption of correctness attributed to the ACOEM Practice Guidelines is rebuttable and may be controverted by a preponderance of 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 as set forth in Labor Code section 4604.5(a). The presumption created is one affecting the burden of proof.

During the pre-rulemaking, comments were submitted requesting that the Administrative Director delineate in the proposed regulations which party carries the burden of proof and the type of evidence necessary to overcome the presumption. Further, in its 2005 report, RAND recommended that “[f]or topics to which the adopted guideline [i.e., ACOEM

Practice Guidelines] does not apply, the state should clarify who bears the burden of proof for establishing appropriateness of care.” (2005 RAND Report, at p. 86.)

Labor Code section 111 provides, in relevant part, that “the Division of Workers’ Compensation is under the control of the administrative director....” Labor Code section 5307.3 provides, in pertinent part, that the “administrative director may adopt, amend, or repeal any rules and regulations that are reasonably necessary to enforce this division, *except where this power is specifically reserved to the appeals board or the court administrator.*” (Emphasis added.)

Labor Code section 111, on the other hand, provides that “[t]he Workers’ Compensation Appeals Board ... shall exercise all judicial powers vested in it under this code[,]” and Labor Code section 5397(a)(4) specifically states that the workers’ compensation appeals board may “[r]egulate and prescribe the nature and extent of the proofs and evidence.” (Emphasis added.) Thus, Administrative Director has no authority to determine the *nature and extent of the proofs and evidence* in the context of the proposed medical treatment utilization schedule regulations as that power lies within the workers’ compensation appeals board pursuant to Labor Code section 5307(a)(4).

Section 9792.22(a) further provides that the ACOEM Practice Guidelines are presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in those guidelines *for both acute and chronic medical conditions*. (Emphasis added.)

During the pre-rulemaking, comments were submitted stating 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. The argument was 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.)²⁰

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

²⁰ “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.)

“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 addresses 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,²¹ 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.

²¹ 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.

Specific Purpose of Section 9792.22(b):

The purpose of this section is to inform the public that for all medical conditions or injuries not addressed by the ACOEM Practice Guidelines, authorized treatment must be in accordance with other scientifically and evidence-based medical treatment guidelines that are generally recognized by the national medical community.

Necessity

Labor Code section 5307.27 requires the Administrative Director to "... adopt, after public hearings, a medical treatment utilization schedule that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by the commission pursuant to Section 77.5...."

Labor Code section 4604.5(b) provides that the "recommended guidelines set forth in the schedule adopted pursuant to subdivision (a) shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed...."

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."

Labor Code section 4600(a) provides that "... [m]edical ... [treatment] 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...."

It is necessary to inform the public, and specifically the medical providers, that not all industrial conditions or injuries are addressed by the ACOEM Practice Guidelines. In this regard, and until the schedule is further amended to include areas not addressed by the ACOEM Practice Guidelines, the claims administrator is required to provide medical treatment pursuant to Labor Code section 4600 as mandated in Labor Code section 4604.5(e). It is noted that the statute itself sets forth the standard for the medical treatment guideline which may be used to provide the required treatment. That guideline must be "evidence-based," "scientifically based," and "generally recognized by the national medical community." (See further explanation in necessity statements for definition of terms "evidence-based" – section 9792.20(e), "medical treatment guidelines" – section 9792.20(h), "nationally recognized" – section 9792.20(j), and "scientifically based" – section 9792(k).)

Specific Purpose of Section 9792.22(c)(1):

This section sets 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 when the following situations exist: (1) where the medical treatment or diagnostic services provided are not addressed or are at variance with the provisions of section 9792.22(a) (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.”

Necessity

Labor Code section 5307.27 requires the Administrative Director to “... adopt, after public hearings, 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.”

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.” Labor Code section 4604.5(a) further provides that “[t]he presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines 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, in relevant part, that the “recommended guidelines set forth in the schedule adopted pursuant to subdivision (a) shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed....”

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.”

In its 2005 report, RAND recommended that “[f]or topics not covered by the adopted guidelines and throughout the claims adjudication process, the state should consider testing the use of a defined hierarchy to weigh relative strengths of evidence.” (2005 *RAND Report*, at p. 86.) RAND’s recommendation is based on the premise that “[w]hen using medical literature to make recommendations regarding clinical practice, it is necessary to determine the degree of confidence one has in the conclusions that have been reached. This is especially the case when a previously accepted treatment, test, or hypothesis has been formally evaluated and found to be lacking.” (ACOEM Practice Guidelines, at p. 501.)

In its November 15, 2004, recommendations to DWC, CHSWC recommended that the “AD consider incorporating into the utilization schedule a process to be followed in determining appropriate treatment conditions that are not addressed by [their recommended] components of the schedule, so that at least minimum decision-making criteria will be applicable even to conditions that are not subject to any other components of the schedule.” This section creates this process by setting forth the hierarchy of evidence which is required to determine the appropriate treatment.

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.

Specific Purpose of Section 9792.22(c)(2):

This section informs the public that the evidence used in connection with section 9792.22(c)(1) must be given the highest weight in the order of the hierarchy of evidence set forth in that section.

Necessity:

The introduction to the hierarchy of evidence presented in the ACOEM Practice Guidelines states that: “[w]hen using medical literature to make recommendations regarding clinical practice, it is necessary to determine the degree of confidence one has in the conclusions that have been reached.” (ACOEM Practice Guidelines, at p. 501.) Medical reports are read by many people, including other physicians, judges and adjusters. They need to have a framework to decide how much weight or confidence should be given to an article that is submitted to support a recommendation. The hierarchy of evidence gives them such a framework.

Consideration of Alternatives:

No more effective alternative to this section, nor equally effective and less burdensome alternative, has been identified by the Administrative Director at this time.

Section 9792.23 Medical Evidence Evaluation Committee

Specific Purpose of Section 9792.23(a)(1):

This section informs the public that the Medical Director shall create a medical evidence evaluation advisory committee to provide recommendations to the Administrative Director on matters concerning the medical treatment utilization schedule. The section further informs the public that the recommendations of the medical evidence evaluation advisory committee are advisory in nature only and shall not constitute scientifically based evidence.

Necessity:

Labor Code section 77.5(a) provides that “the commission shall 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(b) provides that “... the commission shall 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 provides that “... the administrative director, in consultation with the Commission on Health and Safety and Workers' Compensation, shall adopt, after public hearings, a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by the commission pursuant to 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.*” (Emphasis added.)

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. 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 schedule adopted pursuant to subdivision (a) 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 Section 4600 for all injured workers diagnosed with industrial conditions.”

In its 2005 report, RAND found that “[s]takeholders interviews suggest that payors in the California workers’ compensation system are applying ACOEM guidelines ... for topics the guidelines do not address or address only minimally.” (2005 RAND Report, at p. 85.) This reflects the need to supplement the ACOEM Practice Guidelines by some mechanism.

RAND further stated in its report that “[i]f the state wishes to develop a patchwork of existing guidelines addressing work related injuries, [its] 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.” RAND recommended that “[w]hen guidelines within a patchwork have overlapping content, the state may want to identify and resolve conflicting recommendations.” (2005 RAND Report, at p. 86.) The medical evidence evaluation committee will review new evidence and other guidelines that could be used as the basis for supplementing the ACOEM Practice Guidelines in the identified high priority areas.

Moreover, RAND stated in its 2005 report that “[b]ecause high scores in the technical evaluation were not associated with high evaluations by expert clinicians, [RAND] recommend[ed] that future evaluations of existing medical treatment guidelines include a clinical evaluation component.” Specifically, “[RAND] recommend[ed] against adopting guidelines solely on the basis of acceptance by the National Guideline Clearinghouse or a similar standard, because this criterion ensures only the technical quality of listed guidelines.” (2005 RAND Report, at p. 86.)

Likewise, in its proposed recommendations to the Administrative Director, CHSWC recommended that “the DWC and CHSWC jointly establish an ad hoc advisory group to receive expert advice and stakeholder input on the many questions that must be addressed in assembling a comprehensive set of guidelines.” Further, CHSWC recommended the adoption of interim guidelines (see previous discussion starting at page 33), and that “additional guidelines to supplement [the] ACOEM guidelines” be considered “on an ongoing basis as studies and evaluations of those additional guidelines are complete.” (Commission on Health and Safety and Workers’ Compensation, *CHSWC Recommendations to DWC on Workers’ Compensation Medical Treatment Guidelines*, November 15, 2004, at p. 2; http://www.dir.ca.gov./chswc/CHSWC_Med%20Treat_Nov2004.pdf).

Pursuant to the recommendations by RAND and CHSWC, this section informs the public that the Medical Director of the Medical Unit will create an advisory committee composed of various experts from specified specialty fields. The advisory committee is necessary for continuous study of the medical treatment utilization schedule and to provide advice to the Administrative Director from experts in various fields for revisions and/or supplementation of the schedule as necessary in order to comply with the requirements of Labor Code section 5307.27. The advisory committee is solely composed of medical providers as opposed to non-providers because the subjects to be addressed by the committee require medical expertise in subjects relating to the medical treatment utilization schedule. The committee members should have personal experience in treating work related injuries as they will make recommendations on diagnostic and treatment issues.

Specific Purpose of Section 9792.23(a)(1)(A):

The purpose of this section is to inform the public that 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.

Necessity

It is necessary to insure that the work of the medical evidence evaluation advisory committee continues regardless of whether the position of the Medical Director becomes vacant. The appointment of a competent person to assume the authority and duties of the Medical Director as delineated in these regulations will insure that the committee maintains its continuous study of the medical treatment utilization schedule in order to provide advice to the Administrative Director for revisions and/or supplementation of the schedule as necessary in order to comply with the requirements of Labor Code section 5307.27.

Specific Purpose of Section 9792.23(a)(2) and (a)(3):

Section 9792.23(a)(2) informs the public that the members of the medical evidence evaluation advisory committee shall be appointed by the Medical Director of the Medical Unit of the Division of Workers' Compensation, or his or her designee. The section further informs the public that the medical evidence evaluation advisory committee will consist of 10 members of the medical community representing the specialty fields of orthopedic, chiropractic field, occupational medicine field, acupuncture medicine field, physical or occupational therapy field, psychology or psychiatry, and pain specialty. The section also informs the public that three other members of the medical evidence evaluation advisory committee shall be appointed at the discretion of the Medical Director or his or her designee.

Section 9792.23(a)(3) informs the public that the Medical Director, or his or her designee, may appoint an additional three members to the medical evidence evaluation advisory committee as subject matter experts for any given topic in addition to the ten members of the committee appointed under subdivision (a)(2).

Necessity:

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. The ACOEM Practice Guidelines provide with respect to neck and upper back complaints that "acupuncture has no proven benefit in treating" these conditions, but "many pain physicians believe it may help patients presenting in the transitional phase between acute and chronic pain." (ACOEM Practice Guidelines, at pp. 174-175.) For shoulder injuries, the ACOEM Practice Guidelines provides that "some small studies have supported using acupuncture, but referral is dependent on the availability of experienced providers with consistently good outcomes." (ACOEM Practice Guidelines, at p. 204.) For elbow conditions, the ACOEM Practice Guidelines provide at p. 235:

The efficacy of needle acupuncture is not yet clearly supported by quality medical evidence. While limited existing studies support needle acupuncture for short-term relief of lateral elbow pain, clear evidence currently is insufficient to either support or refute using needle acupuncture to treat lateral epicondylitis; and discovery of potential adverse effects is inadequate. More trials, using adequate sample sizes, are needed before conclusions can be drawn regarding the effect of needle acupuncture on lateral epicondylitis.

Regarding the treatment of low back complaints, the ACOEM Practice Guidelines provide that “[a]cupuncture has not been found effective in the management of back pain, based on several high-quality studies, but there is anecdotal evidence of its success.” (ACOEM Practice Guidelines, at p. 300.) Further, on treatment for knee injuries, the ACOEM Practice Guidelines provide that “[s]ome studies have shown that ... acupuncture may be beneficial in patients with chronic knee pain, but there is insufficient evidence of benefit in acute knee problems. (ACOEM Practice Guidelines, at p. 339.)

Because the Labor Code provides for treatment to injured workers in the form of acupuncture, it is necessary for the Administrative Director to further evaluate this field in light of the discussions presented in this area in the ACOEM Practice Guidelines. As it is believed that most of the members of this committee will have little or no training in acupuncture, it is important to include one acupuncturist on the committee to provide the expertise in this field.

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 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.

Specific Purpose of Section 9792.23(b):

This section informs the public that the Medical Director, or his or her designee, shall serve as the chairperson of the medical evidence evaluation advisory committee.

Necessity:

The Medical Director not only will understand the medical aspects of guideline development but will also understand the regulatory requirements for complying with Labor Code section 5307.27. Because the Administrative Director will ultimately make decisions on the revisions of the medical treatment utilization schedule to “address ... the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases” in compliance with Labor Code section 5307.27, the Medical Director will be in the best position to present the recommendations of the medical evidence evaluation advisory committee to the Administrative Director.

Specific Purpose of Section 9792.23(c):

This section informs the public that the members of the medical evidence evaluation advisory committee are required to 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.

Necessity:

It is necessary to insure that the medical evidence being evaluated is evaluated under the same standards by both the public and the medical evidence evaluation advisory committee.

Specific Purpose of Section 9792.23(d):

This section informs the public that the members of the medical evidence evaluation advisory committee, except for the three subject matter experts, shall serve a term of one year period, but shall remain in that position until a successor is selected. The subject matter experts shall serve in the medical evidence evaluation advisory committee until the evaluation of the subject matter guideline is completed.

Necessity:

It is necessary to have the medical evidence evaluation advisory committee properly staffed at all times to allow for the continuous study of the medical treatment utilization schedule. Every member, except the subject matter experts, is required to serve a term of one year. However, if after the one-year term expires the Medical Director is not able to replace that position, it is necessary to maintain that member on staff until the position is filled to insure that the committee continues its work. Further, it is not necessary to have the subject matter experts stay on the committee after the study of the specified subject matter has been completed. This allows the Medical Director to move onto other subject matter studies, and to appoint the appropriate subject matter experts to the committee.

Specific Purpose of Section 9792.23(f):

This section informs the public that the Administrative Director, in consultation with the medical evidence evaluation advisory committee, may revise, update and supplement the medical treatment utilization schedule as necessary.

Necessity:

The purpose of the creation of the medical evidence evaluation advisory committee is to provide the Administrative Director information to make informed decisions regarding revisions, updating and supplementing the medical treatment utilization schedule. It is necessary to provide that the Administrative Director may revise, update and supplement the medical treatment utilization schedule consistent with the requirements of Labor Code section 5307.27.

Consideration of Alternatives:

No more effective alternative to this section, nor equally effective and less burdensome alternative, has been identified by the Administrative Director at this time.