

Kevin Tribout, Executive Director
Government Affairs
Helios

December 18, 2014

Helios would like to thank the Division of Workers' Compensation for the opportunity to provide feedback on this update to Chronic Pain Medical Treatment Guidelines proposed on the DWC forum. Helios – a product of a merger between Progressive Medical and PMSI – provides retail, clinical and mail-order pharmacy services to injured workers in California and across the nation. Helios has reviewed the proposed revisions to existing Chronic Pain Treatment Guidelines and in general supports the update and Division's foresight on maintaining treatment guidelines to assist physicians in treating chronic pain in workers' compensation patients. Helios has outlined a few areas we respectfully request the Division clarify either in this forum or during any subsequent rule-making.

Definition of Chronic Pain – Clarification Across Proposed Guidelines

In the current proposed Chronic Pain Treatment Guidelines, Helios noticed the definition of chronic pain is “*any pain that lasts three months following the injury and can be frustratingly difficult to treat.*” However, in the proposed Guidelines for Use of Opioids to Treat Work-Related Injuries, the definition of chronic pain is “*pain lasting more than three months.*” Helios elevates this difference in definition(s) to urge the Division to address and establish a consistent understanding of pain across both treatment guidelines. Helios believes that treatment of chronic pain utilizing opioids and treatment of chronic pain without opioids should be based upon similar definitions of the underlying symptom/disease, which is chronic pain in injured workers related to a work place injury.

Update of Current Chronic Pain Treatment Guidelines

Helios recognizes the proposed Chronic Pain Treatment Guidelines are not new, but are an update of current guidelines using the recent (2014) Official Disability Guidelines (ODG) Treatment Guidelines with specific CA-DWC nuances as permitted by ODG. In proposed regulatory language, Helios noticed the Division did not use the phrase “*most current version*” of the ODG guidelines. Should this language be inserted, it would permit future California guidelines to evolve and grow with each edition of the ODG guidelines when published by ODG. This would ensure the most up-to-date and current scientific and medical treatment parameters and information is used by physicians when treating chronic pain in the California workers' compensation system. Helios understands the Division may choose not to utilize this ongoing update process by inserting “*most current version*” as the Division tends to insert their own nuances into their guideline(s) updates. However, Helios would contend not inserting this language could stale the guidelines and require ongoing rule-making by the Division each time ODG updates their guidelines.

Use of Guidelines with Future Formulary Requirements

Helios acknowledges recent public statements by the Division of their desire to create a drug formulary for California workers' compensation claims. As the Division moves forward in development of their formulary, Helios will as requested continue to provide insight and assistance to the Division. Helios urges the Division to take all existing and proposed treatment guidelines – specifically the proposed opioid guidelines and chronic pain guidelines – into consideration when creating and adopting any state based workers' compensation formulary. Helios believes treatment guidelines and any future formulary should co-exist and if possible be similar, supportive, clear and easy for all stakeholders to understand, process, adhere to and of course implement. Creation of a formulary process that is at odds with any

existing treatment guideline(s) or based upon a different platform of scientific and evidence based medicine could be problematic and lead to confusion among treating physicians and pharmacies. Helios recommends the Division consider the basis for their treatment guidelines and interaction between these guidelines and formulary treatment requirements when developing their future workers' compensation formulary.

Kristen V. Hedstrom, MPH, Director
Health Economics & Reimbursement, Neuromodulation
Boston Scientific

December 18, 2014

On behalf of Boston Scientific, which is dedicated to transforming lives through innovative medical solutions that improve the health of patients around the world, I appreciate the opportunity to share our concerns regarding the proposed MTUS 2014 Chronic Pain Guideline for the injured worker in the state of California. Boston Scientific opposes the proposed guideline published on December 8th as it limits Spinal Cord Stimulation (SCS) as a treatment option to Complex Regional Pain Syndrome (CRPS). As you know, the current DWC guideline also recommends SCS for Failed Back Surgery Syndrome (FBSS), CRPS and other indications.

Patients who are appropriate candidates for SCS have failed many, if not all possible conservative medical treatments, such as back surgery, injections, physical therapy and medications including narcotics. At times, SCS is the only treatment that provides pain relief necessary to allow a sick or injured worker to return to work. The proposed guideline is inconsistent with the Food and Drug Administration's (FDA) recognition of SCS as an "aid in the management of chronic intractable pain of the trunk or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome." In addition, both the public and private sectors widely cover SCS for FBSS, including Medicare (Noridian Local Coverage Determination L33489, Spinal Cord Stimulators for Chronic Pain) and almost every commercial insurer. SCS is a clinically effective treatment of intractable pain in FBSS patients as supported by randomized controlled trials.

The proposed guideline changes, if implemented, could jeopardize patient access to SCS and negatively impact injured workers and employers alike.

Michelle Lau L.Ac., OMD, President
Council of Acupuncture and Oriental Medicine Assoc.

December 18, 2014

I am the President of The Council of Acupuncture and Oriental Medicine Associations -CAOMA. A professional coalition organization advocates for excellence in Acupuncture and Oriental Medicine. I am former Chief examiner of California State Acupuncture Licensing Examination and Subject Matter Expert.

Thank you for the opportunity to voice our great concern and our opposition to the current proposed changes in Chronic Pain Medical Treatment Guideline to ODG guideline that will reduce the number of acupuncture treatments and Carpal tunnel syndrome without Evidenced based input and review. We disagree the proposal in ODG to determine evidence of reduced pain based on the pain medication reduction which is arbitrary and no merit for the injury workers.

Acupuncture treatment for California injury workers in the DWC system since 1989. Acupuncture treatment is efficacy and cost saving. CAOMA has been working closely more than 10 years ago in 2003 with DWC, under the DWC instruction and following up the RAND Corporation criteria we developed and published the CAOMA Evidence Based Acupuncture guideline in 2004 Which was accepted by National Guideline Clearing House. The current DWC medical guideline for acupuncture is evidence based in many studies and clinical trials. Acupuncture treatment has been working for many conditions and functional pain management including Carpal Tunnel.

According to California code Regulation under 8 CCR Section 9792.24.1, Acupuncture Medical Treatment Guideline clearly states the frequency and duration of Acupuncture treatments. it also clearly states which apply to acupuncture when referenced in the clinical topic of medical treatment Guidelines in the series of section commencing with 9792.23.1 et seq., or in the chronic pain medical treatment guidelines contained in section 9792.24.2.

Therefore, the proposed change Chronic Pain Medical treatment Guideline shall not violate current Acupuncture medical Treatment Guidelines. Adopting the ODG change for acupuncture treatments will harm and create denying access for the injury workers. decreasing the merit for cost saving for DWC.

James A. Kim, MD

December 18, 2014

I am a double board certified anesthesiologist and pain management physician in California. After reviewing the proposed changes to spinal cord stimulation to be restricted to only CRPS patients and eliminate implantable drug delivery devices, I strongly object to these changes.

I have personally seen industrial injured patients with functional benefit from both spinal cord stimulation and pain pumps. These devices are integral to advanced pain management allowing patients to reduce oral intake of opiate pain medications and improved function by lowering pain overall. Patients that have failed or no longer benefit from more conservative treatments like medications and injections will have no other options for pain management if spinal cord stimulation or pain pumps are limited or eliminated as treatment options.

Both SCS and IDDS are recommended treatment options supported by medical journals and evidence based research as well as several physician society guidelines.

These proposed changes are draconian and arbitrary. It would be an injustice to take away these treatment options from these injured workers. I strongly urge DWC not to approve the proposed changes to the MTUS guidelines.

Robert Wood, MD, MPH

December 18, 2014

I am a practicing pain physician, trained in five fields, including anesthesia, pain medicine, internal medicine, pulmonary / critical care, and nutrition, along with an MPH in Health Services and Administration. I have reviewed the comments on the proposed changes by the Work Comp industry for the use of SPINAL CORD STIMULATION (SCS) and INTRATHECAL DRUG DELIVERY SYSTEMS (IDD). I graduated from medical school and finished my internship in 1980. So, I have been a practicing physician for many years and have done many procedures, managed many patients, and have watched their outcomes. I concur with the following statements:

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

· **SCS:** SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.

· **IDD:** IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

To markedly restrict the reasonable use of these modalities for the questionable reasons proposed by the insurance carriers for the Worker's Compensation industry is ill founded, not supported by both clinical experience, nor by scientific studies.

Unfortunately, these insurance carriers are not held by the Hippocratic Oath. And they do not ascribe to it.

Donald Chiu, L.Ac, O.M.D.

December 18, 2014

The proposed changes in the Chronic Pain Medical Treatment Guidelines will reduce the number of acupuncture treatments to 3-4 over six weeks and 8-12 over twelve weeks. This is a reduction of the former guidelines by nearly half. No evidence is provided to justify this reduction. The change appears to be arbitrary and without medical merit. Changes in medical treatment without basis in research

inevitably cost the patient. I am requesting that the prior for comments be extended by six months in order to adequately examine the evidence-based argument for this change.

Bill Mosca, Lac
Executive Director
California State Oriental Medical Association (CSOMA)

December 18, 2014

The proposed CHRONIC PAIN MEDICAL TREATMENT GUIDELINES (December 2014) would reduce the initial trial of acupuncture treatment for chronic pain from the current 3 to 6 treatments to a proposed 3 to 4 treatments and would impose a limit of 12 visits.

The sole acupuncture study cited in the high priority references [Witt CM, Schützler L, Lüdtkke R, Wegscheider K, Willich SN. Patient Characteristics and Variation in Treatment Outcomes: Which Patients Benefit Most From Acupuncture for Chronic Pain? Clin J Pain. 2011 Feb 11.] provides no discernible basis for this reduction. In fact, this study concludes, “[T]he outcome was markedly improved in the acupuncture group ($P < 0.001$).” This strong evidence against the null hypothesis and in favor of acupuncture for chronic pain suggests that DWC should consider expanding, not further limiting, utilization of acupuncture for chronic pain.

David Hiller, MD

December 18, 2014

As an anesthesiologist specializing in interventional pain management, who’s practice consists of nearly 50% workers’ compensation patients, I find the proposed changes to the Chronic Pain Treatment Guidelines regarding spinal cord stimulation unacceptable. The entirety of this calendar year has been spent by myself, my patients, my staff and my colleagues battling insurance carriers and utilization review companies regarding prescription medications, specifically opiates. By reducing the indications that you choose to acknowledge in your guidelines for spinal cord stimulation, you would be removing another non-narcotic tool that has been instrumental in improving function, reducing opiate use, and returning injured worker’s to gainful employment, in my personal experience.

The use of spinal cord stimulation should remain indicated for Failed Back Surgery Syndrome, Lumbar Radiculopathy, as well as Complex Regional Pain Syndrome and the other accepted diagnoses, as these are supported by evidence based guidelines.

William G. Brose, MD

December 18, 2014

I am a Board Certified Anesthesiologist and Pain Medicine Specialist, focused on Functional Restoration, medication management/analgesic adherence, and nerve pain states (CRPS).

My comments on the proposed MTUS/CPMTG changes:

1. The ODG suggests a Functional Restoration Program length of 4-weeks full-time or 160 hours. The proposed MTUS/CPMTG cuts out this reference to 160 hours. This edit suggests that it will be difficult to continue a Functional Restoration Program beyond 4 weeks. This reduces the opportunity for our team to tailor an FRP to the patient's specific needs. It's also inconsistent with the support in ODG for reduced intensity programs. There is only one reference listed regarding length of treatment, from Sanders, et al., however, the Technical Brief on Multidisciplinary Pain Programs for Chronic Noncancer Pain, prepared by Agency for Healthcare Research and Quality for the U.S. Department of Health and Human Services, describes a wide range of pain program duration and intensity (Table D-2. Treatment components, Column titled "MPP Length/Frequency.") The reality is there is currently no EBM establishing one length or method of FRP delivery as superior. Given that you have already included a requirement for programs with proven successful outcomes, this would seem inappropriately restrictive.

http://www.effectivehealthcare.ahrq.gov/ehc/products/212/760/TechBrief8_PainProgramsCancer_20110930.pdf

2. There has been some confusion, in my experience, among utilization review physicians about the requirement for a complete diagnostic assessment and treatment plan prior to a Functional Restoration Program. The proposed CPMTG describes that, "There should be evidence that a complete diagnostic assessment has been made, with a detailed treatment plan of how to address physiologic, psychological and sociologic components." Reviewers frequently deny an Interdisciplinary Evaluation using the "Criteria for the general use of multidisciplinary pain management program." The assessment of whether a patient meets these criteria is the outcome of a complete interdisciplinary diagnostic assessment. Additional information about how a complete diagnostic assessment for FRP differs from the FRP itself would likely be helpful to reviewers and should be included in any revisions.
3. As some other commenters on the forum have mentioned, there are multiple references to the DWC "Guideline for the Use of Opioids to Treat Work-Related Injuries," which has yet to be finalized/adopted. I have concerns about the potential for inconsistencies between the DWC guideline and the new Medical Board of California Guidelines for Prescribing Controlled Substances for Pain.
4. While the proposed CPMTG describes the variety of indications for opioid detoxification, as well as the options for office based opioid tapering and inpatient hospitalization, it fails to outline medical interventions that might be necessary for patients in between these care options. ASAM (American Society for Addiction Medicine) documents five basic levels of care in the continuum of treatment for substance use disorder. It would be beneficial to include these within the revised CPMTG. The levels of care include:

Level 0.5: Early Intervention

Level I: Outpatient Services

Level II: Intensive Outpatient/Partial Hospitalization Services

Level III: Residential/Inpatient Services

Level IV: Medically Managed Intensive Inpatient Services

William L. Wilson, MD

December 18, 2014

As an anesthesiologist specializing in interventional pain management, who's practice consists of nearly 50% workers' compensation patients, I find the proposed changes to the Chronic Pain Treatment Guidelines regarding spinal cord stimulation unacceptable. The entirety of this calendar year has been spent by myself, my patients, my staff and my colleagues battling insurance carriers and utilization review companies regarding prescription medications, specifically opiates. By reducing the indications that you choose to acknowledge in your guidelines for spinal cord stimulation, you would be removing another non-narcotic tool that has been instrumental in improving function, reducing opiate use, and returning injured worker's to gainful employment, in my personal experience.

The use of spinal cord stimulation should remain indicated for Failed Back Surgery Syndrome, Lumbar Radiculopathy, as well as Complex Regional Pain Syndrome and the other accepted diagnoses, as these are supported by evidence based guidelines.

Jeremy Merz, California Chamber of Commerce

December 18, 2014

Jason Schmelzer, CA Coalition on Workers' Compensation

The California Coalition on Workers' Compensation (CCWC) and the California Chamber of Commerce (CalChamber) would like to thank you for the opportunity to provide forum comments on the draft Chronic Pain Medical Treatment Guidelines. The process of efficiently identifying and providing the most beneficial medical treatment for injured workers is vital to the success of California's workers' compensation system. Our broad hope is that the DWC provides a regulatory framework that gives clarity to providers, injured workers, and claims administrators so that the best treatment can be provided in a timely manner, and with minimal dispute.

The draft regulations propose to utilize an edited version of the Official Disability Guidelines (ODG) for medical treatment, but defers to the DWC Opioid Guideline, which has not yet been adopted, for pharmacy. Our broad concern with the approach taken in the draft regulations is that medical providers, payers, and injured workers will be unnecessarily subjected to additional complexity and confusion by the requirement to consult two distinct sets of guidelines. We would respectfully urge the DWC to select a single nationally recognized guideline rather than proceeding with a state-specific guideline.

We would recommend that the DWC utilize the most recent version of the ODG guidelines, which are updated regularly, for both medical treatment and pharmacy purposes. From a claims administration perspective, a single guideline provides medical providers with efficiency in documenting treatment requests, quicker turnaround of utilization review, and reduces the opportunity for friction and dispute. Additionally, we are concerned that the state-specific guidelines will be administratively burdensome to update, whereas the ODG guidelines are updated frequently to reflect the best and most-recent medical science.

We look forward to providing additional in-depth comment on the proposed regulations during the formal rulemaking process. However, we respectfully request that the DWC consider simplifying the process and adopting the most recent ODG guidelines as an alternative to what is currently being proposed.

R. Marie Turner

December 18, 2014

Before there was, MTUS, (which is not perfect, for example citing CMS guidelines rather than California guidelines) and later when the MTUS, Chronic Pain Guidelines were implemented July 18, 2009; the State of California, in and through the State entity having jurisdiction and oversight over the practice of medicine and in turn, all forms of prescribing, was the Medical Board of California (MBC). The California legislature established medical necessity for the treatment of chronic and/or intractable pain by law, so that those who suffered from chronic and/or intractable pain could receive their treatment in a timely and dignified manner without undue pain or suffering. Persons who suffer from chronic and/or intractable pain while they may be dependent or require medication adjustments over time, they are not "addicts".

Pursuant to California law, the MBC implemented its policy for Chronic and/or Intractable Pain. Those guidelines have been in place since 1994, and are meant to guide the prescription of controlled substances and other treatment options for chronic and/or intractable pain, as found in the H&S codes 124960/124961 and B&P codes 2241.5. The State of California now requires CMEs in the treatment of Chronic and Intractable pain. While California licensed physicians are required to provide proof of such CMEs for license renewal, they are not required to treat patients who suffer from chronic and intractable pain if they oppose such treatment or are in any way incompetent to provide such care, but must refer the patient to an appropriate provider qualified in or competent to provide pain management. This policy and guidelines are referenced in MTUS part one (1) and is the first policy to be followed, but since it isn't mentioned in part two (2), confusion results and often the wrong guidelines are consulted or a reviewer ignores that the Legislature established medical necessity as referenced in part one (1), similar to the concept of "presumptive disability", both concepts were made in order to eliminate roadblocks to appropriate and necessary treatment.

The MBC and DCA has put certain organizations on notice, that whatever their intent, Insurance companies, TPAs, MPNs, HCOs, HMOs and like organizations cannot require a physician to prescribe medications/treatment not to exceed a certain dose or frequency if it is within the established prescribing guidelines for California, the patient is monitored, has a pain management contract, the patient has given

informed consent, some of which may vary depending on the qualifications of the physician. If abuse by either the provider or patient is suspected, there are appropriate referrals and investigation, but even this instance does not include delaying/denying/altering prescriptions for necessary pain medication, whether it is deemed necessary by law, AME/QME/Award/Stipulation/Agreement/prior authorization. UR and IMR are not a second bite of the apple nor an excuse to withhold medical records in order to secure a delay/denial/amended prescription. There is case law to this effect.

The MBC has never relinquished oversight over the practice of medicine in California to expert reviewers in UR (some of which are non-medical administrative staff or Chiropractors, who routinely effectively alter lawful prescriptions or appeals) or IMR organizations, or given any such reviewer the right to delay, deny, alter, amend or otherwise change the lawful prescriptions of California licensed physicians who are required to make good faith examinations, in other words, face to face contact.

The MBC has in fact has publicly asserted their authority and their opinion that both UR and IMR "is the practice of medicine", especially when it results in harm, and therefore under their oversight. It is difficult to maintain compliance with California laws especially those protecting the persons least able to advocate for themselves when there is little or no investigation of complaints of the UR process and absolutely no way to discipline unidentified out of state reviewers who are not required to follow California law in either UR or the IMR process.

The State of California and now the Federal government following California's lead has made significant changes in prescribing requirements for scheduled/controlled substances, which went into effect on October 6, 2014, in essence not allowing "oral" prescriptions for scheduled Rx once phoned in vs. written Rx, changing some pain medications to become schedule II medications and requiring a new prescription without refills, thus long term prescriptions for chronic and/or intractable pain, are now by default subject to UR/IMR simply because the RFA form was never corrected to allow for long term prescriptions with prior authorizations and the CA while they may still authorize these medications as they did before when they are lawfully prescribed, now have the opportunity to alter the prescription by creating delays and the medical record by delaying or withholding the medical record.

Eliminating the word, "Intractable Pain" and the MBC policy and guidelines from MTUS, eliminates its necessary, appropriate treatment and the legislative intent established in 1994 and replaces it with suffering and harm. Chronic and intractable pain does not disappear simply because someone rewrites a rule or regulation or fails to check such for conflicts with other established laws and regulations.

The legislative intent for all California residents including injured workers is expressed in the policies posted on the MBC website, including the policy referenced in MTUS, as well as the latest federal changes which took effect on October 6, 2014. California's legislative intent and laws have not changed subsequent to SB899 or SB863. Changes to MTUS will not somehow override California law, the legislative intent or somehow give jurisdiction to the DIR/DWC, or MEEAC which meets in secret and is heavily influenced by URO and insurance interests, to circumvent the jurisdiction of the MBC to determine whether or not pain medications are appropriately prescribed or to allow a reviewer to alter a prescription in violation of California and Federal law, simply because you will not disclose the reviewer's name nor require any effective investigation when violations are identified. Meetings of MEEAC should be open to the public and should have representation by those in the medical arts who actually treat patients, who do not have a conflict of interest, such as an insurance company, URO, being

a UR/IMR reviewer, there should be more members of the public and representatives from the DCA and MBC/other Boards.

The UR regulations should restrict chiropractors to their scope of practice only. They should not have any sort of "Clinical" title or duties, nor should a Medical Director delegate "Medical" duties/decisions to a chiropractor in any way that confuses the public as to their scope of practice or to make medical decisions/delay/amend and/or have any administrative authority regarding the determination of Appeals, grievances or credentialing.

Both URO and IMR panels should be available to the public in advance of any review so that any required due diligence may be timely conducted. All persons handling the review and their professional standing should be included in any review.

Lori C. Kammerer
Kammerer & Company

December 18, 2014

The California Medical Treatment Utilization Schedule (MTUS) notes that the synergy between medications with sedative properties is significant. The DWC Forum proposal on Chronic Pain Medical Treatment Guidelines should specifically address this in the context of treatment of chronic pain, particularly in light of the fact that Guidelines would adopt an "edited" version of the Official Disability Guidelines (ODG). Therefore, the ODG should also be "edited" to reflect suggested changes outlined below:

On page 24 of the DWC Forum proposal on Chronic Pain Medical Treatment Guidelines proposal, the Procedure Summary narrative describes recommendations regarding ANXIETY MEDICATIONS IN CHRONIC PAIN. Specifically, the narrative states:

"Recommend diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Benzodiazepines are not recommended for long-term use unless the patient is being seen by a psychiatrist."

This statement should be modified, to read:

"Recommend diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Benzodiazepines are not recommended **for longer than two weeks. long-term use unless the patient is being seen by a psychiatrist.**"

Similarly, on Page 54 of the DWC Forum proposal on Chronic Pain Medical Treatment Guidelines proposal, the Procedure Summary narrative describes recommendations regarding Cyclobenzaprine (Flexeril®). In that "summary of medical evidence" narrative paragraph, the statement that "treatment

should be brief” should be amended to include a statement that “**This medication is not recommended to be used for longer than 2-3 weeks.**”

This recommendation is essentially a grammatical change, but it is nonetheless important for practitioners. Cyclobenzaprine (Flexeril®) is discussed in the ODG narrative concerning ANTISPASMODICS (See p. 87 of DWC Forum proposal on Chronic Pain Medical Treatment Guidelines proposal), and this statement is included verbatim in that medical evidence narrative as a dosing precaution.

The DWC Forum proposal on Chronic Pain Medical Treatment Guidelines proposal (Procedure Summary) addresses individual medications; however, the potential for adverse outcomes increases with concurrent prescribing of medications with sedative properties. Therefore, concomitant prescribing of opioids, tramadol, benzodiazepenes, and other sedating medications should be discouraged and specifically referred to in the Guidelines. Similarly, the prescribing of psychostimulants to combat the sedating side effects of other medications should be expressly discouraged.

Perhaps the following narrative should be included in the Guidelines with respect to use of “polypharmaceuticals”:

Polypharmaceuticals--Sedatives: The preceding listing of pharmaceuticals addresses individual medications. As noted in other sections of the MTUS, the potential for adverse outcomes increases with concurrent prescribing of medications with sedative properties; thus, concomitant prescribing of opioids, tramadol, benzodiazepenes, and other sedating medications (such as H1 blocker antihistamines) is not recommended (Cheng; Eriksen; Atluri; Green).

Polypharmaceuticals--Stimulants: The prescribing of psychostimulants to combat the sedating side effects of other medications is discouraged. If a pharmacologic intervention produces side effects significant enough to warrant their own treatment, the pharmacologic intervention itself should be considered ineffective secondary to intolerable side effects.

Lori C. Kammerer
Kammerer & Company

December 18, 2014

The DWC Forum proposal on Chronic Pain Medical Treatment Guidelines would adopt an “edited” version of the Official Disability Guidelines (ODG). The DWC proposal differs from ODG regarding the use of functional restoration programs (FRPs). The DWC’s proposed guidelines state that “total treatment duration should generally not exceed (four) weeks” for functional restoration programs, but the ODG adds “20 full days or 160 hours” to the recommended timeframe.

It should be noted that a patient evaluation is normally supposed to be done before referring the patient to a FRP. Although it might be sensible to limit the number of FRP hours, practitioners have to work within the restrictions and common delays inherent in the California workers’ compensation treatment

authorization process. Under the Medical Treatment Utilization Schedule process, it often takes several weeks to obtain approvals. Therefore, providers are often forced to choose between providing care and treatment to patients before treatment approvals are received, or having the patient removed from the FRP for a period of time. Thus, restricting some patients to fewer than 160 hours in FRPs could hurt their chances of recovering from their chronic pain.

Lori C. Kammerer
Kammerer & Company

December 18, 2014

The DWC Forum proposal on Chronic Pain Medical Treatment Guidelines would adopt an “edited” version of the Official Disability Guidelines (ODG). The ODG provides the following criteria for the general use of multidisciplinary pain management programs:

“*Outpatient* pain rehabilitation programs may be considered medically necessary in the following circumstances:

[...]

(10) Treatment is not suggested for longer than 2 weeks without evidence of compliance and significant demonstrated efficacy as documented by subjective and objective gains. (Note: Patients may get worse before they get better. For example, objective gains may be moving joints that are stiff from lack of use, resulting in increased subjective pain.) However, it is also not suggested that a continuous course of treatment be interrupted at two weeks solely to document these gains, if there are preliminary indications that they are being made on a concurrent basis.

Because the DWC proposes to adopt an edited ODG for use in California, the DWC should rewrite the ODG section cited above and include those modifications in the “edited” version of ODG that DWC apparently intends to incorporate into the Chronic Pain Medical Treatment Guidelines. The specific changes are suggested below:

Outpatient pain rehabilitation programs may be considered medically necessary in the following circumstances:

[...]

(10) Once treatment has begun, documentation of clear and objective evidence of program engagement and compliance must be documented. Otherwise continued treatment should not proceed. Goals of treatment should be set by the treatment team and the injured worker initially, and then monitored, recorded, and provided to the claims administrator on a weekly basis. For treatment to continue, a combination of functional gains, improvement in psychosocial variables, and reduction in medication must be documented. At the time of program completion, there should be clear evidence of improved function physically and emotionally with documentation regarding efforts to return to gainful employment.

This course of treatment is up to 160 hours, the time to be allocated to specific disciplines at the discretion of the physician supervising the individualized Program.

When there is clear documented evidence of efficacy to support continued program participation, interruptions in care due to delays in certification are considered clinically problematic and unacceptable, and shall be avoided.

It should also be noted that a comment regarding MMI status upon completion of the Program should be made. Due to the delay inherent in CA approval due to regulation, continued enrollment should be encouraged if objective information of significant progress can be documented.

Peggy Thill, Claims Operations Manager
Dinesh Govindarao, MD, MPH
State Compensation Insurance Fund

December 18, 2014

State Compensation Insurance Fund appreciates the time and effort the Division of Workers' Compensation (DWC) has put into the proposed regulations regarding the Chronic Pain Medical Treatment Guidelines. We offer the following comments for your consideration:

Recommendation:

State Fund recognizes that there is a need for clarity between the multiple guidelines from the DWC. To be more specific, we seek clarity on what the hierarchy is with respect to opioids when referencing the "Chronic Pain Medical Treatment Guidelines" vs. the "Guidelines for the Use of Opioids to Treat Work Related Injuries". This must be clearly outlined.

Lori C. Kammerer
Kammerer & Company

December 18, 2014

Among other things, the proposed amendments to Section 9792.24.2, the Chronic Pain Medical Treatment Guidelines regulations, indicate that Part 2 of the Guidelines consists of an "edited version of the Official Disability Guidelines (ODG) "Treatment in Workers' Compensation – Chapter on Pain (Chronic)" published April 10, 2014, which the Division of Workers' Compensation has adapted with permission from the publisher."

It is unclear what edits to the ODG have been made by the DWC, and the rationale for such changes. In addition, the proposed change does not take into account the fact that the ODG updates regularly. Instead, the proposal should incorporate the ODG by reference, as it may be amended from time to time. Without this change, the DWC Chronic Pain Guidelines run the risk of becoming increasingly irrelevant

over time, or will require continuous updating by way of Notice of Proposed Regulations pursuant to California's Administrative Procedure Act. This approach appears cumbersome.

Finally, the draft guidelines and accompanying regulatory changes, as set forth in the context of the DWC Forum, fail to explain the elimination of all references to or consideration of ACOEM Practice Guidelines.

Jay H. Herdt L.Ac. MBA

December 18, 2014

I am writing to oppose any proposed change to the DWC treatment guidelines of acupuncture therapy for workers with chronic pain issues. The current recommendations are not in alignment with other with the more general acupuncture medical treatment utilization schedules. In addition there are numerous evidence peer reviews articles that support the efficacy of acupuncture modalities specifically listed in the current DWC guidelines.

As an acupuncturist treating this population of patient I have witnessed the value to this community of injured workers. These patients come for treatment on referral from a managing primary care physician who works within the patients' Medical provider network. At present I find that the insurance carrier's medical review to be very conservative in authorizing the physician based recommendations. Further authorizations typically required documentation for functional improvement along the DWC guidelines. My point is that extensive oversight of the application of acupuncture to qualified injured workers is in place and as it stands creates significant barrier to these workers access to acupuncture therapy.

Birch, Stephen Ph.D., L.Ac.; Jamison, Robert N. Ph.D. Controlled Trial of Japanese Acupuncture for Chronic Myofascial Neck Pain: Assessment of Specific and Nonspecific Effects of Treatment. Clinical Journal of Pain. [September 1998 - Volume 14 - Issue 3 - pp 248-255](#)*

Lee TL. Acupuncture and chronic pain management. *Annals of the Academy of Medicine, Singapore* [2000, 29(1):17-21]

Manheimer, E MS; White, A MD, BM, BCh; Berman, B MD; Forys, K MA; and Ernst, E MD, PhD. *Meta-Analysis: Acupuncture for Low Back Pain. Ann Intern Med.* 2005;142(8):651-663. doi:10.7326/0003-4819-142-8-200504190-00014

Robert R. Kutzner, MD
Pain & Addiction Medicine

December 18, 2014

I am compelled to provide "input" as I have done in writing, emails, phone conversations, and even testifying to the DWC personally, multiple times over the years. See [REDACTED] and [REDACTED]

Do not be confused here; the MTUS is simply the compilation of medical science, it is not an entity that exists, it is medical knowledge and as such presumed to be the standard of medical care.

Sadly my efforts have fallen on deaf ears and the MTUS is still not followed BECAUSE the DWC doesn't even ask WC Insurance Companies and WC Providers to even acknowledge the MTUS. This is against our current scientific knowledge, flies against the standard of medical care, and goes against the California Code of Regulations, it's against the law!

So here is the short and long of my input.

Included below is the letter the DWC sent requesting input.

I am flabbergasted that this letter came from the DWC with an included quote from the Medical Director for DWC, Dr. Rupali Das.

This DWC letter, see below, begins with the first sentence stating that the MTUS is “five-year-old guidelines”. This is not true at all; July, 2014: The date the MTUS was updated by MEEAC. I testified at this public hearing regarding the updated MTUS [REDACTED] . This information is posted on the DWC website. This means that this letter is making false statements knowingly and as such is a lie.

The second comment of the DWC letter states that the MTUS is based on a “frozen version of the Official Disability Guidelines from 2009”. Yet the DWC MTUS history shows: 2004: The MTUS was initially based on ACOEM. - 2007: The date the MTUS became effective. The rules also laid out the strength of evidence rating methodology by which specific medical treatments or diagnostic services are evaluated. The rules also established the medical evidence evaluation advisory committee (MEEAC) which meets regularly to review the latest medical evidence and advise the division about incorporating new evidence-based guidelines into its MTUS. - 2009: The date the MTUS was updated by MEEAC. - 2014: The date the MTUS was updated by MEEAC. This information is well known and also represented on the DWC website. The MTUS has never been based on the ODG let alone “frozen” in a 2009 ODG version. So, again, this is a knowingly and blatant misrepresentation of the facts and as such, it is another lie.

The letter goes on to imply that the MEEAC provides input to the ODG which is true but does not mention how ODG filters and twists that input. In fact, those algorithms' are proprietary, biased by the insurance companies, and not open for public viewing or scrutiny. This may not be a lie but it is certainly misleading.

The closing comments are astoundingly from the DWC Medical Director Dr. Rupali Das. He tries to support hiring the ODG to provide guidelines because they would institute a multidisciplinary approach with all of its subsequent benefits. Yet the foundational building blocks of the MTUS insists on the same approach Dr. Das suggests only ODG can provide. His statement is almost a verbatim statement from the MTUS and has been there for over a decade. How can this be? How can the DWC Medical Director make such statements against the MTUS when the very same approach is plastered all over the DWC website, integral with the MTUS approach, and most certainly should be known by the DWC Medical Director? He knows the truth and is perpetuating the lies put forth by every statement in this DWC letter.

Now you plan on using a private, for Profit Company, who is supported by the insurance companies to twist and spin our current standard of medical care without having to show how and why. More lies? Wow!

The American Academy of Orthopedic Surgeons and The American Association of Orthopedic Surgeons and my comments.

To begin, you should read Dr. Crabb's article on The American Academy of Orthopedic Surgeons and The American Association of Orthopedic Surgeons.

<http://www.aaos.org/news/aaosnow/jan14/advocacy1.asp>. I have included many of his insights here.

The modern workers' compensation system evolved in the late 19th century as a no-fault and exclusive remedy. Regardless of how an employee was injured, if the accident occurred in the course of his or her employment, both medical care and an indemnity payment would be provided. In exchange, the worker forfeited the right to sue the employer as a result of the accident.

In the United States, the American Medical Association's *Guides to the Evaluation of Permanent Impairment* is used to measure the extent of impairment as related to normal functional capacity. Until recently, medical treatment was based on the standard of care, "meaning that the physician determined what medical treatment was necessary,"

In 2003, however, California passed a bill requiring the Division of Workers Compensation (Div WC) to organize and use scientifically generated evidence-based medical guidelines (MTUS) in the treatment of workers' compensation injuries. The nationally recognized treatment guidelines published by the American College of Occupational and Environmental Medicine (ACOEM) provided the initial foundation for California's MTUS. Additionally, more than 20 recognized Health Care Providers specializing in work injuries, from every conceivable discipline, gather every 5 years to review all the scientific literature, apply an objective evaluating system adopted from ACOEM, and add that medical science information to update California's Medical Treatment Guidelines (MTUS).

These Doctors, through the authority of the State of California, provide this information in an organized format for the public, other health care providers, patients, employers, and insurance carriers alike. This is science at its best. No hidden agendas, no outside influences, no spins, no lobbying, no twisting fact for personal gain. Pure science, collected, measured, organized, and published to help patients heal and return to functional living. An impressive task for sure. Something Californians should be proud of. Scientific fact, unbiased, altruistic, and honorable. A public expression of doctor's dedication through the Hippocratic Oath.

The DWC MTUS states that "Doctors in California's workers' compensation system are required to provide evidence-based medical treatment. That means they must choose treatments scientifically proven to cure or relieve work-related injuries and illnesses. Those treatments are laid out in the medical treatment utilization schedule (MTUS), which contains a set of guidelines that provide details on which treatments are effective for certain injuries, as well as how often the treatment should be given, the extent of the treatment, and for how long, among other things. All employers or

their workers' compensation claims administrators are required by law to have a UR program. This program is used to decide whether or not to approve medical treatment recommended by a physician which must be based on the medical treatment guidelines.” Unfortunately Utilization Review Providers are representatives of the Insurance Companies and biased in their conclusions. They try to save insurance companies money by delaying treatments and fractionate care while blatantly not following the MTUS Standard of Care, quoting the ODG.

The MTUS is science and represents the current standard of care. It is public domain information for all to see with complete transparency. Whether a patient, third party payer, another provider, or simply someone interested in knowing the latest in medical treatment you can download it at the CA Div WC website here:

https://www.dir.ca.gov/dwc/DWCPPropRegs/MTUS_Regulations/MTUS_Regulations.htm

Doctors treating injuries, work related or not, spend their lives keeping up with all the scientific data humanity generates to help guide their patient care. Medical science is discovered by and for all of humanity. Understandably, the sheer volume, deciphering, and dedication necessitate professionals like doctors. Put these Doctors in a room and have them discuss any injury. Its diagnosis, its treatment plan, and its prognosis would shortly be established and agreed upon. This is not amazing; we are the professionals who know what the scientific evidence is. For most of us, being a physician is more of a vocation than an occupation. This is what we do and live for. We know what to expect when we read California’s Medical Treatment Guidelines (MTUS) or ACOEM and object when there is supportive evidence. This is how it should be.

Since the great state of California established these altruistic and honorable Medical Treatment Guidelines a national effort began to do the same in other states. Why not, it is a great idea. Yet some of those involved did not have the honorable intentions California did. In other states lobbyists twisted guidelines to fit their financial agendas instead of scientific fact. In other states, some physicians influenced guidelines to favor their discipline ignoring medical science. Some entrepreneurs attract insurance company money by creating medical guidelines manipulated by data algorithms which are always proprietary so no one can see.

The Work Loss Data Institute and its ODG is one of these companies.

WLDI outlined its mission: To create, maintain and market information databases to implement standards for managing workforce productivity based on strict principals of evidence-based methodology, with ongoing focus on healthcare cost containment. This is outrageous as WLDI clearly states that they create the standards of care, they maintain their database, they market this information as proprietary for personal gain. This is not science but instead capitalistic enterprise.

The Work Loss Data Institute (<http://www.worklossdata.com>), a private for profit company, out of Encinitas California, markets treatment guidelines to states with the name Official Disability Guidelines (ODG) when, in fact, there is nothing “official” about them. Promoting their own “evidence-based” guidelines, proprietary and not open to the public, claimed to be more authoritative than medical science all the while being funded by insurance carriers is obvious hypocrisy.

Phil LeFevre, who is a Senior Account Executive, with the Work Loss Data Institute (WLDI) spoke on behalf of the ODG and can be seen here: <http://www.lexisnexis.com/legalnewsroom/workers-compensation/b/recent-cases-news-trends-developments/archive/2012/03/23/work-loss-data-institute-warns-of-fox-guarding-the-hen-house-in-state-treatment-guidelines.aspx>

LeFevre stated that the ODG was based on evidence-based medicine (EDM). The EDM model provided for “transparency, literature review, and evidence ranking.” This system’s stated goals included objectively ensuring that medical care providers who treated claimants used the right tool for the job after considering every available treatment. The problem here is that there is no transparency because this is a for profit business whose algorithms are proprietary and not available to the public. This is not the scientific way. Scientific evidence is fact in of itself. As soon as it is supplanted it can be manipulated without transparency and become a tool for lies and abuse. This goes against everything the medical profession is based on and reflected in the Hippocratic oath: “I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow” and “I will apply, for the benefit of the sick, all measures which are required, avoiding those twin traps of overtreatment and therapeutic nihilism.”

When guidelines are not based on known medical science then the burden of proof switches and significantly changes the doctor patient relationship. No longer does the doctor have the presumption of being correct and the insurance company has to prove. Now the guidelines are assumed to be correct and the doctor has to prove it otherwise. This delays treatment as evidenced by Utilization Review (UR) and fractionates medical care which drives up health care costs, exacerbates suffering and chronicity, and promotes prescription addictions.

Mr LeFevre goes on to spin the ODG approach by pointing out that Prior, as opposed to pre, authorization of medical services was identified as an underlying element that achieved the positive results described above. Prior authorization differs from pre-authorization in that diagnosing a condition triggers a right to approved treatment for compensable harm. This is inherent in science based guidelines like the MTUS. Conversely, pre-authorization requires utilization review of treatment that is recommended after diagnosing an injury or disease. Prior authorization follows evidence based on science which avoids reinventing the wheel by eliminating the need to determine the “reasonable and necessary” treatment each time that a claimant sustains the same type of harm that other claimants had sustained. This reduces review-related delays and costs. The reduced review costs help lower workers’ compensation expenses; the reduced delay help claimants return to work earlier because they do not sit around awaiting pre-approval of recommended treatment. These benefits are certainly true when based on evidence based science not the ODG or any other pseudo-science. The whole intent of the MTUS is to accomplish these goals which certain can be attained if the DWC enforces compliance by WC Providers and WC Insurance Companies.

The MTUS is based solely on science and as such benefits us all by:

- Lower health care costs;
- Overflow of treatment guidelines into the general practice of non-WC medicine.
- Proper utilization of medical services
- Reduced lost productivity.

- Increased functionality.
- Lowered prescription addictions and overdoses.
- Less risk of chronicity and disability.
- Greater trust and respect for the Medical and WC system.

One caveat that LeFevre shared was that treatment decisions must be based on the most current version of the ODG. Stated reasons for doing so included ensuring that the utilized guidelines reflected the most recent medical evidence. This is disconcerting again and implies that ODG is the scientific authority not the scientific literature. Treatment must be based on the most current scientific guidelines, established by the scientific literature, and compiled by the California Medical Treatment Guidelines (MTUS).

DWC is paid for by the taxpayer and should be responsible to the citizens of California.

The Division of Workers' Compensation (DWC) monitors the administration of workers' compensation claims, and provides administrative and judicial services to assist in resolving disputes that arise in connection with claims for workers' compensation benefits.

DWC's mission is to minimize the adverse impact of work-related injuries on California employees and employers.

Doctors in California's workers' compensation system are required to provide evidence-based medical treatment. That means they must choose treatments scientifically proven to cure or relieve work-related injuries and illnesses. Those treatments are laid out in the medical treatment utilization schedule (MTUS), which contains a set of guidelines that provide details on which treatments are effective for certain injuries, as well as how often the treatment should be given, the extent of the treatment, and for how long, among other things.

Utilization review (UR) is the process used by employers or claims administrators to review treatment to determine if it is medically necessary. All employers or their workers' compensation claims administrators are required by law to have a UR program. This program is used to decide whether or not to approve medical treatment recommended by a physician which must be based on the medical treatment guidelines (MTUS).

The DWC has the responsibility to administer of workers' compensation claims, and provides administrative and judicial services to assist in resolving disputes that arise in connection with claims for workers' compensation benefits. Their mission is to minimize the adverse impact of work-related injuries on California employees and employers.

“The fact that these guidelines exist is not necessarily bad,” said Dr. Crabb. “It just depends on how they are implemented—and we have little control over that.”

Hippocratic Oath (Modern version)

I swear to fulfill, to the best of my ability and judgment, this covenant:

I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.

I will apply, for the benefit of the sick, all measures which are required, avoiding those twin traps of overtreatment and therapeutic nihilism.

I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.

I will not be ashamed to say "I know not," nor will I fail to call in my colleagues when the skills of another are needed for a patient's recovery.

I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. Above all, I must not play at God.

I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick.

I will prevent disease whenever I can, for prevention is preferable to cure.

I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm.

If I do not violate this oath, may I enjoy life and art, respected while I live and remembered with affection thereafter. May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help.

Written in 1964 by Louis Lasagna, Academic Dean of the School of Medicine at Tufts University, and used in many medical schools today.

As a physician I gave an Oath (The Hippocratic Oath) which clearly states that I will follow science as a standard of care. From the Hippocratic Oath; "I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow."

Science, open and democratic. When not followed, abuse follows. Abuse should not be used as an excuse by the DWC to relegate treatment guidelines, the standard of care, to a private for profit dictatorial company inherently without transparency. Instead the DWC must own up to its given responsibility and require WC Providers and WC Insurance Companies to follow the standard of care, the MTUS.

Brenda Ramirez, Claims & Medical Director
Stacy L. Jones, Research Associate
Michael McClain, General Counsel
California Workers' Compensation Institute

December 18, 2014

These comments on the Chronic Pain Medical Treatment Guidelines are presented on behalf of members of the California Workers' Compensation Institute (the Institute). Institute members include insurers writing 71% of California's workers' compensation premium, and self-insured employers with \$46B of annual payroll (26% of the state's total annual self-insured payroll).

Insurer members of the Institute include ACE, AIG, Alaska National Insurance Company, AmTrust North America, Chubb Group, CNA, CompWest Insurance Company, Crum & Forster, Employers, Everest National Insurance Company, Fireman's Fund Insurance Company, The Hartford, ICW Group, Liberty Mutual Insurance, Pacific Compensation Insurance Company, Preferred Employers Group, Springfield Insurance Company, State Compensation Insurance Fund, State Farm Insurance Companies, Travelers, XL America, Zenith Insurance Company, and Zurich North America.

Self-insured employer members are Adventist Health, Agilent Technologies, Chevron Corporation, City and County of San Francisco, City of Santa Ana, City of Torrance, Contra Costa County Schools Insurance Group, Costco Wholesale, County of San Bernardino Risk Management, County of Santa Clara, Dignity Health, Foster Farms, Grimmway Enterprises Inc., Kaiser Permanente, Marriott International, Inc., Pacific Gas & Electric Company, Safeway, Inc., Schools Insurance Authority, Sempra Energy, Shasta County Risk Management, Shasta-Trinity Schools Insurance Group, Southern California Edison, Sutter Health, University of California, and The Walt Disney Company.

A Single Guideline

The Division is proposing to use the ODG "Treatment in Workers' Compensation - Chapter on Pain (Chronic)" and the DWC "Guideline for the Use of Opioids to Treat Work-Related Injuries." The use of a single source for comprehensive medical treatment guidelines is preferable to multiple source guidelines both because high-quality medical treatment guidelines are continually updated and a single guideline is more valuable for the various end-users. Treatment guidelines must, to the extent practicable, create a clear, bright line for physicians, medical treatment reviewers, workers, attorneys, judges, and claims administrators. Adopting single source guidelines that incorporate opioid management and definitive chronic pain guidance will eliminate many of the problems inherent in a patchwork of potentially conflicting and overlapping guidelines that are based on different standards and criteria.

The Legislature adopted evidence-based medicine as the standard of care in California and applied the presumption in order to deliver the highest quality medical care to injured workers, to limit disputes over treatment, and to ensure that the proper treatment will be promptly provided. The Legislature initially incorporated the ACOEM guidelines for the most common work-related injuries. To enhance the utility of the medical treatment utilization schedule (MTUS) based on the ACOEM structure and philosophy, the Legislature added a legal presumption for all medical care sanctioned by the MTUS. The Supreme Court, in State Compensation Insurance Fund v WCAB (Sandhagen) (2008) 73 CCC 981, affirmed that determination; stating in essence, that reasonable and necessary medical care under section 4600 is any treatment provided in accordance with the medical treatment utilization schedule.

As Dr. Das has noted, the goal of chronic pain guidelines is to restore function, reduce pain, and to encourage return to work following injury. In 2004, the Legislature made the social policy decision that treatment necessary to cure and relieve the effects of the industrial injury would be defined by medical evidence supporting its effectiveness. While the ODG guidelines are comprehensive and well documented, the Institute continues to urge the Division to consider similar chronic pain guidelines being developed by ACOEM or other nationally recognized guidelines that are more definitive and specific.

The preferred pain treatment guideline would comprise a single comprehensive set of evidence-based guidelines with clear recommendations (e.g., recommended, not recommended, no recommendation) developed according to a single set of the highest quality standards and criteria. When promulgating the use of treatment guidelines one must keep in mind that the guidelines are not used exclusively by treating physicians. Rather, the Legislature requires that the guidelines be used by injured workers and their physicians, claims examiners, utilization review physicians, IMR, employers, applicants' attorneys, defense attorneys, judges and the WCAB and the reviewing courts. Therefore, the workers' compensation community must have treatment guidelines that are as straightforward as modern medical science can make them.

Labor Code Section 4610 charges utilization review physicians with the obligation to determine the appropriateness of requested treatment within very tight time frames. Treatment guidelines that provide clear direction, are well supported by scientific medical evidence, and are based on graded peer reviews are essential for the utilization review system to function as intended. Conversely, a treatment guideline that is indefinite and overly conditional is in conflict with the statutory requirements.

Efficacious Treatment and Functional Improvement

The essential determination of whether a treatment modality is effective is whether the pain is adequately controlled and whether the worker's ability to function improves. Treatment guidelines should include definitive milestones and directions to physicians with regard to validating the course of treatment and recommending alternatives. The proposed guidelines, which incorporate DWC opioid use guidelines and ODG chronic pain guidelines, lack specificity in recommendations, validation, and goals with regard to functional improvement.

Effective Date of Guidelines

The chronic pain medical treatment guidelines consist of an introduction (Part 1) and specific interventions and treatments for chronic pain (Part 2), based on the ODG Chapter on Pain. For guidelines regarding opioid use, physicians are to refer to the DWC “Guideline for the Use of Opioids to Treat Work-Related Injuries.” It is therefore essential that these regulations become effective at the same time.

Joshua P. Prager, MD, MS
Director, Center for the Rehabilitation of Pain
Syndromes at UCLA Medical Plaza

December 18, 2014

My name is Joshua Prager, M.D., M.S. I served two full terms on the Medical Evaluation Advisory Committee for the State of California until approximately three years ago. During this time, I served in the capacity of as an expert in helping to develop the Medical Treatment Utilization Schedule (MTUS). During this time, we utilized the Office of Disability Guidelines (ODG) as a basis for developing treatment guidelines for injured workers in the state of California. I served as one of two pain experts in helping to develop the pain section.

With regard to spinal cord stimulation and intrathecal drug delivery, the MTUS we developed was consistent with the ODG guidelines.

I have now seen the proposed new guidelines for intrathecal therapy and spinal cord stimulation for the injured worker in the state of California. I believe this is markedly inconsistent with the medical literature and a departure from the ODG guidelines. We spent considerable work developing the prior guidelines and it is difficult for me to understand why, when there is evidence-based literature demonstrating the efficacy of these therapies, that there would be a change in the treatment guidelines. We had detailed discussions over many weeks when we reached conclusions and developed the current guidelines. Since that time there is more literature to support the use of intrathecal therapy and spinal cord stimulation. As such, I do not understand the disconnect in logic that would deprive appropriately selected patients from receiving the treatment they deserve.

I am aware that there is only one state in the United States where these procedures are not covered for injured workers. That state is the State of Washington. That is also the state from which Dr. Gary Franklin (an non-practicing physician who is not a pain physician appointed as a member of the medical evidence evaluation advisory committee, MEEAC and not a resident or citizen of California) chaired a committee responsible for developing treatment guidelines. I am also aware that during that time, highly regarded national experts were dismissed after a perfunctory few minutes to attempt to address the committee, and thus under Dr. Franklin's aegis, injured workers in the state of Washington are the only injured workers in the United States who are deprived of the therapy of intrathecal drug delivery and appropriate spinal cord stimulation. I see at as a travesty if the same would occur in our State of California. I also hope that the California process will be transparent and with intellectual integrity, allowing those with true expertise to speak and have their points of view considered.

There are two Level I clinical studies that demonstrate that intrathecal drug delivery is an effective therapy. In addition, I personally coauthored publication of an econometric analysis in the state of Minnesota demonstrating the cost effectiveness of intrathecal therapy. This study was conducted in a closed population in a managed care organization.

With regard to spinal cord stimulation, there are numerous high-quality studies demonstrating efficacy. I would be pleased to have the opportunity to meet my colleagues from MEEAC and once again present data to the committee regarding these topics. I would also be pleased to bring with me nationally recognized pain experts to present their data as well as bringing patients who have successfully benefited from these therapies.

To reiterate: I feel there is complete disconnect that has occurred in preparing a proposed guideline that would eliminate intrathecal drug delivery and greater restrict the use of spinal cord stimulation for the injured worker in California. It is a disconnect because we framed our guidelines on the ODG (office of disability guidelines) and that the ODG continues to recommend these therapies. It is a disconnect because since the MTUS was last adopted, the medical literature on which we based our decisions remains as it was except that there are more articles in highly regarded peer reviewed journals demonstrating efficacy of these modalities now than there were at the time the last MTUS was adopted.

Brandon A. Van Noord, MD
Pain Medicine – UCLA
LCDR MC (FS/FMF) – NOSC LA, USNR

December 18, 2014

I have been a practicing physician in California for many years both in the military as during graduate medical education at USC and UCLA .During those years, I have seen the sweeping and continually evolving insurance changes that have affected Pain practices throughout the state .The current insurance climate makes it very difficult for me to make clinical and treatment decisions that are commonly in the best interest of my patients.

It has been brought to my attention that CDWC is proposing a significant change in 2015 that affects a therapy that I use to assist a select group of patients: Spinal Cord Stimulation) SCS.(

Current guidelines allow me to treat CDWC patients that suffer from pain associated with FBSS as well as CRPS/RSD and several other indications. My understanding for 2015 is that CDWC is proposing to limit access to this therapy only to those who suffer from CRPS/RSD.

I am in complete disagreement with your proposal for numerous reasons.

First, I disagree that there are no clinical studies that support the use of SCS for patients who suffer with FBSS. There are numerous randomized controlled trials that support the use of SCS as well as several large post market SCS registries reporting positive outcomes. Even more indicative of the success of the therapy in the literature, are my own outcomes that my practice observes on a weekly basis. I have personally performed over 40 SCS trails and implants with significant quality of life improvement

%50<)pain reduction, functional improvement, less narcotic intake) in the majority of these patients. Not having it as a treatment option for patients moving forward is very disturbing.

Secondly, SCS for the treatment of FBSS, after the patient has tried and failed other surgeries and therapies, is a recommended treatment option for several Pain physician societies and is available to almost all commercially-insured beneficiaries in the United States. For CDWC to not agree and be in alignment with this is very short sighted to say the least.

Thirdly, what does the CDWC propose that I offer this large group of patients at the end of the pain continuum? Increased narcotics??? My answer to that is NO.

In summary, I am in complete opposition of the proposed 2015 changes that the CDWC is looking to make in regards to SCS. I personally have seen many lives significantly changed for the better with this treatment modality .This therapy needs to be an end continuum option for those who suffer from FBSS.

Sharon L. Hulbert, Assistant General Counsel
Zenith Insurance Company

December 18, 2014

Zenith appreciates the extensive work, time and effort expended by the DWC, MEEAC and ODG in developing treatment guidelines. Treatment guidelines are a very important tool in delivering appropriate medical care to injured workers. It is important that every recommendation be clear and evidenced based to expedite appropriate care and to minimize disputes. To this end, Zenith would like to make the following suggestions:

1. Zenith agrees with the CWCI comment that the legislative intent of the guidelines is to provide clear guidance. To do that, the summary for each procedure/topic should be either clearly marked at the beginning of the section as “recommended” or “not recommended”. These notations are not being consistently entered at the beginning of each section in this draft of the guidelines. For instance, the section on lymph drainage therapy clearly states: “Not recommended.” Conversely, the section on genetic testing for potential opioid abuse implies that this testing should not be recommended, but it does not clearly state that. Therefore it is open to dispute. Furthermore, sections that are labelled “under study” such as Chi machine should be changed to “not recommended” as there is insufficient evidence to support a decision to recommend them. Although the wording “under study” is informative in some other setting, it does not assist in rendering medical determinations based on the guidelines and will increase disputes. Sections like this should be clarified to provide the clear direction.
2. Zenith agrees with the CWCI comment that a single set of guidelines should be used for consistency and clarity. Some of the sections in this proposed guideline conflict with existing or proposed guidelines. For instance, the current DWC MTUS acupuncture guideline states that 3-6 treatments should be allowed to produce functional improvement. The section in this proposed guideline references the current guideline but also states that the initial trial is 3-4 visits over two weeks. See page 22 of

proposed guidelines. We suggest that this guideline simply reference the acupuncture guideline which covers both acute and chronic care.

In a similar vein, the way the draft is written, users must go to multiple locations in order to apply the full guideline. For example, the guideline for Codeine begins in the MTUS chronic pain guideline which then refers the user to the DWC Use of Opioids to Treat Work-Related Injuries. See page 43 of proposed guidelines. Therefore, the user is required to review one document for the base guideline and another document for dosing recommendations. Zenith is concerned that this approach will create confusion, lead to inconsistent application of the guideline, and complicate use of the guidelines.

3. Zenith did not see the following addressed in the guidelines and believe they should be added:

- a. Gralise: Specifically whether and when Gralise should be considered instead of generic Neurontin.
- b. Sodium oxybate for fibromyalgia: Specifically whether and when sodium oxybate is appropriate for fibromyalgia.

4. Compound drugs – page 44: This section states “not recommended” as first line therapy but does not contain sufficient criteria to stop unnecessary compounding after first line therapy has failed. This section will open the door to further abuses related to compound drugs. A drug manufacturer would only have to make a new combination drug such as Ibuprofen 800 mg and Omeprazole 20 mg and to satisfy the requirement in this section. Except for very limited circumstances, such as when a patient is being weaned from opioids using a blind cocktail, compound drugs are rarely needed. As there is no evidence in this section that supports the current recommendation, it should be changed to “not recommended.” Similarly, the sections on “Co-packs” and Repackaged drugs” should be changed to “not recommended.”

5. Physician dispensed drugs – page 103: The section on “Physician-dispensed drugs” should be deleted or changed to “not recommended.” The section as drafted does not provide guidance but rather seems to be a discussion or definition. Carriers have other regulations and processes that can be used to address office dispensing as needed. As written, Zenith is concerned that the current guideline may create confusion and should be removed. If this section is included, it should be labeled “not recommended” as only one citation is given in this section and it notes that physician dispensed drugs are associated with higher cost and more lost time. Zenith also believes all sections should be reviewed to assure the discussions do not create opportunity for confusion or additional disputes. See “dry needling” as an additional example where no guidance is provided but rather it refers you to two other sections without addressing whether dry needling is “not recommended” or “recommended” for treatment of chronic pain.

6. Topical analgesics – page 116: There is evidence that single agents can be efficacious when applied topically. However, some physicians are dispensing combinations of medicines that have never been tested at doses that are not standardized. Muscle relaxants, antidepressants, capsaicin and other medications are being combined in novel formulations. Since these have not been studied, there is no evidence to support their use and furthermore there is a real potential for harm from their use. This section should be changed to recommend only those agents that have supportive evidence for a particular dose and formulation and all other compounds should be “not recommended.”

7. Antidepressants – page 16: This section is very well annotated but unfortunately difficult to follow. For instance, it is difficult to discern if SSRIs are recommended or not by reading through the citations. Each class of antidepressants should have its own conclusions with either a label of “recommended” or “not recommended” and for what clinical circumstances. Also, when reading a PTP’s report, it is often very difficult to tell if the provider is prescribing antidepressants for depression, neuropathic pain or nociceptive pain. As this information is crucial to the handling of the request, the guideline should mandate that the doctor give the indication for the requested medication. It would be helpful for this section to state when, if ever, more than one antidepressant is indicated for pain and the evidence that supports that recommendation.
8. Weaning recommendations: The section on Pregabalin on page 22 under Antiepileptic drugs for pain includes a recommendation on the time period needed for weaning. This is very helpful and a similar recommendation should be included in sections for other drugs that require a weaning period.
9. Duplicate sections addressing the same drug: Pregabalin is also an example where recommendations are scattered throughout the document. On page 22, a very well written and thorough section addresses Pregabalin and includes weaning recommendations. However, on page 104 Pregabalin is listed and includes only a brief statement with no weaning recommendations. This type of discrepancy could lead to confusion and unnecessary disputes. Therefore, Zenith recommends that all sections be reviewed to assure that when the same drug is listed in varying sections, any differences in recommendations be clearly explained based on clinical criteria or made consistent.
10. Anxiety medication in chronic pain – page 24: This section should be deleted. The importance of treating the psychosocial aspects in chronic pain is well covered in the introduction. Individual medications such as benzodiazepines are covered in separate sections. Furthermore, describing the treatment of problems such as social anxiety disorder and panic disorders should be included in a guideline for psychiatric conditions instead of a chronic pain guideline.
11. Modafinil – page 85: This section should clearly state that Modafinil is not recommended for the treatment of chronic pain or for the side effects of other medications used to treat chronic pain.
12. Cellulitis treatment – page 35: This section should be deleted as it is not relevant to the treatment of chronic pain.

Kevin S. Smith, MD
Integrated Pain Specialists

December 18, 2014

I am a board certified Anesthesiologist with subspecialty certification in Pain Management. I have been practicing pain management and treating injured workers in California since 1991. I have been

implanting percutaneous Spinal Cord Stimulators (SCS) and Intrathecal Drug Delivery (IDD) systems for 20 years.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.

IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

This proposal goes against all standards of care guidelines for medicare, commercial payers, and many state workers compensation programs. There is extensive evidence based medicine supporting the therapeutic effectiveness of Intrathecal Drug Delivery System Therapy in malignant, and non malignant chronic pain. There is also extensive evidence based medicine supporting the utilization of Spinal Cord Stimulation when treating FBSS and CRPS. This proposal is absurd and just another attempt to withhold appropriate medical care from deserving patients.

Eleanor Marciniak

December 18, 2014

The home health services guidelines on pages 66-67 does not include the definition of homebound. In addition, the guidelines address non-medical services such as shopping, but do not include specific recommendations on frequency or duration. The guidelines indicate an in-home evaluation by a home health care agency would usually be included. However, there would appear to be a conflict of interest because the home health care agency would also be the one receiving reimbursement for the said service.

IMR also has a tendency to provide a blanket overturn requests when the request is medically necessary in part, but not in whole. Without clear guidelines on what is allowed, valid, reasonable reviews are liable to be overturned at IMR for the incorrect reason.

These services include both medical and non-medical services for patients who are homebound and who require one or a combination of the following: (1) Skilled nursing care by a licensed medical professional for tasks such as administration of intravenous drugs, dressing changes, physical therapy,

speech-language pathology services, and occupational therapy; (2) Home health aide services for health-related tasks and assistance with activities of daily living that do not require skills of a medical professional, such as bowel and bladder care, feeding, bathing, dressing and transfer and assistance with administration of oral medications; and/or (3) Domestic services such as shopping, cleaning, laundry that the individual is no longer capable of performing due to the illness or injury. These services do not require specialized training and do not need to be performed by a medical professional. Home health care services are medically necessary where the medical condition results in an inability to leave the home for medical treatment and/or an inability to perform specific custodial or homemaker services. (ACMQ, 2005) (Ellenbecker, 2008) Justification for medical necessity requires documentation of:

- (1) The medical condition that necessitates home health services, including objective deficits in function and the specific activities precluded by such deficits;
- (2) The expected kinds of services that will be required, with an estimate of the duration and frequency of such services; and
- (3) The level of expertise and/or professional licensure required to provide the services.

Evaluation of the medical necessity of Home Health Care services must be made on a case-by-case basis. The physician's treatment plan usually includes an in-home evaluation by a Home Health Care Agency Registered Nurse to assess the appropriate scope, extent, and level of care for home health care services. A one-time home health care evaluation is appropriate if the treatment plan is unclear and not already ordered by the treating physician.

Jay Shery, MD, Department Chair
Moses, Jacob, MD, Committee Chair
California Chiropractic Association

December 18, 2014

On behalf of the California Chiropractic Association (CCA), we appreciate the opportunity to provide comments regarding the Division of Workers' Compensation's (DWC) proposed "Chronic Pain Medical Treatment Guidelines". CCA commends the DWC on using a more current version of the Official Disability Guidelines (ODG) for chronic pain. In fact, we believe the Division should use language which adopts the current version of ODG, rather than a static date, since ODG is constantly updating its language and recommendations to ensure greater clarity, include the most recent research and reduce frictional issues.

While there was a rationale for the imposition of the caps on physical medicine ten year years ago, the requirement for universal utilization review has obviated the need for caps. Either the recommended treatment comports with the MTUS or other science based guidelines as recommended by the Division, or it does not.

The proposed language noted below is problematic for several reasons, and it is our understanding revisions by ODG are currently being reviewed.

<p>Manual therapy & manipulation</p>	<p>Manual therapy and manipulation, also known as chiropractic treatment, are passive interventions that are considered adjuncts to other recommended treatment, especially active interventions (e.g., exercise). Recommended for chronic pain if caused by musculoskeletal conditions, and only when manipulation is specifically recommended by the provider in the plan of care. Manual Therapy is widely used in the treatment of musculoskeletal pain with the intended goal of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. Manipulation under anesthesia is not recommended. See also specific body-part chapters in the DWC MTUS.</p> <p>Recommended treatment parameters:</p> <ul style="list-style-type: none"> a. Time to produce effect: 4 to 6 treatments. b. Frequency: 1 to 2 times per week for the first 2 weeks as indicated by the severity of the condition. Treatment may continue at 1 treatment per week for the next 6 weeks. c. Maximum duration: 8 weeks. At week 8, patients should be reevaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases, treatment may be continued at 1 treatment every other week until the patient has reached MMI and maintenance treatments have been determined. Extended durations of care beyond what is considered "maximum" may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Such care should be re-evaluated and documented on a monthly basis. Treatment beyond 4-6 visits should be documented with objective improvement in function. Palliative care should be reevaluated and documented at each treatment session. (Colorado, 2006) Injured workers with complicating factors may need more treatment, if documented by the treating physician.
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For example, the terms "manual therapy and manipulation", while frequently used by doctors of chiropractic, are not synonymous with "chiropractic treatment" any more than drugs are synonymous with medical care. Chiropractic treatment includes many other forms of treatment and in fact "chiropractic" refers to the profession, not a treatment. In addition, the terms "manual therapy" and "manipulation" are also not synonymous. Manipulation is a form of manual therapy, but not all forms of manual therapy are considered manipulation. Chiropractic manipulation using a high velocity low amplitude technique is not the same thing as a muscle energy technique or myofascial release which would be considered manual therapy. This lack of distinction in the guideline needs to be corrected to reduce the almost certain disputes which would otherwise arise.

In addition, we disagree that manual therapy and manipulation are considered adjuncts to other recommended treatments. Often, either manual therapy or manipulation stands on its own as a treatment

method as evidenced by numerous clinical trials. Research does however indicate that the combination, for example, of manipulation and exercise is more effective than either one on its own but there may be times when exercise is clinically inappropriate while manipulation is not. Therefore manipulation is no more an adjunct to exercise than the other way around, and the term is likely to be used to limit care inappropriately due to its implied meaning, which is likely to result in additional disputes. This language requires clarification.

The California Chiropractic Association recommends that an annual maximum of 18 treatments be adopted for care of chronic conditions. . This recommendation comports with current guidelines and will allow for greater leeway on the part of providers to care for patients while simultaneously providing payors with an upper limit on care. This will again reduce frictional costs, reduce delays and expedite care.

Marc D. Wolfsohn, MD

December 18, 2014

I am a board certified anesthesiologist and pain management specialist who has been in practice for 35 years. The most rewarding life altering interventions in dealing with chronic pain have been with spinal cord stimulators and implanted pumps. They have especially helpful for patients with failed back surgery and CRPS. Where there has been restoration of function and a decrease in other medications and treatments. Literature indicates Level 1 evidence for these modalities. The most recent WC recommendations indicating use of these modalities for CRPS only for spinal cord stimulation and pumps for only cancer pain is restrictive and would deny severely injured patients access to medical care. Please reconsider this recommendation and allow these treatments to be used on the chronic pain patients whom have failed back surgery, radiculopathy, neuropathic pain, and degenerative disease of the spine when appropriate.

Reza Ramezankhani, MD

December 18, 2014

I am a practicing physician and a board certified anesthesiologist in California. I treat injured workers in my practice.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not support by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

· SCS: SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients

with FBSS and believe it should remain a treatment option for injured workers.

· IDD: IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

Michael Chen, L.Ac., Ph.D.

December 18, 2014

I am an acupuncturist with 30 years clinical experience. I am a member of California Acupuncturists Association.

The proposed changes to the acupuncture section in Chronic Pain Medical Treatment Guidelines should not take effect without the inputs from people who understand acupuncture. The professional community has not heard of any survey or any new studies that was done to validate this change to overwrite the current guideline. The proposed change would decrease patients' acupuncture visits by at least half. This will severely harm injured workers' recovery process.

In addition, Carpal Tunnel Syndrome should be a recommended condition for acupuncture. My colleagues and I take care of many Carpal Tunnel Syndrome cases in our office and are effectively alleviating people's CTS pain and numbness each day. I don't see a sufficient study to show that CTS is not effective with acupuncture.

Acupuncture has shown to be an inexpensive and highly effective treatment in many chronic pain cases. Reducing initial acupuncture trial visits from 6 visits to 3-4 visits will not give some chronic pain cases enough time to feel the effectiveness of acupuncture. Having a total of 12 visits of acupuncture may be valid for a light to moderate case, but NOT enough for severe pain cases and for those who have multiple body part injuries and especially not enough for those who have chronic pain for over one or more years.

The unique part of workers' compensation cases is that many cases are due to repetitive strain injury, and the job continues to require them to use that specific injured body part; thus may cause flare ups. In the case of flare ups, another group of 6 or 12 visits may be necessary periodically.

As an acupuncturist who has worked many years with Worker's Compensation cases, I can responsibly comment that if this change gets adopted, many injured workers will lose their chance of returning to work quickly.

Therefore, I OPPOSE this guideline for acupuncture.

Kasra Amirdelfan, MD
Interventional Spine & Pain Medicine
IMP Medical Group, Inc.

December 18, 2014

I am writing to inform you of new, groundbreaking Spinal Cord Stimulation (SCS) evidence that was recently presented on December 11th at a major scientific meeting, the 18th North American Neuromodulation Society (NANS) annual meeting. The data presented is the result of a Level 1, pivotal, FDA-supervised RCT with comparative effectiveness focused on patients with significant back and leg pain. This rigorous study included both traditional low-frequency SCS as well as high-frequency (10 kHz) SCS, a newer application of the therapy, that produced profound and durable pain relief results as well as functional improvement measured by validated instruments, such as the Oswestry Disability Index (ODI). It is noteworthy that the vast majority (87%) of the patients studied have had previous back surgery and about 90% were using opioids at the time of enrollment.

The publication of this landmark, head to head randomized controlled trial is pending; however the peer reviewed posters that were presented at NANS are attached for your reference. It is notable that the one-year responder rate (having at least 50% pain reduction) for 10 kHz high-frequency SCS was 78.7% for both back pain and leg pain, and the reduction in pain for both traditional SCS and 10 kHz high-frequency SCS was between 44% - 69%. (Sitzman, Rationale for the SENZA-RCT Study Design and Comparative Outcomes.) In addition, the outcomes for the 10-kHz high-frequency SCS in the RCT are consistent with those of the previously published on the European study.

As one of the investigators of the SENZA-RCT, I welcome the opportunity to provide you with more detail regarding the study outcomes and patient population for both high frequency SCS as well as traditional SCS.

NOTE: Commenter has provided five informational attachments. These attachments are available upon request.

Edward E. Anguizola, MD

December 18, 2014

World Institute of Pain Medicine, Board Certified, American Society of Interventional Pain Physicians, Board Certified and Board Certified Anesthesiologist that treats injured workers. I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

SCS: SCS is recommended as a treatment option for FESS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FESS. I use this therapy for treating my patients with FESS and believe it should remain a treatment option for injured workers.

IDD: IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/ 50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

Navid Farahmand, MD

December 18, 2014

My name is Navid Farahmand, MD. I am a board certified anesthesiologist with subspecialty training in pain management. I work in Southern California and treat injured workers in my practice.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not support by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

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George Chen, PT, CHT, LAC

December 18, 2014

My name is George Chen. I am a California licensed acupuncturist and physical therapist. I am also a certified hand therapist (CHT). I have worked in this field for almost 20 years. I have treated many injured workers, athletes and personal injury cases. I oppose the proposed changes from current acupuncture treatment guideline in chronic pain (8-12 sessions in 3-4 weeks) to ODG standard (3-4 sessions in 2 weeks).

Although I am not a researcher, I do use Pubmed data base. If you go through Pubmed data base, you

will find that current research on acupuncture treatment for CTS is a mix. You can't draw a conclusion that acupuncture treatment has no effect on CTS. Therefore, I think that ODG standard for acupuncture treatment on CTS is wrong and has no scientific evidence bases.

Based on my 20 years of clinical experience, I see great results (documented functional progress through FOTO-*Focus On Therapeutic Outcomes*, Inc.) with acupuncture for chronic pain in a schedule of 8-12 sessions in 3-4 weeks. Acupuncture works different from Western medications which work quickly but wear off quickly as well. Acupuncture treatment takes time (3-4 weeks) and intensity (8-12 sessions) to build up its effect. Once it takes the effect, it has long lasting effect.

I am a member of AACMA (American Association of Chinese Medicine and Acupuncture) (unity of former CCAA and UCPCM), one of the largest acupuncture association in California and in USA. AACMA represents the rights, the benefits and education issues of acupuncturists in California. Therefore, I strongly urge DWC representatives communicate with AACMA's board for any changes relating to acupuncture treatment.

Linda (Lynn) Clintron, MD

December 18, 2014

Please kindly consider my opposition to the proposed Workers Comp Chronic Pain Medical Treatment Guidelines.

I have practiced in California in the field of pain management for over 12 years. I am a board certified pain management and anesthesia physician, fellowship trained from Stanford and a Qualified Medical Examiner in California. I serve as a Board Member to the California Society of Interventional Pain Physicians, a member of the CSA Pain Task Force and work with the Feinberg Medical Group. I also teach physician trainees and professionals.

I oppose the proposed changes to Spinal Cord Stimulation (SCS) and Implantable Drug Delivery Systems (IDD) in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

I strongly support SCS and IDD because they have been very effective tools in limiting opioids and treating chronic pain disorders safely and effectively in my patients and others. SCS and IDD target pain mechanisms more specifically, provide non-opioid strategies and lower doses of opioids. They help limit costs over time. The tremendous growth of medical technology and applications outpaces the time and resources to carry out medical research trials in the US. We are behind other countries in this area and yet our injured workers are crying for our help. Despite the lag in the US, most of the patients I speak with are very grateful for such interventions. They are life saving and allow patients to return to work and function a more normal life. California has led the country in medical innovation and technology in

the past. This proposal would be devastating for patients and put us behind. I believe it wrong to limit care to our injured workers and as a physician, need to advocate for such patients.

SCS: SCS is recommended as a treatment option for Failed Back Syndrome (FBSS), Complex Regional Pain Syndrome (CRPS) and other medical disorders in several physician society guidelines. It is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and other disorders in appropriate patients and believe it should remain a treatment option for injured workers.

IDD: IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

Mary E. Ryan, Senior Program Manager
State Government Affairs
Medtronic, Inc.

December 18, 2014

Jennifer A. Hinnenthal, Senior Program Manager
Health & Economics & Outcomes Research

We are writing to you in response to the Division of Workers' Compensation (DWC) proposed Chronic Pain Medical Treatment Guidelines, posted December 8, 2014. We are writing to request that the DWC consider broadening the proposed guideline to include coverage of spinal cord stimulation (SCS) for failed back surgery syndrome (FBSS), which is a FDA approved indication for SCS. Additionally, we request you change the proposed guideline to recommend implantable drug pump (or intrathecal drug delivery, IDD) for both cancer and non-cancer pain, as there is sufficient evidence to support IDD therapy for appropriate patients. We have provided a number of references to peer reviewed evidence and currently accepted guidelines.

According to the DWC website: "The medical treatment utilization schedule (MTUS) provides medical treatment guidelines for utilization review and an analytical framework for the evaluation and treatment of injured workers. It helps medical providers understand which evidenced-based treatments have been effective in providing improved medical outcomes to those workers. The MTUS is promulgated by the DWC administrative director under Labor Code sections 5307.27 and 4604.5. The Legislature charged the DWC administrative director (AD) with adopting an MTUS that would be presumed correct on the issue of extent and scope of medical treatment". This standard makes recommendations found in the MTUS equivalent to coverage policies covering injured workers in the State of California.

SCS evidence supporting this request

Failed Back Surgery Syndrome (FBSS) efficacy and effectiveness

SCS is recommended as a treatment option for FBSS including, but not limited to:

- The Neuromodulation Appropriateness Consensus Committee (NACC) of the International Neuromodulation Society (INS)*,
- The American Society Of Interventional Pain Physicians (ASIPP)†,
- The American Pain Society (APS)‡,
- SCS is available to almost all commercially-insured enrollees in the U.S.,
- SCS is covered by a Medicare National Coverage Determination, and
- SCS is covered by 49/50 Workers' Compensation state agencies.

The decision to remove FBSS as an indication for SCS is contrary to the vast majority of commercial, Medicare and state based payer policies.

SCS is a clinically effective and cost-effective treatment option for patients with FBSS that is refractory to conventional medical management (CMM), supported by randomized controlled trials (RCTs). The level 1 clinical studies demonstrate that SCS is an effective therapy in significantly reducing pain in patients with FBSS as compared to best medical therapy or reoperation on the lumbosacral spine, 47-48% for SCS compared to 12% for reoperation and 9% for conventional medical management.^{1,2} The PROCESS study found patients reported significantly improved leg pain relief ($P < 0.0001$), quality of life ($P < 0.01$), and functional capacity ($P = 0.0002$) at 24 months after SCS implant as compared to baseline.³

There are also several large post market SCS registries reporting positive outcomes for 1,377 patients.⁴⁻⁶ One retrospective analysis including the experience of SCS in 452 patients over a 22-year period reports an early success rate of 80% (328 patients), and a long-term success rate of 74% (243 patients) after the mean follow-up period of 97.6 months (approximately 8 years).⁴

FBSS economic evidence

FBSS studies show that SCS is more cost-effective than CMM or reoperation. Five of the 6 cost-effectiveness publications evaluating SCS for FBSS report it is cost effective and below the commonly accepted willingness to pay threshold in the United States.⁷⁻¹¹ The sixth publication reports a SCS incremental cost greater than the pain clinic group at 24 months of \$14,297 and concluded "SCS is very probably not the most cost-effective treatment option at any threshold of willingness to pay because [usual care] patients had much lower costs and very similar outcomes."⁷ However, several methodological limitations are associated with this analysis relating to the underlying cohort study, the inclusion of non-implanted SCS patients in the SCS arm of the cost-effectiveness analysis, and a 24-month timeframe which has been shown to be too short for SCS to reach a cost-effective threshold.

IDD evidence supporting this request

Intrathecal Drug Delivery (IDD) efficacy and effectiveness

IDD is recommended as a treatment option for malignant and non-malignant pain including, but not limited to:

- The American Society of Interventional Pain Physicians (ASIPP)†,
- The American Society of Anesthesiologists (ASA)§,

- IDD is available to almost all commercially-insured enrollees in the U.S.,
- IDD is covered by a Medicare National Coverage Determination, and
- IDD is covered by 48/50 Workers' Compensation state agencies.

The decision to state “There is insufficient evidence to recommend the use of implantable drug-delivery systems (IDDS) for the treatment of chronic pain” is an outlier.

Intrathecal drug delivery is a clinically and economically effective treatment option for patients with chronic intractable pain that is refractory to conventional medical management. While long-term intrathecal delivery of opioids is not without risk, many of these risks can be mitigated through careful patient management and supervision including monitoring and adherence to dosing. The level 1 clinical studies demonstrate that IDD is an effective therapy in significantly reducing pain in patients with non-malignant pain compared to conventional medical management, 16%-31% for IDD compared to 6%-7% for placebo using the Visual Analogue Scale of Pain Intensity (VASPI), and 28% for IDD compared to 12% for placebo using the CGI Satisfaction scale.^{12,13} There are also non-randomized studies, both prospective and retrospective, reporting positive outcomes and reductions in pain for 551 patients with non-cancer pain.¹⁴⁻²⁰ One large prospective multicenter cohort study reported the Numeric Pain Rating (NPR) dropped by more than 47% for back pain and more than 31% for leg pain, more than 65% of implanted patients reduced their Oswestry disability scores by at least one level, 80% of implanted patients were satisfied with their therapy, and 87% said they would undergo the procedure again at the 12 month follow-up.¹⁴ Finally, a Cochrane systematic review concluded “Many patients discontinue long-term opioid therapy (especially oral opioids) due to adverse events or insufficient pain relief; however, weak evidence suggests that patients who are able to continue opioids long-term experience clinically significant pain relief.”²¹ While the majority of Workers' Compensation patients eligible for IDD are affected by non-malignant pain, it is important to note there is also Level 1 evidence for malignant pain. In a randomized controlled trial of 202 patients, IDD patients more often achieved >20% reduction in both pain VAS and toxicity as compared to CMM patients (57.7% vs. 37.5%, P = .02).²²

The use of IDD may lead to the elimination or significant reduction of oral medications. Physicians prescribing IDD can significantly decrease or taper patients off of oral opioids and exclusively deliver the pain medication intrathecally. Retrospective claims data have shown 51% of patients newly implanted with IDD completely discontinue oral opioids within the first year.²³ Using IDD as an alternate route of delivery for pain medication to appropriate patients can also lead to a lower risk of drug misuse and diversion in contrast to pills. With IDD, the pain medication is stored within a pump inside the body, making diversion quite difficult.

IDD economic evidence

Studies evaluating IDD to treat non-malignant pain show that IDD is cost effective and even cost saving compared to conventional pain management.²⁴⁻²⁸ In a retrospective database study using actuarial cost projections over a 30-year time horizon, the IDD financial break-even occurs soon after the second year post implant (27 months).²⁴ After three years of cumulative experience, the financial benefits of IDD therapy are derived from lower inpatient facility costs, fewer emergency department visits, fewer ambulatory surgeries, fewer office visits, fewer adjunctive therapies, and reduced prescription drug costs, with a lifetime annual per patient savings of \$3,111 for IDD compared with conventional pain management.²⁴ Additionally, a recent cost analysis and modeling study reports IDD to treat chronic

non-malignant pain is below the commonly accepted willingness to pay threshold in the United States.²⁵

Proposed MTUS Language

We understand the California guideline has used the Official Disability Guidelines (ODG) as the basis for its coverage decision. In reviewing the proposed MTUS language in comparison to current ODG language, it appears the language for IDD is nearly identical with one notable exception: the phrase “Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated in the blue criteria below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial” is present in ODG yet absent in MTUS. Given no additional evidence citations are present in the proposed MTUS language, we are curious as to how the removal of the first sentence can be substantiated. Similarly, for SCS for FBSS, the language is near verbatim, however, the statement “For use in failed back surgery syndrome (FBSS), see the Low Back Chapter” is present in ODG yet absent in MTUS. When the ODG low back chapter is reviewed for SCS, the first sentence states “Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated.” Again, given no additional evidence citations are present in the proposed MTUS language, we are curious as to how the change to recommending SCS for only CRPS can be substantiated.

We would also like to bring attention to the Washington State Health Care Authority (HCA) report (2008) cited by ODG and, by extension, the MTUS. The underlying technology assessment submitted to HCA by an independent center, the ECRI Institute Health Technology Assessment Information Service, concluded:

- “Implantable infusion pumps are reserved for individuals for whom conservative treatments and in some cases, surgery, have failed and surgical correction of cause(s) of pain is not an option.”
- “Drug infusion with an implantable pump leads to clinically significant pain relief in patients with chronic non-cancer pain.”
- “Intrathecal administration of opioids by implantable pump was associated with an overall decrease in the quantity of other drugs taken or a decrease in the proportion of patients taking other drugs.”

We have attached this report for your convenience.

IDD for cancer and non-cancer pain and SCS for FBSS are well-established treatment options with demonstrated efficacy and effectiveness in selected patients.

NOTE: Commenter submitted two attachments: 1) Systemic Opioid Elimination after Implantation of an Intrathecal Drug Delivery System Significantly Reduced Healthcare Expenditures and 2) HTA Final Report Implantable Infusion Pumps for Chronic Noncancer Pain. Copies available upon request.

I am a Board Certified pain management specialist in full time practice in California. I am also the Immediate Past President of the California Society of Interventional Pain Physicians, a member of the Policy Committee for the North American Neuromodulation Society and a Board Examiner for The American Board Of Interventional Pain Physicians. I am writing today to express great concern about the proposed Chronic Pain Treatment Guidelines.

More specifically I am concerned about the proposed restrictions on the use of Intrathecal Drug Delivery (IDD) and Spinal Cord Stimulation (SCS):

Failed Back Surgery Syndrome (FBSS) is the number one indication for Spinal Cord Stimulation in the United States. The use of SCS for neuropathic pain related to Failed Back Surgery Syndrome is endorsed by numerous specialty societies, including the North American Neuromodulation Society. It is covered by a Medicare National Coverage Determination, and is covered by the vast majority of Workers' Compensation state agencies. SCS has been endorsed for FBSS-related neuropathic pain by these entities because it is a proven and cost-effective treatment option for patients with this difficult to treat ailment. Like most Pain Management specialists, I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.

Similarly, IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines. It is available to almost all commercially-insured patients. In the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

In summary, the proposed restrictions on SCS and IDD run counter to prevailing conventional practice and the specific recommendations of the relevant specialty societies. These short-sighted and arbitrary restrictions will eliminate effective treatment options for injured workers and will only result in worse care and higher costs.

I strongly urge you to reconsider these misguided proposals.

William Longton, MD

December 18, 2014

I am a board certified anesthesiologist and pain physician, treating injured workers as well as senior citizens and cancer pain victims for over 20 years. I can wholeheartedly say that the use of SCS and intrathecal medication delivery is a life altering therapeutic, and is standard of care in refractory severe chronic pain in our country and in Europe. To eliminate the choice in injured workers is very disturbing to say the least.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for

injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

· **SCS:** SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.

· **IDD:** IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

Ruben Karla, M.D.

December 18, 2014

As Chairman of Pain Management for the John Muir Hospitals in Walnut Creek and Concord & as a pain physician taking care of hundreds of CHP officers, police, & fire, I am appalled by the latest guidelines, most notably on the criteria for spinal cord stimulation.

Why is the comment period so brief?

Who wrote these guidelines?

Where was input solicited?

Was input by patients included?

Was input by practicing pain physicians in California incorporated?

Gather the input of CSIMS & CASIPP- the work comp clinician group and California's largest pain clinician nonprofit respectively?

Fair disclosure is needed as these appear to have been written in the interest of saving money in the short-term & not in the interests of taking care of our injured officers & workers.

The data on the use of spinal cord stimulation for post-laminectomy syndrome is strong. I have plenty of CHP & fire patients who have benefitted, able to increase their function, regain a good quality of life, and reduce opiate use.

SCS helps reduce costly opiate use and the potential for addiction

Denial of this option to help our officers who have put their lives on the line is unacceptable,

Kayvan Haddadan, MD

December 18, 2014

SCS is a valuable treatment option for selected patients who still have pain after back surgery! Numerous studies showed the efficacy of the system and therefore its justification of using it is obvious even from financial point of view! Therefore I do not believe taking seat a treatment option from the patient would be beneficial for anybody involved.

Ripu Arora MD, MBA

December 18, 2014

I am an interventional pain physician practicing for past 25 years in South bay. I have been treating the injured workers with chronic pain with good outcomes. I am board certified in Pain management and Anesthesiology.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not support by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

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M. Lynch D.O.

December 18, 2014

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covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

This appears to be another step to eliminate Insurance liability for a treatment modality that will benefit patients.

SCS for Failed Back and a number of other options has been well documented, studied and PROVEN to be a modality that WORKS. But, if you choose to IGNORE the FACTS, then the patients have no option. Big gov't and big insurance takes another financial bite. More profit, less actual care. Soon it will be zero care. What a joke this system has become.

Lillian Huang, L.Ac., O.M.D.

December 17, 2014

I am an acupuncturist, a prior Q.M.E., and a board member of United California Practitioners of Chinese Medicine. I want to OPPOSE the proposed change to acupuncture treatments guideline.

I'm surprised by the proposed change to the acupuncture section in Chronic Pain Medical Treatment Guidelines. The professional community has not heard of any survey or any new studies that was done to validate this change to overwrite the current guideline. The proposed change would decrease patients' acupuncture visits by at least half. This will severely harm injured workers' recovery process.

In addition, I am also surprised about not recommending Carpal Tunnel Syndrome for acupuncture. My colleagues and I take care of many Carpal Tunnel Syndrome cases in our office and are effectively alleviating people's CTS pain and numbness each day. I don't see a sufficient study to show that CTS is not effective with acupuncture.

Acupuncture has shown to be an inexpensive and highly effective treatment in many chronic pain cases. Reducing initial acupuncture trial visits from 6 visits to 3-4 visits will not give some chronic pain cases enough time to feel the effectiveness of acupuncture. Having a total of 12 visits of acupuncture may be valid for a light to moderate case, but NOT enough for severe pain cases and for those who have multiple body part injuries and especially not enough for those who have chronic pain for over one or more years.

The unique part of workers' compensation cases is that many cases are due to repetitive strain injury, and the job continues to require them to use that specific injured body part; thus may cause flare ups. In the case of flare ups, another group of 6 or 12 visits may be necessary periodically.

As an acupuncturist and a QME who has worked many years with Worker's Compensation cases, I can responsibly comment that if this change get adapted, many injured workers will lose their chance of returning to work quickly.

Therefore, I OPPOSE this guideline on acupuncture.

Jonathan F. Kohan, MD

December 17, 2014

I am a physician who has been an advocate of IDDS utilization for intractable lumbar radiculopathy and those with history of FBSS. I am a Board Certified Anesthesiologist with formal training in Pain Medicine practicing for the past 13 years.

I am shocked at best that DWC is considering such update. There are ample literature supporting IDDS for the above diagnosis to a point that Medicare and various health carriers do cover them.

From a personal perspective, I have had great outcomes for those patients who have failed many intervention for their intractable cervical or lumbar pain. Such devices have helped my patients, as predicted by the related support literature, in increasing their function while decreasing the need for oral analgesics. IDDS have in many instances turned patients life around due to significant degree of relief.

I am strongly urging the Board not to adopt such revision and keep such remarkable option available to those in need. I do believe that still patient selection is crucial however to limit such device as noted goes against vast research, literature, and standard of care. It is important to know that IDDS are the last line of treatment for many patients whose life otherwise would stay miserable.

I hope that such drastic measure is not taken and that DWC considers my voice and others in the field who have had the same experience with IDDS.

Sandiford Helm, M.D.

December 17, 2014

The Helm Center for Pain Management

I wish provide some comments regarding the proposed changes to the Chronic Pain MTUS. I would like to specifically comment on the changes regarding spinal cord stimulators and the intrathecal delivery of medication.

I am physician practicing in California. I am a QME. I am board certified in Anesthesiology with subspecialty certification in Pain Medicine. I am also a diplomate of the American Board of Pain Medicine. My practice is limited to interventional pain management.

Spinal Cord Stimulation

The proposed Chronic Pain MTUS limits the use of spinal cord stimulation (SCS) to complex regional pain syndrome (CRPS), removing the current coverage of post lumbar surgery syndrome, also known as failed back surgery syndrome (FBSS). There are two high quality RCTs on the role of SCS in FBSS.[1, 2] Kumar looked at neuropathic leg pain after FBSS. He found that SCS provided improved pain relief, quality of life functional improvement and patient satisfaction compared to medical management. North looked at 50 patients and found that in FBSS patients, SCS was more successful than re-operation. There are also many observational studies showing the efficacy of SCS in FBSS.[3-13] The majority of the studies documented the efficacy of the procedure. SCS has also been studied for cost effectiveness.[14-16] Taylor, for example, found that SCS was cost effective both as a complement to conventional medical therapy and as an alternative to surgery.[14] Thus, with the plethora of high quality studies, both RCTs and observational studies, based upon the principles of evidence-based medicine, FBSS should be included as an indication for SCS.

Intrathecal Drug Delivery

Regarding intrathecal drug delivery (IDD), the proposed guidelines allow the use of IDD only for cancer patients. Again, this position is not consistent with the literature. It is true that Chou's guidelines for the American Pain Society claim a lack of effectiveness based upon limited RCTs. Chou's guidelines, however, were published in 2009 and, as of 1/1/2015, will therefore be more than 5 years old and hence not relevant according to CCR. Further, the ASIPP Guidelines[17] discuss multiple systematic reviews and guidelines. Hayek, in a systematic review based upon 15 observational studies, provided a moderate recommendation for the use of IDD in chronic non-cancer pain.[18] Guidelines from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine (ASRA) published in 2010 found IDD to be effective for neuropathic (non cancer) pain.[19] Falco found 7 non-randomized studies which provided limited evidence supporting the use of IDD.[20] There is substantial evidence documenting the efficacy of IDD. RCTs are extremely difficult to perform, if only for ethical reasons. It is important to not fall into the logical error of assuming that absence of evidence is the equivalent of evidence of absence. Further, Guyatt points out that of more than 9400 graded recommendations in UpToDate, approximately 2/3 are weak recommendations.[21] Guyatt goes on to say that standards are necessary to identify when clinicians can be confident in evidence and when they cannot. Further, Guyatt emphasizes that values and preferences are as important as evidence in determining optimal clinical decisions. A strong recommendation against the use of IDD for non-cancer pain is not supported by the evidence. A weak recommendation supporting the use of IDD for non-cancer pain is supported both by the evidence and by the application of guideline theory.

I respectfully request that DDWC not implement the proposed Chronic Pain Guidelines which exclude both SCS for FBSS and IDD for non cancer pain.

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Brandon A. Van Noord, M.D.
Pain Medicine Physician
Diplomat, American Board of Anesthesia

December 17, 2014

As a pain physician, I know first hand that back pain that doesn't respond to surgery is difficult to manage. I also know that high-dose, chronic opiates can certainly have adverse effects and potentially be counter-productive. I have also seen SCS be life-changing when used properly. We all operate under financial restraints and I appreciate the need to balance the budget and live within our means as a society.

However, please do not remove the indication for spinal cord stimulation for failed back surgery syndrome. There are only so many ways we can treat back pain. SCS has been shown to be more effective than re-operation. If you take away this option, it's one less option we have besides chronic opiates. Given the ongoing prescription drug epidemic, I think it's important to utilize every tool we have.

Max Moradian, MD
Interventional Pain Management
Southern California Orthopedic Institute

December 17, 2014

My name is Dr. Max Moradian, and I am a board certified physiatrist that practices interventional pain management in Bakersfield, CA. I treat a large amount of injured workers.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

- SCS: SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.

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Michael Romanowicz DMD, RPh
Head of Pricing and Healthcare Policy
Jazz Pharmaceuticals

December 17, 2014

We are pleased to submit comments to the California Division of Workers' Compensation (DWC) relating to the December 2014 forum posting of the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines. As a specialty biopharmaceutical company and the manufacturer of PRIALT® (ziconotide) intrathecal infusion, Jazz Pharmaceuticals seeks to improve patients' lives through the identification, development, and commercialization of innovative products that address unmet medical needs in specific therapeutic areas. We aim to ensure that patients have access to necessary therapies, and it is our understanding that some of the information contained in the MTUS Guidelines is incomplete regarding the indication, efficacy, and safety of Prialt and is inconsistent with the most recent (2012) update of the Polyanalgesic Consensus Conference (PACC) recommendations for the use of intrathecal drug delivery systems (IDDS) in the treatment of chronic pain.¹

Through these comments Jazz Pharmaceuticals would like to take this opportunity to clarify information in the MTUS Guidelines as well as provide additional information regarding the use of Prialt in the management of severe chronic pain. We respectfully request that the Division of Workers' Compensation review and consider our evidence-based comments and reconsider the proposed changes.

While page 130 of the MTUS Chronic Pain Guidelines document describes Prialt as a “non-opioid intrathecal therapy for the treatment of chronic pain”, the IDDS section on pages 70-72 appears to focus on intrathecal opioids. The evidence for the use of intrathecal morphine is generally based on nonrandomized studies that lack a placebo control group; however, the efficacy and safety of Prialt for the treatment of chronic pain was studied in three double-blind, placebo-controlled, multicenter studies in a total of 457 patients (268 Prialt, 189 placebo) using two different titration schedules.²⁻⁵ The two initial short-term studies utilized a fast titration schedule involving daily dose increases up to a maximum dose of 57.6 mcg/day in 5 to 6 days. While the fast titration studies demonstrated efficacy, there were high rates of serious adverse events and discontinuations. As a result, the third study was conducted using a slower titration schedule (starting dose ≤ 2.4 mcg/day titrated upward at intervals of ≤ 2 -3 times per week, up to a recommended maximum dose of 19.2 mcg/day), which improved the safety and tolerability of Prialt, and is the basis for the dose initiation and dose titration information in the Prialt prescribing information. The primary efficacy variable in the slow titration study was the mean percent change in the VASPI score from baseline to day 21. In the intent-to-treat efficacy analysis, there was a statistically significant difference between groups in the mean percent change in VASPI score (the primary efficacy variable) from baseline with the Prialt group having a 12% mean improvement at Week 3 compared to a 5% mean improvement in the placebo group. The 95% confidence interval for the treatment difference (Prialt–placebo) was 0.4%, 13%.² Most of the Prialt group had nonmalignant pain 108/112 (96%).⁵ A subsequent open-label study showed that the efficacy of Prialt was maintained during long-term treatment.⁶

The safety of Prialt has been evaluated in 1,254 patients with severe chronic pain, with a mean treatment duration of 193 days.² In evaluating the safety of IDDS it is important to distinguish among pharmacologic agents, because the safety profile of Prialt is substantially different from the safety profiles of opioids.² Unlike opioid medications, Prialt is not associated with tolerance or withdrawal, respiratory depression, and catheter tip granulomas.^{2,6,7,8,9} As noted on page 130 of the MTUS Guidelines, Prialt is associated with neuropsychiatric adverse events. While a history of psychosis is a contraindication to Prialt use, a history of depression is not a contraindication.²

Based on evidence from the aforementioned three randomized, placebo-controlled studies, Prialt was approved in 2004 by the US Food and Drug Administration for the management of severe chronic pain in adult patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatments such as systemic analgesics, adjunctive therapies, or intrathecal morphine.²⁻⁵ Patients who have failed (e.g. intolerant of or refractory to) previous systemic therapies may use Prialt as their first intrathecal agent. Failure of a trial of intrathecal morphine or hydromorphone (as currently stated on page 72 of the MTUS chronic pain guideline) is not required prior to initiating therapy with Prialt.²

The use of Prialt as first-line intrathecal therapy is supported by the 2012 PACC Guidelines.¹ The PACC panel of experts in the field of intrathecal therapy has convened at regular intervals since 2000 to review the research literature and provide updated recommendations regarding best practices for intrathecal therapies in pain management. The 2012 PACC Guidelines recommend that intrathecal drug delivery be considered as an option for patients requiring long-term management of refractory chronic pain. Prialt is recommended as first-line intrathecal therapy for both nociceptive pain and neuropathic pain.¹ Other first-line intrathecal therapies are morphine, hydromorphone, or fentanyl for nociceptive pain, and morphine or morphine + bupivacaine for neuropathic pain.

We also bring to your attention the following item under the Implantable drug-delivery systems/ Intrathecal drug delivery systems (IDDSs) Policy Topic Sections on page 71.

1. On Page 71 it appears there may be a typographical error in the content in the following section:
 - a. Section-Indications for Implantable drug-delivery systems;
 - b. Subsection: Permanently implanted intrathecal (intraspinal) infusion pumps for the administration of opioids or non-opioid analgesics, in the treatment of chronic intractable pain, are considered medically necessary

Content as written:

- “A temporary trial of spinal (epidural or intrathecal) opioids has been successful prior to permanent implantation as defined by a 50% reduction in pain. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met. Used for the treatment of non-malignant (non-cancerous) pain with a duration of greater than 6 months and all of the following criteria are met and documented by treating providers in the medical record:”

We recommend a formatting change on page 71 as reflected below which provides a greater degree of clarity with identifying when permanently implanted intrathecal (intraspinal) infusion pumps for the

administration of opioids or non-opioid analgesics, in the treatment of chronic intractable pain, are considered medically necessary.

Proposed Formatting Change:

- A temporary trial of spinal (epidural or intrathecal) opioids has been successful prior to permanent implantation as defined by a 50% reduction in pain. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met.
- Used for the treatment of non-malignant (non-cancerous) pain with a duration of greater than 6 months and all of the following criteria are met and documented by treating providers in the medical record:

We hope that you will find this information helpful and that patients will continue to have access to this important non-opioid therapy.

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Thomas Ahlborn, PhD, Lac

December 17, 2014

I am an acupuncturist and member of California Certified Acupuncture Association. The proposed changes in the Chronic Pain Medical Treatment Guidelines will reduce the number of acupuncture treatments to 3-4 over six weeks and 8-12 over twelve weeks, which is a reduction of the former

guidelines by nearly half. So far no evidence has been provided that justifies this reduction. This change appears to be arbitrary and without medical merit. Any changes in medical treatment without a basis in research, unfortunately costs the patient and delays their healing. I am requesting that the period for comments be extended by six months in order to adequately examine the evidence-based argument for this change.

Shishir A. Dhruva, MD
Medical Director, TPM Clinic

December 17, 2014

This email is in response to flawed proposed revised guidelines for the indications for Spinal Cord Stimulator (SCS) trial and implantation for injured workers (IWs) in the State of California.

I am a Board Certified pain management physician practicing in Shasta County. Over 90% of my patients are covered by State of California Worker's Compensation (WC) System. I mostly treat patients with chronic pain after an injury. These patients have in general have exhausted reasonable options to cure the effects of injury and now the chronic pain is affecting their lives and the lives of people closely associated with them (such as family members). Since 2004, the treatment options under CA WC system have been chopped away. Most recently use of opioid medications have come under scrutiny by several state and federal organizations (perhaps rightfully so), reducing options for relief from chronic pain. In my experience and also most of my fellow physicians, the expensive "Functional Restoration Programs" have never worked to relieve pain and suffering (despite being touted by the authors of ODG). While the Cognitive Behavioral Therapy (CBT) may help the patient realize that "the glass is half full", yet the fact remains that it does not relieve pain.

The lives of IWs and people around them are affected because of pain. They need help to reduce/relieve their pain to improve their quality of lives. As the treatment options have been gradually limited over the past 10 years, it is extremely unfortunate and unwise to even consider removing SCS as a treatment option for the patients suffering from Failed Back Syndrome (FBS) - a devastating condition after back fusion surgeries.

The SCS modality is accepted worldwide for the treatment of pain from FBS. Over the years, the devices have improved in technology with less risks etc. This non-narcotic treatment option has been proven in numerous scientific studies to help patients with FBS improve their pain and therefore quality of life. This modality is approved by almost every insurance company - including Medicare, Anthem, Blue Shield, Aetna etc. for FBS indication, after failure of reasonable prior treatment options. As you are aware 48 states' WC system approve the procedure for FBS indication. So, why are the IW in the State of CA different??? Why should they be treated with fewer options than the IWs in the rest of this country??? Why are scientific studies results are not applicable in State of California - when they are applicable for the rest of the world???

If the intention of the DWC is to reduce the cost of treatment of FBS, it should focus on the indications for the fusion- instrumentation surgery for treatment of back pain, rather than the treatment of pain after such surgeries. Perhaps too many surgeries are being performed for backs with are NOT unstable and do

NOT threaten spinal cord and nerves. Less such useless surgeries = less FBS = less overall cost to the employers and insurance companies.

Therefore, let's not deny a reasonable treatment of SCS for FBS patients - who have failed to respond to other reasonable treatments. SCS is proven to be effective and has been supported by scientific studies published in respected medical journals. The IWs in California deserve an access to the same treatment available to the rest of the world for FBS.

Carlyle R. Brakensiek, Executive Vice President
California Society of Industrial Medicine & Surgery

December 17, 2014

The California Society of Industrial Medicine and Surgery, Inc. (CSIMS) appreciates this opportunity to provide comments on the proposed modifications to the Chronic Pain Medical Treatment Guidelines (CPMTG).

CSIMS is a professional organization whose members are physicians who provide medical treatment and evaluation to California's injured workers. CSIMS' purpose is to improve the workers' compensation system in California; to increase the public's awareness of the role of medicine in the workers' compensation system; to promote health and safety; to provide continuing education in the field of industrial medicine and to set standards of professional conduct for those in the system.

As a leading organization representing physicians who directly apply and interpret the treatment guidelines promulgated by the Department of Industrial Relations, Division of Workers Compensation, Medical Unit, CSIMS members have very serious concerns about the proposed modifications to the CPMTG which consist of an edited version of the ODG "Treatment in Workers' Compensation-Chapter on Pain (Chronic)," published April 10, 2014.

CSIMS' primary concern focuses on the proposed CPMTG insofar as it deviates from the ODG Guidelines. In several instances, the ODG protocol has been altered in a manner that creates a conflict between the state's recognition of the need to address chronic pain as a separate aspect of injury and the acute injury treatment protocols already in existence in the State's Medical Treatment Utilization Schedule (MTUS) set forth in *California Code of Regulations, Title 8, Sections 9792.20 et seq.* Specifically, there are two general categories of injuries: acute and chronic. Acute injuries are recent in occurrence and require immediate intervention. By definition, acute injuries tend to resolve within the first 90 days of occurrence. As detailed in the CPMTG, chronic pain is "pain that persists beyond the anticipated time of healing without plans for curative treatment that meet MTUS Guidelines, such as surgical options." Hence, chronic pain is pain that exists beyond the anticipated time of healing, generally categorized as 90 days, for which immediate curative surgical options are not available.

CSIMS is concerned that the altered version of the ODG guidelines contained in the proposed CPMTG severely limits the treatment options available to injured workers who suffer from chronic neck, upper and low back pain. This is a major concern to CSIMS members because back complaints are the most common problems presented to occupational health and primary care providers. (See,

ACOEM-Chapter 12 at pg. 287.) The proposed CPMTG removes curative treatment options available to reduce and/or eliminate pain associated with chronic neck, low and upper back orthopedic conditions by referring the physician treating a chronic pain patient to the acute pain protocols. This occurs because the proposed CPMTG incorporates the acute MTUS treatment protocols detailed in *California Code of Regulations, Title 8, sections 9792.23.1* [Neck and Upper Back Complaints] and *979 2. 23. 5* [Low Back Complaints] into the suggested amendments to the CPMTG. These acute spinal MTUS guidelines do not comprehensively address the treatment protocols for chronic pain.

CSIMS does not oppose the adoption of the Official Disability Guidelines on Pain (ODG) published by the Work Loss Data Institute. However, CS IMS is concerned about the modification of the ODG Chronic Pain chapter in that the proposed CPMTG differs from the ODG treatment guidelines published on April 10, 2014.

CSIMS respectfully recommends that the proposed CPMTG be modified to delete any incorporation of the acute DWC treatment guidelines for low back, neck and upper back complaints. The physician treating chronic orthopedic conditions should not be directed to treatment protocols designed solely for acute care patients.

Gary L. Baker, MD, QME, Director
Advanced Pain Specialists of Southern California

December 17, 2014

I have over 15 years of experience in managing chronic pain patients in both medical/legal and private sectors. For a select group of these patients, spinal cord stimulators and intrathecal pumps have proven invaluable in controlling pain, restoring function, improving quality of life, and in the long term reducing costs associated with ER visits, medications, surgeries, and other interventions. Many of these patients have failed spinal injections, opioid medications, multiple surgeries, and behavioral programs. For most of these patients these devices were the last resort option for their intractable chronic pain. I agree with the many concerned physicians who have voiced their concern in this forum regarding the proposed restrictions in accessing these important devices. I would ask that the DWC consider the arguments presented.

Please also consider the unintended consequences of significantly restricting diagnostic indications for intrathecal pumps and spinal cord stimulators. There are at a minimum hundreds of patients who currently have these devices and will need ongoing support such as reprogramming the spinal cord stimulator or refilling the intrathecal pump. Many will also need the batteries replaced over the years to allow continued operation of the devices. Solid criteria (nationally recognized scientifically based medical evidence) was met prior to implanting these devices. Now, based on the new DWC proposal, seemingly arbitrary interpretation may be used to deny any further treatments related to these devices, even if the patient was doing exceptionally well with the device. This has already happened even with the current guidelines. I can only see things becoming untenable if the new DWC proposal for these devices passes as written.

What will happen when patient X (who has used a spinal cord stimulator/ intrathecal pump for failed low back surgery syndrome for many years) now needs the battery changed or the pump medication refilled but they are denied because they no longer meet “diagnostic criteria”?

Jacob Godwin, DAOM

December 17, 2014

I am a clinician and researcher. The proposed changes in the Chronic Pain Medical Treatment Guidelines will reduce the number of acupuncture treatments to 3-4 over six weeks and 8-12 over twelve weeks. This is a reduction of almost half from the former guidelines. No evidence is provided to support this reduction. Any changes to current practice standards should be based on evidence. I am requesting that the prior for comments be extended by six months in order to adequately examine the evidence-based argument for this change.

Wei Wei, L.Ac., Ph.D.

December 17, 2014

I am Wei Wei, a licensed acupuncturist in California. I received my acupuncture education in China and my Doctoral degree in Chinese Medicine in the US. I have practiced acupuncture in California for over 20 years.

I hope the DWC will not low the cap for acupuncture from 24 to 12 sessions. The fundamental purpose of medicine is to heal people through proper treatment. I believe this is the goal of the State Workers Compensation system. The injured worker ideally should be able to return to his/her work position without pain or with minimum tolerable pain after adequate treatment from doctors. If for some reason they are disabled, the treatments will be more an ongoing thing on the as-needed basis. On the other hand, the effect of acupuncture has been proven by NIH study. Its efficiency is accumulative. From my professional experience, patient with chronic pain might response after first 3 visits and start to show improvement after 6 visits. Most of them will reach maximum recovery or recover completely after continued acupuncture treatment for about 24 sessions.

Nathan Miller, M.D.
Coastal Pain & Spinal Diagnostics Medical Group

December 17, 2014

I have been made aware that a draft guideline has recently been issued and that the Division of Workers Compensation is now receiving comments on those proposed guidelines regarding Spinal Cord Stimulation (SCS) and Intrathecal Drug Delivery Systems (IDDS).

With regard to SCS, please be aware that SCS has been around for decades. It is currently and has been a treatment option for Failed Back Surgery Syndrome. The scientific literature strongly supports the use of SCS for the treatment for failed back surgery syndrome. Please refer to studies by Kumar et al Pain 2007:132(1-2):179-88. and North RB et al Spinal Cord Stimulation vs Repeat lumbar sacral spine surgery for chronic pain a randomized common control trial. Neurosurgery. 2005:56:98-107. Further, numerous medical professional society guidelines recommend the use of SCS for Failed Back Surgery Syndrome. In addition, almost all commercial insurance plans and Medicare covers SCS for Failed Back Surgery Syndrome. In addition, it is my understanding that it is covered by 49 of all 50 work compensation state agencies.

Anecdotally, I can report that SCS is clinically effective. I have placed SCS now for more than 10 years and the majority of the implanted units are successful for long term pain relief especially in patients who have few if any other options.

With regard to IDDS, again the literature for the use of these systems is well supported. Please refer to studies by Rauckrl et al. A randomized double blind placebo controlled study of intrathecal ziconotide in adults with severe chronic pain. Journal of Pain and Symptom Management 2006:31(5):393-406. Deer T et al Intrathecal drug delivery for treatment of chronic low back pain: Report from the National Outcomes Registry for low back pain. Pain Medicine. March 2004:5(1):6-13. I will also point out that numerous professional medical societies recommend IDDS for the use for chronic non-malignant pain. In addition, almost all commercially insured enrollees in the United States have coverage for IDDS through their PPO plans. Medicare also covers these systems and is covered by 48 of 50 work compensation state agencies.

In addition to the scientific literature that is available, I can again report anecdotally IDDS have produced significant success in terms of pain relief in number of my patients in over the years. I have been very gratified to see the addition of ziconotide which is a calcium channel blocker only available only by the intrathecal route which has produced substantial pain relief in patients who suffered severe and horrible pain for many years without adequate relief. These systems have been a great blessing to these patients.

Therefore by way of this letter, I am asking that the California Workers Compensation System continue their coverage of the Failed Back Surgery Syndrome for SCS and continue coverage of IDDS for non-malignant pain.

Kevin Kohan, D.O., Q.M.E.

I am a board certified pain management physician practicing in the State of California and recent QME. I am board certified by American Board of Physical Medicine and Rehabilitation, with added qualification in Pain Management.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

The proposed changes to MTUS regarding Spinal Cord Stimulators (SCS) and Intrathecal Drug Delivery (IDD) systems are unduly restrictive and will certainly harm patients who otherwise have no safe reliable option for treatment of chronic pain.

SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers. The number one indication for SCS is back pain. Numerous patients have benefitted from it. Great number of studies published in prestigious journals attest to that. I have many patients that have greatly benefited from SCS therapy for their back pain as well.

IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers. IDD is a last resort therapy for patients who do not respond to conservative therapy and surgeries. New medications and techniques are revolutionizing the way IDD is used for chronic pain. It is unfair to our State's Workers Compensation patients not to have access to this treatment. Criteria for IDD are more limited, but again numerous studies support its use for chronic pain.

Furthermore, unlike most treatment plans, prior to implanting an SCS or IDD device, a temporary trial of the planned treatment is done to make sure the patient actually would benefit from the device. Instead of the proposed deleterious changes to MTUS, we should simply adopt and enforce the strict protocols already in place by various medical societies such as ASIPP and accepted by several insurance companies.

Steven H. Stumpf, Ed.D
Vice President, Education
National Guild of Acupuncturists & Oriental Medicine

December 17, 2014

The proposed changes in the Chronic Pain Medical Treatment Guidelines will reduce the number of acupuncture treatments to 3-4 over six weeks and 8-12 over twelve weeks. This is a reduction of the former guidelines by nearly half. No evidence is provided to justify this reduction. The change appears

to be arbitrary and without medical merit. Changes in medical treatment without basis in research inevitably cost the patient. I am requesting that the prior for comments be extended by six months in order to adequately examine the evidence-based argument for this change.

Paul H. Chiu, MD

December 17, 2014

I am a board certified Anesthesiologists with added qualification in pain management. I am an active interventional pain specialist treating chronic pain patients in Los Angeles area.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not support by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

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Francis Riegler

December 17, 2014

I treat many injured workers here in California.
I am on the Board of the California Society of Industrial Medicine and Surgery.
This cannot be allowed to stand.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for

injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

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Michael Chang, DO

December 16, 2014

As an active practicing physician with 8 years of experience in caring of chronic complex medical and painful conditions in this population, these guidelines will further limit the ability to appropriately care for these patients. Many of the new proposed guidelines are in contrary to several national society and ODG guidelines. In particular, the ASSIP and ISIS guidelines.

One glaring omission is the facet blocks. According to both ASSIP and ISIS guidelines, two sets of differential medial branch blocks should be performed to confirm the source of pain prior to performing a radiofrequency ablation. The proposed MTUS guideline only requires only one set of medial branch block which I believe will lead to greater number of unnecessary radiofrequency ablation procedure. I urged the committee to reconsider this point in particular in the guideline. Thank you for your time and attention.

Bob Hanson, MD

December 16, 2014

I AM BOARD CERTIFIED IN ANESTHESIOLOGY, INTERNAL MEDICINE AND CRITICAL CARE. I PRACTICE PAIN MANAGEMENT AND TREAT MANY WORK COMP PATIENTS.

THE PROPOSED CHANGES TO THE GUIDELINES FOR MANAGING CHRONIC PAIN HAVE SIGNIFICANT PROBLEMS THAT WILL BE DELETERIOUS TO QUALITY OF CARE AND WILL PROHIBIT THE USE OF PROVEN MODALITIES TO TREAT CHRONIC PAIN FOR INJURED WORKERS.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

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Jill Gambaro, Author
The Truth About Carpal Tunnel Syndrome

December 16, 2014

I write these comments on your proposed Chronic Pain Treatment Guidelines as a former injured worker who spent five years in the California workers' compensation system. I remain a chronic pain patient, 14 years later. I'm also a former board member of the Los Angeles Repetitive Strain Injury Support Group and the Cumulative Trauma Disorders Resources Network, as well as the author of *The Truth About Carpal Tunnel Syndrome*.

Overall, your guidelines take the view that chronic pain happens through psychosocial factors that are arguably not work-related, and believe me, lawyers will argue about that. Where does that leave the injured worker? You should be aware that, to patients, chronic pain happens when medical science fails. Fails to understand, fails to accurately diagnose, fails to effectively treat, fails to adequately provide care. Because of your own treatment guidelines, and the legal questions at the crux of the workers' compensation system, the system itself is a psychosocial factor that should be included. A statistical analysis of the injuries and illnesses most prevalent in chronic pain patients in the system, you will see a very definite pattern: those that are difficult to diagnose, require multidisciplinary approach, or who respond far better to treatments not sanctioned by the workers' compensation system.

Specifically, the characterization of chronic pain in these guidelines is taken completely out of context of the workers compensation system itself, which, in my view will provide some improvements in pain management, but do very little to effect the bottom line. Since "Studies have shown that the longer a patient remains out of work the less likely he or she is to return. Similarly, the longer a patient suffers from chronic pain the less likely treatment, including functional restoration efforts, will be effective", the best way to reduce chronic pain in the workers compensation system is to address the delays and inadequacies of care, and delays in disability benefits endemic to the system itself. While I applaud broadening the proposed guidelines to encompass a multidisciplinary approach, absent solutions to the

above I believe these new guidelines will only produce limited results. Particularly in the case of repetitive strain injuries, which account for 60% of all work-related injuries, where, in California, such patients are three times more likely to end up with permanent disabilities and get stuck in the system three times longer than any other injury or illness.

In my opinion, the definition of chronic pain contained in your proposed guidelines is again out of context and shortsighted. "Chronic pain persists beyond the usual course of healing of an acute disease or beyond a reasonable time for an injury to heal." In my experience, chronic pain also persists when an injury is either inadequately treated or is poorly understood by medical science. I recognize there are many reasons for this outside the scope of your guidelines, however, rather than attempt to deny these conditions, these are exactly the ones most likely to produce chronic pain.

Your definition of "Illness behavior model" again omits the critical impact of the stress of navigating the system, of the patient/injured worker at the center of a legal battle, perhaps for the first time in their life, of having so little control over their healthcare, finances, and job status. Enroll them as partners in their care from the onset and you will tremendously reduce their stress, and their chronic pain.

I would propose that certain work-related injuries and illnesses most likely to lead to chronic pain, be handled differently from the beginning of an injured worker's course of treatment. That pain interventions, self-management and functional restoration be addressed immediately with the patient, rather than once their pain is deemed to have transferred from acute to chronic.

Your discussion on functional restoration is really about patient engagement. While it may seem to an outsider that having an excuse to get out of work, any excuse, is better than working, in my experience, this is not true at all. I say this not just for myself, but for all the patients I met in physical therapy, pool therapy, and group psychotherapy, in waiting rooms at every appointment I went to throughout my five years in the system. These number close to a thousand. Each and every one would have been much better off had they been able to maintain some sort of work activity. Work gives us purpose, even if we don't like our job and even if we think we don't want to work. Purpose helps us go on when the rest of our lives have disintegrated entirely, which is what it feels like when you have a catastrophic medical condition, have lost your job and your income. Finding ways to enroll injured workers in their own functional outcomes from the very beginning would provide this purpose and, I believe, present far better return-to-work outcomes.

I suggest this be constructed similar to a vocational rehabilitation model, require employers have a return-to-work program in place, and be implemented as quickly as a claim is filed.

Vincent J. Valdez, MD

December 16, 2014

I am a Pain Management Physician in the Los Angeles area for the past 20 years, and previous director Pain Management at USC. (University of Southern California)

I am writing in regards to concern of proposed Work Comp changes for Chronic Pain patients:

Spinal Cord Stimulation and Intrathecal Drug Delivery devices are both very effective treatment modalities for treatment of intractable pain in the FBSS (Failed Back Surgery Patients) and complex regional pain syndrome patients. It would be a true injustice if the Work Comp patients are denied access to Intrathecal medication delivery pumps and Spinal Cord Stimulation. There are numerous peer review level 1 papers authored by Dr. Richard North and Dr. Kumar demonstrating the effectiveness as well as cost efficacy of Spinal Cord Stimulation as well.

Please vote to keep these therapies viable in the treatment armamentarium to help these patients treatment their intractable pain. Please feel free to visit with any of my patients to discuss the value of life changing modalities.

Miguel A. Dominguez, MD, DABA, DABIPP, FIPP

December 16, 2014

This report is to object the current proposed MTUS 2014 DWC guidelines for the injured worker in the state of California.

As an active practicing physician in caring of chronic complex medical conditions in this population, these new guidelines will further limit the ability to appropriately care for these patients. With the current limitations on the use of pharmacological agents, they will further be limited in options for medical management in the chronic state.

Furthermore, the new proposed, December 2014 guidelines are in contrary to several national society and ODG guidelines.

A few major examples on detrimental changes in the guidelines include the new proposal to deny intrathecal infusions (IDD) and limit spinal cord stimulation to one diagnosis. Multiple studies and experience has shown that these technologies are medically necessary and appropriate for patients with a history of nerve injury (chronic neuropathic pain) to include but not limited to post laminectomy back pain syndrome, phantom pain, other peripheral nerve injury cases. Again for the patient who does not respond to the limited pharmacological approach, he/she will have extremely limited treatment options.

In summary, I urge DWC not to approve the current proposed December 2014 MTUS guidelines with respect to the following treatments:

- 1). SCS: SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.

2).IDD: IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

Miguel A. Dominguez, MD, DABA, DABIPP, FIPP

December 16, 2014

The new proposed MTUS guidelines for injured workers in the state of California are going to further limit appropriate and medically necessary care. The new proposed, December 2014 guidelines, are in contrary to national society and ODG guidelines. A few major examples include the new proposal to limit spinal cord stimulation/intrathecal opioid effusions-IDD to one diagnoses. Multiple studies and experience has shown that this technology is medically necessary and appropriate for patients with a history of nerve injury (chronic neuropathic pain) to include but not limited to post laminectomy back pain syndrome, phantom pain, other peripheral nerve injury cases. Again for the patient had does not respond pharmacologically and who has debilitating pain, will not have the option to undergo trial and treatment with these modalities.

In summary in summary these do not approve the current proposed December 2000 410 MTUS guidelines with respect to the following treatments:

1). SCS: SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.

2).IDD: IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

Kasra Amirdelfan, MD
Interventional Spine & Pain Medicine

December 16, 2014

I am an interventional pain physician with 16 years of experience with spinal cord stimulation. I am very concerned about the proposed changes for the utilization of SCS in the workers' compensation space. First and foremost, spinal cord stimulation (SCS) has proven to be extremely helpful in previous landmark studies performed by reputable physicians, such as Drs. Kumar and North. Moreover, I have seen, firsthand, the positive impact that these devices have had on my patients' lives. I have time and time again been able to reduce the patients' medications and increase their function. This is in par with what we have seen in previous studies. No medication or other modality has been proven to do so.

I believe this modality to be extremely useful in the treatment of multilevel lumbar DDD, Failed Back Surgery Syndrome and Chronic Stable Radiculopathy.

I will be the first to admit that access to such implantable devices should be limited to those who have ample experience with these implantations and those who have shown better than average trial to perm ratios. However, this will take further discussion, in order to be able to implement a practical plan which will save the modality for our patients and curb the cost for the carriers.

I would be more than happy to help in this endeavor if necessary.

Furthermore, the latest research with high frequency technology is able to show much better outcomes (up to 100% better) than the current conventional stimulators. To emphasize its efficacy, we have been able to, for the first time, introduce the concept of remission to pain management just like it has been used in Psychiatry and Oncology.

I believe in better quality of care and monitored access to these and any other modality which has shown to be so effective for our patients. I am also happy to assist in this process as much as possible.

I would ask you to delay any limitation to this modality until we can all have more discussion on providing this type of implanatable technology in a more expeditious manner.

This is also true for implantable pumps which have proven to be an excellent mode of medication delivery, eliminating grave side effects for the patients, while maintaining or increasing their function.

Robert Ward, Clinical Director
CID Management

December 16, 2014

As the California Chronic Pain Medical Treatment Guidelines of May 2009 are now 5 years old, and there are some meaningful changes in the evidence behind treatment of chronic pain, revision is greatly appreciated, as are the efforts of those who created the new draft.

Below are a series of constructive criticisms intended for improvement of the Chronic Pain Guidelines. Each identified issue is paired with at least one suggestion for resolution.

Thank you for your consideration of these comments.

Significant portions of the draft reference a guideline that may not yet exist, preventing contextual assessment

Problem: Recommendations for opiates in the proposed guideline defer to the DWC “Guideline for the Use of Opioids to Treat Work-Related Injuries”.

While a draft of the DWC “Guideline for the Use of Opioids to Treat Work-Related Injuries” was issued for public comment in April 2014, there was no actual adoption of that guideline. Consequently, it is unknown whether the version of the opioids guideline that was submitted for public comment will be adopted; or whether some amended version of it will eventually be adopted.

Because the opioids guideline has not yet been finalized, it is not possible to compare that guideline to the current proposed Chronic Pain Guideline for consistency.

Solution: Consider repeating the public comment process for the Chronic Pain Guidelines of April 2014 after the DWC “Guideline for the Use of Opioids to Treat Work-Related Injuries” has been finalized.

Undefined services create an inherent conflict between the MTUS and the Labor Code

Problem: Instances of MTUS support for a non-specific collection of medical treatment creates a conflict between the MTUS and LC4610(g)(4). This issue can be corrected with very minor amendments.

LC4610(g)(4) requires that "Communications regarding decisions to approve requests by physicians shall specify the specific medical treatment service approved." This is likewise echoed in 8CCR9792.9.1(d)(1), which states that, " All decisions to approve a request for authorization shall specify . . . the specific medical treatment service approved, . . ."

Because any authorization must specify the specific medical services being authorized, in instances where the MTUS supports a model of treatment that is a non-specified collection of services, it follows that a request for the model of treatment cannot be authorized unless the treating physician first specifies the specific services to be included.

However, the draft of the Chronic Pain Medical Treatment Guidelines of April 2014 contains several instances when a non-specific model of treatment is supported. This often leads to a procedural impasse, in which the treating physician can accurately assert that the non-specific treatment plan is supported by the MTUS; and yet authorization for that service cannot be made in a manner consistent with statute.

Nearly all of these instances in the current draft concern recommendations for programs. A program is not a specific medical service. Rather, it is a collection of medical services. It is quite common for program providers to request a number of hours, days or weeks of a particular program type; without providing any indication as to what services are to be included, or what quantity of each service is being requested. Treating physicians are usually reluctant to provide such information when asked, which leads to delays in providing such programs.

A similar issue also exists for the guideline entry for "Detoxification". While the appropriate length of inpatient stay for rapid detox is indicated elsewhere in the draft, it is not uncommon to see a request for authorization of a "detox program", without any indication as to what specific services are being sought.

Suggested solution: For each type of program that is recommended within the MTUS, language can be added that indicates that requests for program authorization must include the specific medical services to be included in the program, and the quantity of each.

Alternatively, a separate, single entry can be created for "Programs" that contains this requirement.

The following programs are named in draft guideline:

- Biopsychosocial model of chronic pain
- Chronic pain programs
- Chronic pain programs, early intervention
- Chronic pain programs, opioids
- Functional restoration programs
- Interdisciplinary rehabilitation programs
- Multidisciplinary programs
- Pain management programs
- Progressive goal attainment program

Similarly, the draft should be amended to indicate that any request for authorization of detoxification should specify the nature and quantity of medical services to be used for that purpose.

The draft inappropriately classifies vocational rehabilitation services as medical treatment

Problem: The current draft classifies vocational rehabilitation as medical treatment; and this will probably create conflicts with LC4658.5 and 4658.7.

Historically, injured workers have had access to 3 major categories of benefits under the worker's compensation system: medical treatment; financial compensation; and vocational rehabilitation.

At the present time, vocational rehabilitation (training the injured worker for alternative employment when it is clear that the effects of the industrial injury or illness will prevent return to their usual and customary employment) is afforded to injured workers when, and as, described in Labor Code 4658.5 and 4658.7.

The current draft recommends vocational rehabilitation as medical treatment; as a component of both any chronic pain program and any functional rehabilitation program. As this could result in authorization of vocational rehabilitation that is different in both timing and nature to that required by Labor Code 4658.5 and 4658.7, this should be corrected.

Solution: Remove any mention of vocational rehabilitation from the recommendations for both chronic pain programs and functional rehabilitation programs.

Recommendations for amendment of specific guideline topics

Anxiety medications in chronic pain: Benzodiazepines are said to be "not recommended for long term use unless the patient is being seen by a psychiatrist." There are 2 potential issues with this

recommendation. The first is that there is no indication as to what would constitute "long term use"; it is recommended that this term be defined in some way. The second is that the necessary and sufficient condition for continuation of use per this guideline is the involvement of a psychiatrist; without any consideration of the status of the actual patient or the outcomes of use of this class of medications. It is recommended that criteria for long term use be established that are based on the patient, and not on the specialty of the treating physician.

Aquatic therapy: Should include clarification that unsupervised pool use is not aquatic therapy.

Armodafinil (Nuvigil): Guideline draft does not actually contain a recommendation for or against the use of this medication for any condition or patient population. It is recommended that criteria for appropriate use be added.

Co-pack drugs: The guideline draft states that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While this is a common occurrence, it is also true that there are co-packs that are a convenience packaging of 2 drugs into a single-dose packet; such as a co-pack of naproxen with omeprazole. It is suggested that the definition of co-pack be expanded to include convenience packaging of multiple medications, even in the absence of medical foods..

Cyclobenzaprine: Recommended as a short course of therapy. It is recommended that the draft be appended to include an upper limit of duration for "short course"; and clinical criteria for exceeding that limit.

Fenoprofen: The available comparative studies of Fenoprofen to other NSAIDs indicate that it is less effective than Naproxen or Ibuprofen and has a higher rate of GI bleeding. Given that this medication is less effective, less safe and much more expensive than other alternatives, there should be some criteria for when this medication, rather than a first-line NSAID, should be used.

Functional improvement measures: It is recommended that this section be appended to contain language that indicates that serial Functional Capacity Evaluations should not be used to monitor functional improvement arising from treatment.

Home health services: Consider setting an upper limit on the time per day or week for such services; based on the notion that at some point, if a patient requires constant or near-constant attention, consideration should be given to whether inpatient care of some type is actually more appropriate. If added, also consider adding criteria for recommending home health services that exceed that upper limit.

As an example, the CMS Benefits Manual currently limits such services to no more than 8 hours in any day and no more than 28 hours in any week.

Nerve blocks: Mentioned under this heading is only IV regional sympathetic blocks for RSD. Consider adding mention of medial branch block and facet neurotomy; selective nerve root block; and peripheral nerve block

Office visits: The language here says, "Recommended as determined to be medically necessary." This suggests that whatever the UR or IMR physicians deem to be necessary is presumed to be correct. If that was not the intended recommendation, then some clarification would be advisable.

Additionally, while this guideline recommendation discusses the frequency and total number of such visits, there is no discussion of the medical necessity of various levels of service (e.g., Level 1 through Level 5; or, 99211 through 99215). It may be worthwhile to add recommendations with respect to the level of service as well.

Opioids, state medical boards guidelines: This entry states that, "Under prescribing pain medications is considered as much a breach of the appropriate standard of care as overprescribing." While the intent of this statement is appreciated, without any guidance as to how to distinguish between ineffective treatment of pain and under treatment of pain, this language creates an inconsistency within the MTUS. In cases where opiates have been used but pain has not been satisfactorily relieved, it will be very difficult for treating and reviewing physicians to determine what outcome (increasing dosage vs. discontinuation) is consistent with the MTUS.

Psychological treatment: The recommendation here indicates why this type of treatment should be initiated. However, there are no suggested patient selection criteria. There are no suggestions regarding duration of appropriate trials of such treatment; no suggestions regarding appropriate outcome measures for such treatment; and no suggestions for criteria for continuation of such treatment. There are also no suggestions for overall duration of such care. It is recommended that such additional information be added to this entry, as without it, any and all requests for psychological care for patients with chronic pain will be supported by the MTUS; on a never-ending basis; even if ineffective.

Testosterone replacement therapy: The recommendation for this topic offers no suggestion as to what levels of serum testosterone on pre-treatment testing indicate a need for supplementation. Consider adding such a recommendation.

Vimovo: This medication is a compounded mixture of esomeprazole and naproxen. The current retail cost of Vimovo is approximately \$17.50 per tablet for 500mg naproxen and 20mg esomeprazole. The current retail cost of a 500mg naproxen tablet is \$0.20, and for a 20mg esomeprazole, \$0.65 (cost per equivalent treatment \$0.85). This makes treatment with Vimovo 20 times as costly as equivalent treatment with 2 separate tablets. Consider recommending against this medication as being excessively costly as compared to identical treatment; and/or providing patient selection criteria for treatment with Vimovo rather than naproxen with a proton pump inhibitor.

Weaning, carisoprodol (Soma): The guideline should be amended to indicate what constitutes high dosage, as this impacts the tapering schedule and method.

The recommendation for tapering from high dosages via transition to phenobarbital is based on a schedule that is not included in the guideline; and the referenced source is a medical textbook that is not publicly/freely available. It is strongly recommended that the guideline entry be amended to include a tapering schedule for this common medication.

Weaning of polypharmaceuticals: The current draft contains no entry on this topic. It should have one.

It is exceptionally common to see chronic pain cases with a patient who is taking multiple classes of medication without satisfactory relief or functional improvement. Often, multiple medications require tapering. There should be a recommendation as to whether multiple medications can be safely and effectively tapered simultaneously; and if not, which medications should be tapered first.

Shahin A. Sadik MD, QME

December 16, 2014

I am a pain management physician practicing in the State of California since 1993. I am a QME since 2005. I am board certified by American Board of Anesthesiology, with added qualification in Pain Management. Last year, I passed my recertification exam for another 10 years. I am also board certified by American Board of Pain Medicine.

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature. I believe that the clinical evidence supports maintaining the recommendations contained in the current version of the CA (MTUS).

The proposed changes to MTUS regarding Spinal Cord Stimulators (SCS) and Intrathecal Drug Delivery (IDD) systems are unduly restrictive and will certainly harm patients who otherwise have no safe reliable option for treatment of chronic pain.

SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers. The number one indication for SCS is back pain. Numerous patients have benefitted from it. Great number of studies published in prestigious journals attest to that. I have many patients that have greatly benefited from SCS therapy for their back pain as well.

IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers. IDD is a last resort therapy for patients who do not respond to conservative therapy and surgeries. New medications and techniques are revolutionizing the way IDD is used for chronic pain. It is unfair to our State's Workers Compensation patients not to have access to this treatment. Criteria for IDD are more limited, but again numerous studies support its use for chronic pain.

Furthermore, unlike most treatment plans, prior to implanting an SCS or IDD device, a temporary trial of the planned treatment is done to make sure the patient actually would benefit from the device. Instead of the proposed deleterious changes to MTUS, we should simply adopt and enforce the strict protocols

already in place by various medical societies such as ASIPP and accepted by several insurance companies.

Barbara Marcanti, Global Director
Healthcare Economics and Health Policy
Neuromodulation Products
St. Jude Medical, Inc.

December 16, 2014

On behalf of St. Jude Medical, Inc., a manufacturer and distributor of Spinal Cord Stimulation systems used in the treatment of chronic intractable pain of the trunk and limbs, we wish to voice our objection related to the proposed changes to the CA DWC Chronic Pain Medical Treatment Guideline posted on the DWC website on December 8, 2014.

St. Jude strongly opposes the elimination of coverage for Spinal Cord Stimulation (SCS) treatment for the indication of Failed Back Surgery Syndrome (FBSS) and respectfully requests that SCS treatment for FBSS be included (reinstated) in the Chronic Pain Medical Treatment Guideline and available for injured workers in the State of California. There does not appear to be any basis for DWC's elimination of coverage for FBSS. The elimination of coverage for FBSS leaves a patient with chronic pain due to FBSS with reduced treatment options potentially diminishing the opportunity for return to maximum medical improvement (MMI) and work.

SCS is recommended as a treatment option for FBSS in several physician society guidelines; and, is available to almost all commercially-insured beneficiaries in the U.S., is covered by a Medicare National Coverage Determination, multiple Medicare Local Coverage Determinations and is covered by 49/50 Workers' Compensation state insurance funds.

Additionally, outside of the U.S. the National Institute for Health and Clinical Excellence (NICE) of the UK in their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluded that SCS is recommended as a treatment option for adults with failed back surgery syndrome lasting at least 6 months despite appropriate conventional medical management.¹

SCS is a clinically effective treatment option for patients with FBSS; supported by randomized controlled trials (RCTs)^{2,3} and several large post market SCS registries reporting positive outcomes for over 1,000 patients.⁴⁻⁵

The Official Disability Guideline (ODG) for Chronic Pain, on which the MTUS is based, clearly includes coverage for FBSS and we believe CA DWC should as well. Therefore, we respectfully request the reinstatement of coverage of SCS treatment for FBSS.

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4. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery*. 2006;58:481-96.
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6. Reig E, Abejón D. Spinal cord stimulation: A 20-year retrospective analysis in 260 patients. *Neuromodulation: Technology at the Neural Interface*. 2009;12:232-9.

Al Liceaga MD
CEO Regional Pain Treatment Medical Center

December 16, 2014

I oppose the proposed changes to SCS and IDD in the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Treatment Guideline. These changes will severely limit access to these therapies for injured workers and are not supported by current medical literature.

I believe that the clinical evidence supports maintaining the recommendations contained in the current CA version of the MTUS.

- **SCS:** SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.
- **IDD:** IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers' Compensation state agencies. IDD is a clinically effective treatment option for patients with chronic intractable pain and should remain a treatment option for injured workers.

Please do not implement these proposed draconian changes.

Charles G. Davis, D.C.

December 16, 2014

Manipulative therapy is more than just a biomechanical event. Manipulative therapy can alter pain biomarkers.

Teodorczyk-Injeyan JA, Triano JJ, McGregor M, Woodhouse L, Injeyan SH. Elevated production of inflammatory mediators including nociceptive chemokines in patients with neck pain: a cross-sectional evaluation. Journal of Manipulative and Physiological Therapeutics, 2011;34(8):498-505.

Koch A, Zacharowski K, Boehm O, Stevens M, Lipfert P, von Giesen HJ, et al. Nitric oxide and proinflammatory cytokines correlate with pain intensity in chronic pain patients. Inflammation Research, 2007;56:32-37.

Bogdan C. Nitric oxide and the immune response. Nature Immunology, 2001;2:907-916.

Teodorczyk-Injeyan JA, Injeyan HS, Ruegg R. Spinal manipulative therapy reduces inflammatory cytokines but not substance P production in normal subjects. J Manipulative Physiol Ther. 2006 Jan;29(1):14-21.

Teodorczyk-Injeyan J, Injeyan HS, Ruegg R. Spinal manipulative therapy (SMT) augments production of anti-inflammatory cytokine IL-10 in normal subjects. Proceedings of the 9th Biennial Congress of the World Federation of Chiropractic, Vilamoura, Portugal, May 17-19, 2007:143-144.

Degenhardt BF, Darmani NA, Johnson JC, Towns LC, Rhodes DC, Trinh C, McClanahan B, DiMarzo V. Role of osteopathic manipulative treatment in altering pain biomarkers: a pilot study. J Am Osteopath Assoc. 2007 Sep;107(9):387-400.

Strong recommendations were made for the treatment of chronic neck pain with manipulation, manual therapy, and exercise in combination with other modalities.

Bryans R, Decina P, Descarreaux M, Duranleau M, Marcoux H, Potter B, Ruegg RP, Shaw L, Watkin R, White E. Evidence-Based Guidelines for the Chiropractic Treatment of Adults With Neck Pain. J Manipulative Physiol Ther. 2014;37:42-63.

Spinal manipulation is superior to needle acupuncture or medication for the successful treatment of patients with chronic spinal pain syndrome, except for those with neck pain. The Neck Disability Index showed that for neck pain, acupuncture achieved a better result than manipulation.

Giles LGF, Muller R. Chronic spinal pain - a randomized clinical trial comparing medication, acupuncture, and spinal manipulation. Spine 2003;28:1490-1503.

Although manipulation of the spine under anesthesia is currently in general use by chiropractic professionals, it is an advanced form of treatment not intended as a first-line therapy or routine service. Treatment is reserved for individuals who have already pursued traditional modes of (including, in part, spinal manipulation), but for whom the condition is recalcitrant. Significant pain and dysfunction typically preclude a return to normal activities, whether personal, occupational or recreational.

Digiorgi D. [Spinal manipulation under anesthesia: a narrative review of the literature and commentary.](#) Chiropr Man Therap. 2013 May 14;21(1):14.

Approximately half of patients previously unresponsive to conservative treatment reported clinically relevant improvement at 2 and 4 weeks post-MUA.

Peterson CK, Humphreys BK, Vollenweider R, Kressig M, Nussbaumer R. [Outcomes for chronic neck and low back pain patients after manipulation under anesthesia: a prospective cohort study.](#) J Manipulative Physiol Ther. 2014 Jul-Aug;37(6):377-82.

A high level of agreement was achieved in developing evidence-informed recommendations about the practice of chiropractic/manual therapy manipulation under anesthesia.

Gordon R, Cremata E, Hawk C. [Guidelines for the practice and performance of manipulation under anesthesia](#). *Chiropr Man Therap*. 2014 Feb 3;22(1):7.

There is better evidence for MUA than for paracetamol (acetaminophen). In which the guideline endorses.

There is a clear need for large, high quality randomized controlled trials evaluating paracetamol, to provide reliable evidence of paracetamol's effectiveness in patients with low back pain and to establish the validity of the recommendations in clinical guidelines.

*Davies RA, Maher CG, Hancock MJ. [A systematic review of paracetamol for non-specific low back pain](#). *Eur Spine J*. 2008 Nov;17(11):1423-30.*

Regular or as-needed dosing with paracetamol does not affect recovery time compared with placebo in low-back pain, and question the universal endorsement of paracetamol in this patient group.

*Williams CM, Maher CG, Latimer J, McLachlan AJ, Hancock MJ, Day RO, Lin CW. [Efficacy of paracetamol for acute low-back pain: a double-blind, randomised controlled trial](#). *Lancet*. 2014 Nov 1;384(9954):1586-96.*

The guideline proposal has a pharmaceutical bias.

Kenneth Grabow MD

December 15, 2014

To Whom it may concern,

I have reviewed the recent proposed changes to the chronic pain treatment guidelines and have noted the changes to implantable devices. I do not see any rationale given for the indication change for either Spinal cord Stimulation or Intrathecal Drug Delivery Systems. The ODG guidelines are the basis for the new MTUS Chronic Pain Treatment Guidelines but the recommendation statements have been dropped. I do not see how this is substantiated.

Please note the following issues as regards these therapies.

SCS

- The decision to remove FBSS as an indication for SCS is an outlier.
 - o SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies.
- SCS is a clinically effective treatment option for patients with FBSS.
 - o SCS for FBSS is supported by randomized controlled trials (RCTs)^{1,2} and several large post market SCS registries reporting positive outcomes for over 1,000 patients.³⁻⁵

IDD

- The decision to state “There is insufficient evidence to recommend the use of implantable drug-delivery systems (IDDS) for the treatment of chronic pain” is an outlier.
 - o IDD is recommended as a treatment option for non-malignant and malignant pain in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 48/50 Workers’ Compensation state agencies.
- IDD is a clinically effective treatment option for patients with chronic intractable pain.
 - o Two level 1 clinical studies demonstrate that IDD is an effective therapy in significantly reducing pain compared to medical management^{6,7} and non-randomized studies report positive outcomes and reductions in pain for over 500 patients.⁸⁻¹⁴
- The use of IDD may lead to the elimination or significant reduction of oral medications along with their side effects and risk of diversion.
 - o Retrospective claims data have shown 51% of patients newly implanted with IDD completely discontinue oral opioids within the first year.¹⁵

CA MTUS Proposed Language

- The California treatment guideline has used ODG as the basis for their coverage decision. In reviewing the proposed MTUS language in comparison to current ODG language, it appears the language for SCS for FBSS and IDD for chronic pain is nearly identical with the exception of both recommendation statements being dropped. Given no additional evidence is cited in the MTUS, how is the new recommendation for non-coverage substantiated?

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4. Mekhail NA, Mathews M, Nageeb F, et al. Retrospective review of 707 cases of spinal cord stimulation: Indications and complications. *Pain Practice*. 2011;11:148-53.
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6. Rauck RL, Wallace MS, Leong MS, et al. A Randomized, Double-Blind, Placebo-Controlled Study of Intrathecal Ziconotide in Adults with Severe Chronic Pain. *Journal of Pain and Symptom Management*. 2006;31(5):393-406.
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Systemic Opioid Elimination after Implantation of an Intrathecal Drug Delivery System Significantly Reduced Healthcare Expenditures. Presented at NANS annual meeting, Las Vegas, Dec 13, 2014.

Rob Friedman

December 15, 2014

Does anyone who works for the State of California, or the DWC, WCAB, or et al, utilize medical cannabis for relief?

California Constitution's mandate that worker's compensation law "shall accomplish substantial justice in all cases expeditiously, inexpensively, and without encumbrance of any character."
(cal. Const., Article XIV, Sec.4)

The Chronic Pain Medical Treatment Guidelines, Utilization Reviewers, QME, etc, are severely biased with regards to the use and efficacy through the safety of medical cannabis compared to that of opiates given that presumed issues of side-effects can be easily screened for as explained in the guide.

"For every disease and disorder for which marijuana has been recommended, there is a better, FDA-approved medication."

Better for who? Not everyone likes having chest pains (cymbalta), a four hour erection aka priapism, soiling their underwear, sweats, increased back pain, or having increased nerve pain due to opiates in addition to painful withdrawals from regularly prescribed pharmaceuticals.

<<http://www.viagra.com/taking-viagra/viagra-side-effects.aspx>>

"This study adds to a growing body of evidence that cannabis may be effective at ameliorating neuropathic pain, and may be an alternative for patients who do not respond to, or cannot tolerate, other drugs."

I am a worker's compensation patient, in pro per, who suffers from injuries dating 2001, of chronic neuropathic pain, muscular skeletal injuries, and more, additionally do not respond well to opiates and other drugs. Medical cannabis provides relief.

"At this time it is difficult to justify advising patients to smoke street-grade marijuana, presuming that they will experience benefit, when they may also be harmed."

As an in pro per applicant, fighting to have medical cannabis paid for since 2004, additionally fighting for cervical spine surgeries, and relieving therapies I can honestly say that applicants are more harmed by the denials, delays involved with having to be married to an insurance company till death do us part, and bound to the WCAB whose objective includes profiting at the expense and pain of individuals injured on the job.

"The results of this preliminary study suggest that dronabinol, a synthetic THC, resulted in additional analgesia among patients taking opioids for chronic noncancer pain."

Dronabinol, a synthetic cannabis once prescribed to this applicant for his pain, did not provide relief for symptoms.

"At this time it is difficult to justify advising patients to smoke street-grade marijuana, presuming that they will experience benefit, when they may also be harmed."

What is the definition of "street grade marijuana"? As this terminology is not on the guideline.

I literally do not acquire my medical cannabis off of the street, that would be unclean at best. Nor do I acquire it from a person who stands on the street. I do acquire it from reputable dispensaries and or caregivers that are capable to provide testing measurements of the medical cannabis strains available.

Additionally the MTUS does not have any mention of vaporizing medical cannabis, an administration method that is well known and recommended for this medicine.

Given that the California medical cannabis industry is legally bound to non-profit statuses, and for-profit insurance companies, doctors, pharmaceutical manufacturers, et al, have no desire to lose out on projected profits or profit sharing anytime soon, I doubt the government, Legislature, or officials whose monthly paychecks or livelihood depends on the delays and denials of medical treatment, will give a damn about people suffering in pain while a substance is available to provide relief from the effects of injuries sustained on the job.

How many individuals injured on the job each year are adolescents, <18 years and <21 years old? The guide makes no mentions while stating that use among those groups have profit related biases in the studied effects.

The following comments raise concerns I have that some of the proposed text make changes to the ODG text without EBM support for those changes. Due to time constraints, I am providing two important examples that are of concern.

I write these comments as one of the Associate Editors of the 2008 ACOEM Chronic Pain Guidelines, an ongoing Reviewer for ACOEM Guidelines and a current Medical Advisor to ODG. I am a treating physician and the Feinberg Medical Group has a Functional Restoration Program that has achieved respect from both the employer/defense and applicant community. I also service in often used Agreed Medical Evaluator.

Chronic pain programs /Multidisciplinary Programs (also see Functional restoration programs [FRPs])

As a treating rehabilitation physician and one whose FRP article is referenced by the MTUS, I am troubled by changes made by the DWC to the ODG on this topic.

The great majority of pain programs in California are 5-6 hours a day for 6-8 week. ODG suggests 4 weeks full time or 160 hours and most programs (see paragraph from ODG below) have dealt with this by dividing the 160 hours up over 6-8 weeks. The proposed MTUS CPMTG (see paragraph below) left out the weeks (20 full-days or 160 hours).

ODG

Total treatment duration should generally not exceed 4 weeks (20 full-days or 160 hours), or the equivalent in part-day sessions if required by part-time work, transportation, childcare, or comorbidities. (Sanders, 2005) If treatment duration in excess of 4 weeks is required, a clear rationale for the specified extension and reasonable goals to be achieved should be provided. Longer durations require individualized care plans explaining why improvements cannot be achieved without an extension as well as evidence of documented improved outcomes from the facility (particularly in terms of the specific outcomes that are to be addressed).

MTUS

(12) Total treatment duration should generally not exceed 4 weeks (or the equivalent in part-day sessions if required by part-time work, transportation, childcare, or comorbidities). (Sanders, 2005) If treatment in excess of 4 weeks is required, a clear rationale for the specified extension and reasonable goals to be achieved should be provided. Longer durations require individualized care plans explaining why improvements cannot be achieved without an extension as well as evidence of documented improved outcomes from the facility (particularly in terms of the specific outcomes that are to be addressed).

While the biopsychosocial model and functional restoration is strongly supported by the MTUS Chronic Pain Medical Treatment Guidelines, the reality of life out here in the real world of caring for injured workers is that FRPs are routinely denied (even with clear written justification). Even when

authorization for two weeks is obtained, many times there is a delay so the program is chopped up and less effective or that we cannot get any more time authorized past the initial two weeks.

The above noted change made by the DWC to ODG on this topic suggests that it will be difficult to get care at all beyond 4 weeks.

The MTUS and ODG adds that “If treatment duration in excess of 4 weeks is required, a clear rationale for the specified extension and reasonable goals to be achieved should be provided. Longer durations require individualized care plans explaining why improvements cannot be achieved without an extension as well as evidence of documented improved outcomes from the facility (particularly in terms of the specific outcomes that are to be addressed).”

The problem we have faced in the past as practitioners is that even a clear and well-reasoned argument with reasonable goals and an individualized care plan to support continued FR does not always translate into authorization. There are certain carriers [redacted] who are very supportive of FRP efforts and have medical directors who are reasonable, but many other payers/employers and their chosen UR companies and physicians take a severe stance and find cause to deny coordinated and continued FR care – even when it is clearly justified and supported.

Additionally, the single reference listed regarding length of treatment is from Sanders, et al., does not meet the criteria for EBM. The reality regarding length of stay is that there is no EBM but the standard of care is California FR Programs has always been 6-8 weeks although the length of stay should always be based on the criteria of significant progress and thus a good FR will have a variable length of stay depending on the needs of the injured worker and whether that individual is benefiting from care. Here is what Forum Posting (and ODG) lists for the Sanders article.

Sanders SH, Harden RN, Vicente PJ. Evidence-Based Clinical Practice Guidelines for Interdisciplinary Rehabilitation of Chronic Nonmalignant Pain Syndrome Patients. World Institute of Pain, *Pain Practice*, Volume 5, Issue 4, 2005 303–315.

The current guidelines recommend interdisciplinary-focused rehabilitation, which is goal-directed and time-limited. Emphasis is placed on educating patients in active self-management techniques that stress maximizing function. Integrated treatment involving medical, psychological/behavioral, physical/occupational therapy, and disability/vocational interventions are recommended on an outpatient basis whenever clinically possible. Note: This issue of this journal was not accepted into Medline, and therefore it is not part of the primary evidence based used for ODG, but it includes a helpful reference list.

I have a copy (and would happy to provide it to anyone who would like to see it) of the full original Sanders article and here is what it actually says:

“Consistent with effective treatment outcome studies,^{14,25,37} is recommended that an upper limit of 20 total treatment days for the CPS patients continues to be applied in most cases. Obviously, this upper limit may need to be extended based on the specific documented outcomes and goals for given treatment program. When more than 20 treatment days are proposed, a clear rationale and specified extension should be documented. The number of recommended therapies in any given modality is uncertain and should be individually assessed based on objective improvement.”

Reference 14: Okifuji A. Interdisciplinary pain management with pain patients: evidence for its effectiveness. *Semin Pain Med.* 2003;1:110–119.

Reference 25: Sanders SH, Brena SF. Empirically derived chronic pain patient subgroups: the utility of multidimensional clustering to identify different treatment effects. *Pain.* 1993;54: 51–56.

Reference 37: Guzman J, Esmail R, Karjalainen K, et al. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain (Cochrane Review). *The Cochrane Library, Issue 3.* Oxford: Update Software; 2003.

These outdated references are not evidenced based and in any case length of treatment is variable with each case but in California the typical length of stay is 6 weeks, 5-6 hours a day.

Here is the section on spinal cord stimulation from ODG and the MTUS

ODG

Recommended only for selected patients with Complex Regional Pain Syndrome (CRPS) Type I. **For use in failed back surgery syndrome (FBSS)**, see the Low Back Chapter. More trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain.

MTUS

Recommended only for selected patients with Complex Regional Pain Syndrome (CRPS) Type I.

The above sentence in bold/underlined and in yellow is left off but at the end the MTUS says

Refer to the DWC MTUS chapter on Low Back Complaints for additional information on issues related to the low back.

There is nothing on SCS in the DWC Low Back Chapter as far as I know. Regardless, SCS should not be separated into different chapters and is only used in chronic pain states and should be fully covered (as in ODG) in the MTUS Chronic Pain Guidelines.

In summary, if the DWC is going to use parts of ODG, then please use it without removing key sections or at least justify such deletions. Respectfully to all that the DWC, given the strong support for the biopsychosocial functional restoration approach to chronic pain, we need more clarifying language not more strict interpretation of unsupported information.

I am a double board certified pain management in California in practice since 1983. I have reviewed the proposed changes to implantable drug-delivery systems (IDDS) and spinal cord stimulation for treatment in chronic pain.

I object to the proposed changes.

1. I have multiple long-term industrial injury patients who have received significant pain and functional benefit with use of implantable drug-delivery systems (IDDS). Benefits have included return to work, decrease or elimination of oral opioid analgesic medications, and decrease or elimination of adverse side effects associated with oral opioid analgesic medications.
2. I [redacted] treat many industrial traumatic spinal cord and brain injury patients that have failed standard oral medication management for spasticity and require intrathecal baclofen infusion via implantable drug-delivery systems (IDDS).
3. I have multiple long-term industrial injury patients with low back and or radicular pain w/wo prior spine surgery who have received significant pain and functional benefit with use of spinal cord stimulation. Benefits have included return to work, decrease or elimination of oral opioid analgesic medications, and decrease or elimination of adverse side effects associated with oral opioid analgesic medications.

Al Liceaga, MD

December 13, 2014

The NEW Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines will significantly curtail Chronic Pain recommendations and treatment. My understanding is that included is a proposal to eliminate (Medtronic) Pumps (Pumps to only have indication for Industrial Cancer Pain) and curtail Spinal Cord Stimulation Therapy *to only CRPS (RSD)*.

This would be a disaster to the many injured workers with Failed Back Surgery Syndrome and other Industrial Spinal Injuries in CA. This, despite the positive evidence provided by ASIPP and the usual practices of the American medical community.

I believe that this proposal mirrors the Washington State policy of No Pumps and No SCS.

I fear that heavy lobbying from the Insurance industry to further "save" money will result in inappropriate restriction and access to care for injured workers.

We strongly oppose the New MTUS Proposals.

Bob Taber, MD, MPH

December 10, 2014

I have comments regarding 2 specific UDT issues.

#1 Quantitative urine drug testing

In the proposed revision of the MTUS Chronic Pain Guideline, the entire citation for Urine drug testing (UDT) is “See DWC “Guideline for the Use of Opioids to Treat Work-Related Injuries” for additional information on urine drug testing”.

Quantitative urine drug testing is not addressed at all in the Guideline for the Use of Opioids to Treat Work-Related Injuries.

Per the ODG Guidelines, 12th Edition 2014, Urine Drug Testing:

Limitations to UDT: There is currently no way to tell from a urine drug test the exact amount of drug ingested or taken, when the last dose was taken, or the source of the drug.

19. Quantitative urine drug testing is not recommended for verifying compliance without evidence of necessity. This is due in part to pharmacokinetic and pharmacodynamic issues including variability in volumes of distribution (muscle density) and interindividual and intraindividual variability in drug metabolism. Any request for quantitative testing requires documentation that qualifies necessity.

Quantitative urine drug testing is routinely performed for forensic purposes (e.g. DOT drug testing). However, in the WC chronic pain population, performing quantitative urine drug testing is only necessary on a limited basis under rare circumstances. Since there is no way to tell from a urine drug test the exact amount of drug ingested or taken, when the last dose was taken, or the source of the drug, the results of quantitative urine drug testing provides little or no additional clinical information to the treating/requesting physician.

The issue: many commercial labs routinely perform confirmatory and quantitative urine drug testing on all drugs included in the UDT test panel (often over 50 drugs/metabolites) even when the drugs have been demonstrated to not be present. The consequence of this is a billing statement that includes charges for quantitative testing for 20-30 or more drugs, which greatly increases the total cost of the UDT, often to over \$1,000 - \$2,000 per UDT.

Why is it necessary to perform and charge for quantitative urine drug testing for 20-30 or more drugs, when the specimen was demonstrated to only be positive for 0-3 drugs?

I suggest including a similar recommendation as currently exists in the ODG Guidelines regarding Quantitative urine drug testing.

#2 Random Urine Drug Testing

Per the DWC Guideline for the Use of Opioids to Treat Work-Related Injuries, p. 30,
During chronic opioid treatment, UDT should be conducted on a random basis...

I suggest providing a definition of Random Urine Drug Testing because many treating physicians clearly do not understand the concept.

Example: a chronic pain patient is seen for a regularly scheduled monthly follow up visit and there has been no change in the patient's chronic stable pain condition. The physician may state, "a random UDT is being performed today on this patient".

The purpose of performing a UDT on a random basis is to get an accurate assessment of a patient's use of prescribed, non-prescribed and illicit drugs. For such a purpose, the UDT must be performed at a time that cannot be predicted by a given patient.

If a sufficiently motivated patient is only going to undergo a UDT at the time of a previously scheduled appointment, s/he knows that the window of detection for most drugs is 1-3 days. S/he can use/abuse the drug of choice for 3 weeks out of the month knowing that such use will not be detected by a UDT on the appointment date. Or if s/he is diverting a prescribed drug, s/he can resume taking the drug a few days before the scheduled appointment and appropriately test positive for the drug.

In both of these scenarios, the patient can easily predict when a UDT might be performed and readily defeat the purpose of it. In either case, the treating physician may incorrectly deduce that a given patient is compliant with the medication regimen and not abusing illicit drugs.

A truly random test would not be performed on the day of a scheduled appointment or on a day that the patient knows s/he will need to return to the clinic/office. Some patient's return to the physician's office every 4 weeks or so to pick up a prescription refill that is dispensed directly to them by the physician but are only "seen" for follow up visits every 6-8 weeks. If it is possible for a patient to undergo a UDT at the time of picking up a refill, when they do not actually see the physician, the patient will be able to anticipate and defeat the purpose of it.

Yehuda Gertel Psy.D, Q.M.E.
Clinical Health Psychologist
Orange County Pain and Wellness

December 10, 2014

I strongly object to the revision of to the ODG guidelines regarding the maximum number of days that should be approved in a functional restoration program (found in the Chronic Pain Program section-
Criteria for the general use of multidisciplinary pain management program

The 2014 ODG Guidelines state:

12) Total treatment duration should generally not exceed 4 weeks (20 full-days or 160 hours),

The MTUS quotes the ODG

12) Total treatment duration should generally not exceed 4 weeks – but leaves out the parentheses. It is unclear if this was deliberate or by accident.

If this was intentional, eliminating this 160 hours is not empirically-based medicine.

Per the ODG and MTUS the source of this 20 hours ceiling is Sanders (et al 2006) who in turn bases this upper 20 day limit on three journal studies, the first two of which do not actually deal with time frame, only the last, Guzman et.al. (2001). Multidisciplinary rehabilitation for chronic low back pain: A systematic review, performed a Meta-Analysis of 10 studies that met the authors requirements for inclusion. Of these 10 studies analyzed, half of them (Bendix et.al. (1995), Bendix et.al. (1996), Mitchell, R.I. & Carmen G.M. (1994), Juckel et al. (1990), Harkapaa et.al. (1990)) provide a treatment model in excess of 20 outpatient days (Bendix – 22.5 days; Mitchell-47 days; Juckel-4-6 week inpatient; Harkapaa – 3 weeks inpatient). It is presumed that Sanders provided the average or median of these treatment durations as the basis for his recommendation. It is clear from Sanders and from the ODG's quote of Sanders that he is referring to 20 full time days which again translate into 160 hours or the part-time equivalent.

By definition, Guidelines that are research-based cannot leave out a very significant detail which was intended by its source and which is directly brought in the 2014 ODG.

I currently work in an FRP program and the elimination of the 160 hours would severely restrict and compromise the functional improvements that we are able to make-especially when there is a concurrent medication weaning involved. It is becoming more and more difficult to treat patients in the current post SB899 and SB863 climate with biased peer reviews and constant delays in authorization. Eliminating 160 hours would probably close our business.

The Guidelines as they read leave out the following section of the 2014 ODG Guidelines for Chronic Pain Program.

Outcomes (in terms of body parts)

Shoulder (and other upper extremity disorders): This large cohort study concluded that an interdisciplinary functional restoration program (FRP) is equally effective for patients with chronic upper extremity disorders, including the elbow, shoulder and wrist/hand, as for patients with lumbar spine disorders, regardless of the injury type, site in the upper extremity, or the disparity in injury-specific and psychosocial factors identified before treatment. (Howard, 2012)

Knee (and other lower extremity disorders): This cohort study demonstrated that FRP was equally efficacious for patients with chronic lower extremity (LE) injuries (involving the hip, knee, ankle, and foot) and low back pain (LBP) injuries. Both patient groups significantly improved on measures of pain, disability, and depression after the FRP, and patients in both groups displayed similarly high return-to-work and work-retention rates one year later. (Mayer, 2013)

Neck (and cervical spine): There are limited studies about the efficacy of chronic pain programs for neck disorders. (Karjalainen, 2003) This may be because rates of cervical claims are only 20-25% of the rates of lumbar claims. In addition, little is known as to chronicity of outcomes. Researchers using PRIDE Program (Progressive Rehabilitation Institute of Dallas for Ergonomics) data compared a cohort of patients with cervical spine disorders to those with lumbar spine disorders from 1990-1995 and found

that they had similar outcomes. Cervical patients were statistically less likely to have undergone pre-rehabilitative surgery. (Wright, 1999)

This section is very helpful and important when dealing with multiple pain areas and should be included in the MTUS.