March 10, 2017

Division of Workers' Compensation
State of California
PO Box 420603
San Francisco, CA 94142

via Email to: *DWCforums@dir.ca.gov*

To Whom It May Concern:

On behalf of the individuals and societies listed below, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, we would like to thank you for the opportunity to provide comments on the California Division of Workers' Compensation's (DWC) proposal to amend the Medical Treatment Utilization Schedule (MTUS). The proposed revisions to the chronic pain chapter, adopting the American College of Occupational and Environmental Medicine (ACOEM) guidelines, will result in the elimination of access to spinal cord stimulation/neurostimulation and other interventional therapies that have been proven to reduce or eliminate pain and improve function with no or minimal adverse events.

In our comments below, we will highlight relevant history related to DWC's 2015 decision, ultimately preserving access to interventional pain therapies, including neurostimulation. We will also explain why implementing the ACOEM guidelines will lead to egregious denial of access to procedures that truly can help patients.

It is important to understand that a similar proposal was made and rejected less than two years ago after significant public engagement. This history is ignored with presentation of the current proposal.

HISTORY OF DWC PROPOSAL TO ELIMINATE COVERAGE FOR MANY INTERVENTIONAL PAIN TREATMENTS, INCLUDING NEUROSTIMULATION

On 12/08/2014, the DWC solicited comments regarding a new chronic pain chapter (https://www.dir.ca.gov/DIRNews/2014/2014-114.pdf). Only 10 days were provided for comment. The proposed chronic pain chapter would eliminate access to neurostimulation and intrathecal therapy for chronic pain for injured workers in the State of California. Numerous

comments were received by the deadline of 12/18/2014. Those comments can be found at: http://www.dir.ca.gov/dwc/DWCWCABForum/ChronicPainMedicalTreatmentGuidelines.htm

In response to the solicitation for comments, a comprehensive evidence table was developed providing an extensive literature review regarding these modalities. Ultimately, a document more than 1-inch thick was provided to the DWC in several parts. An executive summary was provided that reviewed the burden of chronic pain, treatment options, and presented the evidence for neurostimulation and targeted drug delivery in appropriately selected patients with chronic pain. There are appendices that supported the efficacy, safety, and cost effectiveness of these two modalities. In addition, current clinical practice guidelines were provided. This document was endorsed by a physician in an administrative capacity for every academic pain program in the State of California in addition to:

- The American Society of Anesthesiologists
- American Society of Interventional Pain Physicians
- The North American Neuromodulation Society
- The California Society of Anesthesiologists
- California Society of Interventional Pain Physicians
- The California Society of Industrial Medicine

The level of support and consensus regarding the evidence from this number of leading organizations and academic institutions is rare, and together they voiced their commitment to ensuring that access to these modalities for injured workers in the State of California would not cease. The cover letter that accompanied the evidence document is attached as Appendix 1, along with the Executive Summary as Appendix 2. The complete evidence document will be included with these comments as a PDF attachment.

On 09/01/2015, a public hearing on a chronic pain chapter was held. Dr. Joshua Prager testified at that hearing and a transcript of the testimony is available on the DWC web site at https://www.dir.ca.gov/dwc/DWCPropRegs/MTUS-Opioids-ChronicPain/Transcript.pdf. By the time of the hearing, the proposal for change in the guidelines had been modified to include access to neurostimulation and targeted drug delivery as indicated above, but there were several remaining ambiguities.

On 07/28/2016, the DWC published chronic pain guidelines, which included access to the therapies that were originally proposed for elimination.

It is hard to believe that after going through this entire process over a 9-month period less than two years ago, with resolution resulting in inclusion of access to these therapies for injured workers in the State of California, a new proposal would emerge that once again proposes to eliminate them.

SUMMARY

The current chronic pain guidelines are the result of an extensive multi-year interdisciplinary effort by the Medical Evidence Evaluation Advisory Committee (MEEAC), a blue-ribbon committee of physicians vetted and appointed by the State of California to evaluate the medical literature and produce an evidence-based guideline published and codified as the MTUS. The MTUS replaced the ACOEM guidelines, which were presumptive at the time. The current proposal would eliminate the effort of the physicians on MEEAC and replace it with the ACOEM guidelines, which were previously rejected.

Access to interventional pain therapies, including neurostimulation, should be provided to appropriately selected patients for treatment of chronic pain in the State of California. A prior proposal to exclude these therapies was changed, resulting in implementation of guidelines as recently as last year, including this therapy in the revised MTUS.

We are at a time when there is an opioid crisis in the United States. Overdose deaths involving prescription opioids have quadrupled since 1999,[1] and so have sales of these prescription drugs.[2] From 1999 to 2014, more than 165,000 people have died in the U.S. from overdoses related to prescription opioids.[1] Opioid prescribing continues to fuel the epidemic. Today, at least half of all U.S. opioid overdose deaths involve a prescription opioid.[1] In 2014, more than 14,000 people died from overdoses involving prescription opioids. This is a time when therapies that are nonpharmacological and do not include opioids should be considered for treatment of pain. Both the CDC and FDA recommend that other modalities be tried first. Removing access to interventional pain treatment including neurostimulation at this critical time is unconscionable and contrary to public policy promulgated to reduce opioid consumption.

In the absence of access to interventional pain procedures, patient outcomes will include: unnecessary suffering, additional drug dependency, unnecessary surgeries, increased utilization of more expensive therapies, and additional work disability. The aforementioned will result in the delivery of lower quality medical care and contribute to greater consumption of healthcare resources. Elimination of coverage contradicts coverage policies implemented by all major health plans and Medicare. Without access to interventional therapies patients covered under DWC will be left without hope for a future without debilitating pain.

Given the short timeframe that was provided, at this time we do not have adequate time to provide the opportunity to solicit the support of the multitude of organizations that supported the previous document. Since that document was created, there are additional articles in well-regarded peer reviewed journals providing additional data supporting the use of various interventional treatments, including neurostimulation, for treatment of chronic pain. I will be happy to provide additional information and to, once again, meet with the DWC to discuss the necessity to preserve access to these therapies for injured workers in the State of California. Please do not hesitate to contact me with additional questions.

Sincerely,

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Department of Anesthesiology and Internal Medicine
David Geffen School of Medicine at UCLA
Diplomate, American Board of Anesthesiology
Diplomate, American Board of Internal Medicine
Diplomate, American Board of Anesthesiology Subspecialty Pain Medicine
Diplomate, American Board of Pain Medicine
Former two-term member, Medical Evidence Evaluation Advisory Committee

Cosigner Organizations

American Academy of Physical Medicine and Rehabilitation

American Pain Society

American Society of Anesthesiologists

American Society of Neuroradiology

American Society of Regional Anesthesia and Pain Medicine

American Society of Spine Radiology

California Society of Interventional Pain Physicians

Society of Interventional Radiology

Spine Intervention Society

North American Neuromodulation Society

California Society of Industrial Medicine and Surgery

Cosigner Individuals

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Francis Riegler, M.D.
President Elect, American Society of Interventional Physicians

ATTACHMENTS:

- *Appendix 1*
- *Appendix 2*
- *References*
- *PDF of prior presentation is attached via email*

Appendix 1

April 28, 2015
Division of Workers' Compensation
PO Box 420603
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We are writing on behalf of a group of professional societies representing thousands of pain treatment specialists regarding the Division of Workers' Compensation (DWC) proposed Chronic Pain Medical Treatment Guidelines posted on December 8, 2014. The proposed medical treatment utilization schedule (MTUS) language contradicts the Official Disability Guidelines (ODG) on which it is based. The current MTUS is the result of the work of the Medical Evidence Advisory Committee (MEEAC), a vetted group of professionals appointed by the state of California who worked in an iterative fashion with ODG to develop these evidence-based guidelines. The proposed new MTUS ignores this evidence-based work as well as new, high-quality, compelling evidence that supports coverage of spinal cord stimulation (SCS) for failed back surgery syndrome (FBSS) and intrathecal drug delivery (IDD) systems for noncancer pain. We respectfully request that you rescind the portions of the MTUS that remove coverage for these treatments for which there is substantial evidence published in peer-reviewed journals that supports the recommendations of the prior MTUS with regards to both the efficacy and cost-effectiveness of these therapies.

According to the recent independent and authoritative Institute of Medicine (IOM) report on Pain in America, chronic pain is a costly public health problem that requires:

> "a transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess, and treat pain."

To that end, our members are acutely aware that removing effective, Food and Drug Administration-approved treatment options from patients with chronic pain clashes with our professional ethics and deprives patients of therapies with decades of evidence as to their utility.

In support of our request, please consider the accompanying documents:

- An **Executive Summary** that reviews the burden of chronic pain, treatment options, and evidence for using SCS and IDD in appropriately selected patients with chronic pain.
- **Summaries of Peer-Reviewed Literature** (Appendices II, III, VI, VII) that amply support the efficacy, safety, and cost-effectiveness of both SCS and IDD.
- **Current Clinical Practice Guidelines** (Appendices IV, VIII) that include SCS and IDD.

Since the current MTUS was published, subsequent data have supported its conclusions and, absent compelling data to the contrary, there is no rationale for change. As specialists who spend every day caring for patients in pain, we thank you for the opportunity to present these data that emphasize the vital role of SCS and IDD in the treatment of chronic pain.

Appendix 2

Executive Summary in Support of
Spinal Cord Stimulation for Failed Back Surgery Syndrome and
Targeted Intrathecal Drug Delivery for Noncancer Pain

Chronic Pain Is a Costly Public Health Problem

- Chronic pain that lasts beyond the expected healing time or longer than 3 months[3] afflicts at least 110 million Americans, more than the total number affected by cancer, diabetes and heart disease combined.[4]
- The Federal Government recognized that untreated and under-treated pain is a serious problem and mandated that the Institute of Medicine (IOM) convene a highly vetted, distinguished committee to analyze the problems caused by inadequate treatment of pain and make recommendations to improve the situation. The results were published by the Institute of Medicine (US) Committee on Advancing Pain Research, Care and Education as Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research."[5] Significant points included:
    - Chronic pain costs Americans up to $635 billion annually in medical treatment and lost productivity, according to the Institute of Medicine (IOM).[5]
    - "To reduce the impact of pain and the resultant suffering will require a transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess, and treat pain."[5]
    - For many patients cure may be unlikely," according to IOM.[5]

Chronic Pain Can Be "Frustratingly Difficult to Treat"[5]

- Conventional medical management (CMM) for chronic pain consists of medications (including systemic opioids), regional anesthetic interventions, psychological therapies, rehabilitative/physical therapy, and complementary and alternative medicine.[5]
- "A growing, deadly epidemic" of prescription medicine overdose deaths in the U.S.[6] has made access to prescription systemic opioids more difficult, even for medically indicated chronic pain management. Among physicians, 29% of primary care and 16% of pain specialists report they prescribe opioids less often than they think appropriate because of possible regulatory repercussions.[7]

- For patients who suffer intolerable side effects from oral opioids or whose pain is not relieved, few other treatment options exist.
- Spinal cord stimulation (SCS) and targeted intrathecal drug delivery (IDD) can be evaluated before implementation during a screening trial, and offer physician-controlled pain therapy that is safe, effective, and cost-effective.
- Patient satisfaction with SCS and IDD has been consistently high (Appendices II and VII).

Spinal Cord Stimulation Is Effective and Cost-Effective in Treating Failed Back Surgery Syndrome

- A new groundbreaking Level 1, pivotal, Food and Drug Administration-supervised randomized controlled trial (RCT) compared high-frequency 10 kHz SCS to traditional low-frequency SCS.[8] (See Appendix II)
    - 10 kHz SCS produced profound and durable pain relief as well as functional improvement measured by validated instruments, such as the Oswestry Disability Index (ODI).
    - The 1-year responder rate (>50% pain reduction) for 10 kHz high-frequency SCS was 78.7% for both back pain and leg pain.
    - Pain reduction for both traditional SCS and 10 kHz high-frequency SCS was between 44% and 69%.
- Previous RCTs that demonstrated significantly better pain relief and improvement in health-related quality of life (HRQoL) for SCS compared with CMM. (See Appendix II)
- SCS treatment of FBSS resulted in significant functional improvements over baseline in pain intensity, sex life, sitting, social life, standing, traveling, and walking at 6 months compared with CMM. These improvements were maintained at 24 months.[9]
- SCS was also significantly more successful than reoperation for FBSS, with 48% of SCS patients and only 12% of reoperation patients reporting >50% pain relief.[10] Patients preferred SCS to reoperation and were less likely to require increased opioids.[11]
- Pain relief with SCS has proved durable, with 60% patients having pain relief after an average of 8.1 years.[12] Over a 22-year period, the early success rate was 80% (328 patients), and the long-term success rate was 74% (243 patients).[12]
- Numerous studies using actual costs or health economic modeling have found SCS to be cost-effective in treating FBSS (See Appendix III), with the breakeven point for SCS occurring at approximately 2.5 years after implantation.
- SCS is recommended in numerous clinical practice guidelines for treatment of FBSS.

Intrathecal Drug Delivery Is Effective and Cost-Effective in Treating Chronic Noncancer Pain

- The independent ECRI (https://www.ecri.org/Pages/default.aspx) found that IDD leads to clinically relevant pain relief for chronic noncancer pain, and is associated with a decrease in the amount of other drugs taken or in the proportion of patients taking

other drugs.[13] (See Appendix VI) Additional evidence of IDD efficacy and of the therapy-limiting drawbacks of systemic opioids has continued to accumulate since the 2008 ECRI review (Appendix VI).

- Physician control of IDD has the potential to improve both safety and efficacy when opioids are prescribed.
- Improvements in safety, efficacy, compliance, and cost can be achieved by reducing or eliminating concomitant oral opioids in patients treated with IDD for chronic pain. (See Appendices VI and VII)
- IDD patients were less likely than those taking oral opioids to discontinue treatment due to adverse events (8.9% vs. 22.9%, respectively), or insufficient pain relief (7.6% vs. 10.3%, respectively), according to a Cochrane review of thousands of patients.[14]
- IDD has the potential to reduce longitudinal costs (Appendix VII) compared to other routes of opioid delivery, and compared to the costs associated with ineffective therapy, noncompliance, diversion or abuse.
- IDD is recommended by numerous clinical practice guidelines (Appendix VIII).

References:

[1] CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at http://wonder.cdc.gov.

[2] Frenk SM, Porter KS, Paulozzi LJ. Prescription opioid analgesic use among adults: United States, 1999–2012. NCHS data brief, no 189. Hyattsville, MD: National Center for Health Statistics. 2015

3 Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain. An evidence-based clinical practice guideline from the American Pain Society. Spine. 2009;14(10):1066-1077.

4 Tsang A, Von Korff M, Lee S, et al. Common chronic pain conditions in developed and developing countries: gender and age differences and comorbidity with depression-anxiety disorders. J Pain. 2008;9(10:883-891.

5 Institute of Medicine (US) Committee on Advancing Pain Research, Care and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington DC: The National Academies Press; 2011.

6 CDC (Centers for Disease Control). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999-2008. MMWR. 2011;60:1-6.

7 Breuer B, Cruciani R, Portenoy RK. Pain management by primary care physicians, pain physicians, chiropractors, and acupuncturists: a national survey. S Med J. 2010;103(8):738-747.

8 Sitzman T, Kapural L, Yu C, et al. Rationale for the SENZA-RCT study design and comparative outcomes. Presented at: North American Neuromodulation Society; 2014; Las Vegas, NV.

9 Eldabe S, Kumar K, Buchser E, Taylor RS. An analysis of the components of pain, function and health related quality of life in patients with failed back surgery syndrome treated with spinal cord stimulation or conventional medical management. Neuromodulation. 2010;13(3):201-209. PMID: 21992833.

10 North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery. 2005;56(1):98-106; discussion 106-107. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15617591.

11 Taylor RS, Desai MJ, Rigoard P, Taylor J. Predictors of pain relief following spinal cord stimulation in chronic back and leg pain and failed back surgery syndrome: a systematic review and meta-regression analysis. Pain Pract. 2013; Jul 8. doi: 10.1111/papr.12095. [Epub ahead of print]

12 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;58:481-496.

[13] Noble M, Treadwell J, Schoelles K, Sun F. HTA final report. Implantable Infusion Pumps for Chronic Noncancer Pain. Plymouth Meeting, PA: ECRI Institute; 2008. Health Technology Assessment performed for Washington State Health Care Authority.

14 Noble M, Treadwell JR, Tregear SJ, et al. Long-term opioid management for chronic noncancer pain. Cochrane Database Syst Rev. 2010;20(1):CD006605. DOI: 10.1002/14651858. CD006605.pub2.