California Workers' Compensation Institute
1333 Broadway Suite 510, Oakland, CA 94612 • Tel: (510) 251-9470 • Fax: (510) 763 -1592

September 16, 2016

VIA E-MAIL – DWCForums@dir.ca.gov

Maureen Gray, Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
1515 Clay Street, 18th Floor
Oakland, CA 94612

**Re: 1st Forum Comments on Draft Formulary Regulations**

Dear Ms. Gray:

These 1st Forum comments on the draft Drug MTUS Formulary Regulations are presented on behalf of members of the California Workers' Compensation Institute (the Institute). Institute members include insurers writing 72% of California's workers' compensation premium, and self-insured employers with $46B of annual payroll (28% of the state's total annual self-insured payroll).

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

Self-insured employer members include Adventist Health, ALPHA Fund, California State University Risk Management Authority, Chevron Corporation, City and County of San Francisco, City of Santa Ana, City of Torrance, Contra Costa County Schools Insurance Group, Costco Wholesale, Country of Alameda, 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, Special District Risk Management Authority, Sutter Health, University of California, and The Walt Disney Company.

Recommended revisions to the proposed regulation are indicated by underscore and ~~strikeout~~. Comments and discussion by the Institute are indented and identified by *italicized text.*

## Section 9792.27.1. Medical Treatment Utilization Schedule Drug Formulary – Definitions.

**Recommendation**
(i) "First Fill" means the policy relating to the drug prescription issued or drug dispensed at the single initial treatment visit following a workplace injury, where the visit occurs within 7 days of the date of injury.

**Discussion**
*The Institute understands that the first fill is intended to apply only at a single visit per claim -- the first treatment visit. Clarification is necessary to prevent disputes over whether an employee could visit multiple clinics in the first seven days and get a first fill at each one.*

## Section 9792.27.3. MTUS Drug Formulary Transition

**Recommendation**
(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an "unlisted drug"), the physician shall, within six weeks of the effective date of these regulations, either:
(1) Prepare and submit to the claims administrator a treatment plan outlining a safe weaning, tapering, or transitioning of the worker to a Preferred Drug by January 1, 2018, or
(2) Prepare and submit to the claims administrator a Request for Authorization and supporting documentation to substantiate the medical necessity of, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is determined to be reasonably required ~~necessary~~ for the injured worker's condition or ~~necessary~~ for safe weaning, tapering, or transition to a Preferred Drug.

Failure of a physician to submit a treatment plan under subsection (1), or to submit a Request for Authorization and supporting documentation under subsection (2), may constitute a showing of good cause for an employer's petition requesting a change of physician or provider pursuant to Labor Code Section 4603 and may serve as grounds for termination of the physician from the medical provider network or health care organization.

If a physician submits a treatment plan under subsection (1) to transition the worker to a Preferred Drug, but fails to complete that transition by January 1, 2018, such failure may constitute a showing of good cause for an employer's petition requesting a change of physician or provider pursuant to Labor Code Section 4603 and may serve as grounds for termination of the physician from the medical provider network or health care organization.

**Discussion**
*A defined time limit applicable to the transition period is necessary to avoid abuse and provide the injured worker with safe and effective medical care. Clarification is necessary to ensure that submission of either the transition plan or the documentation substantiating medical necessity for Non-Preferred drugs is made directly to the claims administrator. A stated consequence is necessary in the event the physician fails to submit a transition plan or a Request for*

*Authorization and supporting documentation, or fails to complete a transition to a Preferred Drug.*

## Section 9792.27.4. MTUS Drug Formulary – Pharmacy Networks; PBM Contracts.

**Recommendation**
Where an employer or insurer contracts pursuant to Labor Code section 4600.2 with a pharmacy benefit manager or pharmacy network for the provision of drugs for the treatment of injured workers, the drugs available to the injured worker must be consistent with the MTUS guidelines and MTUS Drug Formulary for the injury or condition being treated and may not be further restricted pursuant to the contract.

**Discussion**
*The term "restricted" needs to be clarified in order to avoid frictional costs of UR, IMR, or litigation. For example, where the Formulary or Guidelines are silent on a particular dosage or number of days, the regulation should be clear that a PBM can address these issues through UR without violation of the regulation.*

## Section 9792.27.5. MTUS Drug Formulary - Off Label Use

**Recommendation**
(b) When a physician ~~believes the~~ requests a prescription of a drug for an off label use not addressed by the MTUS Guidelines ~~is medically necessary~~, the permissibility of the treatment outside of the guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for Evaluating Medical Evidence.) The physician must obtain authorization through prospective review prior to the time the drug is dispensed for the off label use. If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied if the drug is found upon retrospective review to be not medically necessary.

**Discussion**
*The permissibility of treatment outside the MTUS Guidelines is governed by the section 9792.21, whether or not a physician believes the prescription of a drug for an off label use that is not addressed by the MTUS Guidelines is medically necessary, and since the question of "medically necessary" is not determined until the review, replacing that term "believes" with "requests" better reflects the process.*

## Section 9792.27.6. MTUS Drug Formulary – Access to Drugs Not Listed in the Preferred Drug List.

**Recommendation**
Drug treatment that is in conformity with the MTUS Guidelines is presumed correct on the issue of extent and scope of medical treatment pursuant to section 9792.21 subdivision (c), and Labor Code section 4604.5. Although the MTUS Preferred Drug List identifies drugs that do not require prospective review when dispensed in accordance with the MTUS Guidelines, other medically necessary drugs are available to the injured worker when authorized through

prospective review. An injured worker may be prescribed any medically necessary FDA-approved prescription drug, FDA-approved nonprescription drug, or nonprescription drug that is marketed pursuant to an FDA OTC Monograph, if it is shown by a preponderance of scientific medical evidence that a variance from the guidelines is required to cure or relieve the injured worker from the effects of his or her injury. ~~Treatment outside~~ Any such variance from the guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for Evaluating Medical Evidence.)

**Discussion**
*This change is recommended to clarify the intent of the rule, and ensure that the "preponderance of scientific evidence" is governed by these sections.*

## Section 9792.27.7. MTUS Drug Formulary – Brand Drugs; Generic Drugs.

**Recommendation**
(a) If a physician prescribes a brand name drug when a less costly therapeutically equivalent generic drug exists, and writes "Do Not Substitute" or "Dispense as Written" on the prescription in conformity with Business and Professions Code section 4073, the physician must document the medical necessity for prescribing the brand drug in the patient's medical chart and in the Doctor's First Report of Injury (Form 5021) or Progress Report (PR-2.) The documentation must include the patient-specific factors that support the physician's determination that the brand drug is medically necessary. The physician must obtain authorization through prospective review prior to the time the brand drug is dispensed. If required authorization through prospective review is not obtained prior to dispensing the brand drug, retrospective review may be conducted to determine if it was medically necessary to use the brand drug rather than the generic therapeutic equivalent. If it is determined that the generic drug but not the brand drug is medically necessary, payment for the drug may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand drug. If it is determined through prospective or retrospective review that neither the generic drug nor the brand drug is medically necessary, payment for the drug may be denied, pursuant to section 9792.27.10.

**Discussion**
*Reference to section 9792.27.10 is necessary so that there is no doubt that payment may be denied if review determines that neither the brand name drug nor a less costly therapeutically equivalent drug is medically necessary.*

**Recommendation**
(b) If a physician prescribes a generic drug when a less costly therapeutically equivalent generic or brand drug exists, the physician must document the medical necessity for prescribing the more costly drug in the patient's medical chart and in the Doctor's First Report of Injury (Form 5021) or Progress Report (PR-2.) The documentation must include the patient-specific factors that support the physician's determination that the more costly drug is medically necessary. The physician must obtain authorization through prospective review prior to the time the higher-priced drug is dispensed. If required authorization through prospective review is not obtained prior to dispensing the more costly drug, retrospective review may be conducted to determine if it was medically necessary to use the more costly drug rather than the less costly therapeutic equivalent. If it is determined that the more costly drug but not the less costly drug is medically necessary, payment for the drug may be made at the fee schedule price for the lowest

priced therapeutic equivalent drug. If it is determined through prospective or retrospective review that neither the more costly nor the less costly drug is medically necessary, payment for the drug may be denied pursuant to section 9792.27.10.

**Discussion**
*Section 1(c) of Assembly Bill 1124 (Perea) states that it is the intent of the Legislature that the Administrative Director create an evidence-based drug formulary, and that the formulary include the "[u]se of generic or generic-equivalent drugs in the formulary pursuant to evidence-based practices, with consideration being given to use of brand name medication when its use is cost-effective, medically necessary, and evidence-based." The Institute believes that adding this proposed language will address this stated intent.*

*As in subdivision (a), the final sentence is necessary to ensure there will be no doubt that payment may be denied if review determines that neither the brand name drug nor a less costly therapeutically equivalent is medically necessary.*

## Section 9792.27.8. Physician-Dispensed Drugs.

**Recommendation**
(b) A physician may dispense up to a seven-day supply of a drug that is listed as "Preferred" in the MTUS Preferred Drug List on a one-time basis without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary.

**Discussion**
*While it may be appropriate for a physician to dispense a seven-day supply to ensure immediate access to the drug, it would be unnecessary to do so again because the patient would have ample time for pharmacy prescription fills. Permitting repeated seven-day supplies at every office visit would create a financial incentive to unnecessarily increase the frequency of office visits for the purpose of dispensing seven-day supplies.*

## Section 9792.27.11. MTUS Preferred Drug List – First Fill.

**Recommendation**
(a) The MTUS Preferred Drug List identifies drugs that are subject to the First Fill policy. Under this policy, a drug that usually requires prospective review because it is "Non-Preferred," will be allowed without prospective review in very limited circumstances, and for a short period of time.

(b) The drug identified as a First Fill drug may be dispensed to the injured worker without seeking prospective review if the following conditions are met:

(1) The drug is prescribed at the single initial treatment visit following a workplace injury, provided that the initial visit is within 7 days of the date of injury; and

(2) The prescription is for a supply of the drug not to exceed the First Fill limit as set forth in the Preferred Drug List; and

(3) The drug is prescribed in accordance with the MTUS Guidelines; and

(4) The prescription is for:

(A) An FDA-approved generic drug or single source brand drug, or,

(B) A brand drug where the physician documents and substantiates the medical need for the brand drug rather than the FDA-approved generic drug. ~~and~~

~~(4)The drug is prescribed in accordance with the MTUS Guidelines~~

(c) An employer or insurer that has a contract with a pharmacy network, pharmacy benefit manager, or a medical provider network that includes pharmacies within the MPN, may provide for a longer first fill period or may cover additional drugs under the first fill policy pursuant to a pharmacy benefit contract or MPN contract.

**Discussion**
*Correction of a minor typographical error is suggested in (a).*

*Clarification is necessary in (b)(1)to prevent disputes over whether an employee could visit multiple clinics in the first seven days and get a first fill at each one.*

*A more precise description is recommended in (b)(2).*

*Re-ordering the list of conditions in (b) is necessary in order to ensure that the drug is prescribed in accordance with the MTUS guidelines under all circumstances.*

## Section 9792.27.12. MTUS Preferred Drug List

**Recommendation**
Add hyperlinks to the guideline references included in the Reference to Guidelines column of the MTUS Preferred Drug List document.

**Discussion**
*The Institute recommends adding hyperlinks that enable a user to automatically link to the pertinent section of the MTUS in order to facilitate efficient use of the guidelines and to support compliance.*

**Recommendation**
Add Opioid Treatments to the guidelines referenced for opioid drugs in the Reference to Guidelines column of the MTUS Preferred Drug List document.

**Discussion**
*The Institute recommends adding the Opioid Treatment Guidelines as a reference for all opioids in the MTUS Drug List in addition to the body part guidelines in order to facilitate adherence to the MTUS guidelines as well as to reinforce the contraindications for opioid use at various stages in clinical treatment.*

## Section 9792.27.14. Pharmacy and Therapeutics Committee – Application for Appointment to Committee Form.

**Recommendation**
(b) Persons applying to be appointed to the P&T Committee shall not dispense drugs to injured employees for outpatient use nor have done so during the 12 months prior to the appointment, nor may drugs be dispensed for outpatient use from his or her practice location, nor have been dispensed from his or her practice location during the 12 months prior to the appointment. Persons applying to be appointed to the P&T Committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or a company engaged in the development of a pharmaceutical formulary for commercial sale, and shall not have been so employed for 12 months prior to the appointment. A P&T Committee member who undertakes such dispensing or employment during the term of appointment shall not be eligible to continue to serve on the committee.

**Discussion**
*Persons who dispense drugs or whose practice locations dispense drugs also have a conflict of financial interest.*

**Recommendation**
(c) Members of the P&T Committee shall not have a substantial financial conflict of interest in relation to a pharmaceutical entity. For purposes of this section, the following definitions apply:

(1) "Pharmaceutical entity" means a pharmaceutical manufacturer, pharmaceutical repackager, pharmaceutical relabeler, compounding pharmacy, pharmacy benefits management company, biotechnology company, or any other business entity that is involved in manufacturing, packaging, selling or distribution of prescription or non-prescription drugs, drug delivery systems, or biological agents.

(2) ~~For purposes of this section,~~ "~~s~~Substantial financial conflict of interest" means that the applicant or committee member, or his or her immediate family member, has a direct or indirect financial interest in a pharmaceutical entity, including:

**Discussion**
*The modifications to (c) are recommended for clarity.*

## Priority Considerations

As issues of particular priority, the Institute strongly recommends that the Division consider incorporating the following suggestions into the MTUS Preferred Drug List:

1. Pertinent conditions and diagnoses, as well as other information such as NDCs and black box warnings, should be incorporated in order to identify drugs that have not been prescribed in accordance with the MTUS Guidelines. If basic factors such as pertinent conditions, diagnoses, and NDCs are not integrated into the list, efficiency will be significantly reduced because a separate review will be necessary to determine whether or not a drug is prescribed in accordance with the MTUS Guidelines. Furthermore, disputes over those determinations will arise, cause delays, and will require an as-yet-unidentified dispute resolution process.

2. Providing links to pertinent MTUS Guidelines regulations and to the pharmaceutical fee calculator, and further enabling users to search and sort the Drug List would greatly facilitate appropriate drug prescription, authorization, and review.

3. Recognizing that the enabling statute calls for a phased implementation period for workers injured prior to July 1, 2017, it is nevertheless imperative that the regulations specify a definitive date by which time all injured workers must be safely transitioned to medications pursuant to the formulary. Without a final deadline, it is likely that compliance will be substantially less than complete and the formulary will not have the intended effect.

4. The proposed formulary appropriately bases Preferred and Non-Preferred status on Evidence-Based Medicine guidelines, but it does not address the costs associated with drugs in the categories. There is tremendous variation in the amounts paid under the Pharmaceutical section of the Official Medical Fee Schedule based on the National Drug Code (NDC) self-assigned to the same therapeutic drugs. A recent CWCI study[1] provided examples of variation in payment values for therapeutically equivalent drugs such as Tramadol HCL ranging from a minimum of $.03 per unit to $16.49 per unit under the Medi-Cal Federal Upper Limit pricing structure and a range of $0.09 to $19.87 in Average Wholesale Price. In order to disincentivize dispensing of higher cost drugs in the same therapeutic class, the Institute recommends incorporating NDCs into the MTUS Drug List. As referenced in the RAND study, organizations such as Milliman can provide an objective cost analysis of NDCs for inclusion in the MTUS Drug List. Alternatively, PBMs could be permitted to address and incorporate the difference in dosages. Providing a method for addressing cost without impacting the therapeutic determinations would enable cost containment while protecting injured workers' access to necessary drugs.

Thank you for the opportunity to comment, and please contact us if additional information would be helpful.

Sincerely,

Brenda Ramirez
Claims & Medical Director

Stacy L. Jones
Senior Research Associate

BR:SLJ/pm

cc: George Parisotto, DWC Acting Administrative Director
CWCI Claims Committee
CWCI Medical Care Committee
CWCI Legal Committee
CWCI Regular Members
CWCI Associate Members

[1] Swedlow, A. & Hayes, S. "*California's Proposed Workers' Compensation Formulary Part 1: A Review of Preferred and Non-Preferred Drugs."* CWCI Spotlight Report. August 2016.