



Western Occupational & Environmental Medical Association
A Component Society of the American College of Occupational and Environmental Medicine

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George Parisotto, Administrative Director
Division of Workers' Compensation
California Dept. of Industrial Relations
1515 Clay St., 17th Floor
Oakland, CA 94612

RE: WOEMA Comment on Implementation of AB 1124 Drug Formulary

Dear Administrative Director Parisotto,

The Western Occupational and Environmental Medical Association (WOEMA) is pleased to comment on the proposed Drug Formulary regulations posted on the DWC Forum. WOEMA is a non-profit professional association representing more than 500 Occupational Medicine physicians and other health care professionals in five Western states including California, who champion workplace and environmental safety and health.

WOEMA believes that the establishment of a Workers' Compensation formulary in California has the potential to improve the quality of medical care for injured workers and to reduce pharmacy costs in a number of areas, particularly with regard to the prescribing of opioids, non-generic medications, and compounded topical medications, as has happened in other states. A carefully chosen set of "Preferred" medications and reliable guidance about their optimal use stands to benefit injured workers under medical treatment, their medical providers, and carriers. In particular, WOEMA is pleased that the chosen list of "Preferred" medications is based on the evidence-based reviews contained in the Reed Group formulary, which in turn has its foundation in the ACOEM Practice Guidelines and their evidence-based methodology.

However, WOEMA also cautions that the details of implementation are critical to ensuring that application of the formulary does not cause harm, whether through delays in filling appropriately prescribed and sometimes time-critical medications, through decreases in patient compliance, or other factors. To that end, WOEMA would draw DWC's attention to ACOEM's (American College of Occupational and Environmental Medicine) policy paper on Workers' Compensation formularies published in August, 2016, titled "Drug Formularies in Workers' Compensation Systems." WOEMA strongly supports the concerns and conclusions expressed in this ACOEM policy paper, and our comments incorporate by reference its general recommendations. The paper is available at:

http://www.acoem.org/uploadedFiles/Public_Affairs/Policies_And_Position_Statements/Guidelines/Position_Statements/DrugFormulariesinWorkersCompensationSystems.pdf

We offer the following specific comments about the proposed regulations:

1. We are concerned that designation of many medications as "Non-Preferred" may be misinterpreted by some payers as meaning "should be denied," when in fact many such drugs may be useful or even critical in some situations. The advent of the formulary should not make legitimate prescription of medications harder, and the DWC should be very clear to so state when it implements a formulary.
2. Subsections 9792.27.5, 9792.27.6, 9792.27.7, 9792.27.8, 9792.27.10, 9792.27.11 and 9792.27.12 of the proposed regulations contemplate that "retrospective review" of a prescription for a drug might find that a prescription already filled was not "medically necessary" and thus payment could be denied. For instance, it will not be a reasonable expectation that the pharmacist would know the diagnosis for which a medication is prescribed, which may determine if it is Preferred or not. In such a case, we are concerned as to how payments for the medication will be handled. If the dispensing entity is ultimately not paid despite prospective assurances, then dispensers may reasonably refuse to take part in filling any workers' compensation prescriptions, badly damaging the whole formulary enterprise. We believe that this must be avoided, and encourage the DWC to deal with this problem explicitly.
3. We believe that additional medications deserve a place on the formulary as "Preferred" in appropriate situations. In particular, those listed in ACOEM's "Drug Formularies in Workers' Compensation Systems" (August 2016), Section G, should be strongly considered for inclusion in order to protect patient health in urgent and/or non-controversial situations as described:

- a) Bloodborne pathogen exposure
- b) Soft-tissue infection complicating a work-related wound
- c) Acute gout complicating a soft-tissue sprain/strain
- d) Severe hypertension complicating a workplace violence episode
- e) Nausea and vomiting complicating heat exhaustion
- f) Asthma exacerbation at work
- g) Deep vein thrombosis

In particular, bloodborne pathogen exposure is a relatively common problem handled under workers' compensation, where prophylactic antiviral medication must be started "as soon as practicable," and optimally within an hour or two of exposure, in order to prevent HIV infection in the exposed worker. Anti-retroviral medications present little risk of abuse, and delay in filling a prescription can be life threatening. Similar considerations apply to the prescribing of antibiotics for certain infections, including soft tissue infections following work-related lacerations and other wounds. The other scenarios on the above list also have strong arguments for their inclusion among the "Preferred" medications.

4. There will be a need for further assessment and ongoing updating of the formulary as time goes on. By the proposed implementation date of July 2017 there are likely to be significant changes in the literature already, so there should be no delay in convening the Pharmacy and Therapeutics Committee ("P&T Committee"), described in subsection Section 9792.27.1(r). In order that the panel may be convened as soon as practicable after the implementation date, we strongly recommend that the members of the P&T Committee be selected and be prepared to meet as soon as possible after the implementation date.

5. There are nine medications listed as eligible for "Special Fill," and nine listed as eligible for "Perioperative Fill" for a total of fifteen drugs eligible for one or the other category (three drugs are listed for both). In every case, those fifteen drugs are shown as not to be so prescribed for more than 4 (four) days. We would like to point out that since existing regulations require that utilization review (UR) decisions must respond to a Request for Authorization (RFA) within 5 (five) days, this leaves the fifth day uncovered for situations in which the drugs are truly necessary. We believe that the DWC should either change the maximum to five days for consistency with UR requirements, or acknowledge that in such situations an expedited review will be necessary. If a significant increase in expedited reviews are expected, preparations will be needed for an increase in such requests.

6. The only drugs listed as being eligible for “Special Fill” and “Perioperative Fill” appear to be related to musculoskeletal disorders and perioperative anticoagulation. The categories listed above under this document’s paragraph (3) should be included in Special Fill and, in the case of antibiotics, Perioperative Fill, as these may be urgently required and are not usually susceptible to abuse.

7. Very problematic is the issue of “legacy” prescriptions, or prescriptions already filled or authorized as of July 1, 2017, but which may not be “Preferred” medications. Legacy prescriptions are addressed in proposed subsection 9792.27.3. We would note that the proposed regulation would place the burden on the treating provider to identify any and all prescriptions previously written which were not “Preferred,” even if the provider had previously submitted an RFA and obtained authorization for the medications, or if they were previously covered under a Future Medical Findings and Award (“F&A”).

While we strongly support optimizing drug regimens according to evidence-based medicine concepts, in fact patients on chronic medications, including chronic pain regimens, are often difficult to manage, and reduction in morphine equivalent doses (MEDs) often requires a great deal of skill, caring, and physician time as well as risk. Efforts to initiate changes in these situations should originate with the payer, not with the treating physician. In our view, it should be up to the payer to initiate an outreach to both the provider and the patient in writing, and first to take an educational approach.

We also note that the statement, "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." seems in conflict with "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply."

A reasonable solution here is to state that the MTUS Drug Formulary “**shall**” 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."

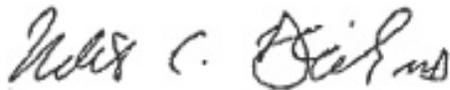
We would encourage DWC to establish administrative or other informal procedures in order to transition patients to “Preferred” medications in situations where such a transition is appropriate, rather than turning immediately to processes requiring more RFAs and UR. Because such transitions will often not be appropriate, it is imperative that there be a substantive peer-to-peer conversation between

the treating physician and the UR reviewing physician. Robust procedures must be in place to encourage such interactions as real clinical dialogue rather than as pro-forma demands for a rigid checklist.

If the treating physician is willing to discuss the case with a pharmacy benefit manager or other UR agent, then appropriate weight must be given to the provider's opinion and recommendations. The length of the transition period will be variable. For some patients on complex chronic pain regimens, a two-year transition period may sometimes be needed. But we also feel that in cases where a change in regimen is judged desirable, initiation of such transition should begin promptly and perhaps even before July 1, 2017. We certainly recognize that in many cases where the provider and patient have agreed to such a transition process, evidence of dose reduction or other optimization may need to be developed if requested in a peer-to-peer conversation, and such evidence may require 90 days or more to collect.

8. Finally, we are concerned regarding the designation of medications as being "Non-Preferred" yet both recommended and non-recommended within MTUS. For example, Cyclobenzaprine is both recommended and non-recommended in the current ACOEM Guidelines. The differentiation is the category of pain for the same condition. Since pain is a subjective experience, how will this differentiation be made? While we agree with the intent of the proposal, the mechanism for the physician to understand the formulary requires both knowledge of the formulary, and reference to the MTUS for the clinical indication. Overall it will lead to a number of challenges for prescribers.

Thank you for your consideration,

A handwritten signature in black ink, appearing to read "Robert C. Blink, MD". The signature is fluid and cursive.

Robert Blink, MD, President