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Hello I am practice physician in Ca for workers compensation claims. I am hoping that we as a state implement changes more along the lines if Texas. Physicians need options when treating injured workers with a formulate similar to one PPO patients have access to. This gives the physicians options and also in my opinion allows educated patients to appreciate the health care they desire. If the body which is deliberating on this issue wish to meet physicians and get out insight I will volunteer my services and I am sure we can get others

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### **Background**

On October 6, 2015, Governor Brown approved Assembly Bill 1124, which provides for the adoption of a drug formulary for the California workers' compensation system. That formulary is intended to be included within the medical treatment utilization schedule and must incorporate the evidence-based, peer-reviewed, national recognized standards of care recommended by the Commission on Health and Safety and Workers' Compensation. The formulary is mandated to address, *at a minimum*, the frequency, duration, intensity and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases.

In other words, insofar as medications are concerned, the Administrative Director of the Division of Workers' Compensation is empowered to tell physicians what to prescribe, when to prescribe it, how to prescribe it, and how much will be paid for the prescription.

### **One Size Fits All—Tailoring Care to the Patient**

Drugs have been shown to be very cost-effective treatments for chronic illness; they forestall complications, reduce attendant medical utilization, and make patients more productive. David P. Goldman, Geoffrey F. Joyce, Moving Towards Better Formulary Management, *The American Journal of Managed Care*, v. 11, no. 1, Jan. 2005, p. 13-14. However, a formulary which does not further the goal of AB 1124 to provide appropriate medications expeditiously while minimizing administrative burden and associate administrative costs, will not appropriately serve the stakeholders in the workers' compensation system.

Of primary concern is the limitation of available options for medical providers and their patients. As pharmacogenomics has demonstrated drugs and dosages that may be effective for a particular patient may not be effective for another. *See* Margaret Mroziewicz, M.Sc.1 and Rachel F. Tyndale, Ph.D., Pharmacogenetics: A Tool for Identifying Genetic Factors in Drug Dependence and Response to Treatment, *Addict Sci Clin Pract.* 2010 Dec; 5(2): 17–29.

Medication decisions made on the basis of ingredient cost leads to poor clinical outcomes. Decisions are based on aggregate measures without tailoring to each patient's circumstances. The result is formularies that are socially wasteful, and that patients perceive as overly intrusive.

### **Dictating the Standard of Care**

In one survey, Veteran's Administration physicians were generally supportive of VA formulary policies including choosing best-value drugs to control pharmaceutical expenditures. Nevertheless, access to nonformulary drugs and timely approval of requests for nonformulary medications were strong predictors of clinician satisfaction and support for cost-containment measures. Peter A. Glassman, MBBS, MSc; Chester B. Good, MD, MPH; Mary E. Kelley, MS; Melissa Bradley, BA; and Michael Valentino, RPh, MHSA, Physician Satisfaction with Formulary Policies: Is it Access to Formulary or Nonformulary Drugs that Matters Most?, *Am J Manag Care*. 2004;10:209-216.

The question, then, is whether the formulary will coincide with the standard of care. Whatever the confines of the formulary, physicians will still be obliged to follow the standard of care. The primary reason to choose a medical treatment cannot be that the government has deemed it worthy, and therefore agreed to lay out precious dollars.

Consideration of the scope of the formulary must start with what the patient might need, not what the insurance industry will support on a restricted list. Once upon a time, the *differential* was a list of possible diagnoses, which might explain the patient's symptoms. Doctors studied the differential diagnosis list to determine the actual disease and then, and only then, the physician picked possible therapies. Now the *differential* is a limited number of the treatments which have been chosen by the insurance industry, possibly because they work and definitely because they are what the corporation, stockholders and taxpayers can afford.

### **Interplay of the FDA and Compounding**

As stakeholders in the workers' compensation system know, the Food & Drug Administration does not directly regulate the business of compounding medication. Naturally, each of the components of a compound must be approved by the FDA. Despite the fact that the compounds themselves are not FDA approved, that does not mean that compounded medications are of no benefit. The evidence based medicine supports the efficacy of compounded medications in facilitating the rapid return of injured workers' to employment following recovery from their injuries.

To ensure and enhance quality of care, any consideration of a formulary must take into account two primary considerations relative to compounds.

First, patients are presently under treatment plans that entail the use of compounded medications (whether topically, orally or intrathecally). By necessity, changing the course of a patient's care—particularly patients who are chronic pain patients on with high dosages—will be ill-

advised. Consequently, the formulary must both permit the continuation of existing patient treatment plans indefinitely and be flexible enough to permit physician selection of appropriate medication modalities for treatment of each patient uniquely.

Second, the presumption must be that the care provided is indicated and appropriate. The preauthorization process is presently unduly cumbersome and time consuming. Nine times out of ten, the carrier does not respond to a request for authorization and payment is denied for lack of authorization—requiring the provider to adjudicate a lien in a lengthy process. Third party payors should be in the position of objecting to medications, whether compounded or not, in a post-payment review process to incentivize quick action on their part and, ultimately, to facilitate the rapid delivery of care to patients.

### **Questions for DWC to Respond To**

Addressing the above concerns and observations, the DWC should answer the following key questions (in writing):

- Insofar as AB 1124 did not contemplate the wholesale change of existing treatment plans for thousands of injured workers and the FDA does not approve medications that are either ineffective or unsafe. ***Should all FDA-approved prescription drugs should be included?***
- The presumption should be that physicians properly exercise their independent professional medical judgment and the burden should be on third party payors to establish that the judgment is inconsistent with medical necessity or appropriateness. ***Should physician discretion should be protected to enable treatment, even if off-label?***
- As long as each of the components in a compound is FDA approved, there are many evidence based scientific studies documenting the benefits and efficacy of certain compounded medications. ***Should specially compounded drugs, including intrathecal medications and topical creams, be included in the formulary and reimbursed under existing methodology?***
- Utilization, pre-payment review as a means of gatekeeping medications provided to injured workers has caused and will continue to cause delays in treatment and recovery that are inconsistent with the acceptable standard of care. Post-payment review of medical necessity makes more sense. ***Should medications be subject to pre-approval or retrospective carrier review?***

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#### FORMULARY RECOMMENDATION

Since injured or ill workers are no different medically from those with similar afflictions due to non-occupational causes, there is absolutely no need for a separate DWC Drug Formulary. Instead, DWC should save its time and the taxpayers' money by adopting the existing and proven Medi-Cal formulary, which has already been developed at public expense by a government agency which knows much more about medical practice than does DWC, and has a much longer track record of assuring cost-effective prescribing while preserving access of its beneficiaries to mainstream medical treatment.

#### ALTERNATIVE ACTION

Rather than re-invent an idiosyncratic variant of the Medi-Cal formulary, DWC should focus its resources on reforming the current corrupt WC UR system, which, at least as to psychiatry, routinely....

- 1) Uses unqualified non-psychiatric physicians for UR, despite the requirement that UR doctors must have the same scope of practice as the treatment physicians, and ...
- 2) Uses irrelevant MTUS/ODG guidelines for such reviews, despite the plain language
  - a. Of ACOEM Chapter 15, which indicates that its guidelines are intended for use by non-psychiatric physicians engaged in pain management and...
  - b. Of the law, which says that other peer-reviewed guidelines (such as those of the American Psychiatric Association for anxiety and depressive disorders, and of the DWC itself for PTSD) may be used when MTUS/ODG guidelines are inapplicable, and ...
- 3) Issues ghost-written denial letters literally rubber-stamped by UR doctors, whose favorable decisions may be overridden by anonymous non-physicians, including insurance company claims adjusters.

The same corrupt practice extends to IMR reviews by **[REDACTED]**, which routinely engages in flawed appellate reviews as per #1 an #2 above, instead of at least using psychiatric reviewers and criteria at this level, as confirmed by (ghost-written?) letters over the signature of **[REDACTED]** an occupational medicine specialist who is the **[REDACTED]** Medical Director.

**[REDACTED]** standard claim that **[REDACTED]** uses "expert reviewers" is factually false, in that the specialties his own letters cite are typically occupational medicine or PMR, not psychiatry. Thus, the only apparent qualification of the **[REDACTED]** pseudo-experts is a

willingness to accept payment for their names and licenses in denying psychiatric medications for injured workers.

The reason that first-level UR denials are upheld 90% of the time by [REDACTED] is because both level reviews are basically crooked, in identical ways as noted above. And, the reason that most challenges to these wrongful UR decisions come from a relatively small number of doctors is that the existing WC UR system has helped drive out the smaller providers, leaving big practices with the knowledge, resources and motivation needed to advocate for their patients.

## CONCLUSION

As a retired Medical Director of the Riverside County Department of Mental Health, I strongly urge the DWC to adopt the Medi-Cal Drug Formulary, and concentrate instead on cleaning out its own Augean Stables, by requiring UR doctors to certify under penalty of perjury that. . .

1. They are board-certified in the same medical specialty as the treating doctor, and ...
2. They have personally reviewed all medical records cited as a basis for their decision, and ...
3. They have personally made at least two calls to the phone number reflected on the treatment doctors' letterheads, for case discussion with treating doctors, and...
4. They have personally read and considered any criteria other than the MTUS/ODG as requested by the treating doctors, and...
5. Any modification or denial letters bearing their stamped signatures are solely their own work, with no ghost-writing.

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## **COMMENTS/QUESTIONS REGARDING THE COMMITTEE**

What is the role of RAND Institution in all of this? Was one of the charges for the RAND Institute to determine the most cost effective way to control costs in relation to a formulary? Was the provision of the highest quality of patient care the primary directive to the RAND Institute in conducting its research? Who is paying for the RAND Institute? Is it just the DIR or other sources also? What are those other source? Is there any direct or indirect funding from insurance carriers or defense attorneys?

Labor Code 5307.29 requires the creation of a committee in conjunction with a drug formulary. Subsection (c)(1) states that "...A committee member shall have knowledge or expertise in one or more of the following: ..." Does this mean that as long as one or two members of the committee have 'knowledge or expertise' in the four defined criteria, the rest of

the members do not have to have any of that ‘knowledge or expertise’? What is the criteria to determine if a committee member has ‘knowledge or expertise’?

Have the candidates already been selected for the committee members?

What is the criteria for the selection of committee members beyond what is listed in Labor Code 5307.29? Thousands of people qualify under the criteria – what additional criteria was/will be utilized in picking committee members? What are the standards that were/will be used in picking committee members?

Additionally, it is well known in the industry that some providers are ‘defense friendly’ and others are ‘applicant friendly’. What are/will be the backgrounds of each committee member? Were/Will the candidates (be) invited to submit applications or were/will they be approached to be a part of the committee? If there was/is no application process, why were/will the specific individuals (be) chosen? Who proposed/proposes their names? What criteria were/will be used?

It is unclear what the scope of the committee will be. Will the committee be charged with creating a formulary or only with adding or excluding medications from an already set up formulary? From a pragmatic standpoint, it makes sense that any formulary that is established be modeled after formularies that are already being successfully utilized in other forums, such as Texas or Medicare. It is impossible for six people to develop a de novo formulary because of the massive amount of time that is involved in reviewing each and every one in the universe medication to decide on whether or not it should be included or excluded. How is it possible for six people to have in-depth knowledge of hundreds of medical specialties and subspecialties (with all their nuances and complexities) to effectively create a formulary that results in the availability of necessary medications for all types of industrial injuries. Along the same lines, there must be transparency with respect to the criteria that will be used to set up a formulary. What safeguards will be implemented to ensure transparency? In other words, to make sure that setting up a formulary is not just a cover story whereas the real agenda is to exclude costly medications such as compounds.

### **COMMENTS/QUESTIONS REGARDING NON-FORMULARY MEDICATIONS AND COMPOUND MEDICATIONS**

Labor Code 5307.27(b) reads: On or before July 1, 2017, the medical treatment utilization schedule adopted by the administrative director shall include a drug formulary using evidence-based medicine. **Nothing in this section shall prohibit the authorization of medications that are not part of the formulary when the variance is demonstrated, consistent with subdivision (a) of section 4604.5** (MTUS presumptively correct on issue of extent and scope, but rebuttable by preponderance of scientific medical evidence establishing variance reasonably required to cure or relieve the injured worker from the effects of his or her injury). Is there a difference between ‘not prohibiting’ and actually allowing? What safeguards will be

implemented to **ensure** that a physician who is actually familiar with the patient is allowed to prescribe or dispense his/her choice of medication (whether on the formulary or not) aimed at curing or relieving the injured worker from the effects of his or her injury? Ultimately, how do we know that despite what the legislative intent is (i.e. injured workers first and cost controls second), the formulary won't be used as a tool solely to control costs, regardless of the impact to injured workers?

The same kinds of comments and concerns apply to compound medications. There are many benefits of compound medications. These include, but are not limited to the fact that they allow for the exclusion of allergenic components, they reduce the amount of pills that must be taken, and they significantly reduce systemic absorption and subsequent side effects of such absorption. Does the exception noted in LC 5307.27(b) apply to compound medications? What if all ingredients in a given compound medication are FDA approved? Is that medication then deemed to be part of the formulary if FDA approval is the main criterion for inclusion in the formulary? Fundamentally, the push to create a formulary appears to be an attempt to implement the legislation prohibiting compound medications that failed in 2011. Will the formulary preclude the use of compound medications altogether? It should be noted that even in the Medicare system, compound medications are allowed.

#### **COMMENTS/QUESTIONS REGARDING APPROVALS AND PAYMENTS**

It is unclear whether prior approval will be required before a physician can prescribe medication that is within the formulary. Any requirement for prior approval of formulary medication serves no purpose other than to add more layers to a bureaucratic system that is already overburdened by significant delays at the expense of injured workers and the providers who service them. It appears from the statutory scheme itself that no such prior approval will be necessary for formulary medications since Labor Code 530.27(b) calls out a specific circumstance when there must be preapproval (i.e. non-formulary medications).

Assuming, however, that prior approval is required, a failure to timely respond to a request for authorization should result in an automatic de facto authorization. Such de facto authorization must be part of the new regulations to ensure that there are no protracted disputes, again at the expense of injured workers and providers who are in compliance with these statutory requirements and are prescribing formulary medications. Providers should not have to bear the burden of delayed payment when they follow the rules.

What mechanisms will be put into place to ensure expedited payments to providers when the prescribed medication is within the formulary and the injured worker has an accepted injury? The formulary cannot be used to restrict physician judgment in the name of costs savings while at the same time leaving the carriers with unchecked power to withhold payment. Therefore, there must also be penalties imposed on carriers for failure to pay timely. Having a formulary should be aimed at improving efficiency and benefit all parties not just the insurance carriers.

