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Implementing AB 1124 (2015): A Background Paper on Creating a Formulary for California's Workers' Compensation

*A Joint Hearing of the Senate Committee on Labor and Industrial Relations
and the Assembly Committee on Insurance*

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Since 1913, California's workers' compensation system has attempted to provide an equitable balance between the needs of California's injured workers and employers. At the core of this balancing act is what is colloquially referred to as the 'grand bargain': injured workers receive necessary treatment (and an award if the injury is permanent), but lose the right to sue--- meaning workers' compensation becomes the exclusive remedy for all workplace injuries. Employers, on the other hand, do not need to worry about workplace injury liability in the courts, but they are liable for the medical treatment for injured workers (as well as a permanent disability indemnity award if the injury is serious).

While the system generally succeeds in providing that equitable balance for most injured workers and employers, few stakeholders would argue that that the system is an unqualified success for all of California's injured workers. One area of significant strain and disputes is in the provision of pharmaceuticals in the workers' compensation system. *The purpose of this backgrounder is to give a brief overview of formulary systems and the requirements of AB 1124, which mandated the creation of a formulary for California's workers' compensation system.*

What is a Formulary?

A **formulary** is generally defined in the medical literature as a list of medications and related policies which is continually updated by experts, such as pharmacists and medical providers, and represents the most up-to-date knowledge of medical treatment and appropriate use of pharmaceutical products. Formularies are the norm in medical care delivery systems: Medicare and Medi-Cal have formularies, as do group health providers and single-payer healthcare systems internationally.

Formularies are used to place limits on the use of medications in order to avoid over-use, ensure that the use of medication matches the latest in medical literature, promote optimal outcomes, and cost-effectiveness. However, formularies are not simply arbitrary limits on drug use. Formularies must be broad enough to provide drug treatment options when they are available, and formulary decisions are guided substantially by the scientific evidence regarding the effectiveness of individual drugs (typically through a review by qualified professionals on a pharmacy and therapeutics committee).

Another potential area of savings is ensuring that the lowest cost version of a specific drug is utilized. For instance, the California Workers Compensation Institute (CWCI) looked at the range of pricing for three of the most commonly prescribed drugs in California's workers compensation system and found variations in prices for those drugs as follows:

- For hydrocodone with acetaminophen 10-325 the average wholesale price (AWP) ranged from \$0.58 per pill to \$3.58 per pill.
- For ibuprofen 800 mg the AWP ranged from \$0.04 per pill to \$5.46 per pill.
- For gabapentin 300 mg the AWP ranged from \$0.12 per pill to \$3.80 per pill.

By driving prescribing to the lowest available cost of a specific drug, a formulary can realize significant savings **while providing the same treatment.**

Equally important, formularies allow medical providers and pharmacists to know what medicines will and will not be paid for, and for what conditions medicines are allowed, reducing friction and making it easy to provide medical services. **Formularies, therefore, hold the promise of both improving healthcare outcomes and reducing burdens for medical providers to provide care.**

California, however, does not have a formulary for its workers' compensation system. Not surprisingly, therefore, pharmaceuticals are significant point of friction in workers' compensation. For example, nearly half of all (42%) Independent Medical Review (IMR) medical disputes involve pharmaceuticals, dwarfing all other categories. These disputes delay medical treatment for injured workers, and are also time-consuming and expensive for both medical providers and payors.

Additionally, there are concerns with how pharmaceuticals are being utilized in the workers' compensation system. For example, between 2002 and 2013, CWCI found that the prescribing of Schedule II Drugs, which include oxycodone, fentanyl and morphine, have grown to 7.3% of California workers' compensation prescriptions and 19.6 percent of California workers' compensation prescription dollars – a nearly 600% and 400% growth, respectively. As Schedule II pharmaceuticals like fentanyl can be more powerful than heroin, this growth is worrying for the long-term outcomes of California's injured workers, and raises concerns of dependence-causing drugs being improperly prescribed.

As was noted above, **a formulary has the potential to solve both issues.** First, a formulary provides a list of pharmaceutical products and when they can be used. This ensures that

medicines are prescribed for medical, and not financial, purposes, and it ensures that the medicines are appropriately used. **Second**, when a medical provider utilizes the formulary, the payor knows why a particular medicine was used and why. This cuts down on medical disputes, ensuring that medical providers are paid and injured workers get the medicines they need.

Formularies in Texas and Washington:

Recent interest in a formulary for California's workers' compensation system intensified after a 2014 study by CWCI, which projected savings between \$124 to \$420 million from California adopting a formulary similar to Texas or Washington. Both Texas and Washington adopted formularies in response to sustained, double-digit growth in their workers' compensation prescription drug costs, and experienced significant declines in the use of opioids. However, both states have very different formularies.

Washington first launched its formulary in 2004 as a part of a larger initiative to control drug purchasing costs across state agencies. At its core, Washington has a short list of preferred drugs that can be prescribed or dispensed by a medical provider. If a medical provider wishes to prescribe something that is not on the list, he or she needs to seek prior authorization from the State of Washington. However, Washington also allows for physicians to write non-preferred drug class prescriptions if the physician has signed up to allow for drug substitution when medically appropriate.

Washington updates and maintains its formulary through the Pharmacy and Therapeutics Committee, which is composed entirely of physicians and pharmacists. The Committee looks at the safety, efficacy, and effectiveness of each drug and then makes a recommendation to the State of Washington. Public comment is also possible for interested stakeholders.

Texas, on the other hand, implemented its formulary in 2011. After looking at several formularies in other states, Texas decided to include all FDA approved drugs in its formulary. However, the guidelines for prescribing drugs were developed by Official Disability Guidelines (ODG), a private company that also developed Texas's medical treatment guidelines. ODG's drug guidelines classify each drug with either an 'N' or 'Y', with 'N' drugs requiring prior authorization. Updates to the formulary are automatically performed by ODG.

While both states developed very different formularies, they share several common traits. **First**, the legislatures in both states delegated the creation of the formulary to their respective workers' compensation administrative entities. **Second**, the final decisions for what drugs are pre-approved or not are decided by committees made up of pharmacists and medical providers. **Third**, the enacting statutes were largely conceptual and left the specifics to the regulatory process.

The Requirements of AB 1124 (Chapter 525, Statutes of 2015):

Last year, AB 1124 (Perea) was passed by the Legislature and signed by the Governor. The bill was the product of multiple stakeholder meetings attempting to find the appropriate balance between empowering the Division of Workers' Compensation (DWC) to create a formulary, yet also address stakeholder concerns on cost, drug access, and reducing medical dispute friction. The final version of the bill created a requirement for the DWC to create a formulary, effective July 1, 2017, but included several "safety valves". These included:

- Declaring the intent of the Legislature that the creation of the formulary be transparent, provide guidance on off-label dispensing, generic drugs, and pain management, as well as guidance on the use of the formulary to minimize administrative burdens and costs;
- Requiring that the formulary allows for variances if a preponderance of evidence suggests such a variance is medically necessary;
- Permitting the formulary to include a phased implementation for workers injured on or after July 1, 2017 to allow those workers to safely transition to medications on the formulary; and
- Requiring the DWC to meet and consult with workers' compensation stakeholders prior to the establishment of a formulary. The stakeholders include, but are not limited to, employers, insurers, private sector employee representatives, public sector employee representatives, treating physicians actively practicing medicine, pharmacists, pharmacy benefit managers, attorneys who represent applicants, and injured workers.

Following the example of Washington State, AB 1124 creates an independent Pharmacy & Therapeutics (P&T) Committee to update the formulary. The job of the P&T Committee is to review and consult with the Administrative Director on available evidence of the relative safety, efficacy, and effectiveness of drugs or a class of drugs in updating to the formulary. The Committee must consist of 7 members, including the Executive Medical Director of the DWC, and be a physician or pharmacist that is an expert in one of the following areas:

- a) Clinically appropriate prescribing of covered drugs;
- b) Clinically appropriate dispensing and monitoring of covered drugs;
- c) Drug use review; or
- d) Evidence-based medicine.

AB 1124 also requires the creation of a conflict-of-interest code for P&T Committee members and requires that the P&T Committee updates the formulary at least quarterly.

Ensuring the Appropriate Implementation of AB 1124:

Today's hearing is taking place a bit more than 15 months before a workers' compensation formulary must be effective in California. As such, it is an opportune moment for the Legislature to consider the progress of the DWC in creating a formulary that addresses the needs of the workers' compensation system's many stakeholders. Specifically, this oversight hearing will cover the following issues in detail:

- I. Looking at the experiences of other states to establish what California can expect with the creation of a formulary;
- II. Questioning the Administration on their progress in implementing a workers' compensation formulary, including their efforts in stakeholder outreach; and
- III. Hearing from a broad cross-section of stakeholders on the implementation of AB 1124 and the proposed formulary.