SENATE COMMITTEE ON LABOR AND INDUSTRIAL RELATIONS
Senator Tony Mendoza, Chair
2015 - 2016 Regular

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Subject: Workers' compensation: prescription medication formulary

KEY ISSUE

Should the Legislature require that the Division of Workers' Compensation (DWC), after receiving recommendations from a Workers' Compensation Formulary Advisory Committee, create a workers' compensation-specific formulary that would govern the prescribing of medicines for injured workers?

ANALYSIS

Existing law establishes a workers' compensation system that provides benefits to an employee who suffers from an injury or illness that arises out of and in the course of employment, irrespective of fault. This system requires all employers to secure payment of benefits by either securing the consent of the Department of Industrial Relations (DIR) to self-insure or by securing insurance against liability from an insurance company duly authorized by the state.

Existing law provides that medical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatuses, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer. (Labor Code §4600)

Existing law requires that pharmacists and prescribing physicians must dispense generic drug equivalent, unless a generic drug equivalent is unavailable or the prescribing physician documents specifically why a non-generic drug should be dispensed. (Labor Code §4600.1)

Existing law provides that employers, insurers, or groups of employers or insurers may contract with a pharmacy, group of pharmacies, or pharmacy benefit network to provide medicines and medical supplies to injured workers. Such a contract must comply with the standards set by the Administrative Director, who is the head of the Division of Workers' Compensation (DWC). (Labor Code §4600.2)

Existing law requires that all employers create a utilization review process, which is a process that prospectively, retrospectively, or concurrently review and approve, modify, delay, or deny, based in whole or in part on medical necessity to cure and relieve, treatment recommendations by physicians, prior to, retrospectively, or concurrent with the provision of medical treatment services. (Labor Code §4610)

Existing law currently sets the maximum reimbursement for pharmacy drugs and services, and also requires that furnishing and dispensing of pharmacy drugs and services are subject to the Official Medical Fee Schedule (OMFS). (Labor Code §5307.1)

Existing law provides that the Administrative Director must adopt, after public hearings, a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care and must address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. (Labor Code §5307.27)

This bill requires the Administrative Director (AD) establishes a formulary for medications prescribed in the workers' compensation system to be effective commencing July 1, 2017.

This bill requires the AD convenes a Workers' Compensation Formulary Advisory Committee to assist in the development of the formulary. The Committee must include, but is not limited to, health care providers, insurers, employers, pharmacists, applicant attorneys, an appointee from the Speaker of the Assembly and appointee from the Senate Rules Committee.

This bill also requires that the Formulary Advisory Committee study and make recommendations on the development of a workers' compensation formulary, and that they meet quarterly and provide their recommendations by December 31, 2016.

This bill also requires that the Formulary Advisory Committee make recommendations on the need for evidence-based revisions to the formulary. The Administrative Director would then have 60 days to approve or reject the recommended revisions.

This bill requires that the formulary include the following:

1) Injured worker access to appropriate opioids, other pain management prescriptions, and off-label prescription drugs, when medically necessary;
2) A gradual detoxification plan for a worker receiving potentially addictive prescription drug treatment; and
3) Timely formulary updates that minimize delays involved in adding new drugs to the formulary.
4) Injured worker access to a non-formulary medication when the only formulary medication available for a worker's covered condition is one that the worker cannot tolerate, or that is not clinically efficacious for the worker, or provider determines medication needed by worker should include abuse deterrent properties. Exceptions to formulary medications as noted in this section shall not be required absent a trial period and issuance of a medical finding by the injured worker's provider outlining the medical basis for the conclusion that the worker cannot tolerate the formulary medication.

COMMENTS

1. 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, and promote optimal outcomes. 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, the California Workers' Compensation Institute (CWCI) found that the prescribing of Schedule II Drugs, which include oxycontin, fentanyl and morphine, have grown to 7.3 percent 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 somewhat 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.

2. Formularies in Texas and Washington:

Recent interest in a formulary for California's workers' compensation system intensified after a 2014 study by the California Workers Compensation Institute (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.

3. AB 1124 and the Workers' Compensation Formulary Advisory Committee:

Under the existing law, the Administrative Director has the authority to create a formulary. However, this authority has not been tested by the courts, and the AD has yet to promulgate a formulary. AB 1124 would require that the Administrative Director do so by January 1, 2017.

However, AB 1124 differs from both Washington and Texas by creating the Workers' Compensation Formulary Advisory Committee (Advisory Committee), which would make recommendations to the AD on both the creation and maintenance of the formulary. The Advisory Committee would consist of both medical professionals and non-medical stakeholders. This may create implementation challenges, which will be discussed below.

a) Advisory Committee Governance and Structure

As was discussed above, the Advisory Committee is created by AB 1124 and tasked with the creation and maintenance of a formulary. Essentially, the Advisory Committee functions as an additional public forum prior to the creation of a formulary through the regulatory process. In performing its function, the Advisory Committee would be required to comply with Bagley-Keene Act and the California Public Records Act, the cost of which would likely come from DIR's budget.

However, it is unclear how the Advisory Committee would function. Would there be a Chairperson? Would questions be decided by a majority vote? What are the terms of the members? Would each stakeholder be represented by a single individual? **Why are there no employee representatives?** Currently, these questions are unanswered.

The Committee may wish to consider if it would be more efficient to mandate a stakeholder outreach process by DIR and DWC in the creation of a formulary, rather than the Advisory Committee. Such a process could cost less, entail fewer litigation risks, and may be more likely to yield expert opinions that would more effectively shape the regulatory process.

b) The Inclusion of Non-Medical Stakeholders in the Advisory Committee

As was noted above, AB 1124 currently requires that the Advisory Committee be composed of multiple stakeholders including, but not limited to, insurers, employers, applicant attorneys, legislative leadership appointees, as well as medical providers and pharmacists. If the Advisory Committee functioned on a majority vote basis, it is possible that non-medical stakeholders could outvote the medical expertise provided by medical providers and pharmacists. **The Committee may wish to consider how non-medical stakeholders could impact the creation of an objective medical guideline for the treatment of injured workers**.

4. AB 1124 and Workers Compensation Administration:

As was noted earlier in the analysis, the promise of a formulary is that it will reduce medical disputes, improving payments for medical providers and reducing frictional costs for employers. However, AB 1124 may face challenges in fulfilling such a promise. Specifically, this is due to the bill's silence on the existing Utilization Review (UR) process, as well as the inclusion of language listing exemptions from the formulary.

Utilization Review and AB 1124:

Under current law, a request for authorization (RFA) for medication would be submitted to the employer by a medical provider. If the employer contested the use of the medication, he or she would then submit the request for UR. However, different employers submit different treatment requests to UR: medication that may be automatically approved by one employer would be disputed by another. Additionally, medical providers prescribe different drugs for the same condition: where one medical provider would prescribe ibuprofen, another may prescribe opioids. This lack of common guidelines leads to disputes that hurt both medical providers and employers.

A formulary helps to rectify this by providing common guidelines for both sides to follow, but also modifying the dispute process. For example, if a medical provider is following the

formulary in Texas, her treatment will not be disputed. Moreover, if an employer has concerns and wishes to dispute the use of a drug, it can only be done retrospectively, ensuring the injured worker receives his or her medication.

AB 1124 retains the current UR process, making the formulary a useful reference, but not a legally binding mechanism to reduce disputes. **Without such a mechanism, it is unclear if the formulary will result in the cost savings for employers and medical providers, or improved outcomes for injured workers.**

Formulary Exceptions and AB 1124:

As currently written, AB 1124 provides for exceptions to the formulary if the injured worker cannot tolerate the medication, if the medication is not clinically efficacious, or if the provider determines that tamper-resistance medication is necessary. While AB 1124 requires a trial period and a medical finding for such a determination, **it is unclear how such an exception would operate.** For example, if a treatment was found to be ineffective, but another treatment on the formulary was effective, would the effective formulary treatment be required? Or would the medical provider still have the ability to deviate from the formulary? Would the employer utilize UR? Or would the physician be presumed correct, and therefore the dispute would need to be litigated through the WCAB?

HOWEVER, the author's office has reported that amendments taken in Committee will address these concerns.

5. Proponent Arguments:

Proponents note that California has some of the highest workers' compensation costs in the country and argue that much of this is due to frictional costs related to the prescribing of prescription drugs. Proponents note the recent CWCI study which projects significant savings in the creation of a formulary, and argue that such savings could bring relief to employers and reduce burdens on medical providers. Proponents believe that AB 1124 would create an evidence-based formulary that would ensure that injured workers receive the drugs they need, reduce disputes, speed up treatment, and combat the inappropriate prescribing of opioids and other dangerous drugs.

6. Opponent Arguments:

The California Applicants' Attorneys Association (CAAA) is opposed unless amended to AB 1124. Specifically, CAAA argues that AB 1124 should include a provision that limits the use of utilization review of drugs on the formulary. CAAA argues that, to the degree that a drug formulary will reduce access to certain prescriptions and limit employee medical treatment options, it is only reasonable that the employee should not be subject to unnecessary delays in approving prescription treatments. As such, CAAA urges that AB 1124 be amended to include limits on the use of utilization review when an injured worker is prescribed a drug from the approved formulary by a medical provider network doctor.

7. Prior Legislation:

AB 378 (Solorio), Chapter 545, Statutes of 2011, regulates the reimbursement rates for compound drugs and certain types of prescription drugs.

SUPPORT

Association of California Insurance Companies
Zenith Insurance

OPPOSITION

California Association of Joint Powers Authorities
Californian Applicants' Attorney Association

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