California Workers' Compensation Institute
1333 Broadway, Suite 510, Oakland CA 94612
(510) 251-9470

BULLETIN

No. 17-13 August 1, 2017

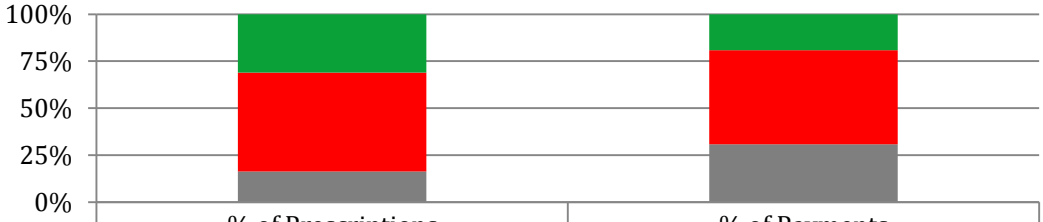
With five months to go before the January 1 effective date for the California Workers' Compensation Prescription Drug Formulary mandated by AB 1124, the DWC appears to be close to wrapping up its work on the final regulations, and the Institute has released an analysis that reviews the potential impact of the proposed Formulary Drug List.

The Formulary Drug List of Drug Ingredients was based upon the American College of Occupational and Environmental Medicine's (ACOEM) pharmaceutical formulary. At the core of the list is a category system that slots each of the 275 drugs into Exempt (formerly called Preferred) and Non-Exempt (Non-Preferred) drugs. Under the proposed regulations, Exempt drugs will not require authorization prior to dispensing as long as the drug therapy is supported by the Medical Treatment Utilization Schedule for the patient's condition and phase of recovery (acute vs. chronic); while Non-Exempt and not listed drugs will be subject to prospective utilization review (UR) prior to dispensing. All pharmaceutical requests, regardless of drug list category, will be subject to retrospective UR.

The latest draft of the proposed formulary regulations, released for a 15-day public comment period two weeks ago, included several changes to the draft regulations that were issued last August. The latest changes include:

- The addition of 36 drugs to the Formulary Drug List, resulting in a larger percentage of drugs that will not require authorization prior to dispensing. These additions to the Exempt list should have a minor impact as these drugs, which were added to reflect updates to ACOEM's Foot and Ankle Guidelines, are not heavily used in workers' comp;
- Changes to two categories of drugs that under certain conditions will not require prospective utilization review:
    - The addition of eight Special-Fill drugs, including Cyclobenzaprine HCL (Flexeril), which a physician may prescribe or dispense without preauthorization at the single, initial visit following the injury when that visit occurs within seven days of the injury date;
    - The addition of a Perioperative Drug category containing 14 drugs that may be dispensed to the injured worker from 4 days prior to surgery to 4 days after surgery without prospective review.

To determine the percentage of prescriptions that would fall into the Exempt or Non-Exempt categories, CWCI used a sample of 650,000 prescriptions with 2016 fill dates from its Industry Research Information System database. The results showed that nearly one-third (31.1 percent) of the prescription drugs dispensed to California injured workers in 2016 are on the proposed formulary's Exempt Drug list, and these drugs accounted for 19.2 percent of the pharmaceutical payments in the sample. In comparison, 27 percent of the drugs dispensed in 2016 were on the comparable "Preferred" drug list from the August 2016 draft regulations and those drugs represented 22 percent of the pharmaceutical payments in the sample.



	% of Prescriptions	% of Payments
Exempt	31.1%	19.2%
Non-Exempt	52.6%	50.0%
Not Listed	16.3%	30.8%

Conversely, nearly 69 percent of the drugs in the sample are Non-Exempt and Not Listed drugs in the formulary, and these drugs accounted for 81 percent of the total prescription drug spend in the sample, while under the 2016 proposal, 73 percent of the drugs were on the Preferred list, and those drugs accounted for 78 percent of the total prescription drug spend.

A review of Exempt and Non-Exempt status of the top 20 therapeutic drug groups in California workers' compensation shows that nearly all (98.3 percent) of the anti-inflammatory analgesics and ulcer drugs (99.2 percent) will be exempt from prospective utilization review, while drugs in several other therapeutic drug groups will fall primarily in the Non-Exempt category. Notably, the primarily Non-Exempt drug groups include opioid analgesics (99.7 percent), which accounted for nearly one out of every four California workers' compensation prescriptions in 2016. With the exception of very limited Special-Fill and Perioperative prescriptions, opioids would be subject to prospective UR. Among other drug groups that are primarily comprised of Non-Exempt drugs are musculoskeletal therapy agents (98.1 percent); anticonvulsants (98.6 percent); and antidepressants (95.5 percent).

In addition to assuring that the prescription drugs provided to injured workers meet evidence-based medicine standards, another key aspect of the formulary regulations is to fulfill the legislative intent of AB 1124 to lower friction costs of pharmaceutical dispute resolution. Prior studies showed that pharmaceutical dispute resolution accounted for 43 percent of UR costs and more than 48 percent of Independent Medical Review (IMR) costs. To measure the proportion of UR and IMR conducted for drugs in the Exempt, Non-Exempt and Not Listed prescription drug categories, the authors used CWCI's UR and IMR databases, which contain more than 250,000 UR events and more than 296,000 IMRs involving pharmaceutical requests for which decisions were rendered in 2015 and 2016. The results showed that 22.5 percent of the pharmacy utilization reviews and 21.4 percent of the pharmacy independent medical reviews involved requests for Exempt drugs. The authors caution, however, that the reductions in frictional costs are not likely to match those percentages, as a review of the IMR decisions found that 60.4 percent of the Exempt drugs reviewed by IMR physicians were co-prescribed along with either Non-Exempt or not listed drugs.

While there are still pathways for those who seek to exploit regulatory loopholes, the study shows that the proposed formulary does represent a significant step toward achieving the legislative intent of AB 1124 by helping to assure that the medications provided to injured workers are in accordance with evidence-based medicine and by addressing the high percentage of medical disputes involving prescription drug requests. In addition, the DWC has added placeholder columns within the Formulary Drug List for future inclusion of information on drug strength, dosage form, and specific drug identifier, which should add helpful detail that can be used to address some of the issues and abuses that continue to plague the system. Furthermore, the adoption of the formulary regulations opens the door for additional controls that could be used to address the high cost of workers' compensation pharmaceuticals. For example, recent and pending changes in Medi-Cal drug pricing, which is the basis for the California workers' compensation Pharmacy Fee Schedule, could offer an independent, partial solution, as detailed in a CWCI Spotlight Report in May of this year, which examined how a pharmacy fee schedule could establish maximum reasonable fees based upon the lesser of its Medi-Cal allowance or the National Average Drug Acquisition Cost of its therapeutic equivalent drug.

The implementation of the Workers' Compensation Prescription Drug Formulary and the Exempt and Non-Exempt Drug Lists will undoubtedly lead to changes in drug utilization and prescribing patterns, and in the volume and mix of pharmaceutical requests that go through the medical dispute resolution process, so the Institute will continue to monitor these trends, as well as related issues that may arise, and comment on any additional changes to the regulations that are proposed. In the meantime, CWCI's analysis examining the impact of the proposed Drug Formulary has been released as a Spotlight Report, "California's Workers' Compensation Formulary, Part 2: A Review of the July 2017 Proposed Formulary Drug List of Exempt and Non-Exempt Drugs." The report is available to CWCI members and subscribers in the Research section at (www.cwci.org), while others may purchase a copy from the Institute's online store.

BY/