



Regulatory Update: California Formulary Draft Rules Published

August 26, 2016 – In conjunction with the publication of the RAND Corporation’s study on the implementation of a closed formulary,¹ the California Division of Workers’ Compensation (DWC) released its initial draft regulations of the much-anticipated pharmacy formulary.² The Formulary, which was necessitated by the passage of AB 1124 (2015), covers “outpatient” prescription medications for injured workers dispensed after July 1, 2017.

While First Script conducts a comprehensive review of the draft rules, with an eye towards recommending commentary to the DWC prior to the September 16th deadline,³ we would like to provide the following highlights of the draft rules:

Administrative Overview

The Formulary, as currently proposed, would apply to ALL claims (irrespective of date of injury) as of the effective date of July 1, 2017. While language exists in the draft rules that suggests appropriate transitional safeguards be afforded to claimants receiving medications that would not be “on-formulary,” no specific cut-over date or time period is provided, as was done in other state-mandated formularies.

Medications are to be administered using both the Formulary’s “Preferred Drug List”⁴ and the existing California Medical Treatment Utilization Schedule (MTUS). This means that the Formulary’s Preferred Drug List alone does not allow/disallow a medication. Medications must also be prescribed in accordance with the MTUS. By way of example, a short-acting opiate may be generally allowable in short supply under the Preferred Drug List, but may not be allowable for the specific prescribed circumstance under the MTUS’s newly updated Opioid Treatment Guidelines.

Utilization Review, both prospective and retrospective, is retained in whole as both necessary and available mechanisms for validating the medical necessity of a prescribed medication. In fact, prospective review would be mandatory with this formula for all Non-Preferred drugs, compounds, off-label prescribed drugs and drugs not incorporated by the Preferred Drug List. Prospective Review is a legal term in California and is only able to be conducted by a properly licensed Utilization Review Organization (URO), though payors may waive prospective review and opt for retrospective review post-dispensing.

Pharmacy Benefit Networks (under both the Labor Code and MPN rules) are permitted to have less restrictive formulary controls, but not more restrictive.

¹ http://www.rand.org/content/dam/rand/pubs/research_reports/RR1500/RR1560/RAND_RR1560.pdf

² <http://www.dir.ca.gov/dwc/ForumDocs/Implementing-AB-1124-Drug-Formularyand-update-of-MTUS-Guideline/Text-of-Regulations.pdf>

³ <http://www.dir.ca.gov/dwc/ForumDocs/Implementing-AB-1124-Drug-Formularyand-update-of-MTUS-Guideline/Implementing-AB-1124-Drug-Formularyand-update-of-MTUS-Guidelines.htm>

⁴ <http://www.dir.ca.gov/dwc/ForumDocs/Implementing-AB-1124-Drug-Formularyand-update-of-MTUS-Guideline/MTUS-Preferred-Drug-List.pdf>

Formulary Construction

The Preferred Drug List consists of a listing of common workers' compensation dispensed medications, associated into three groupings:

1. Preferred Drugs – Those drugs that may be dispensed without prospective review
2. Non-Preferred – Those drugs that may not be dispensed without prospective review
3. First Fill – Those drugs that may be dispensed as part of an initial medical visit, if conducted within seven days from date of injury

In addition, specific classes of drugs are called out requiring prospective review:

- All compounds – Though not compounding kits, which are exempt by the draft rule definition of compounds
- Prescriber-dispensed medications – Except when in a supply of 7 days or less
- Drugs prescribed for “off-label” use
- Drugs not listed on the Preferred Drug List, or are otherwise not FDA approved

The Formulary is expected to be updated on a quarterly basis, and is to be largely overseen by an appointed Pharmacy and Therapeutics Committee.

For additional information as the Formulary rules continue to develop or to provide input to First Script, please consult your Account Manager.