Drug Recalls and Withdrawals

In the U.S., the Food and Drug Administration (FDA) ensures drugs are tested for safety and effectiveness before they become available. A recall can occur when a drug is removed from the market because it is found to be either defective or could be harmful.

There are 3 types of recalls required by the FDA, according to the level of danger involved:

- **Class I:** Dangerous or defective products that could cause serious health problems or death. Example: a label mix-up on a lifesaving drug.
- **Class II:** Products that might cause a short-term health problem or pose only a slight threat of a serious nature. Example: a drug that is under-strength but that is not used to treat life-threatening illness.
- **Class III:** Products that may not cause any bad health reactions, but violate FDA labeling or manufacturing laws. Example: a minor pill bottle defect.

Drug companies may also decide to remove products from the market (market withdrawal). Example, a drug removed from the market due to tampering.

CalOptima's Pharmacy Management department informs members, doctors and pharmacies when there is a Class I or II drug recall. We also inform our members in writing when drugs are withdrawn from the market for safety reasons.

CalOptima reviews drug recalls and withdrawals every 3 months. The review takes place in a meeting of the Pharmacy and Therapeutics (P&T) Committee. You can find details on drug recalls and withdrawals on CalOptima's website at: https://www.caloptima.org/Home/Members/Medi-Cal.aspx.

Please talk to your doctor about any details on drug recalls and withdrawals that may affect you.

Drug Recalls and Withdrawals for 3 Quarter 2020 Addressed at the 11/19/2020 P&T Meeting:

Class I Recalls

- There are no recalls at the time.

Class II Recalls

- There are no recalls at the time.

Market Withdrawals

- Metformin Hydrochloride Extended-Release Tablets USP, 500mg, 750mg and 1000mg
- DDAVP Nasal Spray 10 mcg/0.1mL
- Desmopressin Acetate Nasal Spray 10 mcg/0.1mL
- STIMATE Nasal Spray 1.5 mg/mL
- Nature-Throid and WP Thyroid

Created on 11/20/2020