Aetna Better Health® of New Jersey

Drug Recalls

Drug recalls can occur at any time and for a variety of reasons. A drug recall is the most effective way to protect the public from a defective or potentially harmful product. Drug recalls may be conducted on a company's own initiative or at the request of the Food and Drug and Administration (FDA).

The FDA's role in a recall is to oversee a company's strategy, assess the adequacy of the recall plan and classify the recall.

FDA Recall Classifications

Class I: Dangerous or defective products that predictably could cause serious health problems or death.
Class II: Products that might cause a temporary health problem or pose only a slight threat of a serious nature.
Class III: Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws.

Not all recalls are announced on the FDA.gov website or in the news media. Public notification is generally issued when a product that has been widely distributed or poses a serious health hazard is recalled. Patients also may learn that their medicine has been recalled through notification from the manufacturer, their health care professional or pharmacist.

Generally, Class I recall notifications provide patient instructions along with actions to take. The FDA recommends that patients follow the instructions provided by the recalling company. Each recall is different in its size and scope and may not impact all lots, batches or manufacturers of the recalled drug; therefore, the appropriate actions may also differ.

When patients may be in possession of a recalled drug, a coordinated plan of action between the patient, their prescriber(s) and the dispensing pharmacy is needed. The pharmacy that provided the medication can help confirm for the provider and the patient whether or not their medication is part of the recall. The dispensing pharmacy can also confirm if the prescription can be replaced with unaffected product or if a change in drug therapy may be required.

Aetna takes our member's safety seriously and in the event of a patient level I recall, we work with our Pharmacy Benefits Manager (PBM) partner to send notification letters and instructions to our members who may have been impacted by the recall. A copy of this letter is also distributed to the prescriber of the medications based on Aetna's prescription claims histories.

References:

https://www.fda.gov/Drugs/DrugSafety/DrugRecalls/ucm612550.htm accessed 9.12.18