**Medications Recalls**

**Section:** Pharmacy Operations

**Compliance:** URAC Specialty Pharmacy 2.1

**URAC Standards:** PHARM Core 21, PHARM-OP 8, 11, 14, SDrM 2, 5

**ACHC Standard:** DRX7-7A

**Policy ID:** 7.13

**Approved by:**

**POLICY**

As part of <insert practice name>’s patient safety process, an effective drug recall system is in place in order to prevent harm or adverse patient outcomes**. [SDrM 2 (c)][SDrM 5 (c)]** These procedures address the removal and disposal of medications that have been recalled, discontinued, damaged, contaminate or have expired or been determined to be counterfeit. **[PHARM-OP 8 (b)][PHARM-OP 14 (a-i)]**

**PROCEDURE**

1. The pharmacist, upon receiving information about a recall from manufacturer and/or FDA/DEA, will document the date, as well as the name and quantity of the medication affected by the recall. With the pharmacist’s signature, this document is placed in the “Recall” folder in the pharmacy. Appropriate staff will be notified by the Pharmacist and instructions will be provided in handling the Recalled medication procedures. **[PHARM-OP 11 (a, b)]**
2. In the case of a Class I, II, or III recall, purchase order documentation will be reviewed for recalled lot numbers **[PHARM-OP 11 (d)]**
3. Recalled pharmacy stock will be pulled from the stock levels and segregated in an appropriate area for recall to include medications that are in the process of being shipped or prior to shipping. In addition, all discontinued, expired, damaged, contaminated, unacceptable and/or determined to be counterfeit medications can be identified and removed during the process of being shipped or prior to shipping. **[PHARM-OP 11 (d, e)]**
4. Appropriate disposal of medications that have been recalled, discontinued, expired, damaged, contaminated, unacceptable and/or determined to be counterfeit will be performed. Appropriate disposal may be through a reverse distributor or through addition to hazardous waste containers. **[PHARM-OP 8 (c-i, ii)] [PHARM-OP 11 (f)]**
5. Dispensed recalled product will be audited against patient records and patients will be notified about the recall. **[PHARM-OP 11(c)]**
6. In the event of patient-level recalls, Pharmacy Technicians will assist in communicating recalls to the prescribers of individual patients whose medications have been affected by the recall(s). **[PHARM-OP 11 (c)]**
7. The pharmacy will reclaim any unused recalled pharmaceuticals from patients, taking caution not to alarm any patients. However, communication must be deliberate to ensure the need to return or discard any recalled product. **[PHARM-OP 11 (c)]**
8. In the case of recalls, as well as in other cases where a patient needs to dispose of unused medication, a pharmacist or pharmacy technician will advise the patient to: **[PHARM-OP 11 (f)]**
* Return unused medication to pharmacy for disposal.
* When the unused medication is in an injection device, the pharmacist or pharmacy technician will advise the patient to dispose of the “sharp” item in an approved sharps container and offer to provide one at no charge should the patient not have one. The pharmacist or pharmacy technician will advise the patient has to how to seal the sharps container, and return to the pharmacy for disposal
1. If a patient-level recall drug is in route, a pharmacist or pharmacy technician will contact the patient by phone, email or other expeditious method in an effort to prevent their use of the recalled medication. If unable to reach the patient, they will notify the patient’s prescriber by phone, fax or other expeditious means. **[PHARM-OP 11 (c)]**
2. Written reports of all activities must be completed and filed in the “Recall” folder along with the initial recall document. The Pharmacy Manager of <insert practice name> will also be apprised of all patient level recall activities **[PHARM-OP 11 (a)]** and summary analysis reported to Quality Management Committee **[PHARM Core 21]**

|  |  |  |
| --- | --- | --- |
| **DATE:** | **REVISED BY:** | **REVISION:** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |