Pharmacy Recall Policy & Procedure (08/01/2012)

1. Either pharmacist or technician to does recall products as soon as recall paperwork received if pharmacy does not have the recalled product or product lot numbers they must notate that on the paperwork and file it in the appropriate location.
2. If a product that is being recalled is with in the inventory that the pharmacy has it will immediately procure that product and move to a location in the pharmacy where it can not be used or confused as to being a drug that needs to be placed back on the shelf.
3. When time allows either the pharmacist or technician will review the appropriate paper work from the Wholesaler or other Vendor performing the recall and fill out any necessary paperwork for that specific recalled item.
4. If an opened bottle, individual must at that time count the medication and write on the return sheet how many full or partial bottles are being returned and what lot# each bottle pertains to in the recall.
5. The following a list of the level of recalls the FDA utilizes:
    a. **Class I Recalls** by the US Food and Drug Administration (FDA) are the most severe type of FDA recall. In a Class-I recall there is a potential for serious injury or death.
    b. **Class II Recalls** are issued on products that have a lower chance of causing major injuries or death, but where there is still the possibility of serious enough adverse events to have irreversible consequences.
    c. **Class III Recalls** are not very likely to cause adverse health consequences, but there is still a chance and therefore the product is being recalled.
    d. If medications are issued a recall status of class 1, reports will be generated to see if any patients received any of the recalled medication and will be called and notified in a timely manner of less than 24 to 48 hours. Documentation of patients receiving this medication will be documented in a recall folder and patient's prescribing physician will then be notified. Patient will be instructed as to what action needs to be taken during this level of recall.

Approved By: Shawn Eisenman

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