NORTHERN NEVADA ADULT MENTAL HEALTH SERVICES

POLICY AND PROCEDURE

SUBJECT: MANUFACTURERS SUPPLY AND RECALL

NUMBER: NN-EC-10

ORIGINAL DATE: 08/26/92

REVIEW/REVISE DATE: 08/25/95, 10/29/98, 05/01/03, 05/04/06, 8/20/09, 7/19/12

APPROVAL:________Cody L. Phinney_______, Agency Director

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I. PURPOSE

To establish a system which allows the Northern Nevada Adult Mental Health Services (NNAMHS) Purchasing Department to respond immediately to notification of a supply or equipment recall from a manufacturer or the Federal Food and Drug Administration (FDA).

II. POLICY

NNAMHS will take all reasonable precautions to prevent the use of any item that could be injurious to the user.

III. REFERENCES

1. NNAMHS Policy and Procedure #NN-MM-18 Drug Recalls.
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IV. PROCEDURE

1. Purchasing Department Supervisor shall be responsible for handling all recalls of product lines (except drugs), and for taking the necessary action to withdraw products from use.
2. Drug recalls will be initiated through the NNAMHS Pharmacy If the Purchasing Department Supervisor receives notification of a drug recall, they will notify NNAMHS immediately.
3. The action taken depends upon FDA recall classification as follows:
   a. Class One: Class One recalls involve a situation in which there is a reasonable probability that the use of, or exposure to, a volatile product will cause serious adverse health consequences, or death.
      1) Action: All products are to be immediately impounded and destroyed, or returned to the manufacturer, according to instructions from the FDA or the manufacturer. FDA inspectors usually check to determine the hospital's compliance with the regulations.
   b. Class Two: Class Two recalls involve a situation, in which the use of or exposure to a volatile product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences, or where the probability of serious adverse health consequences is remote.
      1) Action: All products are to be impounded from all areas of the hospital, but not necessarily destroyed, until final instruction by the FDA or the manufacturer.
   c. Class Three: Class Three recalls involve a situation in which the use of or exposure to a volatile product is not likely to cause adverse health consequences.
      1) Action: Products are to be retrieved from all areas of the hospital and either destroyed, returned to the manufacturer for replacement/credit, or held until Administrative judgment is exercised.

4. Upon receipt of a supply or equipment recall notification from the FDA or a manufacturer, the Purchasing Department Supervisor will note the following information:
    a. Brand or official name of the product
    b. Manufacturer
    c. Product Number
    d. Lot Number
5. If it is determined that the product has been purchased, the Purchasing Department Supervisor will prepare the Intra-hospital Supply and Equipment Recall Notification located in the Purchasing Department. This form requests that supply areas be checked and recalled items be returned to the Purchasing Department. Purchasing will distribute the notification forms to all areas to be notified within three (3) days of receiving the notification.
6. The Purchasing Department Supervisor will indicate on the intra-hospital Supply and Equipment Recall Notification Checklist all areas to which the notifications have been sent.
7. Department Heads, Hospital Administrative staff, Nursing Supervisors, Warehouse staff will:
    a. Check all product storage areas and emergency supplies for recalled items.
    b. Complete and return the Intra-hospital Supply and Equipment Recall Notification, along with any recalled stock, to the Purchasing Department within twenty-four (24) hours.
8. The Purchasing Department Supervisor will be responsible to:
    a. Isolate all recalled stock.
    b. Note receipt of the recall notifications and review the checklist for completeness.
    c. File all documented information in the “Supply and Equipment Recall” file.
    d. Return or destroy the recall products as directed by the manufacturer or FDA.

e. Report the status of the recall and final disposition to the Medical Director.
f. Notify all Department Heads of the recall at the next monthly Leadership meeting.