DRUG RECALLS

PURPOSE:

The purpose of this Policy is to provide guidelines for Ascension At Home, LLC and its subsidiaries, (the "Company") to effectively and completely remove recalled medications from its agencies and from its patients.

POLICY:

It is Company policy that it will comply with all recalls initiated by a drug manufacturer or the Food and Drug Administration in a manner that is consistent with the law.

PROCEDURE:

General Principals

- Recalls are actions taken by a pharmaceutical manufacturer to remove a product from the market. Recalls may be conducted on manufacturer's own initiative, at the request of the Food and Drug Administration ("FDA), or by an order by the FDA under statutory authority.

- There are three different categories of drug recalls:

    1. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
    2. A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
    3. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

Recall Procedures

- Upon receipt of written or verbal notification from the manufacturer or the FDA on the recall of a drug product, the Company will initiate removal and recall procedures, which shall include immediate notification to: the Branch Manager and the Pharmacist-in-Charge, who will:

1. Determine immediately whether or not the Company has any of the recalled product and the degree of the recall action necessary.
2. Send a product recall notice to all locations which may have received the drug.
3. Review the Company's storage areas for the product and remove it if present.

- For product that has been delivered to patients, the Branch Manager and/or the Pharmacist-in-Charge will print a drug utilization report, "NDC Usage report" and a product identifier code will be entered (i.e. product NDC number) to list the individual transactions. The report will list all patients who have received prescriptions for the recalled drug. Depending on the degree of recall action necessary, individual patients will be contacted by telephone, e-mail, or letter by the Pharmacist-in-Charge or his designee.

- The Company will maintain documentation recording all issued drug recalls and the specific actions taken in response to such recalls.

- Recalled medications are to be collected and quarantined and/or disposed of in accordance with the recall notice.