



# Compliance Alert

February 1, 2008

## **Express Scripts – Urgent – Emerging Therapeutic Issues Communication**

On January 18, 2008, the U.S. Food and Drug Administration (FDA) announced the recall of all lots and sizes of heparin and normal saline pre-filled flush syringes manufactured by AM2 PAT, Inc. These syringes are used to keep intravenous (I.V.) lines open. These products are recalled after two lots were found to be contaminated with *Serratia marcescens*, a bacterium that can cause serious injury or death. These syringes are manufactured under the brand names Sierra Pre-filled, Inc. and B. Braun.

According to FDA:

- **Consumers should stop using these products immediately.**
- **If patients have the recalled syringes, they should return them to their pharmacy for a replacement.**

For additional information about these changes or to report an adverse event, please access FDA's MedWatch website at: [www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm). You can also call FDA at 1-888-INFO-FDA (automated) or 301-827-4570.

### **Express Scripts response:**

- In an effort to inform patients of the market withdrawals, we have identified patients who may have received a prescription for the recalled heparin and normal saline prefilled lock flush syringes within the past 120 days. We will send a communication to these patients, summarizing information provided by FDA.
- The above communications will be distributed for those clients enrolled in the patient mailing portion of the Emerging Therapeutic Issues Program.
- Express Scripts Mail Service Pharmacies have not purchased any of the recalled products.

***If you have any questions regarding this information, please contact your Group Benefit Services Account Manager at 1.800.638.6085.***

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