

BROADCAST FAX/EMAIL ALERT

TO: Medical Directors, DON's Administrators
DATE: January 22, 2008
RE: FDA MedWatch Notices of Heparin Sodium recalls due to multiple adverse reactions
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**The FDA Safety Information and
Adverse Event Reporting Program**

BAXTER HEALTHCARE AND FDA NOTIFIED HEALTHCARE PROFESSIONALS OF A VOLUNTARY RECALL OF CERTAIN LOTS OF HEPARIN AS A PRECAUTION DUE TO AN INCREASE IN REPORTS OF ADVERSE PATIENT REACTIONS ASSOCIATED WITH THESE LOTS. Baxter is in the process of an in-depth investigation to determine the root cause of the reported reactions.

Reported adverse events include abdominal pain, decreased blood pressure, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, hypotension, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, stomach discomfort, tachycardia, thirst, trismus, and unresponsiveness to stimuli. There have been no reports involving fatality. See the recall notice for a list of affected lots.

Read the complete 2008 MedWatch Safety Summary including a link to the firm's recall notice, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#HeparinInj>

AM2 PAT, Inc., notified healthcare professionals and patients of a nationwide **RECALL OF ALL LOTS OF BOTH HEPARIN AND SALINE PRE-FILLED FLUSHES.** These products are distributed under two brand names, Sierra Pre-Filled Inc and B. Braun. The products are sold in 3ml and 5ml sizes for Heparin and 3ml, 5ml, and 10ml sizes for Normal Saline. One lot of Heparin IV flush syringes (1003-02, Lot 070926H) was contaminated with *Sierratia marcescens* which has resulted in patient infections. This type of bacterial infection could present a serious adverse health consequence that could lead to life-threatening injuries and/or death. User facilities and consumers should stop using the product immediately, quarantine remaining inventory, and return the product to their respective distributor.

Read the complete 2008 MedWatch Safety Summary including a link to the Manufacturer's Recall Notice regarding this issue at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Heparin>