The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Baxter Healthcare Corporation is issuing a voluntary recall of three lots of ExactaMix micro-volume inlets after identifying that a box of air filters used during manufacturing contained a mixture of incorrect 0.8-micron filters and the intended 3-micron filters. Baxter has identified the three finished good lots listed below that may contain the mixed filters and is taking this action out of an abundance of caution.

Use of a 0.8-micron filter in place of the validated 3-micron filter may lead to reduced flow efficiency, incomplete or slower transfers of ingredients, or system alarms. Because this inlet is intended for small-volume ingredients, any undetected under-delivery may result in a meaningful deviation from the prescribed amount of that ingredient in the final admixture. Depending on the specific ingredients affected, this issue may lead to clinical effects such as electrolyte imbalance, metabolic instability, delayed recovery, etc. The likelihood of serious harm is considered low because the compounding process occurs in a controlled pharmacy environment where operators are trained to monitor alarms, observe abnormal flow behavior, and verify completion of each compounding step. No complaints or adverse events related to this issue have been reported.

PRODUCT: ExactaMix vented micro-volume Inlet

UDI NUMBER: 00085412475806

LOT NUMBERS: 804084, 804088, 804089

PRODUCT CODE: H938175