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Centers for Medicare & Medicaid Services
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Center for Medicaid and State Operations/Survey and Certification Group

**Ref: S&C: 08-19**

**DATE:** **May 9, 2008**

**TO:** State Survey Agency Directors

**FROM:** Director
Survey and Certification Group

**SUBJECT:** Alert: Food and Drug Administration (FDA) Heparin Recall For All Provider Types

**Memorandum Summary**

- The FDA has issued recalls for medications that have the potential for serious adverse reactions in patients/residents. The FDA Web site for recalls is located at: http://www.fda.gov/opacom/7alerts.HTML
- It is important that all health care providers are aware of this information regarding recalled products.

We are taking this opportunity to alert you of recent FDA recalls of some medications (e.g., heparin, digoxin, fentanyl patches) that have the potential for serious adverse reactions in patients/residents. It has come to our attention that recalled heparin, in particular, has been found in several health care facilities. Information on recalled products and lot numbers may be accessed at the FDA Web site located at http://www.fda.gov/opacom/7alerts.HTML

Pharmacy providers and distributors and health care providers should be monitoring their supplies, including crash carts, storage cabinets, as examples and removing recalled products in order to assure that recalled products are not available for patient/resident use.

The FDA MedWatch Web site has helpful and timely information on recalls and provides a method of receiving email notifications of alerts, warnings, and recalls. The following information is taken from the FDA Web site:

> "FDA has the responsibility for assuring the safety and efficacy of all regulated marketed medical products.
>
> MedWatch, the FDA Safety Information and Adverse Event Reporting Program, serves both healthcare professionals and the medical product-using public. We provide important and timely clinical information about safety issues involving medical products,

including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products (e.g., medical foods, dietary supplements and infant formulas).

Medical product safety alerts, recalls, withdrawals, and important labeling changes that may affect the health of all Americans are quickly disseminated to the medical community and the general public via this website and the MedWatch E-list. Select Safety Information to see reports, safety notifications, and labeling changes posted to the website since 1996."

State survey agencies should remain diligent in achieving their federal survey & certification obligations through strategies that will not adversely affect completion of Tier 1 and 2 workloads.

These actions should include:

- Distributing a list of recalled heparin drugs to surveyors of facilities that typically use anti-coagulants, including surveyors of hospitals, critical access hospitals, End Stage Renal Disease (ESRD) facilities, Ambulatory Surgery Centers, and rural health clinics;
- Include a check of the possible presence of these recalled drugs during the course of scheduled surveys, including presence in hospital pharmacies, ESRDs, floor storage units, crash carts, medication carts, etc.;
- Request a copy of any written procedures for implementing drug recalls;
- Request a description of staff notification and education efforts used to ensure that recalled heparin is not used for patient care.

Thank you for your assistance in this important matter.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management
Regional Administrators
ESRD Network

Attachment – FDA alert

***May 9, 2008***

# *FDA Bulletin:*

"To Our MedWatch Partners: Please help FDA spread the word about recalls of injectable heparin products and heparin flush solutions that may be contaminated with oversulfated chondroitin sulfate (OSCS). Affected heparin products have been found in medical care facilities in one state since the recall announcement. Although product recall instructions were widely distributed, they may not have been fully acted upon at all sites where heparin is used. There have been many reports of deaths associated with allergic or hypotensive symptoms after heparin administration (see FDA link at http://www.fda.gov/cder/drug/infopage/heparin/adverse_events.htm). We ask that health professionals and facilities please review and examine all drug/device storage areas, including emergency kits, dialysis units and automated drug storage cabinets to ensure that all of the recalled heparin products have been removed and are no longer available for patient use. In addition, FDA would like to inform health professionals about other types of medical devices that contain, or are coated with, heparin. To read this update, and to learn how to report these problems to FDA, please go to: http://www.fda.gov/cdrh/safety/heparin-healthcare-update.html. Please report to FDA adverse reactions associated with these devices, as well as any reactions associated with heparin or heparin flush solutions. If you have questions or would like more information about this request, please contact the Division of Drug Information at 301-796-3400."