

FOR IMMEDIATE ATTENTION

TO: Nursing Supervisors, Medical Directors, Administrators

FROM: Leighann Sauls RN, CDN
Director, Quality Improvement

DATE: May 14, 2008

RE: FDA Heparin Recalls

You will recall recent communications from Network 6 regarding lot #s of heparin sodium injections that were voluntarily recalled by several companies in order to prevent adverse patient reactions. Many more companies are voluntarily recalling this medication. On Friday, May 9, 2008 we received the following e-mail message from the Centers for Medicare and Medicaid, which we are forwarding to all dialysis and transplant facilities in Network 6.

May 9, 2008 FDA Bulletin:

"To Our Med Watch 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."

What you should do with this information:

- Check your entire medication inventory and remove heparin from lot #s and companies listed on the attached tables.
- Be sure to check all drug storage areas, including emergency kits, dialysis units, automated drug storage cabinets and other storage lockers for affected lot #s.
- Remove the medication from the area so that it is not available for patient use.
- Check home dialysis patients' inventory, home care units, acute dialysis units and transplant units for affected medication.
- **Do not use heparin from any of these lot #s**
- Go to: <http://www.fda.gov/cdrh/safety/heparin-healthcare-update.html> to check other types of medical devices that contain, or are coated with heparin.
- Report adverse reactions associated with these devices, as well as any reactions associated with heparin or heparin flush solutions to the FDA.
- If you have questions or would like more information about this request, please contact the FDA Division of Drug Information at 301-796-3400.
- Contact the suppliers and distributors of any of the affected lot #s using the instructions on the Press Releases listed on the FDA web-site. For direct links to the press releases that we are currently aware of go to www.esrdnetwork6.org.
- On the Network 6 web-site you will also find a link to the ASHP (American Society of Health-System Pharmacists) position paper titled, "ASHP Therapeutic Position Statement on the Institutional Use of 0.9% Sodium Chloride Injection to Maintain Patency of Peripheral Indwelling Intermittent Infusion Devices."
- According to a CDC contact, the drug company Abraxis uses API from a source other than China. Contact information for Abraxis can be found at: <http://www.apppharma.com/>

The mission of the Southeastern Kidney Council is to improve the lives of people with or at risk for End Stage Renal Disease by promoting and advancing quality of care.