

FOR IMMEDIATE ATTENTION

TO: Nursing Supervisors, Medical Directors, Administrators

FROM: Leighann Sauls RN, CDN
Director, Quality Improvement

DATE: February 13, 2008

RE: Updated FDA Alert: Heparin Recall

The Network is required to distribute information regarding Federal Drug Administration (FDA) alerts, dialysis recalls, etc. that potentially affect dialysis facilities and/or patients.

Please note that the FDA has issued the following updated alert (<http://www.fda.gov/medwatch/safety/2008/safety08.htm#HeparinInj2>) to advise of reported patient reactions associated with certain lots of Heparin. The manufacture of multiple dose vials of heparin sodium has been suspended pending the completion of an extensive ongoing investigation to determine the root cause of the problem. Because heparin sodium is a medically necessary product and serious public health consequences would result if there were a sudden shortage of the drug, the multiple-dose vials of heparin sodium manufactured by Baxter that are currently in distribution will not be recalled. See the FDA Public Health Advisory for Agency recommendations to healthcare professionals on the use of heparin sodium for injection.

- [February 11, 2008 – Public Health Advisory – FDA]
<http://www.fda.gov/cder/drug/advisory/heparin.htm>
- [February 11, 2008 – Questions and Answers – FDA]
<http://www.fda.gov/cder/drug/infopage/heparin/heparinQA.htm>
- [February 11, 2008 – News Release – FDA]
<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01797.html>

Please visit the above Web site links to read the FDA information in its entirety. There are specific recommendations for the provision of dialysis services. The Network 6 Web site (<http://www.network6.org>) also has this information as provided by the FDA. In the event that you do not have Internet capability, please contact the Network office and the FDA documents can be faxed to you. We will continue to provide updates as information is received in the Network office. Thanks for your time and attention.