

NATIONAL PBM COMMUNICATION · October 2, 2009

Heparin and Change in USP Monograph – Possible Potency Variation

- The U.S. Food and Drug Administration (FDA) has issued a Public Health Alert to inform healthcare providers of a change to the United States Pharmacopeia (USP) monograph for heparin, effective October 1, 2009.¹
 - A new UPS reference standard will be included.
 - A new test method will be included to determine the potency of the drug and to detect impurities that may be present in heparin.
 - The USP unit dose and the WHO International Standard (IS) unit dose will be matched.
- Standardization of heparin will result in approximately a 10% reduction in the potency of the heparin marketed in the United States and in Canada. This change may have clinical significance with respect to the desired anticoagulant effect.¹
- Important information and clinical recommendations from the FDA include:¹
 - *There will be simultaneous availability of heparin manufactured to meet the “old” and “new” USP monograph, with potential differences in potency.*
 - *Labels of most heparin products made according to the new standard will have an “N” in the lot number or following the expiration date.*
 - *Products manufactured by Hospira can be identified by the numbers “82” or higher (e.g., 83, 84) at the start of their lot numbers.*
 - *Consider the potential potency variation when administering heparin, particularly in situations where assurance of aggressive anticoagulation is essential to treat or prevent life-threatening thromboses. Clinicians should now consider the potential for up to 10% estimated decrease in heparin activity per “USP unit.”*
 - *The potency variation may require more frequent or intensive aPTT or ACT monitoring.*
 - *The FDA-approved labeling for heparin has not changed, including the recommended doses. Individualization of heparin dosing has long been the standard for clinical use of the drug and FDA reiterates the importance of clinical judgment in heparin dosing.*
- Additional information on the monograph change can be accessed at: www.usp.org.

REFERENCES:

1. FDA Information for Healthcare Professionals. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm184502.htm> (Accessed October 1, 2009).

ACTIONS:

- **Facility COS and Chief Nurse Executives:** Forward this document to all appropriate providers who prescribe this agent (e.g., inpatient staff, primary care providers, nurses, cath lab personnel, and pharmacy, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).