NHIA Alert: New USP Standards for Heparin Products Will Result in Decreased Potency; Adjustments may be needed to achieve desired anticoagulant effect

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This informational summary has been created from documents posted on the FDA and USP websites regarding the change in heparin manufacturing. Links to those reference documents can be found at the end of this alert.

The U.S. Food and Drug Administration today alerted health care professionals to a change in heparin manufacturing that is expected to decrease the potency of the common blood clotting drug. Key facts regarding this change include:

- The United States Pharmacopeia (USP) has adopted the international standard of manufacturing controls for heparin, which includes a modification of the reference standard for the drug’s unit dose.
- The unit dose of heparin is the measure of the drug’s ability to anticoagulate, and the revised USP reference standard and Unit definition for heparin is approximately 10 percent less potent than the former USP unit.
- While U.S. market manufacturers have begun to incorporate the new standard into heparin production, the FDA requested that they not ship new product until October 8th, giving healthcare providers time to learn about the changes and adjust their processes in preparation.
- Of particular importance to providers of home infusion therapy: Patients who are stabilized on heparin anticoagulation therapy in the inpatient setting and discharged to home on heparin therapy will require careful consideration to ensure a safe transition of care. Home infusion pharmacists should consider taking the following steps:
  - Identify the type of heparin the patient was stabilized on in the hospital: old heparin, or new heparin (approximately 10% less potent)
  - Match the heparin (old vs. new) that is used in the home to that the patient received in the hospital, or be prepared to adjust the dose of heparin the patient is receiving and re-evaluate their coagulation status via lab monitoring

The following is an excerpt from the FDA, available at:

FDA wants to highlight some important information and clinical recommendations during this time of transition:

- There will be simultaneous availability of heparin manufactured to meet the “old” and “new” USP monograph, with potential differences in potency. This overlap of products on the market is necessary to make certain that there is an adequate supply of heparin available for all patients. Products using the new “USP unit” potency definition are anticipated to be available on or after October
8. FDA is working with the manufacturers of heparin to ensure that an appropriate identifier is placed on heparin made under the new USP monograph. Most manufacturers will place an “N” next to the lot number. Products manufactured by Hospira can be identified by the number “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” when deciding what dose to administer in such cases.

- **The potency change may require more frequent or intensive aPTT or ACT monitoring.**

- **Clinical judgment is essential in determining dose of heparin.** Heparin dosing is always individualized to the patient-specific situation. 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.

FDA is working with the heparin manufacturers to study the impact of this variation in potency and will make the results available when the studies have concluded.

**References:**

http://www.usp.org/hottopics/heparin.html