Fresenius Kabi – Recall of Midazolam Injection

- On December 16, 2016, Fresenius Kabi announced a voluntary, user-level recall of certain lots of midazolam hydrochloride 5 mg/mL injection due to out-of-specification (OOS) results for Largest Individual Unknown Impurity (LIUI) at the 33-month stability test station.

- The recalled products were shipped between March 12, 2014 and April 1, 2016.

Product Description	NDC #	Lot #	Expiration Date
Midazolam hydrochloride injection, 5 mg/mL, 5 mL fill in a 5 mL amber vial	63323-412-05	6007327, 6007329	1/2017

- Midazolam is indicated for the following:

  - Intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia;
  - Intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations and other procedures either alone or in combination with other CNS depressants;
  - Intravenously for induction of general anesthesia, before administration of other anesthetic agents. Intravenous midazolam can also be used as a component of intravenous supplementation of nitrous oxide and oxygen (balanced anesthesia);
  - Continuous intravenous infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting.

- An investigation revealed that this issue was limited to the product lots identified above.

  - Product samples yielding OOS results are currently undergoing analytical testing to identify the impurity. The associated health risk to patients is unknown at this time, and will be assessed once the impurity has been identified.
  - Currently, no complaints or adverse events have been reported for either lot number.

- Anyone with recalled product should discontinue distribution, quarantine any product, and contact Fresenius Kabi's Quality Assurance department at **866-716-2459**.

- For medical inquiries, contact Fresenius Kabi's Medical Affairs department at **800-551-7176**.

Action Plan

- Clinical Services did not identify any members that may be affected by the midazolam injection recall, thus mailings will not be conducted.

- Information regarding the midazolam recall will be posted on the optumrx.com portals.