# NATIONAL PBM BULLETIN

**September 23, 2015**

**DEPARTMENT OF VETERANS AFFAIRS**
**PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP),**
**VISN PHARMACIST EXECUTIVES (VPEs), AND THE CENTER FOR MEDICAL SAFETY (VA MedSAFE)**

**UPDATE**

## LOSS OF DRUG POTENCY WITH STORAGE OF MEDICATIONS USING BECTON-DICKINSON (BD) SYRINGES: FDA EXPANDS WARNING

### I. ISSUE

FDA is expanding its original alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to incorporate certain additional syringe sizes including 1 milliliter (mL), 10mL, 20mL and 30mL BD syringes, as well as BD oral syringes.

### II. BACKGROUND

A National PBM Bulletin from August 31, 2015 addressed loss of potency of compounded or repackaged drugs that have been stored in 3mL and 5mL BD syringes due to an interaction with the rubber stopper. BD's 3mL and 5mL plastic syringes are indicated as fluid aspiration and injection devices. They are not approved by the FDA to be used for drug storage.

### III. DISCUSSION

BD has confirmed that certain lots of 1mL, 3mL, 5mL, 10mL, 20mL and 30mL syringes, as well as BD oral syringes, contain the rubber stopper associated with the decreased drug potency. According to BD, decreased drug potency has only been reported when drugs are stored in these syringes. Drugs affected by the rubber stopper include, but may not be limited to: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanyl. Further information on determining which lots are affected is available in BD's letter to their customers available at the following link: http://www1.bd.com/hypodermic/pdf/09-01-15-letter.pdf .

### IV. PROVIDER CONSIDERATIONS/RECOMMENDATIONS

FDA recommends that hospital pharmacies and staff should:

- *Contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products.*
- *Not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available.*

Additionally, the Institute of Safe Medication Practices (ISMP) recommends that hospitals should:

- *Try to limit drug exposure in plastic syringes by using them as promptly as possible after preparation in the pharmacy.*
- *Make sure that clinical staff are aware of the situation and know to report unexpected changes in drug effectiveness, such as a sudden loss of pain control, especially with infusions via a syringe pump.*
- *Monitor patients for signs of decreased efficacy when administering drugs that have been stored in syringes, and use caution when administering sequential doses to avoid a sudden increased effect that could occur when switching from a syringe of medication stored for a period of time to a newly prepared syringe.*

### V. REFERENCES


1. FDA Drug Safety and Availability: FDA expands warning on Becton-Dickinson (BD) syringes being used to store compounded or repackaged drugs. http://www.fda.gov/Drugs/DrugSafety/ucm458952.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery. Accessed 09/21/2015.




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*(continued from page 1)*

2. Becton Medical. BD Letter for U.S. Customers Using BD Plastic Syringes. http://www1.bd.com/hypodermic/pdf/09-01-15-letter.pdf . Accessed 09/21/2015.
3. The Institute of Safe Medication Practices. ISMP Comments on BD Syringe Potency Issue. http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=117 . Accessed 09/21/2015.

***ACTIONS***

- ***Facility Director*** *(or physician designee): Forward this document to the Facility Chief of Staff (COS).*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers and health care staff (e.g.,* ***primary care providers, pain specialists, pharmacy staff, 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).*