NATIONAL PBM BULLETIN

March 26, 2013

**DEPARTMENT OF VETERANS AFFAIRS VETERANS HEALTH ADMINISTRATION (VHA)
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP),
AND CENTER FOR MEDICATION SAFETY (VA MEDSAFE)**

SODIUM BIPHOSPHATE/SODIUM PHOSPHATE ENEMA PRODUCT USE AND FATAL OUTCOME

I. ISSUE

A recent adverse event report described a fatal outcome related to the use of Sodium Biphosphate/Sodium Phosphate enemas used to treat constipation.

II. BACKGROUND

A patient received multiple Sodium Biphosphate/Sodium Phosphate enemas in less than 12 hours. The patient subsequently developed hypernatremia, hypocalcemia, hypovolemia, acute kidney injury, and later died.

III. DISCUSSION

Saline laxative products containing Sodium Biphosphate/Sodium Phosphate are commercially available under the brand name Fleet® Enemas. When used in appropriate dosages and for a limited time, most laxatives do not pose a risk for serious adverse events such as diarrhea, GI irritation, and fluid/electrolyte depletion. However, prolonged use or overuse can lead to dehydration as well as fluid and electrolyte imbalances, possibly resulting in hyponatremia, hypotension and volume depletion, hyperphosphatemia, hypo- or hyperkalemia, metabolic acidosis, severe hypocalcemia, renal failure, EKG changes (i.e., prolonged QT interval), generalized tonic-clonic seizures, and loss of consciousness. Selected adverse effects from Sodium Biphosphate/Sodium Phoshpate products include:

- **Mild**: bloating, stomach pain, tightness in the throat, dizziness, headache;
- **Severe**: rectal bleeding, lack of bowel movements after use, sores or ulcers around rectum, seizures, blackouts, convulsions, irregular heart rate, decreased urination, increased thirst, nausea, vomiting, confusion, swelling, weight gain, shortness of breath, electrolyte abnormalities.

IV. PROVIDER RECOMMENDATIONS

The affected facility engaged in the following actions to safeguard against future medication error with Sodium Biphosphate/Sodium Phosphate enema products.

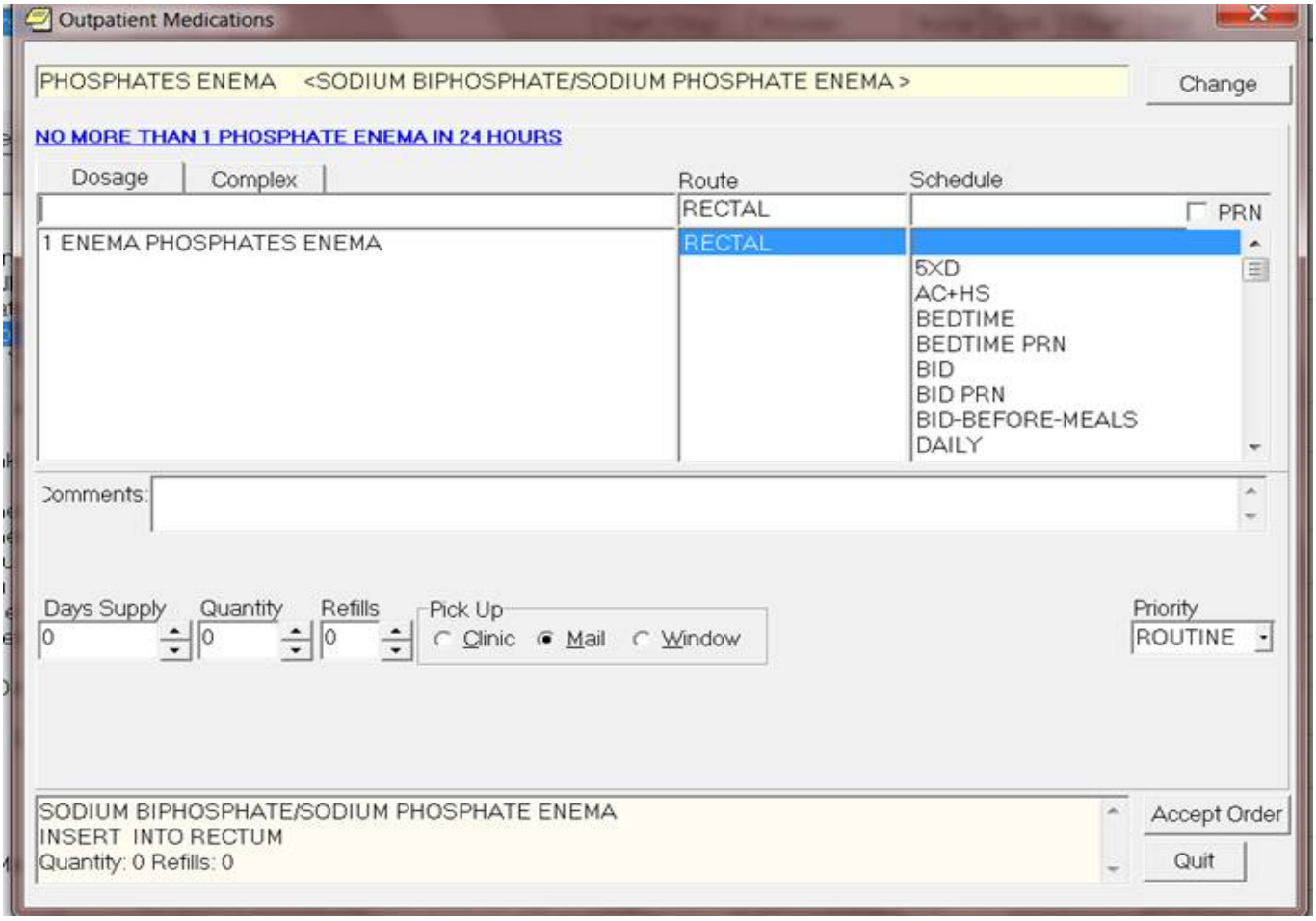
1. Remove “FLEETS” or “FLEET’S” as a synonym to order Sodium Biphosphate/Sodium Phosphate enema as it is a general term for enemas and does not provide further product detail. This would require the order entry selection of the Sodium Biphosphate/Sodium Phosphate enema by name and strength, prompting the provider to focus on the differences among the products (i.e., mineral oil, bisacodyl, phosphate, etc.) and choose the appropriate agent based on the patient’s clinical presentation.
2. Add a comment in the drug file to highlight “NO MORE THAN 1 PHOSPHATE ENEMA IN 24 HOURS” for Sodium Biphosphate/Sodium Phosphate enema products. See Figure 1 on Page 2.
3. Ensure education for providers and applicable health care staff regarding the appropriate use of enemas as well as the risks of their chronic use, overuse, or misuse, specifically:
   - Using more than one enema in 24 hours can be harmful.
   - Exercise caution in patients with renal impairment, cardiac disease, colostomy, or pre-existing electrolyte

disturbances as well as those on concomitant therapy that may affect serum electrolyte concentrations since dehydration, hypocalcemia, hyperphosphatemia, hypernatremia, hypokalemia, and acidosis may occur.

V. REFERENCES

1. Internal Data.
2. McEvoy GK, ed in chief, Snow ED, ed. *AHFS: Drug Information*. Bethesda, MD: American Society of Health-System Pharmacists; 2012: 2950-2954.

Figure 1. One facility added the following verbiage to the ordering template for Sodium Biphosphate/Sodium Phosphate enema products: "**NO MORE THAN 1 PHOSPHATE ENEMA IN 24 HOURS**". This may serve as one option for how to inform providers at the site level of this safety risk.



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 who prescribe these medications (e.g., **primary care providers, nursing staff, and 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).*