Visicol and OsmoPrep (oral sodium phosphate products) and Acute Phosphate Nephropathy

- The FDA is requiring that the manufacturers of Visicol and OsmoPrep (oral sodium phosphate products) add:
  - a BOXED WARNING in the prescription product labeling to relay the risk of acute phosphate nephropathy with use of these products;
  - a risk evaluation and mitigation strategy (REMS);
  - a Medication Guide for patients detailing the possible risk of acute kidney injury;
  - a postmarketing clinical trial to further evaluate the risk of developing acute phosphate nephropathy with these products.
- Oral sodium phosphate products (OSP) are used for bowel cleansing in preparation for colonoscopy or other procedures.
- The FDA extends its concerns to the over-the-counter (OTC) products (i.e., Fleet Phospho-soda).
  - Data show no risk of kidney injury when OTC products are used in lower doses as laxatives.
  - OTC products have the same risk as prescription products when used for bowel cleansing at higher doses.
- Since 2006, the FDA has received 20 reports of kidney injury related to OsmoPrep use:
  - 3 cases of acute phosphate nephropathy confirmed by biopsy;
  - Onset of kidney injury in reported cases varied from within several hours of use up to 21 days after use.
- FDA recommends caution when using OSP prescription products in the certain high-risk groups:
  - Patients >55 years of age;
  - Patients with dehydration, kidney disease, acute colitis, or delayed bowel emptying; and
  - Concomitant use with certain medicines that affect kidney function, such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, and possibly nonsteroidal anti-inflammatory drugs (such as ibuprofen and other arthritis medications).\(^1\)
- FDA recommends that patients do not use OTC products for bowel cleansing.

REFERENCES

ACTIONS
- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS**: Forward this document to all appropriate providers who prescribe these medications (e.g., primary care providers, GI specialists, and Radiologists, 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).