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Long-Term Care Survey Alert

MEDICATION SAFETY: Resident Taking Erythopoiesis-Stimulating Agent? Beware New FDA Alert

Stay on top of the dangers of these anemia-fighting meds.

Many residents receiving chemo or dialysis may be taking ESAs to treat or stave off anemia. But the **U.S. Food and Drug Administration** recently sounded the alarm about the safety of these medications--a warning that you can bet surveyors will check to see that your facility is addressing.

Recent studies show "a higher chance of serious and life-threatening side effects and a greater number of deaths in patients treated with these agents," states the FDA in a March 2007 alert on ESAs. The FDA is currently re-evaluating the safe use of the medications, which include Procrit, Aranasep and Epogen, and requiring their drug-makers to update the package inserts to inform providers of the risks.

Heightened liability risk: "When there is a highly publicized alert or information about a treatment's adverse effect, the facility may have liability if it doesn't address it," cautions **Donna Holshouser Stinson, JD**, partner with the law firm of **Broad and Cassell** in Tallahassee, FL.

Be Aware of These Potential Negative Outcomes

The FDA alert cites these important study results:

• Patients with chronic kidney failure suffered an increased number of deaths and non-fatal heart attacks, strokes, heart failure, and blood clots when they received ESAs adjusted to maintain higher red blood cell levels (hemoglobin more than 12 g/dL).

• Patients with head and neck cancer receiving radiation therapy had faster tumor growth when they received ESAs adjusted to maintain hemoglobin levels higher than 12 g/dL.

• Patients with cancer not receiving chemotherapy died sooner and had no fewer blood transfusions when they received ESAs based on the dosing recommendations for cancer patients receiving chemotherapy.

• Patients scheduled for orthopedic surgery who received ESAs to reduce blood transfusions during and after surgery had more blood clots than those who didn't receive an ESA.

The bottom line: "Once the patient's hemoglobin approaches 11 g/dL, the prescribing clinician should cut back the dosage or stop the drugs," advises **James Cooper, PhD**, at the **University of Georgia** in Athens. "We used to shoot for a hemoglobin of 13 or 14 but the mortality data from recent studies and subsequent FDA alert changes that," Cooper cautions.

Tip: Keep in mind that Aranasep is longer-acting than Procrit or Epogen, says Cooper.

Nurses are on the front line in detecting physician orders related to ESA agents. "A nurse has the responsibility to question a medication order or care practice," says Stinson, who has seen survey agencies take that stance.

Head off F501 tags: "The medical director needs to work with the consulting pharmacist to ensure the nursing facility observes the latest FDA advisories," says **Charles Crecelius, CMD, MD, PhD,** multifacility director of **Delmar Gardens in St. Louis, MO**.

Report problems: The FDA asks healthcare professionals and patients to report serious side effects after using ESAs to the FDA through the MedWatch program by phone (1-800-FDA-1088) or by the Internet at http://www.fda.gov/medwatch.