(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§482.23(c)(5) - There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Interpretive Guidelines §482.23(c)(5)

Adverse drug reactions and drug administration errors

There is a similar but more detailed and prescriptive requirement concerning internal hospital reporting of adverse drug reactions, drug administration errors and incompatibilities under the Pharmaceutical Services CoP at §482.25(b)(6). Therefore, it is not necessary for hospitals to establish a different procedure in the case of adverse drug reactions and drug administration errors for such events when nurses administer drugs or transfusions. Consult the guidance for §482.25(b)(6) to see what must be reported, to whom, and in what timeframe. Failure to make required reports concerning adverse drug reactions and errors in administration of drugs should be cited under §482.23(c)(5) when the drug was administered by a nurse, as well as under §482.25(b)(6).

Transfusion reactions

Transfusion reactions can occur during or after a blood transfusion. A patient's immune system recognizes the foreign blood product and attempts to destroy the transfused cells. Incompatible blood products are typically the cause of transfusion reactions. Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death.

Transfusion reactions are serious and can be life-threatening. The hospital must have policies and procedures in place for the internal reporting of transfusion reactions. The policies must include procedures for reporting transfusion reactions immediately to the practitioner responsible for the care of the patient. The transfusion reaction must also be reported to the hospital-wide quality assessment performance improvement program as an adverse event, in accordance with the QAPI CoP at 42 CFR 482.21(c)(2). The transfusion reaction must be documented in the patient's medical record, including the prompt notification of the responsible practitioner.

Survey Procedures §482.23(c)(5)

- For adverse drug events and medication administration errors, follow the survey procedures for §482.25(b)(6). Deficiencies are to be cited under both §482.23(c)(5) and §482.25(b)(6) when the drug or transfusion related to an adverse drug reaction, transfusion reaction or medication administration error relates to a drug or transfusion administered by a nurse.
- Request the hospital policy and procedure for internal reporting of transfusion reactions.
- Interview nursing staff responsible for administering blood transfusions to determine whether they are familiar with and comply with the hospital's policies.
- Ask to see if there are any transfusion-related incident reports. Is there evidence that the transfusion reaction was reported immediately to the practitioner responsible for the patient's care? Was it reported to the hospital's QAPI program?

