# A-0410(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§482.23(c)(4) - Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

# **Interpretive Guidelines §482.23(c)(4)**

Intravenous (IV) medications and blood transfusions must be administered in accordance with State law and approved medical staff policies and procedures. Further, many of the medications included in the high-alert categories are administered intravenously. (See also the discussion of high-risk/high-alert medications in the guidance for §482.25(b).) Hospital policies and procedures for blood transfusions and IV medications must be based on accepted standards of practice, and must address at least the following:

#### **Vascular Access Route**

Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan. Safe administration of blood transfusions and IV medications includes the correct choice of vascular access. IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication's chemical properties or safety concerns. Hospital policies and procedures must address which medications can be given intravenously via what type of access.

# **Other Patient Safety Practices**

In addition to the basic safe practices that apply to all medication administration (See the discussion of safe medication administration practices, and medication administration in general, at §482.23(c)), there are additional safe practices specific to IV medication administration that require consideration, including but not limited to, the following:

- Tracing invasive lines and tubes prior to administration to ensure the medication is to be administered via the proper route (for example, peripheral catheter versus epidural catheter connections);
- Avoiding forcing connections when the equipment offers clear resistance;
- Verifying proper programming of infusion devices (concentrations, flow rate, dose rate).

#### **Patient Monitoring**

As discussed in the medication administration guidance for §§482.23(c)(1), (c)(1)(i) and (c)(2), patients must be monitored for the effects of medications. To the extent that IV medications have a more rapid effect on the body, it is important that staff administering medications understand each medication and its monitoring requirements. Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements, including assessment of patients for risk factors that would influence the type and frequency of monitoring.

For example: a 50 year old patient with a history of renal failure is receiving IV vancomycin to treat a wound infection. The hospital policy for IV antibiotics, including vancomycin, requires the patient's kidney function to be monitored daily with blood draws. Based on review of the lab results, a practitioner responsible for the care of the patient would be expected to determine on a timely basis whether or not the antibiotic dose needs to be adjusted to protect kidney function or prevent drug toxicity while achieving the desired therapeutic effects. Staff administering the medication would be expected to review the lab results as well, and to raise with a practitioner responsible for the care of the patient any concerns they might have about whether an adjustment in the

medication is needed.

Hospital policies and procedures related to monitoring patients receiving IV medications are expected to address, but are not limited to, the following:

# • Monitoring for Fluid & Electrolyte Balance

Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance. Hospital policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications.

# • Monitoring Patients Receiving High-alert Medications, Including IV Opioids

Policies and procedures related to IV medication administration must address those medications the hospital has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously.

# At a minimum, hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients

Opioids are a class of medication used frequently in hospitals to treat pain. The sedating effects of opioids make it difficult at times to properly assess the patient's level of sedation. It can be erroneously assumed that patients are asleep when they are actually exhibiting progressive symptoms of respiratory compromise - somnolence, decreased respiratory rate, and decrease in oxygen levels. These symptoms, if unrecognized, can progress to respiratory depression and even death.

Certain characteristics, in addition to those discussed in the medication administration guidance for  $\S482.23(c)(1)$ , (c)(1)(i) and (c)(2), place patients receiving opioids at higher risk for oversedation and respiratory depression. These additional factors include, but are not limited to<sup>6</sup>:

- Snoring or history of sleep apnea
- No recent opioid use or first-time use of IV opioids
- Increased opioid dose requirement or opioid habituation
- Longer length of time receiving general anesthesia during surgery
- Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other central nervous system depressants
- Preexisting pulmonary or cardiac disease
- Thoracic or other surgical incisions that may impair breathing

Of particular concern are patients receiving IV opioids post-operatively. The effects of IV opioids in post-operative patients must be monitored vigilantly via serial assessments of pain, respiratory status, and sedation levels.

Hospitals must have policies and procedures related to the use of high-alert medications, including IV opioids for post-operative patients. Policies and procedures must address, at a minimum, the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods. The policies and procedures must also address whether and under what circumstances practitioners

<sup>&</sup>lt;sup>6</sup> Jarzyna D., Junquist C., Pasero C., et al. American Society for Pain Management Nursing - Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression. Pain Management Nursing, Vol 12, No. 3 (September), 2011: pp 118-145

prescribing IV opioids are allowed to establish protocols for IV opioid administration and monitoring that differ from the hospital-wide policies and procedures.

The frequency of the serial assessments and duration of the monitoring timeframe for post-operative patients receiving IV opioids must be determined based on at least the following considerations:

- Patient risk for adverse events;
- Opioid dosing frequency and IV delivery method. (push or patient-controlled analgesia (PCA));
- Duration of IV opioid therapy.

Regardless of the above factors, at a minimum monitoring must include the following:

- Vital signs (blood pressure, temperature, pulse, respiratory rate)
- Pain level;
- Respiratory status;
- Sedation level; sedation levels are important indicators for the clinical effects of opioids. Sedation is a useful assessment parameter to observe the effects of opioids since sedation typically precedes respiratory depression<sup>7</sup>. See the blue box below for information on sedation assessment methods.

# For Information – Not Required/Not to be Cited

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

In addition to vigilant nursing assessment at appropriate intervals, hospitals may choose to use technology to support effective monitoring of patients' respiratory rate and oxygen levels.

For additional information regarding recommendations of expert organizations on postoperative opioid monitoring, including technology-supported monitoring, see blue boxes below. The practices described in the blue boxes below are not required under the regulations.

The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient in order to assess effects of the medications. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

# For Information – Not Required/Not to be Cited Institute for Safe Medication Practices Guidelines for PCA Monitoring

Assessment of Opioid Tolerance	Vital Signs	Pain	Sedation	Respiratory		
				Rate	Quality	SPO <sub>2</sub> * &/or ETCO <sub>2</sub> **
Baseline Assessment before PCA	X	X	X	X	X	X
PCA Initiation or Change in Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
PCA Dose Change or Bolus Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Adverse Event or Patient Deterioration (e.g., adverse change in sedation score) Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Hand-offs/Shift Change	X	X	X	X	X	X

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council

<sup>\*</sup> SPO<sub>2</sub>: Saturation of peripheral oxygen via pulse oximetry

<sup>\*\*</sup> ETCO<sub>2</sub>: End-tidal carbon dioxide via capnography

# For Information – Not Required/Not to be Cited Anesthesia Patient Safety Foundation

- APSF calls for every patient receiving postoperative opioid analgesics to be managed based on the following clinical considerations\*:
  - Individualize the dose and infusion rate of opioid while considering the unique aspects of each patient's history and physical status.
  - Make continuous monitoring of oxygenation (pulse oximetry) the routine rather than the exception.
  - Assess the need for supplemental oxygen, especially if pulse oximetry or intermittent nurse assessment are the only methods of identifying progressive hypoventilation.
  - When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.

APSF also has issued a video on opioid induced ventilatory impairment: <a href="http://apsf.org/resources-video4.php">http://apsf.org/resources-video4.php</a>

\*Stoelting, RK., Weinger MB. Dangers of postoperative opioids: Is there a Cure? *APSF Newsletter* 2009;24:2.

# For Information – Not Required/Not to be Cited

# **The Patient Safety Movement Foundation**

PSMF recommends all patients receiving IV opioids have continuous measure-through motion and low perfusion pulse oximetry, and that patients on supplemental oxygen also have continuous respiration rate monitoring. It also calls for the monitoring system to be linked with a notification system to clinical staff who can respond immediately. It calls for an escalation protocol so that if a staff person does not acknowledge the alert in 60 seconds a second person will be notified.

The Patient Safety Movement Foundation - Actionable Patient Safety Solution (APSS) #1: Failure to Rescue: Post-Operative Respiratory Depression. January 13, 2013

Adverse patient reactions require timely and appropriate intervention, per established protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. (See the guidance for §482.23(c)(5) and §482.25(b)(6), concerning reporting of adverse medication-related events.)

#### **Blood Components and Blood Administration Procedures**

According to the U.S. Department of Health and Human Services, 13,785,000 units of whole blood and red blood cells were transfused in the United States in 2011<sup>8</sup>. The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. However, administration of blood products via transfusion is governed by §482.23(c)(4). Blood transfusions can be life-saving. However,

<sup>&</sup>lt;sup>8</sup> The 2011 National Blood Collection and Utilization Survey Report. Retrieved September 27,2013 from http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf

like IV medications, blood transfusions are not without risk of harm to patients. Transfusion reactions and/or errors can be fatal.

In addition to the safe practices and other safety considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

- Confirming the following prior to each blood transfusion:
  - the patient's identity
  - verification of the right blood product for the right patient

The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.

- Requirements for patient monitoring, including frequency and documentation of monitoring
- How to identify, treat, and report any adverse reactions the patient may experience during or related to transfusion.

## **Staff Training and Competencies**

Intravenous (IV) medications and blood transfusions must be administered by qualified personnel, regardless of whether they are practitioners or non-practitioners. Generally IV medications and blood transfusions are administered to patients by registered nurses (RNs), consistent with State law governing scope of practice, and approved medical staff policies and procedures.

Among other things, personnel must be able to demonstrate competency in venipuncture, in accordance with State law and hospital policy. If other types of vascular access are utilized, staff must have demonstrated competency in appropriate usage, care, and maintenance. Staff must also be trained in early detection of and timely intervention for IV opioid-induced over-sedation and respiratory depression.

Education and training regarding these procedures are typically included in the nurse's hospital orientation. Nursing staff who receive training for intravenous medication administration and/or blood transfusion administration during hospital orientation or during other continuing education programs would meet the requirements of this regulation. Content of the training must address each required component of the approved medical staff policies and procedures.

Other non-practitioners, for example, licensed practical nurses or licensed vocational nurses, with demonstrated competence may also administer IV medications and blood transfusions if they are acting in accordance with State law, including scope of practice law, and the hospital's approved medical staff policies and procedures. (77 FR 29050, May 16, 2012)

For non-practitioners, the appropriate competencies must be documented in the qualified staff person's employee record.

All State law and scope of practice requirements must be met regarding the administration of intravenous medications and blood transfusions, as applicable.

### Survey Procedures §482.23(c)(4)

- Interview nursing staff on different units who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:
  - Venipuncture techniques;
  - Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps;
  - Maintaining fluid and electrolyte balance;
  - Patient assessment for risk related to IV medications and appropriate monitoring;
  - Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients;
  - With respect to blood transfusions:
    - Blood components;
      - Process for verification of the right blood product for the right patient; and
      - Transfusion reactions: identification, treatment, and reporting requirements.
- Review the files for a sample of staff who administer blood products and IV medications, for evidence that competency was assessed and training was provided as appropriate.
- If able, observe blood transfusion and IV medication administration to assess staff adherence to accepted standards of practice.
  - Were safe medication administration practices used?
  - Was the transfused patient correctly identified and matched to the correct blood product prior to administration?
  - Was the appropriate access used for IV medications?
  - Were appropriate steps taken with regard to IV tubing and infusion pumps?
  - o Are patients being monitored post-infusion for adverse reactions?
- If staff appear to not be following accepted standards of practice for patient risk assessment related to IV medications, particularly opioids, and appropriate monitoring of patients receiving IV medications and/or blood transfusions, review policies and procedures for IV medication administration and blood transfusion to determine if they address safe practices considerations.
- Review a sample of medical records.
  - Are blood transfusions and IV medications administered in accordance with State law and approved medical staff policies and procedures?
  - Are blood transfusions and IV medications administered by personnel who are working within their scope of practice in accordance with State law and approved medical staff policies?

