



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: March 14, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids

Memorandum Summary

- ***Medication Administration:*** We are updating our guidance for the hospital medication administration requirements to:
 - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital medication process, but that hospitals are expected, through this and the related requirements under the pharmaceutical services and quality assessment/performance improvement CoPs, to take a comprehensive approach to the medication process.
 - Update our guidance for IV medications and blood transfusions in general; and
 - Reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events.
- ***Immediate Post-operative Care:*** Clarification is also being made to the guidance for the surgical services CoP requirement for hospitals to have adequate provisions for immediate post-operative care, to emphasize the need for post-operative monitoring of patients receiving IV opioid medications, regardless of where they are in the hospital.

Background

According to the draft US Department of Health and Human Services (HHS) National Action Plan for Adverse Drug Event (ADE) Prevention, the Institute of Medicine has defined an ADE as an “injury resulting from medical intervention related to a drug.” An estimated one-third of all hospital adverse events are related to ADEs, affect approximately two million hospital stays

annually, and prolong hospital length of stay by approximately 1.7 to 4.6 days.¹ On September 4, 2013, HHS published its Draft National Action Plan for ADE prevention for public comment (See 78 *FR* 54469). Based on national ADE data from inpatient and outpatient settings, three types of ADEs are considered to be common, clinically significant, preventable, and measureable, and therefore selected as the high-priority targets of this Action Plan: **anticoagulants, diabetes agents, and opioids.**

The medication process in hospitals is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. The regulatory requirements at §482.23(c) within the nursing services CoP relate to the components of medication administration and patient monitoring/reporting. However, errors may occur in other components of the medication process, even when there is strict adherence to sound medication administration practices, for example when there has been a prescribing or a dispensing error. We clarify in our guidance that hospitals are also expected to use a comprehensive systems approach to all components of the medication process, complying with requirements under the Pharmaceutical Services CoP at §482.25 and the patient safety requirements under the Quality Assessment and Performance Improvement CoP at §482.21, in addition to those at §482.23(c). The safety of the medication process is a shared responsibility, not solely the responsibility of hospital nursing staff.

Nevertheless, medication administration practices, including patient risk assessment and appropriate monitoring of patients' response to medications, can play a large role in preventing and minimizing adverse events related to medication. At the same time that HHS has been developing its national ADE action plan, the Centers for Medicare & Medicaid Services (CMS) has been reviewing our guidance related to medication administration and use of IV medications in hospitals in general, and post-surgical use of IV opioid medications in particular, in order to better align our guidance with current accepted standards of practice and to promote the prevention of ADEs.

Each year, serious adverse events, including fatalities, associated with the use of IV opioid medications occur in hospitals. Opioid-induced respiratory depression has resulted in patient deaths that might have been prevented with appropriate risk assessment for adverse events as well as frequent monitoring of the patient's respiration rate, oxygen and sedation levels². Hospital patients on IV opioids may be placed in units where vital signs and other monitoring typically is not performed as frequently as in post-anesthesia recovery or intensive care units, increasing the risk that patients may develop respiratory compromise that is not immediately recognized and treated.

We are clarifying our guidance with respect to:

- §§482.23(c)(1), (c)(1)(i) & (c)(2) (Tag A-0405), concerning medication administration in general, to clarify that assessment and appropriate monitoring of patients receiving medications, documentation, and timely intervention when adverse reactions occur are

¹ Draft National Action Plan for Adverse Drug Event (ADE) Prevention (2013). U.S. Department of Health and Human Services. Retrieved from <http://www.hhs.gov/ash/initiatives/ade/>

² 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

standard components of the medication administration process. We also are providing additional guidance on generally accepted safe medication administration practices, as well as optional information on this topic in “blue boxes.” Information in blue boxes does not represent regulatory requirements and surveyors must not cite hospitals solely because they do not adhere to practices described in a “blue box.”

- §482.23(c)(4) (Tag A-0409), concerning blood transfusions and IV medications. The new guidance includes discussion of vascular access route, verification of tubing connections, verification of proper programming of infusion devices, monitoring of patients for fluid and electrolyte balance, and patient risk assessment and appropriate monitoring to prevent over-sedation and/or respiratory depression related to post-operative patients receiving IV opioids. Hospitals are expected to develop policies and procedures that address, at a minimum, the process for patient risk assessment, including who conducts the assessments.
- Based on the assessment of risk for post-operative patients receiving IV opioids, the frequency of dosing and mode of IV opioid delivery (e.g., whether it is patient-controlled or not), and duration of IV opioid therapy, hospitals must address what is to be monitored and the monitoring frequency and methods. The assessment and monitoring process must be explained to the patient and/or the patient’s representative, to communicate the rationale for frequent monitoring, including that it might be necessary to awaken the patient, to assess the effects of the opioid medication. Patients and their families must also be educated to alert staff to breathing problems or other reactions that may be related to medication. Finally, staff are expected to be trained in early detection and timely intervention for IV opioid-induced over-sedation and respiratory depression.
- With respect to requirements concerning self-administration of medications at §482.23(c)(6) (Tag A-0412), we previously clarified that patient-controlled analgesia (PCA) pumps are a special variant of patient self-administration. We have added to this discussion a cross-reference to the requirements at §482.23(c)(4) for IV medication administration, including patient monitoring.
- §482.51(b)(4) requires adequate provisions for immediate post-operative care of surgical patients. We have expanded our guidance to include discussion of post-operative monitoring of patients on IV opioids regardless of where they are located in the hospital, as well as references to same-day surgery patients.

We have also included discussion of recommendations of patient safety organizations for best practices related to use of IV opioid medications, including sedation assessment, frequency of monitoring and use of technology-supported monitoring, such as continuous pulse oximetry and/or capnography linked to clinical staff notification devices. These recommendations are highlighted in the guidance in “blue boxes.” Although adoption of these recommended best practices is not required under the regulations, hospitals are strongly encouraged to review these practices and consider whether to adopt them.

An advance copy of revised State Operations Manual Appendix A is attached to this memo.

Questions concerning this memorandum may be addressed to hospitalscg@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/

Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

CMS Manual System

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Pub. 100-07 State Operations Provider Certification

Transmittal

(Advance Copy)

Date:

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for various provisions of 42 CFR 482.23(c), concerning medication administration, and 42 CFR 482.51(b)(4), concerning post-operative patient care.

NEW/REVISED MATERIAL - **EFFECTIVE DATE:** Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/ A-0405, §482.23(c) Standard: Preparation and Administration of Drugs /§482.23(c)(1), (c)(1)(i) & (c)(2)
R	Appendix A/ A-0409, §482.23 Standard: Preparation and Administration of Drugs/§482.23(c)(4)
R	Appendix A/ A-0412, §482.23 Standard: Preparation and Administration of Drugs/§482.23(c)(6)
R	Appendix A/ A-0957, §482.51(b) Standard: Delivery of Services/Immediate Post-operative Care/§482.51(b)(4)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2014 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

A-0405

(Rev.)

§482.23(c) Standard: Preparation and Administration of Drugs

(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations....

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

Interpretive Guidelines §§482.23(c)(1), (c)(1)(i) and (c)(2)

According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.¹ It has been estimated that drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7 percent of all stays), and 838,000 treat-and-release ED visits (0.8 percent of all visits).² Although technological advances in electronic order entry, medication administration, and electronic medical records hold a great deal of promise for decreasing medication errors, there are a multitude of human and environmental factors that will impact their success. The increasing complexity of medical care and patient acuity present significant challenges that require an approach to medication administration that takes advantage of available technology while recognizing that it must be integrated into the medication administration work processes in a manner that meets the needs of patients and promotes their safety.

The regulations at §482.23(c) and §482.23(c)(1) promote safety in the preparation and administration of drugs and biologicals to hospital patients by requiring preparation and administration in accordance with:

- Federal and State law;

¹Institute of Medicine. Preventing Medication Errors. WashingtonDC: The National Academies Press, 2007.

²Lucado, Jennifer, et al, *Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments*. Statistical Brief #109, April, 2011. Healthcare Cost and Utilization, Project, Agency For Healthcare Research and Quality, Rockville, MD.

- Accepted standards of practice;
- Orders of the practitioner(s) responsible for the patient's care, as specified under §482.12(c) or of another practitioner as permitted under State law, hospital policy and medical staff bylaws, rules and regulations; and
- Medical staff-approved policies and procedures.

For Information – Not Required/Not to be Cited

Although the regulation addresses both preparation and administration of drugs and biologicals and does not prohibit preparation of drugs by nursing staff, to improve patient safety it is generally preferable for hospitals to avoid nurse preparation of drugs in patient care areas, and instead rely upon pharmacy IV admixture systems and/or commercially available unit dose products.

Federal and State Law

Federal law regulates the approval and classification of drugs and biologicals. Individual States establish laws and regulations which specify the scope of practice for various types of licensed healthcare professionals, including which medications they may prescribe and administer, including controlled substances.

Accepted Standards of Practice

Hospital policies and procedures for the preparation and administration of all drugs and biologicals must not only comply with all applicable Federal and State laws, but also must be consistent with accepted standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in medication preparation and administration. Examples of such organizations include, but are not limited to:

- National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org);
- Institute for Healthcare Improvement (<http://www.ihl.org/ihl>) ;
- U.S Pharmacopeia (www.usp.org) ;
- Institute for Safe Medication Practices (www.ismp.org);
- Infusion Nurses Society (<http://www.insl.org>).

In addition, the Centers for Disease Control and Prevention (CDC) publishes evidenced-based practice guidelines and recommendations on medication preparation and administration practices, designed to reduce the risk of infection associated with these activities.

Orders of an authorized practitioner

Drugs must be administered in response to an order from a practitioner, or on the basis of a standing order which is appropriately authenticated subsequently by a practitioner. (See §482.23(c)(1) (ii) concerning standing orders.) Generally, the ordering practitioner is the practitioner(s) responsible for the care of the patient in accordance with §482.12(c). However, other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations. This includes practitioners ordering outpatient services who do not have privileges in the hospital but who are permitted under their State scope of practice and authorized by hospital and medical staff policy to order outpatient services.

In accordance with standard practice, all practitioner orders for the administration of drugs and biologicals must include at least the following:

- Name of the patient;
- Age and weight of the patient, *to facilitate dose calculation when applicable. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the hospital's policies. (Note that dose calculations are based on metric weight (kg, or g for newborns). If a hospital permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, hospitals must specify a uniform approach to be used by prescribing practitioners. For example, a hospital could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric);;*
- Date and time of the order;
- Drug name;
- Dose, frequency, and route;
- *Dose calculation requirements, when applicable*
- Exact strength or concentration, when applicable;
- Quantity and/or duration, when applicable;
- Specific instructions for use, when applicable; and
- Name of the prescriber.

Medical Staff Approved Policies and Procedures

The hospital's medical staff must approve policies and procedures for medication administration, consistent with the requirements of Federal and State law and accepted standards of practice. It is recommended that the medical staff consult with nurses, pharmacists, Quality Assessment and Performance Improvement program staff, and others in developing these policies and procedures. The adopted policies and procedures must address key issues related to medication administration, which include but are not limited to:

Personnel authorized to administer medication

§482.23(c)(2) requires that all drugs and biologicals are administered by, or under the supervision of, nursing or other personnel, in accordance with Federal or State law and

approved medical staff policies and procedures. State law requirements include licensure requirements. Policies and procedures must identify categories of licensed personnel and the types of medications they are permitted to administer, in accordance with state laws. The policies and procedures must also address education and training for all personnel administering drugs and biologicals.

Medication administration education and training is typically included in hospital orientation or other continuing education for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication administration may include but are not limited to the following:

- Safe handling and preparation of authorized medications;
- Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications;
- Equipment, devices, special procedures, and/or techniques required for medication administration;

Policies and procedures must address the required components of the training and if the training provided during hospital orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

Basic safe practices for medication administration

The hospital's policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (*often referred to as the "five rights" of medication administration practice*):

- ***Right patient:*** the patient's identity— acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the hospital; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.
- ***Right medication:*** the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient *and that the patient does not have a documented allergy to it*;
- ***Right dose:*** the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);

- **Right route:** the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and
- **Right time:** the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

Note: the “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error. Hospitals are also expected to comply with requirements under the Pharmaceutical Services CoP at §482.25 and the patient safety requirements under the Quality Assessment and Performance Improvement CoP at §482.21, using a comprehensive systems approach to all components of the medication process.

For Information – Not Required/Not to be Cited

Recent literature identifies up to nine “rights” of medication administration including:*

- Right patient*
- Right drug*
- Right route*
- Right time*
- Right dose*
- Right documentation*
- Right action (appropriate reason)*
- Right form*
- Right response*

However, other sources refer to 8 or 10 “rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 “rights.”

**Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.*

Hospitals are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly, whether they arise prior to the preparation, dispensing, or administration of the medication.

Timing of Medication Administration

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them. The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration. Consequently, the application of a uniform required window of time before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately. This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, hospital policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration. The policies and procedures must address at least the following:

- Medications **not eligible** for scheduled dosing times;
- Medications **eligible for** scheduled dosing times;
- Administration of eligible medications outside of their scheduled dosing times and windows; and
- Evaluation of medication administration timing policies, including adherence to them.

Medications *or categories of medication* not eligible for scheduled dosing times

The policies and procedures must identify medications *or categories of medication* which are not eligible for scheduled dosing times, either in general or in specific clinical applications. These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors. Examples of medications that hospitals may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

- Stat doses (immediate);
- First time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);
- One-time doses; doses specifically timed for procedures;
- Time-sequenced doses; doses timed for serum drug levels;
- Investigational drugs; or
- Drugs prescribed on an as needed basis (prn doses).

The policies and procedures must ensure timely administration of such medications. In addition they must specify if the policy for the administration of these medications will be applied hospital-wide or only for specific diagnosis types, hospital units or clinical situations.

Medications eligible for scheduled dosing times

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc. The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time.

Medication administration policies and procedures typically establish standardized dosing times for the administration of all 'scheduled' medications. For example, medications prescribed for BID (twice a day) administration might, under a given hospital's policies and procedures, be scheduled to be administered at 8am and 8pm. Another hospital might choose to schedule BID medications at 7:30 am and 7:30 pm. Use of these standardized times facilitates the medication administration process, e.g., by providing to the hospital's pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration. For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address: first dose medications, including parameters within which nursing staff are allowed to use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times; retiming of missed or omitted doses; medications that will not follow scheduled dosing times; and patient units that are not subject to following the scheduled dosing times.

Time-critical scheduled medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. Accordingly, scheduled medications identified under the hospital's policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of 1 hour.

It is possible for a given medication to be time-critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients. Therefore, hospital policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical. Examples of time-critical scheduled medications/medication types may include, but are not limited to:

- Antibiotics;
- Anticoagulants;
- Insulin;
- Anticonvulsants;
- Immunosuppressive agents;

- Pain medication (*non-IV*);
- Medications prescribed for administration within a specified period of time of the medication order;
- Medications that must be administered apart from other medications for optimal therapeutic effect; or
- Medications prescribed more frequently than every 4 hours.

Non-time-critical scheduled medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm. For such medications greater flexibility in the timing of their administration is permissible. Specifically:

- Medications prescribed for daily, weekly or monthly administration may be within 2 hours before or after the scheduled dosing time, for a total window that does not exceed 4 hours.
- Medications prescribed more frequently than daily but no more frequently than every 4 hours may be administered within 1 hour before or after the scheduled dosing time, for a total window that does not exceed 2 hours.

Missed or late administration of medications

The hospital's policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time. This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration. Likewise, policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff are allowed to use their own judgment regarding the rescheduling of missed or late doses and when notification of the physician or other practitioner responsible for the care of the patient is required prior doing so. In either case, the reporting of medication errors that are the result of missed or late dose administration must be reported to the attending physician in accordance with requirements at §482.25(b)(6). See interpretive guidance at §482.25(b)(6) for more details on internal reporting requirements

Evaluation of medication administration timing policies

Hospitals must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration. Consistent with the QAPI requirements at 42 CFR 482.21(c)(2), medication errors related to the timing of medication administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the medical staff must consider whether there is a need to revise the policies and procedures governing medication administration timing.

Assessment/Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;*
- Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.*

Certain types of medications are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. (See also the discussion of high-risk medications (typically referred to as "high-alert" medications) in the guidance for §482.25(b))

For Information – Not Required/Not to be Cited

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. The current list may be found at: <http://www.ismp.org/Tools/highAlertMedicationLists.asp>

In addition, certain factors place some patients at greater risk for adverse effects of medication. Factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea, patient weight (obesity may increase apnea or smaller patients may be more sensitive to dose levels of medications), asthma, history of smoking, drug-drug interactions, and first-time medication use may contribute to increased risk.

Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance

continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients' medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are transferred internally from one unit to another, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established hospital 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.)

An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient who is receiving pain medication via a patient controlled analgesia (PCA) pump. Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all hospital settings in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. (See also the discussion of the requirements for intravenous medications at §482.23(c)(4))

As part of the monitoring process, staff are expected to include the patient's reports of his/her experience of the medication's effects. Further, when monitoring requires awakening the patient in order to assess effects of the medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. 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.

Hospital policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the hospital's requirements for the method(s) of communication.

Documentation

Note that documentation of medication administration is addressed in the Medical Records CoP, at §482.24(c), which specifies the required content of the medical record. Within this regulation §482.24(c)(vi) requires that the record contain: "All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition." Documentation is expected to occur after actual administration of the medication to the patient; advance documentation is not only inappropriate, but may result in medication errors. Proper documentation of medication administration actions taken and their outcomes is essential for planning and delivering future care of the patient. See the guidance for the various parts of §482.24(c) concerning

documentation in the medical record. Deficiencies in documentation would be cited under the applicable Medical Records regulation.

Survey Procedures §§482.23(c)(1), (c)(1)(i), and (c)(2)

Verify that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:

- Verify that there are policies and procedures approved by the medical staff and governing body concerning ordering of drugs and biologicals by practitioners.
- Verify that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.
 - Verify nursing staff authorized to administer drugs and biological are practicing within their State-permitted scope of practice.
 - Are personnel other than nursing personnel administering drugs or biologicals? If yes, determine if those personnel are administering drugs or biologicals in accordance with Federal and State laws and regulations, including scope of practice laws, hospital policy, and medical staff by-laws, rules and regulations. Use the above procedures to determine compliance.
- Verify that there are policies and procedures approved by medical staff addressing the timing of medication administration.
 - Verify that the hospital has, consistent with its policies, identified medications: which are:
 - not eligible for scheduled dosing times;
 - Eligible for scheduled dosing times and are time-critical; and
 - Eligible for scheduled dosing times and are not time-critical.
 - Verify the hospital has established total windows of time that do not exceed the following:
 - 1 hour for time-critical scheduled medications
 - 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours; and
 - 4 hours for medications prescribed for daily or longer administration intervals.
- Verify that the hospital's policy describes requirements for the administration of identified time-critical medications. Is it clear whether time-critical medications or medication types are identified as such for the entire hospital or are unit-, patient diagnosis-, or clinical situation- specific?

- Review a sample of medical records to determine whether medication administration conformed to an authorized practitioner's order, i.e., that there is an order from an authorized practitioner, or an applicable standing order, and that the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and procedures. Check that the practitioner's order was still in force at the time the drug was administered.
- Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed.
 - Is the patient's identity confirmed prior to medication administration?
 - Are procedures to assure the correct medication, dose, and route followed?
 - Are drugs administered in accordance with the hospital's established policies and procedures for timely medication administration?
 - Does the nurse remain with the patient until *oral* medication is taken?
 - *Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?*
 - *Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?*
 - *Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?*
- Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.
 - Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?
 - Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?

A-0409

(Rev.)

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

Interpretative 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 §§482.23(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 to³:

- *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*

³ 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

- *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 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 depression⁴. See the blue box below for information on sedation assessment methods.*

⁴ *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

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 post-operative 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.

For Information – Not Required/Not to be Cited

Institute for Safe Medication Practices Guidelines for PCA Monitoring

<i>Assessment of Opioid Tolerance</i>	<i>Vital Signs</i>	<i>Pain</i>	<i>Sedation</i>	<i>Respiratory</i>		
				<i>Rate</i>	<i>Quality</i>	<i>SPO₂* &/or ETCO₂**</i>
<i>Baseline Assessment before PCA</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>PCA Initiation or Change in Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>PCA Dose Change or Bolus Q 1 hour x 4 hours Then Q 2 hours</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>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</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>Hand-offs/Shift Change</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>

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

** SPO₂: Saturation of peripheral oxygen via pulse oximetry*

*** ETCO₂: 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.*

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:

http://apsf.org/resources_video4.php

**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 2011⁵. 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, 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

⁵ *The 2011 National Blood Collection and Utilization Survey Report. Retrieved September 27, 2013 from <http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf>*

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 oversedation 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?*
 - *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?

A-0412

(Rev.)

§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.

- (i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:**

- (A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.**
- (B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).**
- (C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).**
- (D) Address the security of the medication(s) for each patient.**
- (E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.**

Interpretative Guidelines §482.23(c)(6)(i)

Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of hospital-issued medications. The existence of this regulatory option does not mean that a hospital must offer medication self-administration programs or that a patient has a right to self-administer their medications.

A hospital program for patient self-administration of hospital-issued medications could be beneficial for the appropriate patients if the proper precautions are taken in designing and implementing such a program. Generally such a program would apply only to inpatients, but there may be circumstances under which a hospital finds it appropriate to permit self-administration of hospital-issued medications by outpatients or their caregivers/support persons.

Among the potential benefits of medication self-administration, teaching patients or their caregivers/support persons adherence to the proper medication regimen could reduce hospital inpatient length of stay and also might have a positive effect on continued compliance with the regimen after discharge, potentially avoiding an emergency department visit or inpatient readmission secondary to post-hospital patient medication administration errors and noncompliance.

Hospitals have the discretion to establish policies providing for different levels of patient self-administration, and may make these levels across-the-board, patient-specific, or medication-specific. For example, a hospital may choose whether or not a nurse must be present to supervise the self-administration, and whether this supervision requirement could vary according to the type of medication or the capacity of the individual patient (or the patient's caregiver/support person). A hospital may also determine through its policies and procedures whether supervision requirements must be addressed in the practitioner's order or whether this may be left to the discretion of the nurse who assesses the patient. A hospital may choose to exclude certain medications from patient self-administration, for example, because they pose too great a medication security challenge, or because the manner in which they must be administered does not lend itself to safe self-administration. (77 FR 29052, May 16, 2012) It must be clear

in the hospital's policies and procedures whether it has established such a policy and what kind of limitations it has established for its program of patient self-administration of hospital-issued medications.

It is expected that the medical staff, nursing and pharmacy departments are to collaborate in developing policies and procedures governing self-administration of hospital-issued medications which are approved by the governing body.

Required elements of a self-administration program:

If the hospital chooses to develop programs for self-administration of hospital-issued medications by patients (and/or their caregiver/support persons), the following must be in place:

- **An order allowing the patient to administer hospital-issued medications.** The order must be consistent with the hospital's policy concerning self-administration of hospital-issued medications and be written by a practitioner who is responsible for the care of the patient and who is authorized to order medications, in accordance with hospital policies and procedures, State law, including scope of practice laws, and medical staff by-laws, rules, and regulations.
- **A documented assessment of the capacity of the patient (or their caregiver/support person) to successfully administer medications for which self-administration has been authorized.** Nurses are expected to exercise their clinical judgment and to inform the practitioner responsible for the care of the patient about any reservations the nurse might have about an individual patient's (or caregiver/support person's) capacity to safely self-administer medications. The assessment must be documented and must highlight the findings that are affirmative – i.e., support patient-self-administration – and negative – i.e., call into question patient self-administration. The nurse is also expected to document any discussions with the practitioner responsible for the care of the patient regarding the nurses' concerns about patient's (or caregiver/support person's) capacity to safely self-administer medications. Hospitals may, as a matter of policy, permit a nurse to return to nurse administration for particular doses of a medication for which there is a self-administration order, without a discussion with the responsible practitioner if, based on the nurse's assessment, the patient's capacity has been temporarily diminished and there is no caregiver/support person who is assisting the patient with self-administration of medication. For example, a patient who has just had an invasive test or procedure may not be fully alert for a period thereafter, or the parent of a minor patient, who is administering medications to the patient may for whatever reasons not be available and a scheduled medication dose is close to being overdue.
- **Instruction in self-administration.** As part of the assessment of the patient's self-administration capacity, nurses are expected to identify the patient's (or the patient's caregiver/support person's) education and/or training needs. These needs may be related to type of medication, unique individual medication requirements, delivery route, dosage and scheduling, equipment (e.g. syringes, pill-cutters, measuring containers, etc.) intravenous access, potential adverse side effects and what to do if they occur, infection control measures, storage, medication disposal, among others. Education and training needs, and how they

were addressed, must be documented in the medical record.

- **Security of the self-administered medications.** The security of a patient's self-administered medications is extremely important, but does not lend itself well to a one-size-fits-all regulatory requirement. There are Federal and State laws, including the Pharmaceutical Services CoP, which require a higher level of security for certain medications (for example, controlled substances). Hospitals are expected to comply with these already-established requirements and laws, and generally should not include such medications as part of a patient self-administration program.
- Note that Patient-controlled Analgesia (PCA) pumps are a special variant of patient self-administration. Such pumps allow patients, within tightly controlled, pre-determined parameters with respect to dosage and minimum time intervals between doses, to release an intravenous dose of a controlled substance pain medication that has been pre-loaded into the PCA pump in a manner that prevents tampering by an unauthorized person. PCA pumps are considered secure despite their use of controlled substances.

PCA pumps allow for the self-administration of intravenous (IV) medications to patients. See the interpretive guidelines for §482.23(c)(4) concerning assessment and monitoring requirements for post-surgical patients receiving IV opioids, including via patient-controlled analgesia (PCA) pumps, in and out of the post-anesthesia care and intensive care units.

Hospitals are also free to exclude other medications besides controlled substances from their patient self-administered medication programs when the hospital has concerns over its capacity to address the *safety and* security of these other medications for patients.

A hospital may choose to have a policy where it maintains a list of medications that it excludes from self-administration entirely, due to security concerns. It may choose to have a policy that addresses the security of a particular medication on a patient-by-patient basis. Or it may establish a policy that is a combination of both of these approaches to medication security. (77 FR 29052, May 16, 2012)

- **Documentation of medication administration.** Under the regulation, a nurse must document the self-administration of a medication. In cases where the nurse directly supervised the self-administration, the nurse is expected to indicate that the medication administration was observed and confirmed. On the other hand, where direct nurse supervision is not required, the nurse is required to document only what the patient, or the patient's caregiver/support person, reports to the nurse as to the time and amount of medication administered. Nurses are expected to assess whether the reports of the patient or patient's caregiver/support person indicate, with respect to timing and dosage, that the patient is receiving the medication as ordered.

Survey Procedures §482.23(c)(6)(i)

If the hospital permits patient self-administration of hospital-issued medications:

- Ask the hospital to identify current inpatients for whom self-administration of hospital-issued medications is permitted.
 - Interview of several of these patients (or their caregivers/support persons when applicable) to verify that they received instruction on how to administer their medications
 - Interview nurses caring for the selected patients. Ask them:
 - What the applicable hospital policies and procedures are regarding supervision of self-medication.
 - How they assess a patient's (or patient's caregiver/support person's) capacity to self-administer medication. If they have concerns, how do they communicate them to the responsible practitioner? Does their hospital permit nurses to return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient's caregiver/support person? If so, how do the nurses make this assessment?
 - How they instruct a patient (or patient's caregiver/support person's) in medication self-administration.
 - How self-administered medications are secured.
 - How they document self-administration of medications.
 - To provide a copy of the hospital's policies and procedures. Are they following the policies and procedures?
 - Review the medical records for the selected patients. Is there documentation of:
 - An order for self-administration of specific medication(s).
 - A nurse assessment of the patient's (or patient's caregiver/support person's) capacity to self-administer medication.
 - Documentation of nurse instruction to the patient or (or patient's caregiver/support person) in safe and appropriate techniques for self-administration of medication.
 - Documentation of self-administration times and doses, as reported by the patient or (or patient's caregiver/support person) or directly observed by a nurse.
 - Do the hospital's policies and procedures for self-administration of hospital-issued medications address:
 - Limitations on medications not eligible for self-administration or patient conditions which exclude self-administration;

- Orders for self-administration of medication;
- Requirements, if any, for supervision of self-administration;
- Assessment of self-medication capacity;
- Instruction in self-medication;
- Security of self-administered medications; and
- Documentation of self-administration.

A-0957

(Rev.)

§482.51(b)(4) - There must be adequate provisions for immediate post-operative care.

Interpretive Guidelines §482.51(b)(4)

Adequate provisions for immediate post-operative care means:

- Post-operative care must be *provided to all surgical patients, including same-day surgery patients*, in accordance with acceptable standards of practice.
- *A* post-operative care area, *usually referred to as the post-anesthesia care unit (PACU)*, is a separate area of the hospital. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the *PACU*. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the *PACU* includes, *but is not limited to*:
 - Level of activity;
 - Respirations;
 - Blood pressure;
 - Level of consciousness;
 - *Level of pain*;
 - Patient color; and

- If a patient is not transferred to the *PACU*, determine that provisions are made for close observation until the *patient has* regained consciousness, e.g., direct observation by a qualified RN.

Post-operative Monitoring

Hospitals are expected to develop and implement policies and procedures addressing the minimum scope and frequency of patient monitoring in post-PACU care settings, consistent with accepted standards of practice.

Patients receiving post-operative intravenous (IV) opioid medications are of particular concern, due to the higher risk for oversedation and respiratory depression⁶. Once out of the PACU, patients receiving IV opioid medication may be placed on units where vital signs and other monitoring traditionally has not been done as frequently as in the PACU or intensive care units, increasing the risk that patients may develop respiratory compromise that is not immediately recognized and treated. (See the interpretive guidelines at §482.23(c)(4)). When post-surgical patients are transferred out of the PACU to another area of the hospital but continued on IV opioid medications, they need vigilant monitoring, even if post-PACU care is not typically referred to as “immediate” post-operative care. Opioid-induced respiratory compromise has resulted in inpatient deaths that might have been prevented with appropriate assessment and vigilant monitoring of respiration and sedation levels.⁷

Survey Procedures §482.51(b)(4)

- Verify that the hospital has provisions for post-operative care.
- *Observe care provided to patients in a PACU to determine whether patients are monitored and assessed appropriately prior to transfer or discharge (in the case of same-day surgery patients) from the PACU.*
- *Does the hospital have a system for identifying and addressing the monitoring needs of post-operative patients transferred from the PACU to other areas of the hospital?*

Ask staff in the PACU and in units who receive patients from the PACU how the needs of post-operative patients for vigilant monitoring is addressed when the patients are transferred from the PACU to other areas of the hospital.

See for example: ⁶ Institute for Safe Medication Practices (ISMP), Medication Safety Alert- High Alert Medication Feature Reducing Patient Harm from Opiates. February 22, 2007.

⁷ 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