16.00.00 Condition of Participation: Nursing Services.  
The hospital must have an organized Nursing Service that provides 24-hour Nursing services. The nursing services must be furnished or supervised by a registered nurse.

§482.23

Nursing services are available 24 hours a day for inpatients. A registered nurse is available to plan, provide and/or supervise the nursing care of patients. The hospital must have an organized nursing service and must provide on premise nursing services 24 hours a day, 7 days a week with at least one registered nurse furnishing or supervising the service 24 hours a day, 7 days a week. (Exception: small rural hospitals operating under a waiver as discussed in §482.23(b)(1)).

The Social Security Act (SSA) at §1861(b) states that nursing services must be furnished to inpatients and furnished by the hospital.

The SSA at §1861(e) further requires that the hospital have a RN on duty at all times (except small rural hospitals operating under a nursing waiver).

The nursing service must be a well-organized service of the hospital and under the direction of a registered nurse.

The nursing service must be integrated into the hospital-wide QAPI plan.

DOCUMENT REVIEW AND INTERVIEW
1. Determine if the nursing service is integrated into the hospital-wide QAPI plan.
2. Interview the chief nursing officer.
3. Review the organizational chart(s) for nursing services in all locations where the hospital provides nursing services.
4. Review job descriptions for all nursing personnel including the director’s position description.
5. Verify that there is a hospital-employed registered nurse scheduled on every shift in every location where nursing care is provided.
6. Verify that a hospital employed, unit based registered nurse is accountable for oversight of patient care for every shift and in every location where care is provided. Utilize care plans, medical records, patient interviews, investigative reports, staffing schedules, nursing policies and procedures, and QAPI activities to determine the adequacy of the department.
7. Interview patients for information relative to the delivery of nursing services.

OBSERVATION
Select at least one patient from every inpatient care unit.

1. Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care.

2. Other sources of information to use in the evaluation of the nursing services are:
   - nursing care plans,
   - medical records,
   - patients, family members,
   - accident and investigative reports,
   - staffing schedules,
   - nursing policies and procedures, and QAPI activities and reports.

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<td>16.00.02</td>
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<td><strong>16.00.03</strong> Nursing Organization.</td>
<td>The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the nursing service.</td>
<td>DOCUMENT REVIEW</td>
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<td>The hospital may have only one nursing service hospital-wide and the single nursing service must be under the direction of one RN.</td>
<td>1. Review the organizational chart or plan for nursing services. Determine that the organizational chart(s) displays lines of authority that delegates responsibility within the nursing department.</td>
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<td>The director of the nursing service must be a currently licensed RN and he/she is responsible for the operation of the nursing service. The operation of the nursing service would include the quality of the patient care provided by the nursing service.</td>
<td>2. Verify that the hospital has only one nursing service hospital-wide and the single nursing service is under the direction of one RN.</td>
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<td>The director of the nursing service must determine and provide the types and numbers of nursing care personnel necessary to provide nursing care to all areas of the hospital.</td>
<td>3. Review the position description. Determine the nursing director meets the requirements.</td>
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<td>The organization will include various configurations of the following hospital personnel as determined necessary by the hospital and the Director of Nursing:</td>
<td>4. Read the position description for the director of nursing (DON) to determine that it delegates to the DON specific duties and responsibilities for operation of the service.</td>
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<td>- Assistant / Associate Director(s);</td>
<td>5. Verify that the director is currently licensed in accordance with state licensure requirements.</td>
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<td>- Supervisors / Coordinators;</td>
<td>6. Verify that the DON is involved with or approved the development of the nursing service staffing policies and procedures.</td>
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<td>- Head Nurses / Nurse Managers;</td>
<td>7. Verify that the DON approves the nursing service patient care policies and procedures.</td>
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<td>- Staff Nurses;</td>
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<td>- Unit Secretaries / Clerks;</td>
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<td>- Nurse’s Aide / Orderlies.</td>
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| **16.00.04** Staffing and Delivery of Care. | The Nursing Service budget is based upon historical and projected data and indicates the minimum required staff and the flexible ranges for staffing. |
| The nursing service must have | DOCUMENT REVIEW, OBSERVATION & INTERVIEW |
| | There is evidence that the budget is approved | |

2014 updated August 2014

Healthcare Facilities Accreditation Program (HFAP)
Accreditation Requirements for Psychiatric Hospitals
adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

§482.23(b)

The nursing service must ensure that patient needs are met by ongoing assessments of patients’ needs and provides nursing staff to meet those needs. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit.

There must be a RN physically present on the premises and on duty at all times.

- Every inpatient unit / department / location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the immediate availability of a RN for the bedside care of any patient.

A RN would not be considered immediately available if the RN was working on more than one unit, building, floor in a building, or provider (distinct part SNF, RHC, excluded unit, etc.) at the same time.

Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.

by governance as part of the overall hospital budget. The budget is based upon reliable history and projections utilizing a system, which provides for at least one budgeted RN, per shift, per unit, unless a 24-hour nursing waiver has been granted.

2. Obtain copies of actual and planned staffing for inpatient units for the week prior to the survey, and for a full week six months prior to the survey. Verify:

   - There is at least one employed RN, each shift, for each organized inpatient unit.

3. Determine that there are written staffing schedules which correlate to the number and acuity of patients.

4. Verify that there is supervision of personnel performance and nursing care for each department or nursing unit.

5. To determine if there are adequate numbers of nurses to provide nursing care to all patients as needed, take into consideration:

   - Physical layout and size of the hospital;
   - Number of patients;
   - Intensity of illness and nursing needs;
   - Availability of nurses’ aides and orderlies and other resources for nurses, e.g., housekeeping services, ward clerks etc.;

This standard is not met as evidenced by:
16.00.05 24-Hour Provision of Services.
The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.

§482.23(b)(1)

The hospital must provide nursing services 24 hours a day, 7 days a week. An LPN can provide nursing services if an RN, who is immediately available for the bedside care of those patients, supervises that care.

EXCEPTION: Section 488.54(c) sets forth certain conditions under which rural hospitals of 50 beds or fewer may be granted a temporary waiver of the 24-hour registered nurse requirement by the regional office.

Rural is defined as all areas not delineated as "urbanized" areas by the Census Bureau, in the most recent census.

Temporary is defined as a one year period or less and the waiver cannot be renewed.

DOCUMENT REVIEW
Review the nurse staffing schedule for a one-week period. If there are concerns regarding insufficient RN coverage, review the staffing schedules for a second week period to determine if there is a pattern of insufficient coverage.

Document daily RN coverage for every unit of the hospital.

- Verify that there is at least one RN for each unit on each tour of duty, 7 days a week, 24 hours a day. Additional nurses may be required for vacation or absenteeism coverage.

EXCEPTION: If the hospital has a temporary
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waiver of the 24-hour RN requirement in effect, verify and document the following:

- 50 or fewer inpatient beds.
- The character and seriousness of the deficiencies do not adversely affect the health and safety of patients.
- The hospital meets all the other statutory requirements in §1861(e)(1-8).
- The hospital has made and continues to make a good faith effort to comply with the 24 hour nursing requirement.
  - Determine the recruitment efforts and methods used by the hospitals' administration by requesting copies of advertisements in newspapers and other publications as well as evidence of contact with nursing schools and employment agencies.
  - Document that the salary offered by the hospital is comparable to three other hospitals, located nearest to the facility.
- The hospital's failure to comply fully with the 24 hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.
- A registered nurse is present on the premises to furnish the nursing service during at least
16.00.06 **Licensure.** The nursing service must have a procedure to ensure that the hospital nursing personnel for whom licensure is required have valid and current licensure.

§482.23(b)(2)

The licensure verification process is in conformance with State Laws regarding copying / not copying the license. The process is applied to employee, agency, and contractual providers.

The hospital’s procedure must ensure that all nursing personnel have valid and current licensure that complies with State licensure laws.

Furthermore, the Condition of Participation (CoP) Compliance with Federal, State and local laws (42 CFR §482.11) requires the hospital to assure that personnel meet applicable standards (such as continuing education, certification or training) required by State or local law.

**DOCUMENT REVIEW**

1. Review the nursing service licensure verification policies and procedures. Is licensure verified for each individual nursing services staff person for whom licensure is required?

2. Determine the facility has a licensure verification mechanism that conforms with state mandates. Determine the licensure policy:
   - Is employed for all individual employee and non-employee nursing personnel practicing in the hospital for whom licensure is required.

**FILE REVIEW**

1. Review hospital personnel records or records kept by the nursing service to determine that RNs, LPNs, and other nursing personnel for whom licensure is required have current valid licenses.

16.00.07 **Not Applicable.**
### 16.00.08 Not Applicable.

### 16.00.09 Supervision of Care.

A registered nurse must supervise and evaluate the nursing care for each patient.

§482.23(b)(3)

An RN must supervise the nursing care for each patient.

An RN must evaluate the care for each patient upon admission and when appropriate on an ongoing basis in accordance with accepted standards of nursing practice and hospital policy.

Evaluation would include assessing the patient’s care needs, patient’s health status / conditioning, as well as the patient’s response to interventions.

### DOCUMENT REVIEW

Review staffing schedules and assignments. Determine:

- An RN is assigned to supervise and evaluate the nursing care furnished to each patient.

### 16.00.10 Plan of Care.

The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.

§482.23(b)(4)

A nursing care plan is based on assessing the patient’s nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient’s treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs.

The nursing care plan is kept current by ongoing assessments of the patient’s needs and of the patient’s response to interventions, and updating or revising the patient’s nursing care plan in response to assessments.

### CHART REVIEW

Review a sample of nursing care plans. Verify that the Nursing Care Plans:

1. Are initiated as soon as possible after admission for each patient.
2. Describe patient goals and address, as appropriate, the physiological and psychosocial factors as well as discharge planning.
3. Are consistent with the attending Doctor of Medicine/Doctor of Osteopathic Medicine’s plan for medical care.
4. Are revised as the needs of the patient changes.
5. Are nursing care plans implemented in a
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<td>The nursing care plan is part of the patient’s medical record and must comply with the medical records requirements at §482.24. Hospitals have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient’s care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient’s health care team. The required documentation for the nursing component of an interdisciplinary care plan remains the same.</td>
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<td>6. Select a sample of nursing or interdisciplinary care plans. Approximately 6 – 12 plans should be reviewed. For each plan reviewed, with respect to the nursing care component:</td>
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<td>• Was the plan initiated as soon as possible after admission for each patient?</td>
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<td>• Does the plan describe patient goals as part of the patient’s nursing care assessment and, as appropriate, physiological and psychosocial factors and patient discharge planning?</td>
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<td>• Is the plan consistent with the plan for medical care of the practitioner responsible for the care of the patient?</td>
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<td>• Is there evidence of reassessment of the patient’s nursing care needs and response to nursing interventions and, as applicable, revisions to the plan?</td>
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<td>• Was the plan implemented in a timely manner?</td>
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- For other components, the hospital should follow the current documentation policies that it uses to document services provided by other disciplines, such as services provided by physical therapists, occupational therapists, speech-language pathologists, and others.
- Documentation should follow the standards of practice for those disciplines in addition to any specific requirements that the hospital might want to establish.
- The documentation must also comply with the requirements of the medical records requirement at §482.24. (77 FR 29049, May 16, 2012)
### 16.00.11 Care Assignments

A registered nurse must assign the nursing care of each patient to nursing personnel in accordance with the patient’s needs and the specialized qualifications and competence of the nursing staff available.

§482.23(b)(5)

A RN must make all patient care assignments. The director of the nursing service and the hospital are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

### DOCUMENT REVIEW & INTERVIEW

Review the nursing assignments for at least three (3) weeks of staffing plans against the patient acuity to determine the requirements are met. Determine:

1. Did an RN made the assignments.
2. Assignments take into consideration the complexity of patient’s care needs and the competence and specialized qualification of the nursing staff.

Ask the charge nurse what considerations are necessary when making staff assignments. Answers must include:

- Patient needs
- Complexity of patients
- Any special needs of individual patients
- Competence of nursing personnel
- Qualifications of nursing personnel
- Education of nursing personnel
- Experience of nursing personnel.
### 16.00.13 Supervision of Non-employee Staff

Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing services.

§482.23(b)(6)

The hospital must ensure that there are adequate numbers of clinical nursing personnel to meet its patients' nursing care needs. In order to meet their patient's needs, the hospital may supplement their hospital employed licensed nurses with volunteer and or contract non-employee licensed nurses.

The hospital and the director of the nursing service are responsible for the clinical activities of all nursing personnel. This would include the clinical activities of all non-employee nursing personnel (contract or volunteer).

Non-employee licensed nurses who are working at the hospital must adhere to the policies and procedures of the hospital.

The hospital and the director of the nursing service are responsible for ensuring that non-employee nursing personnel know the hospital's policies and procedures in order to adhere to those policies and procedures.

The hospital and the director of the nursing service ensure that each non-employee nursing care staff person is adequately supervised and that their clinical activities are evaluated. This supervision and evaluation of the clinical activities of each non-employee nursing staff person must be conducted by an appropriately qualified hospital-employed RN.

#### DOCUMENT REVIEW

1. Review the method for orienting non-employee licensed nurses to hospital policies and procedures. The orientation must include at least the following:
   - The hospital and the unit
   - Emergency procedures
   - Nursing service policies and procedures
   - Safety policies and procedures

2. If the hospital uses non-employee nursing personnel, are they supervised by an RN who is a regular employee of the hospital?

#### FILE REVIEW

3. Determine if non-employee personnel are appropriately oriented prior to providing care.

4. Verify that non-employee personnel:
   - Are licensed in accordance with State law.
   - Are evaluated regularly.

#### OBSERVATION

Observe the care provided by non-employee nursing personnel.
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<td>Do they know and adhere to hospital policies?</td>
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<td>Do they know appropriate emergency procedures?</td>
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<td>Are they adequately supervised by an appropriately experienced hospital employed RN?</td>
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<td>Are their clinical activities being evaluated adequately?</td>
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<tr>
<td>Are they licensed in accordance with State law?</td>
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**INTERVIEW**

1. Confirm with the director of nurses that a non-employee nurse’s performance is evaluated by the hospital at least once a year.

2. If the performance evaluation is not considered confidential, review two evaluations.

16.00.14 Not Applicable.

16.00.15 Not Applicable.

16.00.16 Not Applicable.
16.01.01 Medication Preparation and Administration of Drugs.

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.

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.

CHART REVIEW AND OBSERVATION

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

1. Verify that there are policies and procedures approved by the medical staff and governing body concerning ordering of drugs and biologicals by practitioners.

2. 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.

3. Verify nursing staff authorized to administer drugs and biological are practicing within their State-permitted scope of practice.

4. 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...
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 by or under the supervision of nursing or other personnel in accordance with:

- Federal and State law;
- 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.

**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.

5. Verify that there are policies and procedures approved by medical staff addressing the timing of medication administration.

6. 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.

7. 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.

8. Verify that the hospital’s policy describes requirements for the compliance.
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.ihi.org/ihi);
- U.S. Pharmacopeia (www.usp.org);
- Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: www.ismp.org/Newsletters/acute care/articles/20110113.asp;
- Infusion Nurses Society (http://www.ins1.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 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?

B. 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.

C. Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed.

1. Is the patient’s identity confirmed prior to medication administration?
2. Are procedures to assure the correct medication, dose, and route followed?
3. Are drugs administered in accordance with the hospital’s established policies and procedures for timely medication
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 patients, to facilitate dose calculation when applicable. Policies and administration?

4. Does the nurse remain with the patient until oral medication is taken?

D. Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?

E. Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?

F. Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?

G. Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.

1. Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?

2. 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?
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:

A. 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 prepare and administer, in accordance with state laws. The policies and procedures must also address education and training for all personnel preparing and administering drugs and biologicals.

Medication preparation and 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 preparation and 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

• 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.

B. 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:
  o The patient’s full name; an identification number assigned by the hospital; or date of birth.
  o Identifiers must be confirmed by patient
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<td>o 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.</td>
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<td><strong>Right Medication:</strong> 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;</td>
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<td><strong>Right Dose:</strong> 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);</td>
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<td><strong>Right Route:</strong> 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</td>
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<td><strong>Right Time:</strong> the appropriate time, to ensure adherence to the prescribed frequency and time of administration.</td>
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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.

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.

C. 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 workarounds 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.

D. 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.

E. 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.
F. 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.

G. 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.

H. 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 interpretative guidance §482.25(b)(6) for more details on internal reporting requirements.

I. Evaluation Of Medication Administration Timing

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.

J. 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
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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)).

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.,
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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.

K. 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. Accepted standards of practice include maintaining compliance with applicable Federal and State laws, regulations (including all the hospital Conditions of Participation (CoP) such as Pharmacy, Medical Records, Patients’ Rights, QAPI), and guidelines governing drug and biological use in hospitals, as well as, any standards and recommendations promoted by nationally recognized professional organizations.

16.01.02 Not Applicable.

16.01.03 Medication Orders.

- Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.12(c)(3).

- With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of

All orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, must be documented and signed by a practitioner who is responsible for the care of the patient, as specified under §482.12(c), or who is another practitioner who is authorized by hospital policy and medical staff bylaws, rules and regulations, and who is acting in accordance with State law, including scope of practice laws.

**Flu and Pneumonia Vaccines**

Influenza and pneumococcal vaccines may be administered per physician-approved hospital policy, i.e., hospital policy approved by the physician members of the medical staff. There must be an

**DOCUMENT REVIEW & CHART REVIEW**

1. Review the hospital’s policy for drug and biological orders. Does it require that all administration of drugs or biologicals be based on either an applicable standing order or the order of a practitioner who is responsible for the care of the patient or otherwise authorized by hospital policy medical staff policy and in accordance with State law to write orders?

2. Interview nursing staff to determine whether they initiate medications in accordance with standing orders. Are they familiar with the hospital’s policies and procedures for using

Compliant

Not Compliant

This standard is not met as evidenced by:
Contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c).

Orders for drugs and biologicals may be documented and signed by 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.

§482.23(c)(1)(ii)
§482.23(c)(3)
§482.23(c)(3)(iii)

Assessment of contraindications prior to administration of the vaccine(s). There is no requirement for authentication by a practitioner when influenza and pneumococcal vaccines are administered to a patient in accordance with hospital policy and State law.

Standing Orders
Nurses or other personnel authorized by hospital policy and in accordance with State law may administer drugs and biologicals in accordance with pre-printed and electronic standing orders, order sets, and protocols for patient orders, collectively referred to in this guidance as "standing orders," to address well-defined clinical scenarios involving medication administration.

The requirements governing the hospital’s development and use of standing orders are found at the Medical Records CoP, under §482.24(c)(3).

For the nursing services requirement under §482.23(c)(1)(ii), compliance assessment focuses on whether nurses comply with the hospital’s established standing orders policies and procedures when administering drugs or biological in accordance with a standing order.

Standing orders? Are they following the policies and procedures? Ask to see the protocol for a standing order used by nursing staff, and ask nursing staff to explain how their practice conforms to the protocol.

3. Review a sample of open and closed patient medical records. Although the regulation applies to both inpatient and outpatient medical records, the sample should be weighted to include more inpatient records.

4. Determine whether all orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, are included in the patient’s medical record and authenticated by a practitioner who is authorized to write orders by hospital and medical staff policy and in accordance with State law, and who is responsible for the care of the patient.

5. Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner.

6. Determine whether all orders for drugs and biologicals contain the required elements.

7. Verify that the prescribing practitioner has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.
### STANDARD / ELEMENT

16.01.04 Verbal Orders

If verbal orders are used, they are to be used infrequently.

§482.23(c)(3)(i)

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- Verbal orders, if used, must be used infrequently.
- This means that the use of verbal orders must not be a common practice.
- Verbal orders pose an increased risk of miscommunication that could contribute to a medication or other error, resulting in a patient adverse event.
- Verbal orders should be used only to meet the care needs of the patient when it is impossible or impractical for the ordering practitioner to write the order or enter it into a computer (in the case of a hospital with an electronic prescribing system) without delaying treatment. Verbal orders are not to be used for the convenience of the ordering practitioner. (71 FR §68679)

Hospitals are expected to develop appropriate policies and procedures that govern the use of verbal orders and minimize their use, policies which:

- Describe situations in which verbal orders may be used as well as limitations or prohibitions on their use;
- Provide a mechanism to establish the identity and authority of the practitioner issuing a verbal order;
- List the elements required for inclusion in the verbal order process;
- Define the types of personnel who may issue verbal orders;

#### DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW

1. Are there policies and procedures in place to minimize the use of verbal orders?
2. Interview direct care staff to determine whether actual practice is consistent with verbal order policies and procedures.
3. Review both open and closed patient medical records for the use of verbal orders.
4. Were the policies and procedures for the use of verbal orders followed?
5. Does the number of verbal orders found in the sampled records suggest routine use, which the regulations do not permit? The number of verbal orders is not in itself evidence of noncompliance, but should result in more focused analysis. For example:

- Is there a pattern to the use of verbal orders? Some patterns might make sense – e.g., for orders entered between midnight and 7am., it might be plausible that it was impossible for the prescribing practitioner to write / computer-enter the order. On the other hand, if one patient care unit has a high proportion of verbal orders, while another does not, this might be a flag for inconsistent implementation of the hospital’s policies and procedures for verbal orders.

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*2014 updated August 2014*

Healthcare Facilities Accreditation Program (HFAP)

Accreditation Requirements for Psychiatric Hospitals
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<td>and receive verbal orders; and</td>
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<td>• Establish protocols for clear and effective communication and verification of verbal orders.</td>
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<td>The content of verbal orders must be clearly communicated. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order. (71 FR §68680)</td>
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<td>As required by §482.24(b), all verbal orders must be promptly documented in the patient’s medical record and signed by the individual receiving the order.</td>
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<td>16.01.05 Accepting Verbal Orders. When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law. §482.23(c)(3)(ii)</td>
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<tr>
<td>A verbal order for drugs and biologicals may only be accepted by an individual who is permitted by Federal and State law and hospital policy to accept verbal orders.</td>
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<td>Consistent with the requirements of §482.24(b), the person who received the verbal order must promptly document it in the medical record.</td>
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<td>• Are verbal orders used frequently for certain types of situations, and if so, is it reasonable to assume that it is impossible or impractical for the prescribing practitioners to write / enter the orders in such situations?</td>
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<td>• Do certain practitioners use verbal orders frequently? From the limited number of records sampled it may be difficult to detect trends related to specific practitioners, but if a surveyor finds such evidence, further investigation is warranted to determine if it is evidence of noncompliance.</td>
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**DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW**

- Determine whether the hospital has policies and procedures, consistent with Federal and State law, governing who is authorized to accept verbal orders.
- Review open and closed patient medical records containing verbal orders for drugs and biologicals.
  - Determine whether the orders were accepted and documented by authorized hospital personnel.
- Interview several direct care staff to determine if they are permitted to take verbal orders for drugs and biologicals, and
16.01.06 Administration of Blood Products & IV Medications.

Blood transfusions and intravenous medications 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:

1. **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 compliance requirements.

**SCORE**

**SCORING PROCEDURE**

Determine whether such staff have been authorized to do so in accordance with hospital policy.

**DOCUMENT REVIEW, FILE REVIEW, AND CHART REVIEW**

1. Verify the hospital has a special training program for administering blood transfusions and intravenous medications.

   - Training should include:
     - Fluid and electrolyte balance;
     - Blood components; and
     - Venipuncture techniques, demonstrations and supervised practice.

2. Interview nursing staff on different units who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:

   a. Venipuncture techniques;

   b. Safe medication administration practices, including general practices applying to all types of medications and practices.

This standard is not met as evidenced by:
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safety concerns. Hospital policies and procedures must address which medications can be given intravenously via what type of access.

2. 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).

3. 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 concerning IV tubing and infusion pumps;

c. Maintaining fluid and electrolyte balance;
d. Patient assessment for risk related to IV medications and appropriate monitoring;
e. Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients;
f. 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.

3. 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.

4. If able, observe blood transfusion and IV medication administration to assess staff adherence to accepted standards of practice.

   a. Were safe medication administration practices used?
   b. Was the transfused patient correctly identified and matched to the
### EXPLANATION

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:

1. **Monitoring for Fluid & Electrolyte Balance**
   Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalances. Staff must monitor patients for signs and symptoms of these imbalances and take appropriate steps to correct them.

2. **Correct Blood Product Prior to Administration**
   Before administering a blood transfusion, staff must verify the correct blood type and Rh status of the blood product, as well as the patient's identity, using two independent methods of identification.

3. **Appropriate Access for IV Medications**
   Staff must ensure that the appropriate access site is used for IV medication administration, and that the access site is appropriately secured to prevent dislodgement or infiltration.

4. **IV Tubing and Infusion Pumps**
   Staff must follow hospital policies and procedures for setting up and maintaining IV tubing and infusion pumps to ensure accurate delivery of IV medications.

5. **Post-Infusion Monitoring**
   After administering an IV medication, staff must monitor the patient for adverse reactions and document any observed changes in their condition.

6. **Staff Education and Competency**
   Staff must have the knowledge and skills necessary to safely administer IV medications and monitor patients receiving these medications. This includes understanding the specific medications and their effects, as well as the potential side effects and monitoring requirements.

7. **Review Policies and Procedures**
   Hospitals are expected to review their policies and procedures for IV medication administration and blood transfusions at least annually to ensure they are current and effective.

8. **Sample Medical Records**
   Hospitals must review a sample of medical records to ensure that patients receiving blood transfusions and IV medications have received them in accordance with established policies and procedures.

### SCORING PROCEDURE

- a. Was the correct blood product administered prior to administration?
- b. Did the appropriate access site for IV medications are used?
- c. Was the appropriate access used for IV medications?
- d. Were appropriate steps taken with regard to IV tubing and infusion pumps?
- e. Are patients being monitored post-infusion for adverse reactions?

5. 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.

6. Review a sample of medical records of patients that received a blood transfusion and/or IV medications.

   - a. Are blood transfusions and IV medications administered in accordance with State law and approved hospital policies and medical staff policies and procedures?
   - b. Determine the identity of staff who
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<td>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.</td>
<td>administered blood components and/or IV medications and review their employee records.</td>
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<td>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.</td>
<td>• Do they have documented special training?</td>
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<tr>
<td>At a minimum, hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients.</td>
<td>2. Monitoring Patients Receiving High-alert Medications, Including IV Opioids</td>
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<td>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.</td>
<td>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.</td>
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<td>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.</td>
<td>3. Are blood transfusions and IVs administered by personnel who are trained and working within their scope of practice in accordance with State law and hospital and Medical Staff policies?</td>
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<tr>
<td>Review personnel files of staff that administered blood transfusions and IV medications.</td>
<td>4. Review personnel files of staff that administered blood transfusions and IV medications.</td>
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<td>a. Is there evidence that the competency of these staff was assessed with respect to:</td>
<td>a. Blood components;</td>
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<td>1) Maintaining fluid and electrolyte balance;</td>
<td>b. Blood administration procedures per hospital policy, State law, and nationally recognized standards of practice;</td>
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<tr>
<td>2) Venipuncture techniques;</td>
<td>4) Patient monitoring</td>
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respiratory depression. These additional factors include, but are not limited to:

- 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

requirements, including frequency and documentation of monitoring;

5) Process for verification of the right blood product for the right patient; and

6) Transfusion reactions: Identification, treatment, and reporting requirements.
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.

1. 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.

2. 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.

3. 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:

1. Vital signs (blood pressure, temperature,
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<td>pulse, respiratory rate)</td>
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<td>2. Pain level;</td>
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<td>3. Respiratory status;</td>
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<td>4. 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.</td>
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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.

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.

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.

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:
1. Confirming the following prior to each blood transfusion:
   a. the patient’s identity
   b. verification of the right blood product for the right patient

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

3. Requirements for patient monitoring, including frequency and documentation of monitoring

4. 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.

- Content of the training must address each required component of the approved medical staff policies and procedures.

- 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.

- Other non-physician personnel, 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.

The appropriate competencies must be documented in the qualified staff person’s employee record.

Content of the training is based on nationally recognized standards for intravenous medication administration and blood transfusion and must address at least the following:

1. Fluid and electrolyte balance;
2. Venipuncture techniques, including both demonstration, and supervised practice; and,
3. Blood transfusion training:
   - Blood components;
   - Blood administration procedures based on hospital policy, State law, and nationally recognized standards of practice;
   - Requirements for patient monitoring, including frequency and documentation of monitoring;
### Adverse Drug Reactions, Transfusion Reactions & Medical Error Reporting

There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§482.23(c)(5)

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<td>16.01.07 Adverse Drug Reactions, Transfusion Reactions &amp; Medical Error Reporting</td>
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<td>Adverse Drug Reactions And Drug Administration Errors</td>
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<td>There is a similar but more detailed and prescriptive requirement concerning internal hospital reporting of adverse drug reactions, drug administration errors and incompatibilities under the Pharmaceutical Services CoP at §482.25(b)(6). Therefore, it is not necessary for hospitals to establish a different procedure in the case of adverse drug reactions and drug administration errors for such events when nurses administer drugs or transfusions. Consult the guidance for §482.25(b)(6) to see what must be reported, to whom, and in what timeframe. Failure to make required reports concerning adverse drug reactions and errors in administration of drugs should be cited under §482.23(c)(5) when the drug was administered by a nurse, as well as under §482.25(b)(6).</td>
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<td>Transfusion Reactions</td>
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<td>Transfusion reactions can occur during or after a blood transfusion. A patient’s immune system recognizes the foreign blood product and attempts to destroy the transfused cells. Incompatible blood products are</td>
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**DOCUMENT REVIEW**

1. Review the procedure for reporting transfusion reactions to determine that the requirements are met.
2. Review incident reports or other documents to validate the procedure is implemented and monitored through the QAPI program.
3. For adverse drug events and medication administration errors, follow the survey procedures for §482.25(b)(6).

Deficiencies are to be cited under both §482.23(c)(5) and §482.25(b)(6) when the drug or transfusion related to an adverse drug reaction, transfusion reaction or medication administration error relates to a drug or transfusion administered by a nurse.

4. Request the hospital policy and procedure for internal reporting of transfusion reactions.
5. Interview nursing staff responsible for administering blood transfusions to determine whether they are familiar with and comply with the hospital’s policies.

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typically the cause of transfusion reactions. Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death. Transfusion reactions are serious and can be life-threatening.

The hospital must have policies and procedures in place for the internal reporting of transfusion reactions.

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

6. Ask to see if there are any transfusion-related incident reports.
   - Is there evidence that the transfusion reaction was reported immediately to the practitioner responsible for the patient’s care?
   - Was it reported to the hospital’s QAPI program?

16.01.08 Not Applicable.
16.01.09 Self-Administration of Medications: Hospital-Issued Medications.

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.

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

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/supervisors 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-

DOCUMENT REVIEW, MEDICAL RECORD REVIEW, AND OBSERVATION

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

1. 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.

2. 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?
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.

§482.23(c)(6)
§482.23(c)(6)(i)
§482.23(c)(6)(i)(A)
§482.23(c)(6)(i)(B)
§482.23(c)(6)(i)(C)
§482.23(c)(6)(i)(D)
§482.23(c)(6)(i)(E)

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

- 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?

2. 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.

3. Do the hospital’s policies and procedures for
patients (and/or their caregiver/support persons), the following must be in place:

1. **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.

2. **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 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.
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<td>the nurses’ concerns about patient’s (or caregiver/support person’s) capacity to safely self-administer medications.</td>
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<td>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.</td>
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<td>**3. **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</td>
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training needs, and how they were addressed, must be documented in the medical record.

4. **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 postsurgical patients receiving IV opioids, including via patient-controlled analgesia (PCA) pumps, in and
5. **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
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<td><strong>16.01.10 Self-Administration of Medications: Medications Brought into the Hospital.</strong></td>
<td>Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of medications the patient brings himself or herself to the hospital. 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 retain and self-administer medications they bring with them from home.</td>
<td><strong>DOCUMENT REVIEW, MEDICAL RECORD REVIEW AND OBSERVATION</strong></td>
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<td>If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:</td>
<td>A hospital program for patient self-administration of medications the patient brings from home 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 medications that outpatients or their caregivers/support persons bring with them.</td>
<td>If the hospital permits patient self-administration of medications brought from home:</td>
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<td>(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.</td>
<td>Among the potential benefits of permitting self-administration of medications the patient brings from home is that problems are avoided related to the hospital's formulary not including a particular medication that a patient needs to continue to take during his/her hospital stay, and the patient prefer to avoid medication substitution. The hospital also gains an opportunity to identify suboptimal patient medication administration techniques for these drugs</td>
<td>1. Ask the hospital to identify current inpatients for whom self-administration of medications brought from home is permitted.</td>
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<td>(B) Assess the capacity of the patient (or the patient’s caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine if the patient (or the patient’s caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).</td>
<td>2. Interview of several of these patients (or their caregivers/support persons when applicable) to ask if they received instruction on how to self-administer their medications consistent with hospital policy.</td>
<td>2. Interview of several of these patients (or their caregivers/support persons when applicable) to ask if they received instruction on how to self-administer their medications consistent with hospital policy.</td>
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<tr>
<td>(C) Identify the specified medication(s) and visually evaluate the respect to timing and dosage, that the patient is receiving the medication as ordered.</td>
<td>3. Interview nurses caring for the selected patients. Ask them:</td>
<td>3. Interview nurses caring for the selected patients. Ask them:</td>
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- 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.
medication(s) for integrity.

(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.

§482.23(c)(6)(i)(A)
§482.23(c)(6)(i)(B)
§482.23(c)(6)(ii)(C)
§482.23(c)(6)(ii)(D)
§482.23(c)(6)(ii)(E)

and to provide instruction designed to ensure that the patient is administering his/her medications properly.

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. 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 medications the patient brings from home.

It is expected that the medical staff, nursing and pharmacy departments are to collaborate in developing policies and procedures for self-administration of medications the patient brings from

and to provide instruction designed to ensure that the patient is administering his/her medications properly. 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 safe and proper medication self-administration when educational needs have been identified.

- 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?

4. 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 and identification of whether or not there are educational needs that have been met.

- Documentation of the identification and visual assessment of medications brought from home.

- Documentation of self-administration
home 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 medications brought from home by patients (and/or their caregiver/support persons), the following must be in place:

1. **An order allowing the patient to administer medications brought from home.**
   
The order must be consistent with the hospital’s policy concerning self-administration of medications brought from home 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.

2. **A documented assessment of the capacity of the patient (or their caregiver/support person) to successfully administer the medication(s) specified in the order, including a determination whether the patient (or their caregiver/support person) needs instruction in the safe and accurate administration of the specified medication(s).**
   
   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) times and doses, as reported by the patient or (or patient’s caregiver/support person) or directly observed by a nurse.

5. **Do the hospital's policies and procedures for self-administration of medications brought from home address, consistent with the regulatory requirements, the following:**
   
   - Limitations on medications eligible for self-administration or patient conditions which exclude self-administration;
   - Orders for self-administration of medications brought from home;
   - Requirements, if any, for supervision of self-administration;
   - Assessment of self-medication capacity, including identification of educational needs and how they are to be met;
   - Identification and visual inspection for integrity of self-administered medications brought from home;
   - Security of self-administered medications; and
   - Documentation of self-administration in the medical record?
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. (77 FR 29052, May 16, 2012)

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.

As part of the assessment of the patient’s self-administration capacity, nurses are expected to
3. **Identification/visual evaluation for integrity.**

Hospitals must have policies and procedures addressing how they will identify the medications the patient has brought from home. Identification is important because the label on the patient’s medication container may not accurately reflect the contents. Further, the medication might have expired or have not been stored correctly in the patient’s home, requiring hospitals to at least conduct a visual inspection to see if the medication appears to have retained its integrity. It is recognized that a visual inspection for integrity may not be definitive, but the regulation
4. **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.

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 brought from home 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.

5. **Documentation of medication administration.**

Under the regulation, a nurse must document the
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<th>SCORING PROCEDURE</th>
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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.