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16.01.01 Preparation and Administration of Drugs.

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

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

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

Drugs and biologicals must be prepared and administered in accordance with Federal and State laws.

According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.[3]

It has been estimated that drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7 percent of all stays), and 838,000 treat-and-release ED visits (0.8 percent of all visits).[4]

3 Institute of Medicine. Preventing Medication Errors. Washington DC: The National Academies Press, 2007.

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

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

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

☐ 1 = Compliant
☐ 2 = Not Compliant

This standard is not met as evidenced by:

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§482.23(c)
§482.23(c)(1)
§482.23(c)(1)(i)
§482.23(c)(2)

their success. The increasing complexity of medical care and patient acuity present significant challenges that require an approach to medication administration that takes advantage of available technology while recognizing that it must be integrated into the medication administration work processes in a manner that meets the needs of patients and promotes their safety.

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

compliance.

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

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administer, including controlled substances.

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

Examples of such organizations include, but are not limited to:

1. **American Society of Health-System Pharmacists** (http://www.ashp.org/default.aspx)
2. National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org);
3. Institute for Healthcare Improvement (http://www.ihi.org/ihi);
4. U.S Pharmacopeia (www.usp.org);
5. Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: **www.ismp.org/Newsletters/acutecare/articles/20110113.asp;**
6. Infusion Nurses Society **(http://www.ins1.org).**

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. **If immediate-use CSPs are prepared**

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

Orders of an Authorized Practitioner

Drugs must be administered in response to an order from a practitioner, or on the basis of a standing order which is appropriately authenticated subsequently by a practitioner. (See §482.23(c)(1) (ii) concerning standing orders.)

Generally, the ordering practitioner is the practitioner(s) responsible for the care of the patient in accordance with §482.12(c). However, other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations.

This includes practitioners ordering outpatient services who do not have privileges in the hospital but who are permitted under their State scope of practice and authorized by hospital and medical staff policy to order outpatient services.

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

outside of the pharmacy, are practices consistent with USP<797>?

4. Are drugs administered in accordance with the hospital's established policies and procedures for **safe and** timely medication administration?

5. 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?

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1. Name of the patient;

2. Age and weight of the patients, to facilitate dose calculation when applicable.

3. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the hospital's policies. (Note that dose calculations are based on metric weight (kg, or g for newborns).

   - If a hospital permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, hospitals must specify a uniform approach to be used by prescribing practitioners.

   - For example, a hospital could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric);
     a. Date and time of the order;

     b. Drug name;

     c. Dose, frequency, and route;

     d. Dose calculation requirements, when applicable;

     e. Exact strength or concentration, when

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?

applicable;

f. Quantity and/or duration, when applicable;

g. Specific instructions for use, when applicable; and

h. 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.

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	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. <u>Basic Safe Practices For Medication Administration</u>

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):

1. **Right Patient**: the patient's identity— acceptable patient identifiers include, but are not limited to:
    a. The patient's full name; an identification number assigned by the hospital; or date of birth.

    b. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital's policy.

    c. 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.

2. **Right Medication**: the correct medication, to ensure that the medication being given to the

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patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;

3. **Right Dose:** the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);

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

5. **Right Time:** the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

Note: the "5 rights" focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages:

- ordering/prescribing;
- transcribing and verifying;
- dispensing and delivering;
- administering; and
- monitoring / reporting.

Errors may occur in other components of the process, even when there is strict adherence to the "5 rights" of medication administration, for example when there has been a prescribing or a

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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.

Hospitals must also ensure staff adherence to accepted standards of practice required to prevent healthcare-associated infections related to medication preparation and/or administration. Adherence to these standards is assessed under the infection control CoP at 42 CFR 482.42, and details about the required practices are found in the Hospital Infection Control Worksheet.

Compounded sterile preparations (CSPs) may also be a source of healthcare-associated infection if proper precautions are not followed.

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The applicable standards of practice for safe sterile compounding are, at a minimum, the standards published in The United States Pharmacopeia National Formulary Chapter <797> ("Pharmaceutical Compounding – Sterile Preparations") and other relevant USP/NF Chapters (USP <797>).

- **(See the guidance for §482.25(b)(1) for more information on the role of USP/NF standards and for discussion of the term "compounding.")**

Hospitals must ensure that they meet all currently accepted standards for safe preparation and administration for CSPs, whether they are the type of CSP that must be compounded in an aseptic pharmacy location that meets USP <797> standards for low, medium or high-level risk CSPs or are "immediate-use CSPs" prepared outside of the pharmacy.

Nurses commonly prepare sterile medications that are categorized by USP <797> as "immediate-use CSPs," which are needed for immediate or emergency use for a particular patient and are not to be stored for anticipated needs.

The following USP <797> standards apply when preparing an immediate-use CSP:

1. **Preparation of an immediate-use CSP must only involve "simple transfer of not more**

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than three commercially manufactured…sterile nonhazardous products from the manufacturer's original containers and not more than two entries into any one container or package (e.g. bag, vial) of sterile infusion solution or administration container/device;"

2. **"Administration begins not later than one hour following the start of the preparation of the CSP (if not, the CSP must be appropriately discarded);"**

3. **Meticulous aseptic technique must be followed during all phases of preparation. If the CSP is not administered to the patient as soon as it is ready, "the finished CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces…," contamination and/or confusion with other CSPs; and**

4. **"Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer…," the CSP must be labeled with at least:**

   a. **Patient identification information;**

   b. **The names and amounts of all ingredients;**

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c. The name or initials of the person who prepared it; and

d. The exact one hour "beyond use date" (see below).

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the U.S. Food and Drug Administration's (FDA) approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.

Beyond Use Date (BUD)

1. **A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later.**

2. **The BUD is the date and time after which the medication must not be used, stored or transported.**

3. **The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for**

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dispensing and administration, and/or during the compounding process if it is a compounded medication.

4. **The BUD is to be based on information provided by the manufacturer, whenever such information is available. The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer.**

5. **The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the USP/NF (USP).[3]**

6. **According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively. The section in USP <797> entitled "Determining Beyond-Use Dates," which addresses sterile compounding, notes that "the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies." It provides an example of testing considered more appropriate for certain types of CSPs such as "CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity…."**

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It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables. The former is the preferred approach, while the latter results in a "theoretical BUD," which has an inherent likelihood of inaccuracy or error.

[3] All references to "USP" herein are from: United States Pharmacopeial Convention. USP on Compounding: A Guide for the Compounding Practitioner. Current with USP 37-NF32 through First Supplement. Rockville, MD: United States Pharmacopeial Convention, 2014.

C. <u>Timing of Medication Administration</u>

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

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administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration.

Consequently, the application of a uniform required window of time before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately. This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, hospital policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration.

The policies and procedures must address at least the following:

1. Medications not eligible for scheduled dosing times;
2. Medications eligible for scheduled dosing times;
3. Administration of eligible medications outside of their scheduled dosing times and windows;

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and

4. Evaluation of medication administration timing policies, including adherence to them.

D. <u>Medications or Categories of Medication Not Eligible For Scheduled Dosing Times</u>

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. <u>Medications Eligible For Scheduled Dosing Times</u>

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

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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

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- patient units that are not subject to following the scheduled dosing times.

F. <u>Time-Critical Scheduled Medications</u>

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

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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. <u>Non-Time-Critical Scheduled Medications</u>

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.

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- 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. <u>Missed Or Late Administration Of Medications</u>

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

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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

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corrective action.

Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;

- Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.

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

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levels of medications), asthma, history of smoking, drug-drug interactions, and first-time medication use may contribute to increased risk.

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

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

An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may

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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

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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

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	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.		