
CMS Manual System

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

Transmittal 77

(Advance Copy)

Date: December 22, 2011

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for 42 CFR 482.23(c), concerning medication administration.

REVISED MATERIAL - EFFECTIVE DATE*: December 22, 2011
IMPLEMENTATION DATE: December 22, 2011

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/§482.23(c) Standard: Preparation and Administration of Drugs/A-0405

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

IV. ATTACHMENTS:

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

A-0405

(Rev.77, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§482.23(c) Standard: 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.

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

Interpretive Guidelines §§482.23(c) and (c)(1)

According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.¹ Studies indicate that 400,000 preventable drug-related injuries take place in hospitals each year, as a result of errors that occur at various points in the medication administration process.² Although technological advances in electronic order entry, medication administration, and electronic medical records hold a great deal of promise for decreasing medication errors, there are a multitude of human and environmental factors that will impact their success. The increasing complexity of medical care and patient acuity present significant challenges that require an approach to medication administration that takes advantage of available technology while recognizing that it must be integrated into the medication administration work processes in a manner that meets the needs of patients and promotes their safety.

The regulations at §482.23(c) and §482.23(c)(1) promote safety in the preparation and administration of drugs and biologicals to hospital patients by requiring preparation and administration 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); and*
- Medical staff-approved policies and procedures.*

Federal and State Law

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

² *Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs*. Research in Action, Issue 1. AHRQ Publication Number 01-0020, March 2001. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/qual/aderia/aderia.htm>

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

Accepted Standards of Practice

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

- *National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org);*
- *Institute for Healthcare Improvement (<http://www.ihl.org/ihl>) ;*
- *U.S Pharmacopeia (www.usp.org) ;*
- *Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: www.ismp.org/Newsletters/acutecare/articles/20110113.asp;*
- *Infusion Nurses Society (<http://www.insl.org>).*

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

Orders of the practitioner or practitioners responsible for the patient's care

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

- *Name of the patient;*
- *Age and weight of the patients, or other dose calculation requirements, where applicable;*
- *Date and time of the order;*
- *Drug name;*
- *Dose, frequency, and route;*
- *Exact strength or concentration, when applicable;*
- *Quantity and/or duration, when applicable;*
- *Specific instructions for use, when applicable; and*
- *Name of the prescriber.*

Medical Staff Approved Policies and Procedures

The hospital's medical staff must approve policies and procedures for medication administration, consistent with the requirements of Federal and State law and accepted

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

Personnel authorized to administer medication

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 of administered medications;*
- *Equipment, devices, special procedures, and/or techniques required for medication administration;*

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

Training content and documentation of competence must be in accordance with §482.23(c)(3). See the interpretive guidance for §482.23(c)(3) for more detail.

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:

- *the patient's identity. Acceptable patient identifiers include but are not limited to: the patient's full name; an identification number assigned by the hospital; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.*

- *the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient;*
- *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);*
- *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*
- *the appropriate time, to ensure adherence to the prescribed frequency and time of administration.*

Timing of Medication Administration

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

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

Medications not eligible for scheduled dosing times

The policies and procedures must identify medications which are not eligible for scheduled dosing times, either in general or in specific clinical applications. These are medications that require exact or precise timing of administration, based on diagnosis type, treatment

requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors. Examples of medications that hospitals may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

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

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

Medications eligible for scheduled dosing times

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

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

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

Time-critical scheduled medications

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

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

- *Antibiotics;*
- *Anticoagulants;*
- *Insulin;*
- *Anticonvulsants;*
- *Immunosuppressive agents;*
- *Pain medication;*
- *Medications prescribed for administration within a specified period of time of the medication order;*
- *Medications that must be administered apart from other medications for optimal therapeutic effect; or*
- *Medications prescribed more frequently than every 4 hours.*

Non-time-critical scheduled medications

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

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

Missed or late administration of medications

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

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

Evaluation of medication administration timing policies

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

Standing orders

Hospitals may adopt policies and procedures that permit the use of standing orders to address well- defined clinical scenarios involving medication administration. The policies and procedures must address the process by which a standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by physicians or practitioners responsible for the care of the patient.

The specific criteria for a nurse or other authorized personnel to initiate the execution of a particular standing order must be clearly identified in the protocol for the order, i.e., the specific clinical situations, patient conditions or diagnoses in which initiating the order would be appropriate. Policies and procedures must address the education of the medical, nursing, and other applicable professional staff on the conditions and criteria for using standing orders and the individual staff responsibilities associated with their initiation and execution. An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter. Likewise, standing order policies and procedures must specify the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders after the fact,

with the exception of influenza and pneumococcal polysaccharide vaccines, which do not require such authentication in accordance with §482.23(c)(2).

The policies and procedures must also establish a process for monitoring and evaluating the use of standing orders, including proper adherence to the order's protocol. There must also be a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions.

Survey Procedures §§482.23(c) and (c)(1)

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

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

medications or medication types are identified as such for the entire hospital or are unit-, patient diagnosis-, or clinical situation- specific?

- Review a sample of *medical records to determine whether medication administration conformed with a practitioner's order, i.e., that the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and procedures. Check that the practitioner's order was still in force at the time the drug was administered.*
- Observe the preparation of drugs and their administration to patients [*medication pass*] in order to verify that procedures are being followed.
 - *Is the patient's identity confirmed prior to medication administration?*
 - *Are procedures to assure the correct medication, dose, and route followed?*
 - *Are drugs administered in accordance with the hospital's established policies and procedures for timely medication administration?*
 - Does the nurse remain with the patient until medication is taken?
- *Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.*
 - *Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?*
 - *Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?*
- *If the hospital uses standing orders, verify that there are policies and procedures that address the process by which a standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by physicians or practitioners responsible for the care of the patient.*
- *Ask to see an example of one or more standing orders involving medication administration, including the documentation on the development of the order, evidence of training of personnel on the order's protocol, and periodic evaluation of the use of the standing order, including adherence to policies.*
- *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 standing orders? Are they following the policies and procedures?*