

A-0413

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

§482.23(c)(6)(ii) 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:

- (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.
- (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).
- (C) Identify the specified medication(s) and visually evaluate the 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.

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

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.

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.

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 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 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:

- **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.
- **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'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 identify whether the patient (or the patient's caregiver/support person) needs instruction in the safe and accurate administration of the specified medication(s). Even though the patient has been taking the medication at home, the patient (or the patient's caregiver/support person) may not be using optimal administration techniques. Patient needs may be related to type of medication, unique individual medication requirements, delivery route, dosage and scheduling, equipment (e.g. syringes, pill-cutters, measuring containers, etc.) intravenous access, potential adverse side effects and what to do if they occur, infection control measures, storage, medication disposal, among others. Education and training needs identified, and how they were addressed, must be documented in the medical record.

- **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 does not require use of more complex methods.

- **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 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.

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

Survey Procedures §482.23(c)(6) and (c)(6)(i)

If the hospital permits patient self-administration of medications brought from home:

- Ask the hospital to identify current inpatients for whom self-administration of medications brought from home is permitted.
 - Interview of several of these patients (or their caregivers/support persons when applicable) to ask if that they received instruction on how to self-administer their medications consistent with hospital policy.
 - Interview nurses caring for the selected patients. Ask them:
 - What the applicable hospital policies and procedures are regarding supervision of self-medication.
 - How they assess a patient's (or patient's caregiver/support person's) capacity to self-administer medication. If they have concerns, how do they communicate them to the responsible practitioner? Does their hospital permit nurses to return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient's caregiver/support person? If so, how

do the nurses make this assessment?

- How they instruct a patient (or patient's caregiver/support person's) in 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?
- 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 times and doses, as reported by the patient or (or patient's caregiver/support person) or directly observed by a nurse.
- Do the hospital's policies and procedures for self-administration of 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?