

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

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

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

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

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

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

Hospitals have the discretion to establish policies providing for different levels of patient self-administration, and may make these levels across-the-board, patient-specific, or medication-specific. For example, a hospital may choose whether or not a nurse must be present to supervise the self-administration, and whether this supervision requirement could vary according to the type of medication or the capacity of the individual patient (or the patient's caregiver/support person). A hospital may also determine through its policies and procedures whether supervision requirements must be addressed in the practitioner's order or whether this may be left to the discretion of the nurse who assesses the patient. A hospital may choose to exclude certain medications from patient self-administration, for

example, because they pose too great a medication security challenge, or because the manner in which they must be administered does not lend itself to safe self-administration. (77 FR 29052, May 16, 2012) It must be clear in the hospital's policies and procedures whether it has established such a policy and what kind of limitations it has established for its program of patient self-administration of hospital-issued medications.

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

Required elements of a self-administration program:

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

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

one-size-fits-all regulatory requirement. There are Federal and State laws, including the Pharmaceutical Services CoP, which require a higher level of security for certain medications (for example, controlled substances). Hospitals are expected to comply with these already-established requirements and laws, and generally should not include such medications as part of a patient self-administration program.

- Note that Patient-controlled Analgesia (PCA) pumps are a special variant of patient self-administration. Such pumps allow patients, within tightly controlled, pre-determined parameters with respect to dosage and minimum time intervals between doses, to release an intravenous dose of a controlled substance pain medication that has been pre-loaded into the PCA pump in a manner that prevents tampering by an unauthorized person. PCA pumps are considered secure despite their use of controlled substances.

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

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

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

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

Survey Procedures §482.23(c)(6)(i)

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

- Ask the hospital to identify current inpatients for whom self-administration of hospital-issued medications is permitted.
- Interview of several of these patients (or their caregivers/support persons when applicable) to verify that they received instruction on how to administer their medications
- Interview nurses caring for the selected patients. Ask them:
- What the applicable hospital policies and procedures are regarding supervision of self-medication.

- How they assess a patient's (or patient's caregiver/support person's) capacity to self-administer medication. If they have concerns, how do they communicate them to the responsible practitioner? Does their hospital permit nurses to return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient's caregiver/support person? If so, how do the nurses make this assessment?
- How they instruct a patient (or patient's caregiver/support person's) in medication self-administration.
- How self-administered medications are secured.
- How they document self-administration of medications.
- To provide a copy of the hospital's policies and procedures. Are they following the policies and procedures?
- Review the medical records for the selected patients. Is there documentation of:
 - An order for self-administration of specific medication(s).
 - A nurse assessment of the patient's (or patient's caregiver/support person's) capacity to self-administer medication.
 - Documentation of nurse instruction to the patient or (or patient's caregiver/support person) in safe and appropriate techniques for self-administration of medication.
 - Documentation of self-administration times and doses, as reported by the patient or (or patient's caregiver/support person) or directly observed by a nurse.
- Do the hospital's policies and procedures for self-administration of hospital-issued medications address:
 - Limitations on medications not eligible for self-administration or patient conditions which exclude self-administration;
 - Orders for self-administration of medication;
 - Requirements, if any, for supervision of self-administration;
 - Assessment of self-medication capacity;
 - Instruction in self-medication;
 - Security of self-administered medications; and
 - Documentation of self-administration.