Medicare/Medicaid: CMS Announces New Conditions Of Participation For Hospitals.

PART 482–CONDITIONS OF PARTICIPATION FOR HOSPITALS
Sec. 482.13 Condition of participation: Patient’s rights.

(g)(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient’s death:
   (i) Each death that occurs while a patient is in restraint or seclusion.
   (ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
   (iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that the use of restraint or placement in seclusion contributed directly or indirectly to a patient’s death, regardless of the type(s) of restraint used on the patient during this time. “Reasonable to assume” in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient’s wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:
   (i) Any death that occurs while a patient is in such restraints.
   (ii) Any death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(3) The staff must document in the patient’s medical record the date and time the death was:
   (i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or
   (ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

The new Conditions of Participation take effect July 16, 2012.
Subjects affected by the new regulations include:
- Reporting of restraint-related deaths;
- Nursing care plans;
- Administration of medications and blood transfusions;
- Standing orders, verbal orders and authentication of orders; and
- Infection control.

In addition to the excerpts reproduced here verbatim we have placed CMS’s entire forty-three page May 16, 2012 Federal Register announcement on our website at [www.nursinglaw.com/CMS051612.pdf](http://www.nursinglaw.com/CMS051612.pdf) with the new regulations beginning on PDF page 41, Federal Register page 29074.

FEDERAL REGISTER May 16, 2012
Pages 29034-29076

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:
   (i) Each entry must be made not later than seven days after the date of death of the patient.
   (ii) Each entry must document the patient’s name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under Sec. 482.12(c), medical record number, and primary diagnosis(es).
   (iii) The information must be made available in either written or electronic form to CMS immediately upon request.

Sec. 482.23 Condition of participation: Nursing services.
(b) (4) 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.

(c) Standard: 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 Sec. 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 Sec. 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.

   (ii) 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 Sec. 482.24(c)(3).

   (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.

   (3) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under Sec. 482.12(c).
New Conditions Of Participation For Hospitals (Continued.)

[Verbal Orders]
(i) If verbal orders are used, they are to be used infrequently.
(ii) 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.
(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under Sec. 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.
(4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.
(5) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

[Medications/Self-Administration]
(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), 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.

(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.

Medication Error: Hospital Admits Liability, Patient Appeals Verdict.

The patient was brought to the E.R. for an allergic reaction to a bee sting. The E.R. physician ordered sub q epinephrine which was successful at first but later a second dose was necessary.
The E.R. nurse gave the second dose of epinephrine IV rather than sub q.
The nurse stood by to monitor the patient’s reaction. The patient immediately complained of pain in her head. Her heart rate jumped from 101 to 190 and her BP went from 136/55 to 205/129.
The E.R. physician was called in and sent the patient to the ICU. Supraventricular tachycardia, a reaction to the IV epinephrine, subsided after about one minute but the patient was kept in the ICU for eight hours before being sent home.

This medication error could have caused permanent damage to the heart and peripheral nervous system, but there was no evidence it did so in this case.
COURT OF APPEAL OF LOUISIANA May 2, 2012

In the patient’s lawsuit the hospital admitted that the E.R. nurse was negligent for giving the epinephrine IV. The jury had only to assess the damages.
The patient appealed the jury’s verdict of $25,000 claiming the amount was unreasonably low. The Court of Appeal of Louisiana upheld the jury’s verdict.
The nurse monitored the patient for a reaction and there was an appropriate response when the reaction occurred. The nurse and her employer never tried to hide the fact the nurse made a mistake or that the mistake caused painful and frightening consequences for the patient. However, the patient’s own cardiologist and a consulting psychiatrist discounted the extensive long-term physical and emotional injuries the patient was claiming. Langley v. American Legion Hosp., 2012 WL 1521520 (La. App., May 2, 2012).