New Long Term Care Regulations Quality of Care and Pharmacy

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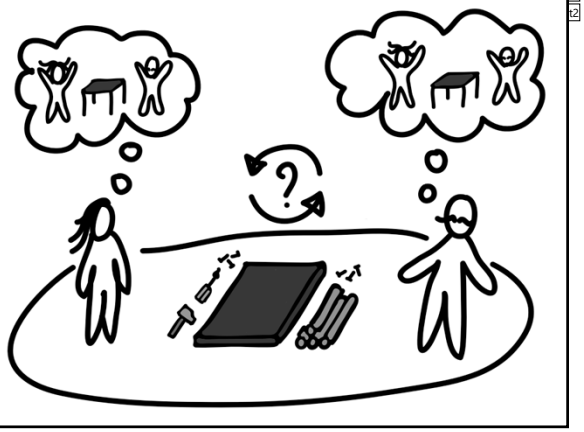


68688 Federal Register / Vol. 81, No. 192 / Tuesday, October 4, 2016 / Rules and Regulations
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489
[CMS–3260–F]
RIN 0938–AR61
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities
AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.
ACTION: Final rule.
DATES: ***Effective date: These regulations*** are effective on November 28, 2016

Slide 2

t1 test, 10/21/2016

t2 test, 10/21/2016

Quality of Care §483.25

Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents.

Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices, including but not limited to the following

"I'd like to begin by making the same point about twenty times in a row."

QUALITY OF CARE IS BASED ON

- Comprehensive assessment of a resident
- Comprehensive person-centered care plan
- Professional Standards of Practice
- Resident Choices

QUALITY OF CARE IS BASED ON

- Comprehensive assessment of a resident

QUALITY OF CARE IS BASED ON

- *Comprehensive person-centered* care plan

QUALITY OF CARE IS BASED ON

- Professional Standards of Practice

Current F281 Guidance for Standards of Practice

- "Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency.

Current F281 Guidance for Standards of Practice

- Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include:

Current F281 Guidance for Standards of Practice

- Current manuals or textbooks on nursing, social work, physical therapy, etc.
- Standards published by professional organizations such as the American Dietetic Association, American Medical Association, American Medical Directors Association, American Nurses Association, National Association of Activity Professionals,

Current F281 Guidance for Standards of Practice

- Clinical practice guidelines published by the Agency of Health Care Policy and Research.
- Current professional journal articles.

QUALITY OF CARE IS BASED ON

- Resident Choices

Quality of Care §483.25

Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents.

Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices, including but not limited to the following

Quality of Care §483.25

- (b) Skin integrity – (1) Pressure ulcers Based on the comprehensive assessment of a resident, the facility must ensure that

  (i) A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual's clinical condition demonstrates that they were unavoidable; and

Quality of Care §483.25

- (b) Skin integrity (1) Pressure ulcers Based on the comprehensive assessment of a resident, the facility must ensure that

  (ii) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection and prevent new ulcers from developing.

Quality of Care §483.25

- (b)(2) Foot Care – To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must

  (i) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and

Quality of Care §483.25

- (b)(2)

  (ii) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from such appointments.

Quality of Care §483.25

- Recommend you develop and implement policies and procedures related to foot care according to professional standards of practice and with involvement of Medical Director

Quality of Care §483.25

- (c) Mobility

  (1) The facility must ensure that a resident who enters the facility without limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

Quality of Care §483.25

- (c) (2) A resident with limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion
- (c) (3) A resident with limited mobility receives appropriate services, equipment, and assistance to maintain or improve mobility with the maximum practicable independence unless a reduction in mobility is demonstrably unavoidable

Quality of Care §483.25

- (d) Accidents The facility must ensure that-
- (1) The resident environment remains as free of accident hazards as is possible; and
- (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

Quality of Care §483.25

- (e) Incontinence

(1) The facility must ensure that a resident who is continent of bladder and *bowel* on admission receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain

Quality of Care §483.25

(e) (2) (ii) A resident who enters the facility with an indwelling catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary, and

(e) (2) (iii) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore continence to the extent possible.

Quality of Care §483.25

- (3) For a resident with fecal incontinence, based on the resident's comprehensive assessment, the facility must ensure that a resident who is incontinent of bowel receives appropriate treatment and services to restore as much normal bowel function as possible.

Quality of Care §483.25

- (f) Colostomy, urostomy, or ileostomy care. The facility must ensure that residents who require colostomy, urostomy, or ileostomy services, receive such care **consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.**

Quality of Care §483.25

- (g) Assisted nutrition and hydration. (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident -

Quality of Care §483.25

- (g)(1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;

Quality of Care §483.25

- (j) Prostheses. The facility must ensure that a resident who has a prosthesis is provided care and assistance, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences, to wear and be able to use the prosthetic device.

Quality of Care §483.25

- (g)(2) Is offered sufficient fluid intake to maintain proper hydration and health; and
- (g)(3) Is offered a therapeutic diet when there is a nutritional problem and the health care provider orders a therapeutic diet.

Quality of Care §483.25

- (g)(4) A resident who has been able to eat enough alone or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was clinically indicated and consented to by the resident; and

Quality of Care §483.25

- (g)(5) A resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding including but not limited to aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormities and nasal-pharyngeal ulcers

Quality of Care §483.25

- (h) Parenteral fluids – Parenteral fluids must be administered consistent with professional standards of practice and in accordance with physician orders, the comprehensive person-centered care plan, and the resident's goals and preferences.

Quality of Care §483.25

(i) Respiratory care, including tracheostomy care and tracheal suction. The facility must ensure that a resident who needs respiratory care, including tracheostomy care and tracheal sunction, is provided such care, consistent with professional standards of practice, the comprehensive person-centered care plan, the residents goals and preferences, and 483.65 of this subpart. (483.65 of this subpart is specialized rehabilitative services)

Quality of Care §483.25

- (k) Pain Management. The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

Quality of Care §483.25

- (l) Dialysis. The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

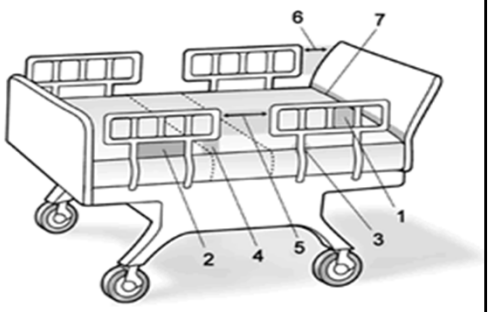
Quality of Care §483.25- *Phase III implementation (November 28, 2019)*

- (m) Trauma-informed care. The facility must ensure that residents who are trauma survivors receive culturally-competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re traumatization of the resident.

Quality of Care §483.25

(n) Bed rails. The facility must attempt to use appropriate alternatives prior to installing a side, or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use and maintenance of bed rails, including but not limited to the following elements.

Potential Zones of Entrapment



http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072662.htm

FDA and Bed Rails

- Between January 1, 1985 and January 1, 2013, FDA received 901 incidents of patients caught, trapped, entangled, or strangled in hospital beds. The reports included 531 deaths, 151 nonfatal injuries, and 220 cases where staff needed to intervene to prevent injuries. Most patients were frail, elderly or confused.
- http://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/hospitalbeds/default.htm

Quality of Care §483.25 (n) cont.

(1) Assess the resident for risk of entrapment from bed rails prior to installation.

(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.

Quality of Care §483.25 (n) cont.

(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.

(4)Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/UCM397178.pdf

§483.45 Pharmacy Services

- The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.70(g). The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

§483.45 Pharmacy Services

- (c) Drug Regimen review

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) *This review must include a review of the resident's medical chart.(Implementation Date: November 28, 2017)*

§483.45 Pharmacy Services

Implementation Date: November 28, 2017

- *(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limed to, drugs in the following categories:*

§483.45 Pharmacy Services

Implementation Date: November 28, 2017

- *(i) Anti-psychotic;*
- *(ii) Anti-depressant;*
- *(iii) Anti-anxiety; and*
- *(iv) Hypnotic*

§483.45 Pharmacy Services

- 483.45(c)(3) originally included opoids in the definition of psychotropic drug.
  - Removed it and not in the final rule.
  - CMS will address opoid use in the sub-regulatory interpretive guidance and refers us to:

http://www.cdc.gov/drugoverdose/prescribing/guideline.html

§483.45 Pharmacy Services

- (4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

§483.45 Pharmacy Services

- (i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.

§483.45 Pharmacy Services

- (ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

§483.45 Pharmacy Services

- (iii) The attending physician must document, in the resident's medical record the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

§483.45 Pharmacy Services

- (5)The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

Policies and Procedures – from comments and response in CFR

- CMS encourages facilities to include (but not limited to) the follow policies and procedures:
  - Procedure (that include timeframes) pharmacists should follow so that the appropriate individuals are notified if the pharmacist believes that an irregularity needs to be reviewed immediately due to potential for harm to a resident.
  - Procedures for nurses if she or he is concerned about any medication order.

Policies and Procedures – from comments and response in CFR

- Facilities are encouraged by CMS to have procedures that details the system a facility has in place so that physicians don't have to repeatedly document the same rationale in the record, once a clinically acceptable rationale is already documented in the medical record for a specific medication.

§483.45 Pharmacy Services

- (d) Unnecessary drugs- General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—
  - (1) In excessive does (including duplicate drug therapy); or
  - (2) For excessive duration; or
  - (3) Without adequate monitoring; or
  - (4) Without adequate indications for its use; or

§483.45 Pharmacy Services

- (d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
- (d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

§483.45 (e) Pharmacy Services -

Implementation Date: November 28, 2017

- (e) Psychotropic drugs. Based on a a comprehensive assessment of a resident, the facility must ensure that
- (1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

§483.45 Pharmacy Services

Implementation Date: November 28, 2017

- (e) (2) Residents who use psychotropic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

§483.45 Pharmacy Services

Implementation Date: November 28, 2017

- (e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

§483.45 Pharmacy Services

Implementation Date: November 28, 2017

- (e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

§483.45 Pharmacy Services

Implementation Date: November 28, 2017

(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

§483.45 Pharmacy Services

- (f) Medication errors. The facility must ensure that its
  - (1) Medication error rates are not 5 percent or greater; and
  - (2) Residents are free of any significant medication errors.

Questions?