

42 CFR 483.60

This section is current through the March 20, 2014 issue of the Federal Register

Code of Federal Regulations > TITLE 42-- PUBLIC HEALTH > CHAPTER IV-- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES > SUBCHAPTER G-- STANDARDS AND CERTIFICATION > PART 483-- REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES > SUBPART B-- REQUIREMENTS FOR LONG TERM CARE FACILITIES

§ 483.60 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

- (a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.
- (b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who--
 - (1) Provides consultation on all aspects of the provision of pharmacy services in the facility;
 - (2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and
 - (3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.
- (c) **Drug regimen review.**
 - (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
 - (2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.
- (d) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.
- (e) Storage of drugs and biologicals.
 - (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.
 - (2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

Statutory Authority

AUTHORITY NOTE APPLICABLE TO ENTIRE PART:

Secs. 1102, 1128I and 1871 of the Social Security Act ([42 U.S.C. 1302](#), 1320a-7j, and 1395hh).

History

[56 FR 48875, Sept. 26, 1991, as amended at [57 FR 43925](#), Sept. 23, 1992]

Annotations

Case Notes

LexisNexis® Notes

Public Health & Welfare Law : Healthcare : Services for Disabled & Elderly Persons : Care Facilities :
 Public Health & Welfare Law : Social Security : Medicaid : Coverage : Pharmaceutical Services
 Public Health & Welfare Law : Social Security : Medicaid : Providers : Payments & Reimbursements :
 Public Health & Welfare Law : Social Security : Medicare : Providers : Types : Nursing Facilities
 Torts : Negligence : Standards of Care : Special Care : Highly Skilled Professionals

Public Health & Welfare Law : Healthcare : Services for Disabled & Elderly Persons : Care Facilities :

[Greenbrier Nursing & Rehab. Ctr. v. United States HHS, 686 F.3d 521, 2012 U.S. App. LEXIS 14583](#) (8th Cir July 17, 2012).

Overview: *Resident's care plan called for monthly testing, per physician, and physician told state surveyor that patient taking stable dose of drug at issue should have had monitoring once a month. It was reasonable for DHHS to conclude standard of care did not allow staff to send fax to doctor and wait indefinitely for response that might never come.*

- [42 C.F.R. § 483.25](#) requires facilities to provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being of their residents. The Department of Health and Human Services interprets this regulation to require facilities to meet professional standards of care. Section 483.25(j) requires the facility to provide each resident with sufficient fluid intake to maintain proper hydration and health. And [42 C.F.R. § § 483.60\(c\)](#) requires that each resident's drug regimen be reviewed at least once a month by a licensed pharmacist and that the pharmacist report any irregularities to the attending physician. *Go To Headnote*

[Universal Healthcare/king v. United States HHS, 2010 U.S. App. LEXIS 2043](#) (4th Cir Jan. 29, 2010).

Overview: *Findings of the DHHS that a skilled nursing facility was not in compliance with 42 C.F.R. §§ 483, § 483.13(c), 483.60(a), and 483.25, relating to residents' well-being and safety, were supported by substantial evidence, a finding of immediate jeopardy was not clearly erroneous, and the civil monetary penalties that were imposed were reasonable.*

- [42 C.F.R. § 483.60\(a\)](#) requires that a skilled nursing facility provide pharmaceutical services adequate to meet the needs of each resident. *Go To Headnote*

[Hayward v. Jack's Pharm., Inc., 141 Idaho 622, 115 P.3d 713, 2005 Ida. LEXIS 94](#) (Idaho June 15, 2005).

Overview: *Medical director was not sometimes a medical director and sometimes a physician;*

instead, he was at all times some of each, so under Idaho Code § 6-1012, his standard of care included the minimum standards set by applicable state and federal law, not local standards. Decedent's medical malpractice case against him and local pharmacy could proceed.

- Nursing homes are required to follow federal and state guidelines relating to patient care, including the prescription of pharmaceuticals, and that they are responsible when those standards are not met. [42 U.S.C.S. § 1396r](#); [42 C.F.R. §§ 483.25, 483.60](#); Idaho Admin. Code § 16.03.02.154.01.c. Therefore, it follows that the standard of care for a physician treating a patient in a nursing home would be governed by those standards. [Go To Headnote](#)

[Long Term Care Pharm. Alliance v. Ferguson, 260 F. Supp. 2d 282, 2003 U.S. Dist. LEXIS 13138](#) (D Mass Apr. 1, 2003).

Overview: *A pharmacy alliance was entitled to a preliminary injunction where the Director of the Commonwealth of Massachusetts Division of Health Care Finance and Policy's prescription drug reimbursement rate change rule violated the Medicaid Act.*

- [42 U.S.C.S. § 1396r](#)(b)(4)(A)(iii) explicitly requires nursing facilities to provide, among other services, pharmaceutical services. Federal regulations contain similar service requirements for nursing facilities. [42 C.F.R. §§ 483.5, 483.60](#). [Go To Headnote](#)

[Am. Soc'y of Consultant Pharmacists v. Concannon, 214 F. Supp. 2d 23, 2002 U.S. Dist. LEXIS 15578](#) (D Me Aug. 19, 2002).

Overview: *National society of pharmacists was not entitled to an injunction barring state from enacting an emergency rule reducing the reimbursement rates for prescription drugs under Medicaid since the rate reduction did not affect nursing facility services.*

- The Medicaid statute defines "nursing facility services" as services which are or were required to be given an individual who needs or needed on a daily basis nursing care (provided directly by or requiring the supervision of nursing personnel) or other rehabilitation services which as a practical matter can only be provided in a nursing facility on an inpatient basis. [42 U.S.C.S. § 1396d](#)(f). For elaboration of the term "services required to be given," courts look to the implementing regulations, which require that a nursing facility provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement with an outside pharmacist. [42 C.F.R. § 483.60](#). [Go To Headnote](#)

Public Health & Welfare Law : Social Security : Medicaid : Coverage : Pharmaceutical Services

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Public Health & Welfare Law : Social Security : Medicaid : Providers : Payments & Reimbursements :

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Torts : Negligence : Standards of Care : Special Care : Highly Skilled Professionals

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Research References & Practice Aids
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NOTES APPLICABLE TO ENTIRE CHAPTER:

[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at [45 FR 53806](#), Aug. 13, 1980; [50 FR 12741](#), Mar. 29, 1985; [50 FR 33034](#), Aug. 16, 1985; [51 FR 41338](#), Nov. 14, 1986; [53 FR 6634](#), Mar. 2, 1988; [53 FR 47201](#), Nov. 22, 1988; [56 FR 8852](#), Mar. 1, 1991; [66 FR 39450, 39452](#), July 31, 2001; [67 FR 36539, 36540](#), May 24, 2002; [77 FR 29002, 29028](#), May 16, 2012.]

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