

(k) Residents shall be assisted in performing either passive or active range-of-motion exercises every day, unless their level of physical activity makes this unnecessary.

(l) Toileting needs of all residents shall be met.

(m) Measures to prevent contractures shall be used, and contractures shall be identified, documented, and managed by rehabilitative nursing and physical therapy.

(n) Indwelling catheters shall not be used for the convenience of staff.

8:39-27.6 Mandatory general resident services

(a) Residents shall be afforded the opportunity to eat in a group setting unless contraindicated with the reasons noted in the resident's medical record. The need for feeding assistance shall not constitute an acceptable contraindication.

(b) Residents shall be afforded an opportunity to go outdoors on a regular basis.

(c) Clothing, including undergarments and footwear, shall be clean, comfortable, and personally assigned to each resident, and shall reflect personal preference and safety.

(d) Residents shall be encouraged and helped to select the clothing they will wear each day.

8:39-27.7 Mandatory supplies and equipment for resident care

(a) Prostheses, including eyeglasses, dentures, and hearing aids, shall be functional and individualized, and shall be kept available to the resident, unless the resident specifically rejects their use.

(b) Adaptive devices and equipment shall be functional and individualized, and shall be kept available to the resident unless the resident specifically rejects their use.

(c) All drinking water containers shall be washed daily and sanitized weekly. Containers that cannot be sanitized shall be discarded.

(d) The facility shall maintain at least one bag-valve-mask resuscitator.

(e) Bath thermometers or other temperature controls shall be used to monitor the temperatures of each bath or shower.

Case Notes

Nursing home violated regulation establishing maximum permitted hot water temperature; penalty assessed. Sterling Manor Nursing Center v. Department of Health. 92 N.J.A.R.2d (HLT) 14.

SUBCHAPTER 28. ADVISORY QUALITY OF CARE

8:39-28.1 Advisory policies and procedures for resident care

(a) The facility conducts scheduled interdisciplinary staff discussions, and discussions with residents and families, about the right of residents to die with dignity.

(b) The facility develops and provides individualized non-restrictive equipment meeting individual needs which fosters and supports a restraint-free environment for all residents.

(c) The facility maintains an on-going and on-site program of preventative treatment and referral to mental health services which includes prevention, treatment, and referral directed by a qualified mental health professional.

8:39-28.2 Advisory resident care services

(a) There are education programs provided on at least a quarterly basis, open and accessible to residents, families, and significant others addressing the following issues:

1. The enhancement and maintenance of physical and mental well-being;
2. The prevention of deterioration;
3. The teaching of self-care; and
4. Death, dying and bereavement.

(b) There are education and training programs provided on at least a quarterly basis, open and accessible to families and significant others, which teach skills and help in the provision of support services that enable residents to leave the facility for visits and vacations.

(c) The facility promotes residents' sense of personal control in acquiring clothing, for example, through the establishment of a clothing concession in the facility or clothing vendors' periodic visits to the facility, the arrangement of shopping excursions, and/or the use of catalogue shopping by residents.

(d) Donated clothing is made available so that residents can select desired items.

(e) The facility provides a non-commercial washer and dryer for residents who wish to launder their own personal items.

SUBCHAPTER 29. MANDATORY PHARMACY

8:39-29.1 Mandatory pharmacy organization

(a) A New Jersey licensed pharmacist shall serve as director of pharmaceutical services or as consultant pharmacist.

(b) The facility shall have an interdisciplinary pharmacy and therapeutics committee, appointed by and reporting to the administrator and consisting of at least the administrator, a representative of the nursing staff, and the consultant pharmacist, with oversight as needed by the medical director. The committee may include a licensed pharmacist representing the provider pharmacy. The committee shall hold meetings as needed and records, including the dates of meetings, attendance, activities, findings, and recommendations, shall be maintained.

(c) The facility shall appoint a consultant pharmacist who is not also the director of pharmaceutical services or pharmacist provider and does not have an affiliation with either the director of pharmaceutical services or the pharmacist provider.

(d) If the facility keeps emergency injectable or oral controlled substances, a current Drug Enforcement Administration registration and Controlled Dangerous Substance registration for that location shall be available. (See N.J.S.A. 24:21-10 for registration requirements; registration application procedures are specified at N.J.A.C. 8:65-1.4.)

8:39-29.2 Mandatory drug administration policies and procedures

(a) The pharmacy and therapeutics committee shall establish and enforce procedures for documenting drug administrations in accordance with law.

(b) The facility shall have a system to accurately identify recipients before any drug is administered.

(c) Self-administration of drugs shall be permitted only as specified by the recommendations of the pharmacy and therapeutics committee or the interdisciplinary team. Self-administration procedures shall include, at a minimum, the following:

1. The written order of the prescriber;
2. Storage of medications in the resident's room, based on resident assessments;
3. Specifications for labeling, including directions for use;
4. Methods for documentation in the medical record, based on resident assessment;
5. Training of residents in self-administration by the nursing staff or the consultant pharmacist; and
6. Policies for individual assessment of residents' ability to self-administer medications.

(d) Medications shall be accurately administered by properly authorized individuals who shall ensure that the right drug is administered to the right resident in the right dose through the right route of administration at the right time.

8:39-29.3 Mandatory pharmacy reporting policies and procedures

(a) The consultant pharmacist shall conduct a drug regimen review and enter appropriate comments into the medical record of every resident receiving medication, at least monthly, on a pharmacist consultation sheet or another portion of the medical record in accordance with N.J.A.C. 13:39.

(b) The consultant pharmacist shall report any irregularities to the attending physician and to the director of nurses and these reports shall be acted upon.

(c) Drug product defects and adverse drug reactions shall be reported in accordance with the ASHP-USP-FDA (American Society of Hospital Pharmacists, United States Pharmacopoeia, Food and Drug Administration) Drug Product Defect Reporting System and the USP Adverse Drug Reaction Reporting System.

(d) Drug allergies shall be documented in the resident's medical record and on its outside front cover and communicated to the provider or dispensing pharmacy.

(e) Drugs that are not specifically limited as to duration of use or number of doses shall be controlled by automatic stop orders. The resident's attending physician shall be notified of the automatic stop order prior to the last dose so that he or she may decide whether to continue use of the drug.

(f) If medication is withheld, the reason for withholding the medication shall be documented in the resident's medical record.

(g) Medication errors and adverse drug reactions shall be reported immediately to the director of nursing or the alternate to the director of nursing, and a description of the error or adverse drug reaction shall be entered into the medical record before the end of the employee shift. If the resident has erroneously received medication, the resident's physician shall be notified immediately. If a medication error originated in the pharmacy, the pharmacy shall be notified immediately.

8:39-29.4 Mandatory pharmacy control policies and procedures

(a) The label of each resident's individual medication container or package shall be permanently affixed and contain the following information:

1. The resident's full name;
2. The physician's name;
3. The prescription number;
4. The name and strength of drug;
5. The quantity dispensed;

6. The lot number;
7. The date of issue;
8. The expiration date;
9. The manufacturer's name if generic; and
10. Cautionary and/or accessory labels.

i. If a generic substitute is used, the drug shall be labeled according to the Drug Utilization Review Council Formulary, N.J.S.A. 24:6E-1 et seq. and N.J.A.C. 8:71.

ii. Required information appearing on individually packaged drugs or within an alternate medication delivery system need not be repeated on the label.

(b) If a unit dose distribution system is used ("unit dose drug distribution" means a system in which drugs are delivered to the resident areas in single unit packaging), the following requirements shall be met:

1. Each resident shall have his or her own medication tray labeled with the resident's name and location in the facility;
2. Each medication shall be individually wrapped and labeled with the generic or trade (brand) name and strength of the drug, lot number or reference code, expiration date, dose, and manufacturer's name, and shall be ready for administration to the resident;
3. Cautionary instructions shall appear on the resident's record of medication, and the system shall include provisions for noting additional information, including, but not limited to, special times or routes of administration and storage conditions; and
4. Delivery and exchange of resident medication trays shall occur promptly, and at least one exchange of resident medication trays shall occur every 24 hours, including weekends and holidays.

(c) Both over-the-counter and prescription medications may be kept as stock. A limited amount of prescription medications may be kept as stock for the administration of stat (emergency) doses, lost doses, or doses not sent by the provider pharmacy. These medications shall be approved by the pharmacy and therapeutics committee, monitored for accountability, and labeled to include drug name, drug strength, manufacturer's name, lot number, expiration date, recommended dosage for over-the-counter medications, and applicable cautionary and/or accessory labels.

(d) The consultant pharmacist shall:

1. Make monthly inspections of all areas in the facility where medications are dispensed, administered, or stored;
2. Periodically, as determined by the quality assurance program, observe a medication pass and review the crediting system; and

3. Document any problems and propose solutions to these problems.

(e) The contents of emergency kits shall have been approved by the pharmacy and therapeutics committee. Emergency kits shall be stored securely at each nursing unit, but not kept under lock and key, checked after each use, and checked at least monthly by the consultant pharmacist. Emergency kits shall not be accessible to residents but shall be accessible to staff in a timely manner.

(f) All medications repackaged by the pharmacy shall be labeled with an expiration date, name and strength of drug, lot number, date of issue, manufacturer's name if generic, and cautionary and/or accessory labels, in accordance with United States Pharmacopoeia (U.S.P.) requirements and applicable FDA regulations.

(g) The pharmacy and therapeutics committee shall establish and enforce procedures for removal of discontinued, unused, expired, recalled, deteriorated, and unlabeled drugs and intravenous solutions and for removal of containers of medications with worn, illegible, damaged, incomplete, or missing labels.

(h) All medications shall be stored in accordance with manufacturers' and United States Pharmacopoeia (U.S.P.) requirements and all medications shall be kept in locked storage areas.

(i) All medication destruction in the facility shall be witnessed by at least two persons, each of whom shall be either the pharmacist consultant, a registered professional nurse or a licensed practical nurse. A record of each instance of drug destruction shall be maintained.

(j) Where allowable by law, the facility shall generate a crediting mechanism for medications dispensed in a unit-of-use drug distribution system, or other system which allows for the re-use of medications. The crediting system shall be monitored by the provider pharmacist and a facility representative. (The operative date of these requirements shall be deferred until 12 months after the adoption of these rules.)

(k) The pharmacy and therapeutics committee shall establish and enforce procedures for the inventory of controlled substances in accordance with law.

(l) The facility shall implement written methods and procedures for obtaining prescribed prescription medications and biologicals from a pharmacy licensed by the New Jersey State Board of Pharmacy. The telephone number of the pharmacy and procedures for obtaining drugs shall be posted at each nursing unit.

(m) If the facility utilizes drugs marked "sample," the pharmacy and therapeutics committee shall develop a mech-

anism for the control and limitation of these drugs, in accordance with N.J.A.C. 13:35-6.6.

(n) The facility shall develop and implement a system whereby instructions for use are provided whenever medications are released to residents. Instructions shall be written in a manner intended to promote proper storage, secure handling, and safe administration of medications released to residents. Documentation of released medications shall be entered into the resident's medical record.

8:39-29.5 Mandatory pharmacy staff qualifications

If the facility maintains a pharmacy in-house, the pharmacy shall be licensed by the New Jersey State Board of Pharmacy, and shall possess a current Drug Enforcement Administration registration and a Controlled Dangerous Substance registration from the New Jersey State Department of Law and Public Safety.

8:39-29.6 Mandatory resident pharmacy services

(a) The facility shall provide pharmaceutical services, either directly or by contract with a provider pharmacy, 24 hours a day, seven days a week.

(b) If a resident obtains medications from a pharmacy which is not the facility provider pharmacy, the following conditions shall be met:

1. The pharmacy provider shall comply with all labeling requirements specified at N.J.A.C. 8:39-29.4(a); and
2. The facility shall establish a plan for obtaining the resident's drugs on an emergency basis.

(c) A resident may obtain medications from a pharmacy that is not the facility provider pharmacy unless:

1. The resident is expressly informed during the admission process and within the admission agreement that this service is not permitted in the facility, or
2. For existing residents, the facility submits documentation to the Department, prior to denying the request, demonstrating a significant risk to the health and safety of residents as a result of this practice.

8:39-29.7 Mandatory pharmacy supplies and equipment

(a) Medication containers and carts shall be handled properly to prevent damage, injury, and harm.

(b) Needles and syringes shall be stored, used, and disposed of in accordance with New Jersey State law, and a record shall be maintained of the purchase, storage, and disposal of needles and syringes.

(c) Controlled substances shall be stored, and records shall be maintained, in accordance with the Controlled Dangerous Substances Acts and all other Federal and State laws and regulations concerning procurement, storage, dispensation, administration, and disposition. Controlled substances shall be stored separately from all other substances except in a unit dose drug distribution system.

(d) Pharmaceutical reference materials and other information sources about drugs, including investigational drugs, if used, shall be approved by the pharmacy and therapeutics committee and shall be current.

8:39-29.8 Mandatory pharmacy quality assurance

The pharmacy and therapeutics committee shall review medication errors and adverse drug reactions.

SUBCHAPTER 30. ADVISORY PHARMACY

8:39-30.1 Advisory pharmacy staff qualifications

The consultant pharmacist holds current certification by the Joint Board of Certification of Consultant Pharmacists.

8:39-30.2 Advisory pharmacy staffing amounts and availability

The consultant pharmacist or a licensed pharmacist representing the provider pharmacy provides or arranges for quarterly meetings open to residents, families, and interested others to discuss medication issues.

8:39-30.3 Advisory pharmacy resident services

The consultant pharmacist reviews the records of all newly admitted residents within 14 days of admission.

8:39-30.4 Advisory pharmacy quality assurance

The consultant pharmacist performs at least one Drug Utilization Evaluation (DUE) study per year, as part of a continuous quality improvement program.

SUBCHAPTER 31. MANDATORY PHYSICAL ENVIRONMENT

8:39-31.1 Mandatory space and environment; all facilities

(a) All exit doors to the facility shall be kept externally locked from 8:00 P.M. until 6:30 A.M.

(b) All residents shall have, in their rooms:

1. A bed and a mattress of the correct size to fit the bed;