

SUBCHAPTER 29. MANDATORY PHARMACY

8:39-29.1 Mandatory pharmacy organization

(a) A facility shall have a consultant pharmacist and either a provider pharmacist or, if the facility has an in-house pharmacy, a director of pharmaceutical services.

(b) A New Jersey licensed pharmacist shall serve as director of pharmaceutical services or as consultant pharmacist. The pharmacist shall comply with Federal and State statutes, rules, regulations and currently accepted standards of practice.

(c) 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 but at least quarterly and records, including the dates of meetings, attendance, activities, findings, and recommendations, shall be maintained.

(d) 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.

(e) 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 by qualified residents only as specified by the policy of the pharmacy and therapeutics committee and the assessment of 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 and documented by properly authorized individuals, as per prescribed orders and stop order policies.

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. The drug regimen review shall be performed in accordance with Federal and State Statutes, rules and regulations, and currently accepted standards of practice for rational drug therapy.

1. The consultant pharmacist shall report any irregularities promptly to the attending physician or advanced practice nurse and to the director of nurses and these reports shall be acted upon. These reports shall include, but are not limited to, problems and recommendations about drug therapy which may be affected by biologicals, laboratory tests, special dietary requirements and foods used or administered concomitantly with other medication to the same recipient. Also, these reports are required to include monitoring for potential adverse effects, allergies, drug interactions, contraindications, rationale, and drug evaluation.

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

3. All known drug allergies shall be documented in the resident's medical record including the medication administration records and physician or advanced practice nurse order sheets and on the outside front cover and communicated to the provider or dispensing pharmacy.

4. 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 or advanced practice nurse 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.

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

6. 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 or advanced practice nurse shall be notified immediately. If a medication error originated in the pharmacy, the pharmacy shall be notified immediately. The Department shall be notified of an adverse drug reaction that results in death.

8:39-29.4 Mandatory pharmacy control policies and procedures

(a) The label of each resident's individual medication container or package shall be labeled in accordance with the New Jersey State Board of Pharmacy regulations at N.J.A.C. 13:39- 5.9, permanently affixed, and contain the following information:

1. The resident's full name;
2. The prescriber'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;
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-1et 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; and

11. The name, address, and telephone number of the pharmacy.

(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, if a 24-hour unit-dose system is used, then 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, manufacturers' 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 inspection 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 N.J.A.C. 13:39-5.9, 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 that allows for the re-use of medications. The crediting system shall be monitored by the provider pharmacist and a facility representative.

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

(l) Based on prescriber's orders for medications, drug tests, diet and treatments, the facility shall implement written methods and procedures for obtaining prescribed prescription medications and biologicals from a pharmacy that has a permit from the New Jersey State Board of Pharmacy, in accordance with N.J.A.C. 13:39-4. 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 mechanism 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 that 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.

(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 reports of medication errors and suspected adverse drug reactions and shall summarize these reports yearly.

SUBCHAPTER 30. ADVISORY PHARMACY

8:39-30.1 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.

8:39-30.2 Advisory pharmacy resident services

The consultant pharmacist reviews drug records within 48 hours of admission via a facsimile service. All dated and signed comments and recommendations made by the consultant pharmacist shall be added to the resident's medical record and shall be distributed to the attending physician or advanced practice nurse and director of nurses for review and action.

8:39-30.3 Advisory provider formulary criteria

The provider pharmacy through the Pharmacy and Therapeutics Committee, may establish a formulary which is not in contradiction to the Drug Utilization Review Council Formulary, N.J.S.A. 24:6E-1et seq., and N.J.A.C. 8:71. The formulary policies must be approved by the Pharmacy and Therapeutics Committee and every prescriber with prescriptive authority in the facility. The Pharmacy and Therapeutics Committee establishes policies for the prescribing of non-formulary agents. The formulary is developed to avoid negative outcomes.

8:39-30.4 Advisory consultant pharmacist certification

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