410 IAC 16.2-3.1-14 PERSONNEL

... (j) Medication shall be administered by licensed nursing personnel or qualified medication aides. If medication aides handle or administer drugs or perform treatments requiring medications, the facility shall ensure that the persons have been properly qualified in medication administration by a state-approved course. Injectable medications shall be given only by licensed personnel.

410 IAC 16.2-3.1-25 PHARMACY SERVICES

Authority: IC 16-28-1-7; IC 16-28-1-12 Affected: IC 16-28-5-1; IC 25-26-13

Sec. 25. (a) The facility must provide routine and emergency drugs and biologicals to its residents or obtain them under an agreement.

(b) The administration of drugs and treatments, including alcoholic beverages, nutrition concentrates, and therapeutic supplements, shall be as ordered by the attending physician and shall be supervised by a licensed nurse as follows:

(1) Medication shall be administered by licensed nursing personnel or qualified medication aides. When other than licensed personnel administer drugs, the facility shall ensure that the person has been properly qualified in medication administration by a state approved course.

(2) The resident shall be observed for effects of medications. Documentation of any undesirable effects shall be contained in the clinical record. The physician shall be notified immediately if undesirable effects occur, and such notification shall be documented in the clinical record.

(3) The individual administering the medication shall document the administration indicating the time, name of drug or treatment, and dosage (if applicable), with name or initials.

(4) Medication shall be administered by the person who has set up the doses, except under a single unit dose package system.

(5) Setting up of doses for more than one (1) scheduled administration is not permitted.

(6) Injectable medications shall be given only by licensed personnel.

(7) No medication shall be used for any resident other than the resident for whom it was prescribed.
(8) Per required need (PRN) medications may be administered only upon authorization of a licensed nurse or physician. All contacts with a nurse or physician not on the premises for authorization to administer PRNs shall be documented in the nursing notes indicating the time and date of the contact.

(9) Any error in medication administration shall be noted in the resident’s record. The physician shall be notified of any error in medication administration when there are any actual or potential detrimental effects to the resident. The facility must ensure that it is free of medication error rates of five percent (5%) or greater and that residents are free of any medication errors that jeopardize their health, safety, or welfare.

(c) The facility may permit qualified medication aides and student nurses to administer drugs under the general supervision of a licensed nurse following successful completion of the state qualifying test for medication aides.

(d) Student nurses may administer medications when under the direct supervision of the instructor and the activity is part of the student’s educational programs.

(e) The facility must employ or obtain the services of a licensed pharmacist who is required to do the following:

(1) Provide consultation and written reports on all aspects of the provision of pharmacy services in the facility.

(2) Establish a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation.

(3) Determine that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(f) If a facility operates its own duly licensed pharmacy, it shall comply with IC 25-26-13.

(g) The facility shall only utilize a pharmacy that:

(1) complies with the facility policy regarding receiving, packaging, and labeling of pharmaceutical products unless contrary to state and federal laws and rules on pharmacy practices;

(2) provides prescribed drugs, including the availability of a twenty-four (24) hour prescription service on a prompt and timely basis; and

(3) refills prescription drugs, when needed, in order to prevent interruption of drug regimens.

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

(i) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.
(j) Over-the-counter medications, prescription 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.

(k) Labeling of prescription drugs shall include the following:

(1) Resident's full name.

(2) Physician's name.

(3) Prescription number.

(4) Name and strength of drug.

(5) Directions for use.

(6) Date of issue and expiration date (when applicable).

(7) Name and address of the pharmacy that filled the prescription. If a facility is supplied medication in a unit dose packaging, reasonable variations that comply with the acceptable pharmaceutical procedures are permitted.

(l) Over-the-counter medications must be identified with the following:

(1) Resident name.

(2) Physician name.

(3) Expiration date.

(4) Name of drug.

(5) Strength.

(m) In accordance with state and federal law, 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.

(n) 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.

(o) Discontinued, outdated, or deteriorated medication shall not be maintained or used in the facility. Medications shall be disposed of in compliance with federal, state, and local laws.

(p) All unused portions of any properly labeled medications, including controlled substances, shall be released to the discharged resident, along with instructions for their use, upon written order of the physician.
(q) Unopened and unexposed medication may be returned to the issuing pharmacy for credit to the appropriate party.

(r) Unused portions of medications not released with the resident or returned for credit shall be destroyed on the premises within seven (7) days by the consultant pharmacist or licensed nurse with a witness.

(s) Disposition of any released, returned, or destroyed medication shall be written in the resident's clinical record and shall include the following information:

(1) The name of the resident.

(2) The name and strength of the drug.

(3) The prescription number.

(4) The reason for disposal.

(5) The amount disposed of.

(6) The method of disposition.

(7) The date of disposal.

(8) The signatures of the persons conducting the disposal of the drug.

(t) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b), (c), (f), (g), (i), (j), (k), (l), (m), (n), or (o) is a deficiency;

(2) subsection (d), (e), (h), (p), (r), or (s) is a noncompliance; and

(3) subsection (q) is a nonconformance. (Indiana State Department of Health; 410 IAC 16.2-3.1-25; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1548, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; filed May 16, 2001, 2:09 p.m.: 24 IR 3027; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)