TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule
LSA Document #20-603

DIGEST

Amends 410 IAC 16.2-3.1-25 to remove language allowing for unused portions of medications to be destroyed within seven days and replace with language to render nonretrievable within three days, to define rendering nonretrievable, and to add authorized storage containers as a method of disposing of unused portions of medications. Amends 410 IAC 16.2-5-6 to align with 410 IAC 16.2-3.1-25. Effective 30 days after filing with the Publisher.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

410 IAC 16.2-3.1-25; 410 IAC 16.2-5-6

SECTION 1. 410 IAC 16.2-3.1-25 IS AMENDED TO READ AS FOLLOWS:

410 IAC 16.2-3.1-25 Pharmacy services

Authority: IC 16-28-1-7
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~~ **rendered nonretrievable within three (3) days,** by the consultant pharmacist or licensed nurse ~~with~~ **and** a witness.

(s) To be rendered nonretrievable, a medication must be rendered chemically unusable, to such an extent that the medication cannot be recovered or used in the chemically transformed form, and disposed of pursuant to federal, state, or local law, or it must be stored in a locked, authorized storage container within the facility.

(t) An authorized storage container must contain a locked, hard outer layer securely attached to a permanent structure of the building and a removable inner liner and shall include the following requirements:

(1) An inner liner shall meet the following requirements:

(A) The inner liner shall be waterproof, tamper evident, and tear-resistant.

(B) The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents.

(C) The contents of the inner liner shall not be viewable from the outside when sealed.

(D) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon).

(E) The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.

(2) Access to the inner liner shall be restricted to the consultant pharmacist or a licensed nurse of the facility.

(3) The inner liner shall be sealed by the consultant pharmacist or a licensed nurse, and a witness, immediately upon removal from the permanent outer container, and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.

(4) At the time of removal, the contents of the inner liner must be destroyed in the sealed inner liner, returned via a mail-back program, or returned to the original distributor's registered location by common or contract carrier pick-up.

~~(s)~~ **(u)** 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)~~ **(v)** 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)~~ **(u)** 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; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

SECTION 2. 410 IAC 16.2-5-6 IS AMENDED TO READ AS FOLLOWS:

410 IAC 16.2-5-6 Pharmaceutical services

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

Sec. 6. (a) Residents who self-medicate may keep and use prescription and nonprescription medications in their unit as long as they keep them secured from other residents.

(b) The facility shall maintain clear written policies and procedures on medication assistance. The facility shall provide for ongoing training to ensure competence of medication staff.

(c) If the facility controls, handles, and administers medications for a resident, the facility shall do the following for that resident:

(1) Make arrangements to ensure that pharmaceutical services are available to provide residents with prescribed medications in accordance with applicable laws of Indiana.

(2) A consultant pharmacist shall be employed, or under contract, and shall:

(A) be responsible for the duties as specified in 856 IAC 1-7 (expired);

(B) review the drug handling and storage practices in the facility;

(C) provide consultation on methods and procedures of ordering, storing, administering, and disposing of drugs as well as medication record keeping;

(D) report, in writing, to the administrator or ~~his or her~~ **the administrator's** designee any irregularities in dispensing or administration of drugs; and

(E) review the drug regimen of each resident receiving these services at least once every sixty (60) days.

(3) The medication review, recommendations, and notification of the physician, if necessary, shall be documented in accordance with the facility's policy.

(4) 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.

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

(A) Resident's full name.

(B) Physician's name.

(C) Prescription number.

(D) Name and strength of the drug.

(E) Directions for use.

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

(G) Name and address of the pharmacy that filled the prescription.

If medication is packaged in a unit dose, reasonable variations that comply with the acceptable pharmaceutical procedures are permitted.

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

(A) Resident name.

(B) Physician name.

(C) Expiration date.

(D) Name of drug.

(E) Strength.

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

(e) Medicine or treatment cabinets or rooms shall be appropriately locked at all times except when authorized personnel are present. All Schedule II drugs administered by the facility shall be kept in individual containers under double lock and stored in a substantially constructed box, cabinet, or mobile drug storage unit.

(f) Residents may use the pharmacy of their choice for medications administered by the facility, as long as the pharmacy:

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

(2) provides prescribed service on a prompt and timely basis; and

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

~~(g) Medications administered by the facility shall be disposed in compliance with appropriate federal, state, and local laws, and disposition of any released, returned, or destroyed medication shall be documented 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 the disposal.~~
~~(8) The signature of the person conducting the disposal of the drug.~~
~~(9) The signature of a witness, if any, to the disposal of the drug.~~

(g) Unused portions of medications not released with the resident or returned for credit shall be rendered nonretrievable within three (3) days by the consultant pharmacist or licensed nurse, and a witness.

(h) To be rendered nonretrievable, a medication must be rendered chemically unusable, to such an extent that the medication cannot be recovered or used in the chemically transformed form, and disposed of pursuant to federal, state, or local law, or it must be stored in a locked, authorized storage container within the facility.

(i) An authorized storage container must contain a locked, hard outer layer securely attached to a permanent structure of the building and a removable inner liner and shall include the following requirements:
(1) An inner liner shall meet the following requirements:
(A) The inner liner shall be waterproof, tamper evident, and tear-resistant.
(B) The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents.
(C) The contents of the inner liner shall not be viewable from the outside when sealed.
(D) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon).
(E) The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.
(2) Access to the inner liner shall be restricted to the consultant pharmacist or a licensed nurse of the facility.
(3) The inner liner shall be sealed by the consultant pharmacist or a licensed nurse, and a witness, immediately upon removal from the permanent outer container, and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.
(4) At the time of removal, the contents of the inner liner must be destroyed in the sealed inner liner, returned via a mail-back program, or returned to the original distributor's registered location by common or contract carrier pick-up.

(j) 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.

~~(h)~~ **(k)** For purposes of IC 16-28-5-1, a breach of:
(1) subsection (c)(2), (c)(4), (c)(5), (c)(6), (d), or (e) is a deficiency; and
(2) subsection (a), (b), (c)(1), (c)(3), (f), or (g) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-5-6; filed May 2, 1984, 2:50 p.m.: 7 IR 1498; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1579, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Jan 21, 2003, 8:34 a.m.: 26 IR 1932, eff Mar 1, 2003; readopted filed May 22, 2007, 1:44 p.m.:

20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

Notice of Public Hearing

Posted: 02/10/2021 by Legislative Services Agency
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