

59A-36.008 Medication Practices.

Pursuant to Sections 429.255 and 429.256, F.S., and this rule, licensed facilities may assist with the self-administration or administration of medications to residents in a facility. A resident may not be compelled to take medications but may be counseled in accordance with this rule.

(1) SELF ADMINISTERED MEDICATIONS.

(a) Residents who are capable of self-administering their medications without assistance must be encouraged and allowed to do so.

(b) If facility staff observes health changes that could reasonably be attributed to the improper self-administration of medication, staff must consult with the resident concerning any problems the resident may be experiencing in self-administering the medications. The consultation should describe the services offered by the facility that aid the resident with medication administration through the use of a pill organizer, through providing assistance with self-administration of medications, or through administering medications. The facility must contact the resident's health care provider when observable health changes occur that may be attributed to the resident's medications. The facility must document such contacts in the resident's records.

(2) PILL ORGANIZERS.

(a) Only a resident who self-administers medications may maintain a pill organizer.

(b) Unlicensed staff may not provide assistance with the contents of pill organizers.

(c) A nurse may manage a pill organizer to be used only by residents who self-administer medications. The nurse is responsible for instructing the resident in the proper use of the pill organizer. The nurse must manage the pill organizer in the following manner:

1. Obtain the labeled medication container from the storage area or the resident,
2. Transfer the medication from the original container into a pill organizer, labeled with the resident's name, according to the day and time increments as prescribed,
3. Return the medication container to the storage area or resident; and,
4. Document the date and time the pill organizer was filled in the resident's record.

(d) If there is a determination that the resident is not taking medications as prescribed after the medicinal benefits are explained, it must be noted in the resident's record and the facility must consult with the resident concerning providing assistance with self-administration or the administration of medications if such services are offered by the facility. The facility must contact the resident's health care provider regarding questions, concerns, or observations relating to the resident's medications. Such communication must be documented in the resident's record.

(3) ASSISTANCE WITH SELF-ADMINISTRATION.

(a) Any unlicensed person providing assistance with self-administration of medication must be 18 years of age or older, trained to assist with self-administered medication pursuant to the training requirements of Rule 59A-36.011, F.A.C., and must be available to assist residents with self-administered medications in accordance with procedures described in Section 429.256, F.S. and this rule.

(b) In addition to the specifications of Section 429.256(3), F.S., assistance with self-administration of medication includes, orally advising the resident of the name and dosage of the medication and verbally prompting a resident to take medications as prescribed.

(c) In order to facilitate assistance with self-administration, trained staff may prepare and make available such items as water, juice, cups, and spoons. Trained staff may also return unused doses to the medication container. Medication, which appears to have been contaminated, must not be returned to the container.

(d) Trained staff must observe the resident take the medication. Any concerns about the resident's reaction to the medication or suspected noncompliance must be reported to the resident's health care provider and documented in the resident's record.

(e) When a resident who receives assistance with medication is away from the facility and from facility staff, the following options are available to enable the resident to take medication as prescribed:

1. The health care provider may prescribe a medication schedule that coincides with the resident's presence in the facility,
2. The medication container may be given to the resident, a friend, or family member upon leaving the facility, with this fact noted in the resident's medication record,
3. The medication may be transferred to a pill organizer pursuant to the requirements of subsection (2), and given to the resident, a friend, or family member upon leaving the facility, with this fact noted in the resident's medication record, or
4. Medications may be separately prescribed and dispensed in an easier to use form, such as unit dose packaging.

(f) Assistance with self-administration of medication does not include the activities detailed in Section 429.256(4), F.S.

(g) As used in Section 429.256(4)(h), F.S., the terms “judgment” and “discretion” mean interpreting vital signs and evaluating or assessing a resident’s condition.

(h) All trained staff must adhere to the facility’s infection control policy and procedures when assisting with the self-administration of medication.

(4) MEDICATION ADMINISTRATION.

(a) For facilities that provide medication administration, a staff member licensed to administer medications must be available to administer medications in accordance with a health care provider’s order or prescription label.

(b) Unusual reactions to the medication or a significant change in the resident’s health or behavior that may be caused by the medication must be documented in the resident’s record and reported immediately to the resident’s health care provider. The contact with the health care provider must also be documented in the resident’s record.

(c) Medication administration includes conducting any examination or other procedure necessary for the proper administration of medication that the resident cannot conduct personally and that can be performed by licensed staff.

(d) A facility that performs clinical laboratory tests for residents, including blood glucose testing, must be in compliance with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) and Chapter 483, Part I, F.S. A valid copy of the federal CLIA Certificate must be maintained in the facility. A federal CLIA certificate is not required if residents perform the test themselves or if a third party assists residents in performing the test. The facility is not required to maintain a federal CLIA Certificate if facility staff assist residents in performing clinical laboratory testing with the residents’ equipment. Information about the federal CLIA Certificate is available from the Laboratory and In-Home Services Unit, Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop 32, Tallahassee, FL 32308; telephone (850)412-4500.

(5) MEDICATION RECORDS.

(a) For residents who use a pill organizer managed in subsection (2), the facility must keep either the original labeled medication container; or a medication listing with the prescription number, the name and address of the issuing pharmacy, the health care provider’s name, the resident’s name, the date dispensed, the name and strength of the drug, and the directions for use.

(b) The facility must maintain a daily medication observation record for each resident who receives assistance with self-administration of medications or medication administration. A medication observation record must be immediately updated each time the medication is offered or administered and include:

1. The name of the resident and any known allergies the resident may have;
2. The name of the resident’s health care provider and the health care provider’s telephone number;
3. The name, strength, and directions for use of each medication; and,
4. A chart for recording each time the medication is taken, any missed dosages, refusals to take medication as prescribed, or medication errors.

(c) For medications that serve as chemical restraints, the facility must, pursuant to Section 429.41, F.S., maintain a record of the prescribing physician’s annual evaluation of the use of the medication.

(6) MEDICATION STORAGE AND DISPOSAL.

(a) In order to accommodate the needs and preferences of residents and to encourage residents to remain as independent as possible, residents may keep their medications, both prescription and over-the-counter, in their possession both on or off the facility premises. Residents may also store their medication in their rooms or apartments if either the room is kept locked when residents are absent or the medication is stored in a secure place that is out of sight of other residents.

(b) Both prescription and over-the-counter medications for residents must be centrally stored if:

1. The facility administers the medication;
2. The resident requests central storage. The facility must maintain a list of all medications being stored pursuant to such a request;
3. The medication is determined and documented by the health care provider to be hazardous if kept in the personal possession of the person for whom it is prescribed;
4. The resident fails to maintain the medication in a safe manner as described in this paragraph;
5. The facility determines that, because of physical arrangements and the conditions or habits of residents, the personal possession of medication by a resident poses a safety hazard to other residents, or
6. The facility’s rules and regulations require central storage of medication and that policy has been provided to the resident before admission as required in Rule 59A-36.006, F.A.C.

(c) Centrally stored medications must be:

1. Kept in a locked cabinet; locked cart; or other locked storage receptacle, room, or area at all times;
2. Located in an area free of dampness and abnormal temperature, except that a medication requiring refrigeration must be kept refrigerated. Refrigerated medications must be secured by being kept in a locked container within the refrigerator, by keeping the refrigerator locked, or by keeping the area in which the refrigerator is located locked;
3. Accessible to staff responsible for filling pill-organizers, assisting with self-administration of medication, or administering medication. Such staff must have ready access to keys or codes to the medication storage areas at all times; and,
4. Kept separately from the medications of other residents and properly closed or sealed.

(d) Medication that has been discontinued but has not expired must be returned to the resident or the resident's representative, as appropriate, or may be centrally stored by the facility for future use by the resident at the resident's request. If centrally stored by the facility, the discontinued medication must be stored separately from medication in current use, and the area in which it is stored must be marked "discontinued medication." Such medication may be reused if prescribed by the resident's health care provider.

(e) When a resident's stay in the facility has ended, the administrator must return all medications to the resident, the resident's family, or the resident's guardian unless otherwise prohibited by law. If, after notification and waiting at least 15 days, the resident's medications are still at the facility, the medications are considered abandoned and may be disposed of in accordance with paragraph (f).

(f) Medications that have been abandoned or have expired must be disposed of within 30 days of being determined abandoned or expired and the disposal must be documented in the resident's record. The medication may be taken to a pharmacist for disposal or may be destroyed by the administrator or designee with one witness.

(g) Facilities that hold a Special-ALF permit issued by the Board of Pharmacy may return dispensed medicinal drugs to the dispensing pharmacy pursuant to Rule 64B16-28.870, F.A.C.

(7) MEDICATION LABELING AND ORDERS.

(a) The facility may not store prescription drugs for self-administration, assistance with self-administration, or administration unless they are properly labeled and dispensed in accordance with Chapters 465 and 499, F.S., and Rule 64B16-28.108, F.A.C. If a customized patient medication package is prepared for a resident, and separated into individual medicinal drug containers, then the following information must be recorded on each individual container:

1. The resident's name; and,
2. The identification of each medicinal drug in the container.

(b) Except with respect to the use of pill organizers as described in subsection (2), no individual other than a pharmacist may transfer medications from one storage container to another.

(c) If the directions for use are "as needed" or "as directed," the health care provider must be contacted and requested to provide revised instructions. For an "as needed" prescription, the circumstances under which it would be appropriate for the resident to request the medication and any limitations must be specified; for example, "as needed for pain, not to exceed 4 tablets per day." The revised instructions, including the date they were obtained from the health care provider and the signature of the staff who obtained them, must be noted in the medication record, or a revised label must be obtained from the pharmacist.

(d) Any change in directions for use of a medication that the facility is administering or providing assistance with self-administration must be accompanied by a written, faxed, or electronic copy of a medication order issued and signed by the resident's health care provider. The new directions must promptly be recorded in the resident's medication observation record. The facility may then obtain a revised label from the pharmacist or place an "alert" label on the medication container that directs staff to examine the revised directions for use in the medication observation record.

(e) A nurse may take a medication order by telephone. Such order must be promptly documented in the resident's medication observation record. The facility must obtain a written medication order from the health care provider within 10 working days. A faxed or electronic copy of a signed order is acceptable.

(f) The facility must make every reasonable effort to ensure that prescriptions for residents who receive assistance with self-administration of medication or medication administration are filled or refilled in a timely manner.

(g) Pursuant to Section 465.0276(5), F.S., and Rule 61N-1.006, F.A.C., sample or complimentary prescription drugs that are dispensed by a health care provider, must be kept in their original manufacturer's packaging, which must include the practitioner's name, the resident's name for whom they were dispensed, and the date they were dispensed. If the sample or complimentary prescription drugs are not dispensed in the manufacturer's labeled package, they must be kept in a container that bears a label containing the following:

1. Practitioner's name,
2. Resident's name,
3. Date dispensed,
4. Name and strength of the drug,
5. Directions for use; and,
6. Expiration date.

(h) Pursuant to Section 465.0276(2)(c), F.S., before dispensing any sample or complimentary prescription drug, the resident's health care provider must provide the resident with a written prescription, or a faxed or electronic copy of such order.

(8) OVER THE COUNTER (OTC) PRODUCTS. For purposes of this subsection, the term over the counter includes, but is not limited to, over the counter medications, vitamins, nutritional supplements and nutraceuticals, hereafter referred to as OTC products, that can be sold without a prescription.

(a) A facility may keep a stock supply of OTC products for multiple resident use. When providing any OTC product that is kept by the facility as a stock supply to a resident, the staff member providing the medication must record the name and amount of the OTC product provided in the resident's medication observation record. All OTC products kept as a stock supply must be stored in a locked container or secure room in a central location within the facility and must be labeled with the medication's name, the date of purchase, and with a notice that the medication is part of the facility's stock supply.

(b) OTC products, including those prescribed by a health care provider but excluding those kept as a stock supply by the facility, must be labeled with the resident's name and the manufacturer's label with directions for use, or the health care provider's directions for use. No other labeling requirements are required.

(c) Residents or their representatives may purchase OTC products from an establishment of their choice.

(d) A health care provider's order is required when a nurse provides assistance with self-administration or administration of OTC products. When an order for an OTC product exists, the order must meet the requirements of paragraphs (b) and (c) of this subsection. A health care provider's order for OTC products is not required when a resident self-administers his or her medications, or when unlicensed staff provides assistance with self-administration of medications.

(9) This rule is in effect for five years from its effective date.

Rulemaking Authority 429.256, 429.41 FS. Law Implemented 429.255, 429.256, 429.41 FS. History—New 10-17-99, Amended 7-30-06, 4-15-10, 10-14-10, 3-13-14, 5-10-18, Formerly 58A-5.0185, Amended 8-16-21.