59A-8.0219 Medication Administration

(1) Medication Administration.

(a) For the purpose of this rule, the following terms are defined below:

1. "MAR" means the Medication Administration Form, AHCA Form 3110-XXXX, July 2022, incorporated by reference and available at: http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX or at: http://www.ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Lab_HomeServ/HHA/index.shtml, or an alternate electronic form that collects all of the information required and collected on the AHCA form.

2. "MDR" means the Medication Destruction Form, AHCA Form 3110-XXXX, July 2022, incorporated by reference and available at: http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX or at: http://www.ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Lab_HomeServ/HHA/index.shtml, or an alternate electronic form that collects all of the information required and collected on the AHCA form.

3. "MER" means the Medication Error Form, AHCA Form 3110-XXXX, July 2022, incorporated by reference and available at: http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX or at: http://www.ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Lab_HomeServ/HHA/index.shtml, or an alternate electronic form that collects all of the information required and collected on the AHCA form.

(b) It is the responsibility of the licensee and the Director of Nursing to ensure that any home health aide or CNA administering medication to patients meets the requirements of this rule.

(c) A home health aide or CNA may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medications, including over the counter products prescribed to the patient by a health care provider, that are not Schedule II, III, or IV controlled substances in accordance with section 464.0156, F.S. A home health aide or CNA shall limit his or her assistance to the minimum necessary to ensure proper administration while preserving the patient's independence.

1. A home health aide or CNA shall not administer medication to patients unless he or she has successfully completed a basic medication administration training course and obtained a current validation for the route by which the medication is administered in accordance with Rule 59A-8.0216, F.A.C.

2. A home health aides or CNA shall not administer prescribed enteral formula unless he or she has completed a Prescribed Enteral Formula Administration training course and received the corresponding training certification and validation cetification in accordance with Rule 59A-8.0216, F.A.C.

3. Home health aides and CNAs who are validated to administer whole (not crushed) oral medication may give the medication in any dietary or nutritional food substance that facilitates swallowing and is tolerated by the patient.

4. A home health aide or CNA who has been validated to administer prescribed enteral formulas may administer prescribed enteral formulas through gastrostomy tubes, including percutaneous endoscopic gastrostomy ("PEG"), button-style gastrostomy, and jejunal ("JT"), except as specified in section (4) of this rule.

(d) In cases where a home health aide or a CNA will administer medications, an assessment of the medications for which administration is to be provided shall be conducted by the registered nurse (RN) who delegated the task.

(e) The delegating RN shall ensure the home health aide or CNA administers the medication in accordance with their training and competency, and with the medication prescription.

(f) The home health agency must maintain a medication administration record (MAR) for each patient who receives medication administration from a home health aide or CNA. The MAR must be immediately updated by the home health aide or CNA each time the medication is offered or administered and include:

1. The name of the patient and any known allergies the patient may have;

2. The name of the patient'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.

5. If the directions for use are "PRN", "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 patient 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.

6 Any change in directions for use of a medication that the home health agency is responsible for administering must be accompanied by a copy of a medication order issued and signed by the patient's health care provider. The new directions must promptly be recorded in the patient's MAR. The home health agency 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 MAR.

7. The delegating RN is required to review the MAR every three months, or more frequently if needed, for each patient receiving medication administration from a home health aide or CNA.

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

(h) Medication administration includes conducting any examination, including vital signs (temperature, blood pressure, heart rate, and/or respirations) for the proper administration of medication that the patient cannot perform personally and that can be performed by a licensed health care practitioner, or a home health aide or CNA as delegated by an RN.

(i) A home health aide or CNA should always contact the supervising or delegating RN if unclear about administering a medication.

(2) Medication Administration Procedures. Home health aides and CNAs shall:

(a) Only administer medication as prescribed or ordered by the patient's health care practitioner and which are properly labeled and dispensed in accordance with chapters 465 and 499, F.S.;

(b) Comply with new or changed orders for a specific medication, which override the previous orders for that medication. No order to discontinue the previous order is necessary;

(c) Comply with the time limit as provided for in time-limited orders (i.e. those that are ordered for a specific number of doses or days). Such orders do not require an order to discontinue at the completion of the time allotted in the time-limit;

(d) Before administering medication, review the patient's medical history and medication background with the delegating RN and locate the name and contact numbers of the patient's prescribing practitioner for consultation regarding the prescribed medications;

(e) Perform appropriate hand sanitation measures before administering medication to the patient, with repeated sanitization as needed during medication administration and when there is a change in the administration route. The home health aide or CNA must also sanitize his or her hands prior to administering medication to the next patient;

(f) Following the administration of medication, return each patient's medication to its portable or permanent medication storage location;

(g) Contact the patient's primary care provider within 24 hours to reconcile the patient's medications with those ordered upon the patient's discharge from any inpatient, emergency, or urgent care facility. The contact must be documented, along with the primary care provider's response, including any instructions for medication administration and follow up. The primary care provider's failure to respond should also be documented, along with continued attempts to contact him or her. If no licensed person is present to take the instructions from the primary care provider, the home health aide or CNA must also ask for faxed or electronically supplied instructions;

(h) Immediately report torn, damaged, illegible, or mislabeled prescription labels to the dispensing pharmacist and, if a patient is residing in a residential facility, notify the facility supervisor;

(i) Check the directions and expiration date of each medication to ensure that expired medications (those which are no longer current) or those no longer prescribed are not administered;

(j) Continue to provide medications for which there is a current prescriber order and the medication is not expired, but the prescription itself is expired, until the current supply is exhausted, or, in the case of a PRN medication, for no longer than 6 months after the date the prescription expired;

(k) Administer as prescribed and via the route instructed by the patient's prescribing health care professional. Each time medication is administered:

1. Verify that the correct medication is administered to the correct patient, at the correct time, with the correct dosage, by the correct route, and for the correct reason, as prescribed by the health care practitioner;

2. Observe complete ingestion of oral medication before leaving the patient and before recording or documenting the administration of the medication on the MAR;

3. Record the date, time, dosage, and name of each regularly scheduled medication or PRN medication on the MAR immediately following administration and sign or initial the entries. For PRN medications, the home health aide or CNA must also enter the reason for the medication on the back of the medication administration record or in a place provided for such an entry on a pharmacy-provided or electronic medication administration record;

4. Following the first three doses of a new medication, including PRN medications, observe the patient directly for a minimum of 20 minutes and document observations to detect and respond immediately to potential side effects, unless ordered differently by the prescribing health care practitioner, and review the medication administration record for any special instructions by the prescribing practitioner regarding required observations. This documentation shall include both adverse reactions or a lack of adverse reactions to the new medication;

5. Enter the response to the medication on the back of the medication administration record for PRN medications (state whether the medication alleviated the symptom for which it was given, e.g. "headache is better") or in the place provided for such an entry on a pharmacy provided or electronic medication administration record. This entry should indicate date and time of entry, and be initialed or signed by the home health aide or CNA;

(l) Ensure that the prescription for a medication is promptly refilled so that a patient does not miss a prescribed dosage of medication. If the home health aide or CNA is not responsible for routine refills of a medication, he or she shall notify the individual responsible for refilling the patient's prescriptions that the patient needs a medication refill and document this notification;

(m) Keep on-site a copy of the prescription, order, or pharmacy profile with the patient's medication administration record or medical record, written or printed legibly and displaying the following information:

1. The patient's name;

2. The name of the medication;

3. The prescribed dosage;

4. The time intervals or specific times the medication must be given;

5. The administration route by which the medication must be given;

6. Specific directions for use;

7. The medical reason or diagnosis for which the medication was ordered or prescribed; and

8. For PRN medications, the patient's complaint for which the medication is ordered, the maximum number of days that the medication should be given, the maximum number of doses per day, and conditions under which the health care practitioner should be notified.

(3) In the administration of medications, a home health aide or CNA shall not:

(a) Administer medications, including PRN and OTC medications or medication samples without a written order and instructions for preparation and use from the patient's physician, PA, or APRN;

(b) Administer medications for which the health care provider's prescription or order does not specify the medication schedule, medication amount, dosage, route of administration, purpose for the medication, or with medication that would require professional medical judgment by the home health aide or CNA.

(c) Crush, dilute, or mix crushed medications without instructions from the prescribing health care practitioner or licensed pharmacist that have been transcribed to the medication administration record;

(d) Administer medications via a medication route for which the home health aide or CNA has not been validated, with the exception of a rectal gel prescribed for seizures and administered only in an emergency situation;

(e) Prepare syringes for a patient's use during the self-administration of medication via a parenteral, subcutaneous, intra-dermal, intra-muscular or intravenous route;

(f) Administer medications by injection via a parenteral, subcutaneous, intra-dermal, intra-muscular or intravenous route, with the exception of an epi-pen administered in an emergency situation. This prohibition includes the administration of insulin.

(g) Administer medication that is inserted vaginally, or administered via a tracheostomy;

(h) Administer medications for which the health care provider's prescription or order does not specify the medication schedule, medication amount, dosage, route of administration, purpose for the medication, or with medication that would require professional medical judgment by the home health aide or CNA.

(4) A home health aide or CNA who has been validated to administer prescribed enteral formulas shall not:

(a) Administer prescribed enteral formulas through a Gastrojejunal ("GJ") tube or any tube that requires venting or suction;

(b) Administer prescribed enteral formulas utilizing any procedures that require clinical judgement, which is the process by which a licensed health care professional decides on data to be collected about a patient, makes an interpretation of the data, arrives at a diagnosis, and identifies appropriate medical intervention; this involves problem solving, decision making, and critical thinking;

(c) Attempt to unclog an obstructed tube;

(d) Replace or attempt to replace a dislodged tube;

(e) Administer prescribed enteral formulas through nasal tubes of any type. These are commonly known as, but not limited, to nasogastric ("NG"), nasoduodenal ("ND"), and nasojejunal ("NJ") tubes.

(5) Home health aides and CNAs shall not:

(a) Falsify any records regarding medication administration;

(b) Continue to provide services as a home health aide or CNA if he or she fails to successfully pass required re-validation on his or her primary route(s);

(c) Continue to provide medication administration or supervision of medication administration via any of the non-primary routes if he or she fails to successfully maintain his or her validation for the non-primary route.

(d) Provide services as a home health aide or CNA while not currently authorized to do so by the State of Florida;

(e) Provide services as a home health aide or CNA after the home health agency has determined the home health aide or CNA shall not continue to provide medication administration assistance.

(6) If a home health aide or CNA violates any provision of sections 400.489, 400.490, 464.0156 or 464.2035, F.S., or this rule, the home health agency shall:

(a) Prohibit the home health aide or CNA from providing medication administration services to patients of the agency;

(b) Require the home health aide or CNA to:

1. Successfully complete the Basic Medication Administration Course and corresponding validation;

2. Successfully complete the Prescribed Enteral Formula Administration Course and corresponding validation;

3. Participate in and successfully complete a corrective action plan; and

4. Comply with remediation requests.

(7) Any person, including licensed health care practitioners, who in good faith renders emergency care or treatment in violation of this chapter, either in direct response to emergency situations related to and arising out of a public health emergency declared pursuant to section 381.00315, F.S., a state of emergency which has been declared pursuant to section 252.36, F.S., or at the scene of an emergency outside of a hospital, doctor's office, or other place having proper medical equipment, without objection of the injured victim or victims, shall not be held responsible for the administrative violation as a result of such care or treatment where the person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.

(8) Medication Errors. A "medication error" is any of the following:

(a) Administration or assistance with the self-administration of a wrong medication, including:

1. Medication for any symptom, illness, or reason other than the one for which the medication was prescribed;

2. Medication for which there is no current prescriber order;

(b) Administration or assistance with the self-administration of a wrong dose, including;

1. An incorrect dose of medication;

2. More than one dose of the same medication in a scheduled time period;

(c) Administration or assistance with the self-administration of a medication to the wrong patient, which means medication that is prescribed or ordered for someone other than the patient;

(d) Administration or assistance with the self-administration of medication via the wrong route;

(e) Failure to administer or assist with the self-administration of medication within 60 minutes of the prescribed dosage time;

(f) Failure to immediately and accurately document administration or assistance with the self-administration of medication on the MAR;

(g) Administration or assistance with the self-administration of a medication which has expired or is improperly labeled;

(h) Failure to conduct an accurate medication count for controlled medications;

(i) Failure to administer or assist with the self-administration of a medication, for any of the following reasons:

1. Patient refused the medication;

2. The home health aide or CNA did not administer or assist with the self-administration of the medication;

3. Medication was not available;

4. New order not initiated within 24 hours;

5. Refill not ordered timely;

6. Insurance issue;

7. Pharmacy issue;

8. Family error;

9. Other reason not listed above;

(j) Administration of medication by a home health aide or CNA not validated as required in Rule 59A-8.0097.

(k) Immediately following an error as listed in subsection (a) above, the home health aide, CNA or RN must take the following steps:

1. Notify the Administrator or Director of Nursing;

2. In the case of administration of a wrong medication, a wrong dosage, or the provision of medication to the wrong patient, immediately notify the patient's health care practitioner, observe the patient closely for a minimum period of 60 minutes after the medication was administered or assistance with self-administration was provided, or for as long as directed by the health care practitioner, and immediately report any observed changes in the patient's condition to the prescribing health care practitioner, and call 911 to request emergency services if the patient exhibits respiratory difficulty or other potentially life-threatening symptoms;

3. For all errors listed in subsection (a) above, with the exception of subsections 5., 6., 7., 8., and 9., notify the patient's prescribing health care practitioner of the error, and if there is no licensed health care professional present, request that the practitioner prepare and electronically transmit via fax or secure email a medication directive addressing the error to the patient's home, place of residence, or pharmacy, and document the patient's health care practitioner's response or lack of response; and

4. Fully document all observations and contacts made regarding a medication error on the MER. The home health aide, CNA or registered nurse shall place a copy of the MER in the patient's file.

(l) If a medication error occurs in the patient's home or place of residence, the home health aide, CNA or registered nurse must:

1. Submit the MER to the the home health agency administrator or director of nursing, and the facility administrator if applicable, within 24 hours of discovering the error; and

2. Maintain a copy of the report in the patient's record and with the medication administration record for review.

(m) If the home health agency administrator or director of nursing determines that the medication error justifies corrective action, the administrator or director of nursing will notify the home health aide, CNA, or his or her supervising RN in writing of the necessary corrective action plan, including a specific and reasonable timeframe for completion of the corrective action plan. If the home health aide or CNA fails to comply with the corrective action plan, the administrator or director of nursing may prohibit the home health aide or CNA from providing medication administration services.

(9) Authorization for Medication Administration and Informed Consent Requirement.

(a) A patient's need for assistance with medication administration must be documented by the patient's physician, PA, or APRN on Authorization for Medication Administration, AHCA Form 3110-XXXX, July 2022, incorporated by reference and available at: http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX or at:

http://www.ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Lab_HomeServ/HHA/index.shtml.

1. The patient's current Authorization for Medication Administration must be maintained in the patient's home or place of residence, with a copy of the form in the patient's record. The home health agency is responsible for assuring that all home health aides and CNAs that administer medication to a patient have an up-to-date copy of the Authorization for Medication Administration.

2. The Authorization for Medication Administration must be reviewed and updated by the patient's physician, PA, or APRN at least annually and upon any change in the patient's medical condition or self-sufficiency that would affect the patient's ability to self-administer medication or tolerate particular administration routes.

(b) In addition to an executed Authorization for Medication Administration Form and prior to a home health aide or CNA administering medication to a patient, the home health agency must also obtain from the patient, patient's guardian or legal representative, a signed Informed Consent for Medication Administration, AHCA Form 3110-XXXX, incorporated by reference in Rule 59A-8.0216, F.A.C.

1. The Informed Consent for Medication Administration must be updated annually or at any point when there is any change in the patient's home or residential facility provider's address.

2. The current Informed Consent for Medication Administration must be maintained in the patient's home or place of residence where the patient is receiving administration of medication. A copy of the Informed Consent for Medication Administration for each home health aide or CNA administering medication to the patient must also be in the patient's record.

3. The home health aide or CNA may not act as the patient's health care surrogate or proxy or sign the Informed Consent for Medication Administration referenced above. The delegating RN or other home health agency staff may witness the execution of the form by the patient.

(c) A home health aide or CNA shall limit his or her assistance to the minimum necessary to ensure proper administration of the medication while preserving the client's independence.

(d) The requirements of this section do not apply to the following:

1. Health care practitioners whose professional licenses include administration of medication, except an RN who delegates the task of administering medications to home health agency patients must ensure the medication administration related documentation requirements are maintained to ensure the safety and welfare of the patients.

2. Patient family members or friends who provide medication assistance without compensation, as permitted by section 464.022(1), F.S.;

3. Providers employed by or under contract with State Medicaid intermediate care facilities for the developmentally disabled, regulated through chapter 400, part VIII, F.S., hospices (except as referenced in paragraph (a), above) regulated under chapter 400, part IV, health care service pools (except as referenced in paragraph (a), above) regulated through chapter 400, part IX, F.S., or providers employed by or under contract with assisted living facilities regulated through chapter 429, part I, F.S.

(10) Documentation and Record Keeping. The home health aides and CNAs shall maintain an up-to-date MAR for each patient requiring assistance with medication administration. The home health aide or CNA must document the administration of medication immediately on the MAR.

(a) The MAR form must include the following information:

1. The patient's name;

2. Any patient food or medication allergies;

3. The name of each medication prescribed for the patient;

4. The medication strength (e.g., 5mg/ tsp);

5. The prescribing health care practitioner for each medication;

6. The date that the medication was ordered and any date the medication was changed (including stop date);

7. Prescribed dosage for each medication;

8. Scheduled time of administration for each medication;

9. Prescribed route of administration for each medication;

10. Prescribed instructions for crushing, mixing, or diluting of specific medications, if applicable;

11. The dates each medication was administered;

12. The initials and signatures of the home health aides or CNAs who administered;

13. A record of any medication dosage refused or missed, documented by the home health aide or CNA for administering the scheduled dosage, by drawing a circle around the appropriate space on the MAR form and initialing it; and,

14. The reasons for not administering a medication, annotated and initialed by the home health aide, CNA, or licensed health care practitioner in the comments section on the MAR form.

(b) If necessary, it is acceptable for more than one page of the MAR to be attached to any medication administration record to allow for more entries and explanations.

(c) It is permissible for home health aides, CNAs, or licensed health care practitioners to use a medication administration record provided by a pharmacy or from an electronic system if that medication administration record collects and records the same information in paragraph (a).

(d) Each patient's record must contain the following medication documentation, recorded in a manner that effectively communicates to the home health agency and other health care providers, and which is readily available to the delegating RN and home health agency, and for an AHCA surveyor review upon request:

1. Completed medication administration record forms;

2. A list of potential side effects, adverse reactions, and drug interactions for each medication. The drug monograph provided by the pharmacy, or an electronic health program is sufficient to meet this requirement;

3. A record of drug counts for each controlled medication;

4. Written determination by the patient's physician that the patient requires assistance with the administration of his or her medications, utilizing the Authorization for Medication Administration, as adopted in subsection (9); and,

5. The current Informed Consent form adopted in subsection (9), permitting a home health aide or CNA to assist with the administration of medication.

(11) Medication Storage and Disposal Requirements.

(a) Home health aides and CNAs must observe the following medication storage and disposal requirements:

1. Store each medication at the temperature appropriate for that medication, including refrigeration if required;

2. Notify the delegating RN of any prescription medication that has expired per the pharmacist's label, or the label provided by the manufacturer on over the counter (OTC) medications or is no longer prescribed on the MDR. Outdated medication must be properly destroyed by the delegating RN must sign the MDR before a third-party witness;

3. Maintain medications in their original containers labeled by the dispensing health care practitioner or pharmacy with the patient's name, the practitioner's name, and the directions for administering the medication;

4. Maintain OTC medications in their original containers;

5. Store the medications centrally in a locked container in a secured enclosure if the patient requiring the medication assistance is residing or receiving services in a residential or facility setting;

6. Organize and maintain stored medications in a manner that ensures their safe retrieval and minimizes medication errors;

7. Store all medications that require refrigeration in a refrigerator, in their original containers either within a locked storage container that is clearly labeled as containing medications, or in a medication dedicated refrigerator located in a locked, secured medication storage room for a patient whose residence is not in the home;

8. Return each medication to its portable or permanent storage unit immediately following medication administration assistance.

(b) A patient's medications must be centrally stored and retrieved by the home health aide or CNA if:

1. The patient's physician documents in the patient's file that leaving the medication in the personal possession of the patient would constitute a threat to the health, safety, or welfare of the patient or others;

2. The patient fails to securely maintain the medication in a locked place;

3. The home health aide or CNA determines that, based on the home's physical arrangements, the patient's personal possession of medication poses a threat to the safety of the patient, or

4. The patient or the patient's authorized representative requests in writing that the patient's medication be centrally stored.

(c) Either the delegating RN, home health aide or CNA must securely maintain keys to the locked containers and storage enclosures containing medications and provide written procedural provisions for accessibility to medications in cases of emergency.

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