Notice of Proposed Rule

DEPARTMENT OF CHILDREN AND FAMILIES
Agency for Persons with Disabilities

RULE NO.:	RULE TITLE:
65G-7.001	Definitions
65G-7.002	Authorization for Medication Administration and Informed Consent Requirement
65G-7.0025	Self-Administration of Medication without Supervision
65G-7.003	Medication Administration Trainer Requirements
65G-7.0033	Medication Administration Training Course Curriculum Requirements
65G-7.0035	Validation Trainer Requirements
65G-7.004	Medication Assistance Provider Training and Validation Requirements
65G-7.005	Medication Administration Procedures
65G-7.006	Medication Errors
65G-7.007	Storage Requirements
65G-7.008	Documentation and Record Keeping
65G-7.009	Off-site Medication Administration

PURPOSE AND EFFECT: The purpose and effect of these rule amendments is to update Chapter 65G-7, F.A.C., to comply with statutory changes to s. 393.506, F.S., as adopted by the Florida Legislature in Ch. 107, Laws of Fla, (2018).

SUMMARY: The language addresses medication administration and necessary updates to Chapter 65G-7, F.A.C., to comply with statutory changes to s. 393.506, F.S., as adopted by the Florida Legislature in Ch. 107, Laws of Fla, (2018).

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will **not** have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

Because this rule does not have an adverse impact on small business and will not likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule, the rule is not expected to require legislative ratification. The rule does not have an adverse impact on small business and is not likely to increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule because the rule simply clarifies the requirements of incident reporting that were previously in place.

Any person who wishes to provide information regarding a statement of estimated regulatory costs or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: s. 393.501, 393.506, F.S

LAW IMPLEMENTED: s. 393.506, F.S.

A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: February 5, 2019, 9:00 a.m.

PLACE: Agency for Persons with Disabilities, 4030 Esplanade Way, Room 301, Tallahassee, Florida 32399-0950.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this hearing is asked to advise the agency at least 48 hours before the hearing by contacting R. Kathleen Brown-Blake at (850) 922-9399. If you are hearing or speech impaired, please contact the Commission

office using the Florida Dual Party Relay System which can be reached at 1(800)955-8700 (Voice) or 1(800)955-8771 (TTD).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Kathleen Brown-Blake, Senior Attorney, Agency for Persons with Disabilities, 4030 Esplanade Way, Suite 335, Tallahassee, FL 32399, Kathleen.Brown-Blake@apdcares.org, (850) 922-9399

THE FULL TEXT OF THE PROPOSED RULE IS:

65G-7.001 Definitions.

Substantial rewording of Rule 65G-7.001, F.A.C. follows. See Florida Administrative Code for current text.

The terms and phrases used in this chapter shall have the meanings defined below:

(1) "Administration of medication" means the obtaining and giving of one or more doses of medicinal substances by an authorized person to an Agency client for his or her consumption.

(2) "Administration route" means the path through which medication or prescribed formula is delivered to a client. For purposes of this Chapter, administration routes include the following:

(a) "Enteral," which means medication or prescribed enteral formula is delivered by gastrostomy jejunostomy tube, or gastrostomy-jejunostomy tube, via the body's gastrointestinal system.

(b) "Inhaled," which means medication is administered as nose drops or nose spray, or medication is inhaled by mouth, such as an inhaler or nebulizer.

(c) "Ophthalmic," which means solution or ointment medication is instilled into the eye or applied on or around the eyelid.

(d) "Oral," which means medication including, but not limited to, tablet, capsule, liquid, or powder form is introduced into the gastrointestinal tract by mouth.

(e) "Otic," which means solutions or ointment medication is placed in the outer ear canal or applied around the outer ear.

(f) "Parenteral," which means medication is injected into the body through some route other than the digestive tract, such as subcutaneous, intra-dermal, intra-muscular, or intravenous administration.

(g) "Rectal," which means any medication including, but not limited to, capsule, enema, gel, or suppository is administered via the rectum.

(h) "Topical," which means medication including, but not limited to, salve, lotion, ointment, cream, spray, shampoo, or solution is applied locally to a body part.

(i) "Transdermal," which means a patch containing a pre-measured or measured amount of topical medication that is absorbed into the body via the epidermis (outer layer of skin).

(j) "Vaginal," which means any medication including, but not limited to, capsule, cream, or ointment that is administered via the internal vagina. This route does not include medications applied to the epidermis external to the vagina.

(3) "Advanced Practice Registered Nurse" or "APRN" means any person licensed or authorized by the State of Florida to practice professional nursing and certified in advanced or specialized nursing practice, including certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners, pursuant to Chapter 464, F.S.

(4) "Client's record" means a file maintained by the Waiver Support Coordinator for each client that contains the client's name and date of birth, written authorization for routine medical/dental care from the client or legal representative medical summary, the name address and telephone number of the client's physician(s) and dentist(s), a record of the client's illnesses and accidents, the legal status of the client, current services and support plan, and client financial documentation. This shall be taken to include any central client record as maintained under the Agency data management system, whether paper or electronic in format.

(5) "Controlled medication" means any substance enumerated in Schedules I, II, III, IV, and V, in Section 893.03, F.S.

(6) "Corrective Action Plan" means a written plan of action developed by the provider in cooperation with the Agency for correcting cited deficiencies in compliance with this Chapter.

(7) "Current prescriber order" means a prescription or order that has not been discontinued by the prescriber and may be dispensed until the prescribed number of refills has been fulfilled and administered, or until the medication has expired.

(8) "Dispense" means the same as defined in section 465.003(6), F.S.

(9) "Drug monograph" means the informational documents that are provided every time a new medication is ordered for a patient that contains specific drug-related uses, warnings, side effects and other information, depending

on the medication dispensed.

(10) "Expiration date of a prescription" is the date after which the prescription may not be dispensed by the pharmacy, or one year after the written date of the prescription, except in the case of a controlled medication, which, depending on class, could expire at any time, from immediately after the first fill to twelve months from the written date of the prescription.

(11) "Expired medication" is a medication that shall not be administered because the expiration date of the medication has passed. The expiration date of a medication is the date after which the medication expires per the pharmacist's label or the label provided by the manufacturer on over-the-counter medications.

(12) "Facility" means a residential facility licensed under Chapter 393, F.S., or other facility staffed by direct service providers where Agency clients receive training, respite care, or other services on a regularly scheduled basis.

(13) "Informed Consent for Medication Administration" means the specific consent a client or client's legal representative gives to a provider that allows that provider to assist the client with medication administration, and on which the client or the client's legal representative acknowledges that the provider is not professionally licensed to provide medication administration assistance.

(14) "Legal Representative" means:

(a) For clients under the age of 18 years, the legal representative or health care surrogate appointed by the Florida court to represent the child or anyone designated by the parent(s) of the child to act in the parent(s)' behalf (e.g., due to military absence).

(b) For clients age 18 years or older, the legal representative could be the client, anyone designated by the client through a Power of Attorney or Durable Power of Attorney, a medical proxy under Chapter 765, F.S., or anyone appointed by a Florida court as a guardian or guardian advocate under Chapter 393 or Chapter 744, F.S.

(15) "Licensed Practical Nurse" or "LPN" means any person licensed or authorized by the State of Florida to practice practical nursing pursuant to Chapter 464, F.S.

(16) "Medical Case Manager" or "MCM" means a health care practitioner employed by the Agency to provide consultation and technical assistance regarding the health and safety of Agency clients.

(17) "Medication" means over-the-counter medications and prescribed medications.

(18) "Medication Administration Record" or "MAR" means the chart maintained for each client that records the medication administration information required by this Chapter. Other information or documents pertinent to medication administration may be attached to the MAR.

(19) "Medication Administration Trainer" or "Trainer" means an individual who is licensed or authorized to practice nursing by the State of Florida pursuant to Chapter 464, F.S., and who obtains Agency approval to train MAP applicants in Basic Medication Administration or Prescribed Enteral Formula Administration, pursuant to Rule 65G-7.003, F.A.C.

(20) "Medication Assistance Provider" or "MAP" means a direct service provider not otherwise licensed to administer medication who has successfully completed an Agency-provided training course taught by an Agency-approved Trainer and has current validation to provide clients with medication administration or supervise clients with self-administration of medication.

(21) "Nebulizer" means an electrically-powered (including battery-powered) machine that turns liquid medication into a mist so that it can be breathed directly into the lungs through a mouthpiece or face mask.

(22) "Over-the-counter or "OTC" medication" means a medication for general distribution that is available to the general public for use in the treatment of human illnesses, ailments, or injuries.

(23) "Pharmacist" means any person licensed pursuant to s. 465.003, F.S., to practice the profession of pharmacy.

(24) "Pharmacy profile" means the electronic file kept by the client's pharmacy that maintains client-specific information and prescription history, such as date of birth, diagnoses, allergies, insurance information, and medication history.

(25) "Physician" means a Doctor of Medicine or Osteopathy who holds a valid and active license in full force and effect pursuant to the provisions of Chapter 458 or 459, F.S.

(26) "Physician Assistant" or "PA" means a person who is a graduate of an approved program or its equivalent or who meets standards approved by the Board of Medicine and is licensed to perform medical services delegated by the supervising physician or osteopathic physician pursuant to Chapters 458 and 459, F.S.

(27) "Prescribed medication" means simple or compound substances, mixtures of substances, or prescribed enteral formulas that are prescribed for the care, mitigation, or prevention of disease or for health maintenance by a licensed practitioner authorized by the laws of the State of Florida to prescribe or order such substances.

(28) "Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of

communication by a practitioner licensed or legally authorized by the State of Florida to prescribe such drugs or medicinal supplies and which is intended to be dispensed by a pharmacist. The term also includes a verbally transmitted order to the pharmacist by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186, F.S. Prescriptions may be retained in written form or the provider may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request, per s. 465.003(14), F.S.

(29) "Primary route of medication administration" or "primary route" means the oral route, or in the case of a MAP who primarily administers medication via the enteral route, this term means the enteral route. The primary route refers to the route of medication administration that is used to determine the annual validation date of a specific MAP for the purpose of requiring retraining and validation if a lapse in validation occurs.

(30) "Provider" means either a single person providing services to a client of the Agency, including a CDC+ provider, or a business entity such as a Group Home or Adult Day Training Center providing services to clients of the Agency.

(31) "PRN" or "pro re nata" means the administration of medication on an as-needed basis rather than per a prescribed schedule.

(32) "Regional Office" is one of the local offices responsible for managing one of the Agency's six service areas.

(33) "Registered Nurse" or "RN" means any person licensed or authorized by the State of Florida to practice professional nursing, pursuant to Chapter 464, F.S.

(34) "Self-administration of medication without supervision" means that the client self-administers their own medications without any supervision, monitoring, verbal prompting, physical assistance, or cuing from staff.

(35) "State Office" is the Agency's headquarters, situated at 4030 Esplanade Way, Suite 380, Tallahassee, FL 32399-0959; main telephone number (850) 488-4257.

(36) "Supported living" means the provision of supports necessary for an adult who has a developmental disability to establish, live in, and maintain his or her own household in the community.

(37) "Unlicensed" means, for purposes of this rule, any direct service provider not licensed, authorized, certified, or otherwise permitted by Florida law to administer medication or to supervise a client's self-administration of medication.

(38) "Validation" means a MAP or MAP applicant's on-site demonstration of competency in administering or supervising self-administration of medication(s) to a client, certified by a Validation Trainer following the direct service provider's successful completion of an Agency-provided medication administration training course, or successful annual completion of an Agency provided in-service on medication error prevention and medication administration.

(39) "Validation Trainer" means a practitioner who is licensed or authorized to practice nursing by the State of Florida pursuant to Chapter 464, F.S., or who is licensed or authorized to practice medicine by the State of Florida pursuant to Chapter 458 or 459, F.S., and who obtains Agency approval to validate MAPs or MAP applicants in Medication Administration or Prescribed Enteral Formula Administration, pursuant to Rule 65G-7.0035, F.A.C.

(40) "Validation by simulation" means the in-person, one-on-one imitation by a MAP or MAP applicant of the actual process utilized when administering medication or supervising the self-administration of medication by a particular route, which must occur as part of the required Medication Administration Training Course.

(41) "Waiver Support Coordinator" or "WSC" means a Support Coordinator as defined in s. 393.063(41), F.S.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New 3-30-08, Amended _____.

65G-7.002 Authorization for Medication Administration and Informed Consent Requirement.

Substantial rewording of Rule 65G-7.002, F.A.C. follows. See Florida Administrative Code for current text.

(1) An Agency client's need for assistance with medication administration or ability to self-administer medication without supervision must be documented by the client's physician, PA, or APRN on an "Authorization for Medication Administration," APD Form 65G-7.002 A, effective December 2018, incorporated here by reference, which may be obtained at _____.

(a) The client's current Authorization Form must be maintained in the client's current place of residence, with a copy of the form in the client's record. The WSC is responsible for assuring that all providers that assist a client with medications have an up-to-date copy of the Authorization.

(b) The Authorization Form must be reviewed and updated by the client's physician, PA, or APRN at least annually and upon any change in the client's medical condition or self-sufficiency that would affect the client's ability to self-administer medication or tolerate particular administration routes. Any provider who accompanies a client to a medical professional when a change to the Authorization Form is made is responsible for notifying the WSC of any new Authorization Form.

(2) In addition to an executed Authorization for Medication Administration Form and before providing a client with medication assistance, an unlicensed provider must also obtain from the client or the client's legal representative a signed "Informed Consent for Medication Administration" APD Form 65G-7.002 B, effective December 2018, incorporated herein by reference, which may be obtained at _____.

(a) The Informed Consent for Medication Administration must be updated annually or at any point when there is any change in the client's residential facility provider or other provider agency.

(b) The current Informed Consent for Medication Administration must be maintained in each location or facility in which the client is receiving supervision of self-administration of medication or administration of medication. A copy of each provider's Informed Consent for Medication Administration must also be in the client's record.

(c) The MAP may not act as the client's health care surrogate or proxy or sign the Informed Consent for Medication Administration referenced above. Providers or other facility staff may witness the execution of the form by the client.

(3) A MAP will limit his or her assistance to the minimum necessary to ensure proper administration or supervised self-administration of the medication while preserving the client's independence.

(4) The requirements of this Chapter do not apply to the following:

(a) Health care practitioners whose professional licenses include administration of medication, except all health care practitioners who provide medication assistance to Agency clients must ensure the medication administration related documentation requirements attached to Agency clients are maintained pursuant to this Chapter to ensure the safety and welfare of the clients. This includes the use of the following forms in cases where the client is served by both MAPs and licensed health care practitioners:

1. The Authorization for Medication Administration, pursuant to subsection (1);

2. A medication administration record to document any medications given as instructed in Rule 65G-7.008, F.A.C. The health care practitioner may utilize the Medication Administration Record Form, APD Form 65G7-00, as adopted in Rule 65G-7.008, F.A.C.;

3. The Off-Site Medication Form as adopted in Rule 65G-7.009, F.A.C.;

4. The Medication Destruction Record, form APD 65G7-06, as adopted in Rule 65G-7.007, F.A.C.;

5. The Medication Error Report, form APD 65G7-05, as adopted in Rule 65G-7.006, F.A.C.;

6. The Controlled Medication form, APD Form 65G7-007, adopted in Rule 65G-7.007, F.A.C.;

(b) Client family members or friends who provide medication assistance without compensation, as permitted by Section 464.022(1), F.S.;

(c) Providers employed by or under contract with State Medicaid intermediate care facilities for the developmentally disabled, regulated through Chapter 400, Part VIII, F.S., providers employed by or under contract with licensed home health agencies regulated (except as referenced in (a), above) under Chapter 400, Part III, hospices (except as referenced in (a), above) regulated under Chapter 400, Part IV, health care service pools (except as referenced in (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.; and

(d) Clients authorized to self-administer medication without assistance or supervision as described in Rule 7.0025, F.A.C., except as pertains to storage of medications as outlined in Rule 65G-7.007, F.A.C.

Rulemaking Authority 393.501, 393.506 FS. Law Implemented 393.506 FS. History–New 3-30-08, Amended _____.

65G-7.0025 Self-Administration of Medication Without Supervision

A client who is authorized by his or her health care practitioner to self-administer medication without the supervision of a MAP or a licensed or authorized nurse, as set forth in the Authorization for Medication Administration Form adopted in Rule 65G-7.002, F.A.C., may do so. Any provider who helps the client may do so by making the medication available and reminding the client to take medication at appropriate times. Medications for the self-administering client may be stored pursuant to Rule 65G-7.007, F.A.C., and the entire container of medications provided to the client at the appropriate time(s), without further assistance. A pill organizer (also known as "pill minder" or "pill box") may be utilized by a client who self-administers without supervision, however the client must fill the pill organizer without any supervision, monitoring, verbal prompting, physical assistance, or

cuing from staff. MAPs may not transfer the medications from the original container to any other container.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New .

65G-7.003 Medication Administration Trainer Requirements.

Substantial rewording of Rule 65G-7.003, F.A.C. follows. See Florida Administrative Code for current text.

(1) RNs or LPNs must receive Agency approval before providing or offering to provide either of the following two medication administration courses to MAP applicants:

(a) Basic Medication Administration Training; or

(b) Prescribed Enteral Formula Administration Training.

(2) Trainer Eligibility: To be eligible for approval to provide either medication administration course, individuals must:

(a) Be licensed or authorized to practice nursing by the State of Florida pursuant to s. 464, F.S.;

(b) Apply on a "Medication Administration Trainer Application Form," APD Form 65G-7.003 A, effective December 2018 adopted and incorporated herein, which may be obtained at . The application must include the full address, email address, and telephone number of the applicant, and his or her name, nursing license number and license expiration date. Applicants that wish to provide the prescribed enteral formula administration course must clearly indicate so on the Medication Administration Trainer Application Form.

(c) Complete the training required in subsection (5). The application for training is not considered complete until the Medication Administration Trainer Application Form indicates that the training has been successfully completed by the MCM providing the overview course.

(3) If the Agency denies an application to offer training, it will identify the reasons for the denial in writing in a notice to the applicant. This notice shall include a statement of the applicant's due process rights to a hearing pursuant to ss. 120.569, and 120.57, F.S.

(4) Approved Trainers shall:

(a) Only provide training for courses which they have been approved to train;

(b) Utilize standard course curriculum provided by the Agency for all medication administration training and prescribed enteral formula administration training, with the exception of providers utilizing previously approved web-based curriculums as of July 1, 2018. Such web-based providers may continue to utilize those web-based courses, so long as the curriculum continues to meet curriculum standards as set forth in Rule 65G-7.0033, F.A.C. Otherwise, the Agency-provided curriculums are the only course curriculums that may be utilized for training MAP applicants. Failure to teach the curriculum to the Agency standards and requirements as set forth in Rule 65G-7.0033, F.A.C. shall subject the trainer's approval to disciplinary action, including and up to revocation of approval;

(c) Submit proof of nursing license renewal to their Regional Office MCM within 30 days of renewal in order to maintain approval for training. The proof of nursing license renewal may be submitted via email, by mail or other delivery, or in person;

(d) Inform the Regional Office within 30 days of occurrence when the Trainer's nursing license is revoked, or the Trainer otherwise loses the authority to practice nursing in the State of Florida. If the Trainer's nursing license is revoked or if the Trainer otherwise loses the authority to practice nursing in the State of Florida, the approved Trainer shall immediately be removed from any training he or she may be scheduled to provide;

(e) Notify the Regional Office within 30 days of any changes to the Trainer's contact information, including telephone number, email address, or mailing address;

(f) Provide a schedule of training courses to the local Regional Office MCMs and any other Regional Office MCMs in whose areas their course may be provided. This schedule must include all courses, including place, date, and time. If a course is scheduled or changed after the training dates have been provided, an email including the updated place, date, and time of the course to any Agency Office previously notified as soon as the course is scheduled is sufficient. If a Trainer works for an entity that employs Trainers for the purpose of providing this training, the entity may submit the course dates to the Regional Office for the Trainer. The Trainer is responsible for ensuring the course schedule is provided to the Regional Office;

(g) Make provision for Agency employees to observe their training upon request. This requirement includes Trainers providing web-based distance learning courses. The Agency shall randomly attend training to ensure that Trainers are meeting the requirements of the provided Agency curriculum. In addition, the Agency shall attend trainings if specific complaints have been received regarding the training to ensure that Trainers are meeting the requirements of the provided Agency curriculum.

(5) All Trainers must attend:

(a) An Initial Training providing an overview of Chapter 65G-7, F.A.C., provided by a Regional Office MCM before the application to provide medication administration training is approved. Locations and information on how

to attend this training can be obtained from the Regional Office. Contact information for each Regional Office may be found at www.apdcares.org/locations;

(b) An Annual Update Training course provided by a Regional Office MCM, which is due no later than June 30th of each year. Trainers approved within 6 months prior to June 30th may forego taking the annual update until the year following the year the Trainer is initially approved.

(6) The Agency shall assign a Trainer Number to each Approved Trainer that the Trainer must display on all materials used in connection with the courses taught. The individual who has obtained a Trainer Number is authorized to teach medication administration courses, prescribed enteral formula administration courses, or both throughout the State of Florida.

(7) Any Approved Trainer who has received a Trainer Number prior to January 1, 2019, may continue to provide training using the most current curriculum provided by the Agency. The Trainer shall not be required to attend the initial Chapter 65G-7, F.A.C. overview mentioned in paragraph (5)(a). The Trainer shall be required to attend the Annual Update Training described in paragraph (5)(b).

(8) The Agency may deny a Trainer's application for failure to comply with the application or eligibility requirements or for any of the following:

(a) Obtaining or attempting to obtain approval through fraud, deceit, false statements, or misrepresentation of material facts, whether such statements are made knowingly or negligently;

(b) Failing to provide complete and accurate information in the initial application for approval or in any request for information from the Agency during the application process;

(c) Failing to notify the Agency within 30 days of a change in the information required for approval, including contact and address information;

(d) Failing to provide information regarding the applicant's eligibility requirements or providing information indicating that the applicant does not meet eligibility requirements. Nursing licenses or authorizations in current but inactive status must be updated to active status before an approval may be provided.

(9) Failure to comply with Chapter 393.506, F.S., or any provision of Chapter 65G-7, F.A.C., shall subject the Trainer's approval to disciplinary action, including use of a corrective action plan, suspension, or revocation of the Trainer's approval. If revoked, the Trainer may not subsequently be approved to provide medication administration training or prescribed enteral formula administration training. The Agency may take action against a Trainer's approval if the Trainer fails to comply with Chapter 393.506, F.S., or Chapter 65G-7, F.A.C., including any of the following actions or omissions:

(a) Obtaining or attempting to obtain approval through fraud, deceit, false statements, or misrepresentation of material facts, whether such statements are made knowingly or negligently;

(b) Failing to provide complete and accurate information in the initial application for approval or in any notification of change in information, including contact information;

(c) Failing to notify the Agency within 30 days of a change in the information required for approval;

(d) Falsifying any records regarding the course;

(e) Failing to attend the required annual review through a Regional Office;

(f) Failing to maintain any required records regarding the course, including attendance, hours of training, date of course, name of course, and any other persons assisting the Trainer;

(g) Failing to maintain the course curriculum in the format and content provided by the Agency, with the exception that a Trainer may make minor alterations to the format when developing a web-based curriculum;

(h) Permitting Trainers who are not currently actively licensed or authorized to practice nursing by the State of Florida to provide training;

(i) Permitting individuals who have not been approved by the Agency to provide training;

(j) Failing to notify the Agency of individuals who are providing training that the Trainer knows are not approved by the Agency;

(k) Permitting individuals who have had their approval revoked to provide training;

(l) Providing training while not currently licensed or authorized to practice nursing by the State of Florida or providing training after the nursing license or authorization has been revoked or otherwise acted upon by the State of Florida;

(m) Failing to notify the local Regional Office in a region in which their course may be provided of all scheduled medication administration training courses, including place, date, and time;

(n) Sharing the course exam with persons not participating in the course in any form, including on the internet, or to a student prior to the student taking the exam;

(o) Providing training that the Agency determines does not meet the standards set forth pursuant to Rule 65G-7.0033, F.A.C.;

(p) Failing to provide simulation of all approved routes of medication administration during a medication administration course, unless the course is web-based and the simulation will be provided by the Validating Trainer under the supervision or direction of the Medication Administration Trainer.

(10) Training Certificates:

(a) Certificate Requirements for Trainer: Upon successful completion of the Initial Training and the Annual Update Training, the Agency shall issue the Trainer a completed Certificate of Completion. The Certification shall include the Trainer Number issued by the Agency. Trainers who have successfully completed the Initial Training or the Annual Update Training must maintain the original Certificate indicating successful completion of training and provide it to the Agency upon request.

(b) Certificate Requirements for MAP Applicants:

1. Upon successful completion of the Basic Medication Administration examination, the Trainer shall issue the examinee a completed Certificate of Completion for Basic Medication Administration Training, APD Form 65G-7.003 B, effective December 2018, adopted and incorporated herein, which may be obtained at _____. The Certificate shall contain the name of the Trainer, the Agency-assigned Trainer Number, date(s) of course administration, name of the examinee, and the signature of the Trainer. Upon successful completion of the validation by simulation and the course exam, the Trainer shall issue the examinee a partially completed Basic Medication Administration Validation Certificate, APD Form 65G-7.003 C, effective December 2018, adopted and incorporated herein, which may be obtained at _____. This Validation Certificate Form shall reflect the examinee's successful completion of the validation by simulation only and may not be issued prior to the successful completion of the exam.

2. Upon successful completion of the Prescribed Enteral Formula Medication Administration examination, the Trainers shall issue the examinee a completed Prescribed Enteral Formula Administration Certificate of Completion, APD Form 65G-7.003 C, effective December 2018, adopted and incorporated herein, which may be obtained at_____.

3. The Certificate(s) shall contain the following:

a. Trainer's name and Trainer Number;

b. Trainer's nursing license number and date of expiration

c. Date(s) of course;

d. Name of the student; and

e. Signature of Trainer.

4. Trainers shall not substitute a different form for the certificate forms listed in paragraph (10)(b).

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New 3-30-08, Amended _____.

65G-7.0033 Medication Administration Training Course Curriculum Requirements

(1) The Agency shall provide Medication Administration Training curriculum for the following courses:

(a) Basic Medication Administration course; and

(b) Prescribed Enteral Formula Administration course.

(2) Basic Medication Administration course curriculum requirements:

(a) Basic Medication Administration Courses shall:

1. Not be less than 6-hours in length;

2. Be limited to no more than 20 participants in each class; and

3. Utilize the test provided by the Agency.

(b) The Basic Medication Administration Course Curriculum, as provided by the Agency covers:

1. Safe storage, handling, and disposal of medications;

2. Understanding medication instructions;

3. Medical indications and purposes of commonly used medications;

4. Common side effects;

5. Symptoms of adverse reactions;

6. Proper administration of medications, including the following routes:

a. Oral;

b. Enteral;

c. Transdermal, including validation by simulation;

d. Ophthalmic;

e. Otic, including validation by simulation;

f. Rectal;

g. Inhaled; and

h. Topical, including validation by simulation.

7. Safety and sanitation while administering medication;

8. Medication administration documentation and recordkeeping;

9. Medication errors and error reporting;

10. Administrative documentation requirements including, but not limited to:

a. Authorizations; and

b. Consents.

11. Offsite medication procedures; and

12. Validation requirements.

(c) Web-Based course curriculum requirements: Basic Medication Administration Trainers may provide the Agency course via web-based distance learning if the course complies with the following curriculum requirements in addition to the requirements provided for in subparagraphs (2)(a) and (2)(b):

1. The course taught must:

a. Demonstrate:

i. Interactivity between the student and course provider within 24 hours;

ii. How interactivity promotes student involvement, and

iii. That the course measures learning and addresses comprehension of content at regular intervals;

b. Monitor student enrollment, participation, and course completion;

c. Provide for in-person simulation of routes as indicated in 65G-7.004, F.A.C.;

d. Be able to satisfactorily demonstrate that stated course hours (minimum of 6) are consistent with the actual course hours spent by the student to complete the course;

e. Assure qualified instructors will be available to answer questions and provide students with necessary support during the course; and

f. Require that the student complete a statement at the end of the course indicating that he or she personally completed each module/session of instruction.

2. A Trainer may make minor changes to the format of the Agency-provided curriculum when developing a web-based course, so long as the changes have been approved by the Agency;

3. To meet the requirements for competency in otic, transdermal, and topical medication simulation set forth in s. 393.506(2)(a), F.S., the Validation Trainer may supervise the simulation for the completion of the initial training under written instruction from the Medication Administration Course Trainer for web-based courses only.

(3) Prescribed Enteral Formula Administration Course Requirements:

(a) Prescribed Enteral Formula Administration Training shall:

1. Not be less than two hours in length and include didactic, demonstration, and return demonstration elements;

2. Be limited to no more than 6 participants for each class;

3. Utilize the test provided by the Agency.

(b) The Prescribed Enteral Formula Administration Course Curriculum, as provided by the Agency covers:

1. Safe storage, handling, and disposal of prescribed enteral formulas;

2. Understanding administration instructions;

3. Symptoms of adverse reactions;

4. Proper administration of prescribed enteral formulas; and

5. Validation requirements.

(c) The Prescribed Enteral Formula Administration Training may not be provided via web-based training.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New _____.

65G-7.0035 Validation Trainer Requirements

(1) Individuals must first receive Agency approval as a Validation Trainer before validating or offering to validate the competency of a MAP or MAP applicant to provide either:

(a) Basic medication administration assistance; or

(b) Prescribed enteral formula administration.

(2) Validation Trainer Eligibility: To be eligible for approval as a Validation Trainer, individuals must:

(a) Be licensed or authorized to practice:

1. Nursing in the State of Florida pursuant to Ch. 464, F.S.; or

2. Medicine as a physician in the State of Florida pursuant to Chs. 458 or 459, F.S.

(b) Apply on a "Validation Trainer Application Form," APD Form, APD Form 65G-7.0035 A, effective

December 2018, adopted and incorporated herein, which may be obtained at . The application must include the full address, email address, and telephone number of the applicant, and his or her name, professional license number, and expiration date. Applicants who wish to validate the competency of MAPs or MAP applicants to provide prescribed enteral formula administration must clearly indicate so on the Validation Trainer Application Form.

(c) Complete the validation requirements overview required in subsection (5). The application for training is not considered complete until the Validation Trainer Application Form indicates that the validation requirements overview has been successfully completed by the MCM providing the overview course.

(3) If the Agency denies an application to offer Validation training, it will identify the reasons for the denial in writing in a notice to the applicant. This notice shall include a statement of the applicant's due process rights to a hearing pursuant to ss. 120.569, and 120.57, F.S.

(4) All Validation Trainers must:

(a) Submit proof of professional license renewal to their Regional Office within 30 days of renewal to maintain approval for training. The proof of professional license renewal may be submitted via email, by mail or other delivery, or in person;

(b) Inform the Regional Office within 30 days of occurrence when a Validation Trainer's professional license is revoked or loses the authority to practice nursing or medicine in the State of Florida. If the Validation Trainer's professional license is revoked or the Trainer otherwise loses the authority to practice medicine or nursing in the State of Florida, the Validation Trainer shall immediately be removed from any training he or she may be scheduled to provide;

(c) Notify the Regional Office within 30 days of any changes to contact information, including telephone number, email address, or mailing address;

(d) Make provision for Agency MCMs or other Agency employees to observe the Validation Trainer's validation training upon request.

(5) All Validation Trainers must attend:

(a) An initial validation requirements overview provided by a Regional Office MCM before their application to provide validation is approved. Information on how to contact the Regional office can be found at http://apdcares.org/region/. Medication Administration Trainers who have been approved by the Agency to provide Basic Medication Administration Training may provide Validation Training without attending an initial validation requirements overview, but must comply with all other requirements of this Rule;

(b) A for-cause follow-up review of validation requirements upon notification by a Regional office MCM. A for-cause follow-up review may be requested by an MCM in the case of a complaint submitted to or discovered by the Agency, or a statutory or regulatory amendment.

(6) The Agency shall assign a Validation Trainer Number to each Approved Validation Trainer that the Validation Trainer must display on all materials used in connection with the validations completed. The individual who has obtained a Validation Trainer Number is authorized to validate medication administration, prescribed enteral formula administration, or both throughout the State of Florida.

(7) The Agency may deny a Validation Trainer's application for failure to comply with application or qualification requirements or for any of the following:

(a) Obtaining or attempting to obtain approval through fraud, deceit, false statements, or misrepresentation of material facts, whether such statements are made knowingly or negligently;

(b) Failing to provide complete and accurate information in the initial application for approval or in any request for information from the Agency during the application process;

(c) Failing to notify the Agency within 30 days of a change in the information required for provider approval, including contact and address information;

(d) Failing to provide information regarding the applicant's eligibility requirements or providing information indicating that the applicant does not meet eligibility requirements. Professional licenses in current but inactive status must be updated to active status before an approval may be provided.

(8) Failure to comply with Section 393.506, F.S., or any provision of Chapter 65G-7, F.A.C., shall subject the Validation Trainer's approval to disciplinary action, including use of a corrective action plan, suspension, or revocation of the Validation Trainer's approval. If revoked, the Validation Trainer may not subsequently be approved to provide validation training. The Agency may take action against a Validation Trainer's approval for any of the following actions or omissions:

(a) Obtaining or attempting to obtain approval through fraud, deceit, false statements, or misrepresentation of material facts, whether such statements are made knowingly or negligently;

(b) Failing to provide complete and accurate information in the initial application for approval or in any

notification of change in information, including contact information and address;

(c) Failing to notify the Agency within 30 days of a change in the information required for approval;

(d) Falsifying any records;

(e) Failing to attend any required overview or review through a Regional Office;

(f) Failing to maintain any required records regarding the validation of competency;

(g) Permitting Validation Trainers who are not currently actively licensed or authorized to practice nursing or medicine by the State of Florida to validate competency for MAPs or MAP applicants;

(h) Permitting individuals who have not been approved by the Agency to validate competency for MAPs or MAP applicants;

(i) Permitting individuals to provide validation training after their approval has been revoked;

(j) Providing validation while not currently licensed or authorized to practice nursing or medicine by the State of Florida or providing validation after the professional license or authorization has been revoked or otherwise acted upon by the State of Florida.

(9) Training Certifications:

(a) Certificate Requirements for Validation Trainers: Upon successful completion of the initial overview, the Agency shall issue the Validation Trainer a completed Certificate of Completion. Validation Trainers who have successfully completed the initial overview must maintain the original Certificate indicating successful completion and provide it to the Agency upon request.

(b) Certificate Requirements for MAP Applicants:

1. Upon successful completion of the on-site validation, the Validation Trainers shall complete the Basic Medication Administration Validation Certificate, APD Form 65G-7.003 B, effective December 2018, adopted and incorporated in Rule 65G-7.003, F.A.C.

2. Upon successful completion of the on-site validation completed during the Prescribed Enteral Formula Administration validation, the Validation Trainers shall issue the examinee a completed Prescribed Enteral Formula Administration Validation Certificate, APD Form 65G-7.0035 B, effective December 2018, adopted and incorporated herein, which may be obtained at _____.

3. The Certificate(s) shall contain the following:

a. Medication Administration Trainer's name and Trainer Number;

b. Validation Trainer's name, Trainer Number, and signature;

c. Validation Trainer's nursing or physician licensing number and date of expiration;

d. Date(s) of validation(s);

e. Name of the student; and

f. All routes validated.

4. Validation Trainers shall not substitute a different form for the certificate forms listed in paragraph (8)(b).

5. If the Validation Trainer provides subsequent validations for a MAP who has previously been validated on other routes, the Validation Trainer shall document the subsequent successful validations on the MAP's original Validation Certificate, in the space provided.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New _____.

65G-7.004 Medication Assistance Provider Training and Validation Requirements.

Substantial rewording of Rule 65G-7.004, F.A.C. follows. See Florida Administrative Code for current text.

(1)(a) Unless otherwise authorized by law in the State of Florida, an individual shall not administer medication or supervise the self-administration of medication to Agency clients unless he or she has successfully completed an Agency-provided medication administration training course and obtained a current validation for the route by which the medication is administered. These requirements are necessary in order for an individual to become or remain a MAP.

(b) Unless otherwise authorized by law in the State of Florida, individuals who are not currently recognized by the Agency as a MAP permitted to administer prescribed enteral formulas or supervise the self-administration of prescribed enteral formulas to Agency clients are prohibited from doing so. MAPs or other unlicensed direct service providers administering prescribed enteral formulas who have previous training in the administration of prescribed enteral formula at the time this rule becomes effective shall have 180 days from the effective date of the rule to obtain the training and validation required to continue administering prescribed enteral formulas to clients, during which time they may continue to administer prescribed enteral formulas.

(2) An individual who wishes to obtain authorization as a MAP to administer medication or supervise the self-administration of medication to Agency clients must:

(a) Complete the Agency-approved Basic Medication Administration Training, including validation by

simulation for the otic, transdermal, and topical routes as part of the training course. If the individual is not given the opportunity by the Trainer to obtain the required validation by simulation, he or she may obtain on-site validation from the Validation Trainer by either simulation or with an actual client using the client's medication. A list of available Trainers may be obtained from the Regional Office MCM;

(b) Complete a two-part, Agency-provided exam within three calendar days of completing the Medication Administration Training, achieving a score of at least 85% on the Course Content section of the exam and 100% on the MAR section of the exam. If the individual fails to obtain a passing score, he or she may be permitted by the Trainer to retake the examination once to attempt to obtain a passing score. If the individual fails to obtain a passing score the second time, he or she must retake the Medication Administration Training prior to being permitted to attempt to obtain a passing score. If the individual fails to take the exam within three calendar days, he or she must take the course again in order to sit for the exam; and

(c) Obtain validation pursuant to subsections (4) and (5), prior to being permitted to assist in medication administration.

(3) A MAP or MAP applicant who wishes to administer or supervise self-administration of prescribed enteral formulas must:

(a) Be authorized as a MAP for the administration or supervision of self-administration of medication, pursuant to subsection (2);

(b) Complete the Agency-provided Prescribed Enteral Formula Administration Training. A list of available Trainers may be obtained from the Regional Office MCM;

(c) Complete a two-part, Agency-provided exam following the Prescribed Enteral Formula Administration training, achieving a score of at least 85% on the course content section of the exam and 100% on the simulated return demonstration. If the individual fails to obtain a passing score, he or she may be permitted by the Trainer to retake the examination once to attempt to obtain a passing score. If the individual fails to obtain a passing score the second time, he or she must retake the Prescribed Enteral Formula Administration Training prior to being permitted to attempt to obtain a passing score;

(d) Obtain validation focused on prescribed enteral formula administration pursuant to subsections (4) and (5), in addition to the Agency-provided medication administration training course and validation; and

(e) MAPs or other unlicensed direct service providers administering prescribed enteral formulas who have previous training in the administration of prescribed enteral formula at the time this rule becomes effective shall have 180 days from the effective date of the rule to obtain the training and validation required to continue administering prescribed enteral formulas to clients, during which time they may continue to administer prescribed enteral formulas.

(4) Validation Requirements:

(a) Any MAP who has already been successfully validated for otic, transdermal, or topical routes on the effective date of these rules is not required to become revalidated for those three routes, unless the validation for the MAP's primary route lapses. Any MAP who holds a current validation for administration routes other than otic, transdermal, or topical routes, may obtain validation for these three routes via on-site validation from the Validation Trainer by either simulation or with an actual client using the client's medication.

(b) MAP applicants must be assessed and validated as competent to administer medication or to supervise the self-administration of medication by an approved Validation Trainer after obtaining a passing score on the training examination. A list of available Validation Trainers may be obtained from the Regional Office MCM.

(c) MAP applicants who wish to administer prescribed enteral formula medication or to supervise the self-administration of prescribed enteral formula medication shall obtain a separate validation specific to prescribed enteral formula administration in addition to the validation required for Basic Medication Administration pursuant to paragraph (4)(a). A list of available Validation Trainers may be obtained from the Regional Office MCM.

(d) The MAP must achieve a score of 100% proficiency in the validation prior to being approved to provide medication administration assistance or prescribed enteral formula administration.

(e) MAP applicants must successfully complete their initial validation for their primary non-simulated medication administration routes within 180 days of completion of the Medication Administration Training, including Basic Medication Administration Training and Prescribed Enteral Formula Training.

(5) Successful assessment and validation require that the applicant demonstrate his or her capability to correctly administer medication and supervise the self-administration of medications in a safe and sanitary manner in an on-site client-setting using the client's prescribed medications, except for the simulated routes, which include otic, transdermal, and topical administration routes.

(a) Validation for Basic Medication Administration includes a demonstration of the following proficiencies:

1. The ability to comprehend and follow medication instructions on a prescription label, physician's order,

and properly complete a MAR form;

2. The ability to administer medication by oral, transdermal, ophthalmic, otic, rectal, enteral, inhaled, or topical administration routes;

3. The ability to obtain pertinent medication information, including the purpose of the medication, its common side effects, and symptoms of adverse reactions to the medication, either from the package insert that comes from the pharmacy, or other professionally recognized medication resource, and to maintain~~ing~~ this information for easy access and future reference;

4. The ability to write legibly, convey accurate information, and communicate with Agency staff and other health care providers through the applicant's writings in a manner that ensures the health, safety, and well-being of the clients;

5. The ability to comply with medication administration record-keeping requirements;

6. The ability to communicate in a manner that permits health care providers and emergency responders to adequately and quickly respond to emergencies,

7. Knowledge of the proper storage and handling of medications;

8. Knowledge of proper disposal of expired or unused medications;

9. Knowledge of special requirements relating to storage and disposal of controlled medications;

10. Knowledge of requirements for obtaining authorizations for medication administration assistance, authorization for self-administration of medication without supervision, and informed consent for medication administration assistance; and

11. Adequate training on the correct positioning and use of any adaptive equipment or use of special techniques required for the proper administration of medication.

(b) Validation for Prescribed Enteral Formula Administration includes a demonstration of the following proficiencies:

1. The ability to comprehend and follow prescribed enteral formula instructions on a physician's order and properly complete a MAR form;

2. The ability to administer prescribed enteral formula by the enteral administration route;

3. The ability to write legibly, convey accurate information, and comply with medication administration record-keeping requirements;

4. The ability to communicate in a manner that permits health care providers and emergency responders to adequately and quickly respond to emergencies;

5. Knowledge of the proper storage and handling of prescribed enteral formulas;

6. Adequate training on the correct positioning and use of any adaptive equipment or use of special techniques required for the proper administration of prescribed enteral formulas.

(c) Subsequent validations for additional routes may be completed by the MAP following his or her initial validation(s). If the MAP obtains a subsequent validation, he or she must ensure that the Validation Trainer documents the subsequent validation(s) on the MAP's original Validation Certificate, in the space provided.

(6) To maintain his or her ability to administer or supervise the self-administration of medication, a MAP must attend an Update Training Course and be revalidated annually, subject to the following qualifications:

(a) Update Training Course:

1. MAPs that administer or supervise self-administration of medications must attend an annual update training course in Basic Medication Administration provided by the Agency, prior to the expiration of their current validation. Upon successful completion of the Basic Medication Administration annual update, the MAP shall receive a Certificate of Completion for Basic Medication Administration Annual Update, APD Form 65G-7.004 A, effective December 2018, adopted and incorporated herein, which may be obtained at .

2. MAPs that administer or supervise self-administration of prescribed enteral formulas must attend an annual update training course in Prescribed Enteral Formula Administration provided by the Agency prior to their re-validation. This course is required in addition to the Basic Medication Administration annual update training course. Upon successful completion of the Prescribed Enteral Formula Administration annual update, the MAP shall receive a Certificate of Completion for Prescribed Enteral Formula Administration Annual Update, APD Form 65G-7.004 B, effective December 2018, adopted and incorporated herein, which may be obtained at .

3. MAPs who are required to re-validate within the first 60 days following the effective date of this rule are permitted to complete the re-validation without completing the Update Training Course prior to re-validation.

(b) Re-Validation Requirements:

1. Effective and Expiration Dates:

a. Primary routes

i. The effective date of a MAP's primary route validation is the date that the MAP successfully completed the initial validation for that route.

ii. The expiration date for his or her primary route validation is based on the date of his or her initial validation received for a primary route of medication administration. The validation for the primary route of medication administration expires annually on the anniversary date of his or her initial effective date.

b. All other routes, except otic, transdermal, and topical routes

i. The effective date of a MAP's non-primary route(s), except otic, transdermal, and topical routes, is the date of the most recent validation, regardless of when the MAP successfully completed the initial validation for that route.

ii. The expiration date for a MAP's non-primary route(s), except otic, transdermal, and topical routes, is one year from the date of the most recent validation.

c. Otic, Transdermal, and Topical Routes

i. The effective date of a MAP's otic, transdermal, and topical routes is the date that the MAP successfully completed the initial validation by simulation or with an actual client.

ii. Otic, transdermal, and topical routes do not expire.

2.a. If the MAP's validation for the all administration routes other than the primary route expire, the MAP is not required to complete the required courses provided for in subsection (2). In this case, the MAP may continue to administer medications or supervise the administration of medications for routes for which the MAP maintains a current validation.

b. If the MAP's validation for the primary routes expires, the MAP must complete the required courses provided for in subsection (2) and be revalidated for the primary route and all other routes, regardless of whether the non-primary route validations have expired, prior to being permitted to continue administering medications or supervising administration of medications. '=

3. MAPs shall, at least annually, through demonstration, be assessed and revalidated as competent to:

a. Administer medication or supervise the self-administration of medication;

b. Administer prescribed enteral formulas, if previously validated for prescribed enteral formula administration. This revalidation is in addition to the required revalidation for Basic Medication Administration.

4. A MAP must be re-validated annually within the 60 days preceding the expiration of his or her current validation.

5. MAPs who fail to acquire revalidation for the primary route of administration before the expiration of their validation for the primary route must retake the Basic Medication Administration Course and obtain current validation for their primary route within 180 days of completion of the Basic Medication Administration Course, prior to continuing to administer or supervise self-administration of medication;

6. MAPs who fail to acquire revalidation for prescribed enteral formula administration before the expiration of their validation must retake the prescribed enteral formula administration course and successfully revalidate within 180 days of completion of the Prescribed Enteral Formula Administration Course, prior to continuing to administer prescribed enteral formulas.

7. MAPs must successfully complete their re-validation for their primary non-simulated medication administration routes within 60 days of completion of the Update Training Course, including the Update for Basic Medication Administration and Prescribed Enteral Formula.

(7) A MAP may only assist in the administration of medication through an administration route for which the MAP holds a current, active validation.

(a) When a client is prescribed a medication requiring an administration route for which the MAP has not yet been validated or for which his or her validation has expired, the MAP must obtain a validation for that specific administration route before administering the medication to the client via that route.

(b) Emergency Validation

1. When a client is prescribed a medication requiring an administration route for which the MAP has not been validated, the MAP may obtain an emergency validation for only that specific administration route and only that specific client from any individual licensed or authorized to practice nursing in the State of Florida pursuant to Ch. 464, F.S., or licensed to practice medicine as a physician in the State of Florida pursuant to Chs. 458 or 459, F.S., if:

a. The prescribed medication is necessary to ensure the health and safety of the client;

b. The MAP or the MAP's supervisor attempts and is unable to contact a MAP who is able to administer the medication at the appropriate dosage times and who is validated for the specific administrative route;

c. The MAP obtains a validation in that administration route from an Agency-approved Validation Trainer as soon as possible within 30 days of the date the emergency validation was signed by the medical professional;

d. The nurse or physician documents the validation either utilizing Emergency Validation Form, Form 65G-

7.004 C, effective December 2018, adopted and incorporated herein, which may be obtained at _____, or utilizing a document with the nurse or physician's letterhead on it indicating:

i. That the nurse or physician validated the MAP;

ii. The date of validation;

iii. The route of administration validated;

iv. The length of time the validation is necessary in order to ensure the client obtains the medication as prescribed and to provide time for the MAP to either obtain a validation from an Agency-approved Validation Trainer or locate a MAP who is validated in the appropriate administration route to provide the medication. Under no circumstances shall an Emergency Validation last longer than 30 days from the date of validation.

2. If the doctor or nurse utilizes a form with the nurse or physician's letterhead on it rather than the Emergency Validation Form, the document utilized to record the Emergency Validation must be attached to the Emergency Validation Form. Completed Emergency Validation forms must be maintained by the MAP and his or her employer and be available to the Agency for review upon request.

3. An Emergency Validation can only be obtained for the following routes:

a. Oral;

b. Enteral, except for prescribed enteral formulas;

c. Transdermal;

d. Ophthalmic;

e. Otic;

f. Rectal;

g. Inhaled; and

h. Topical.

(c) If the client is prescribed an enteral formula, the MAP must obtain the required training and validation specific to prescribed enteral formula administration before administering prescribed enteral formula.

(8) Once trained and validated on one nebulizer or intermittent positive pressure breathing machine, a MAP is not required to train on subsequent machines of the same type to qualify as validated for nebulizers or intermittent positive pressure breathing machines.

(9) Trained and validated MAPs must maintain the original certificates indicating successful completion of training and validation. Employers of MAPs must maintain a copy of the training certificate and proof of current validation of each employee providing medication administration assistance at the site where the medication administration assistance is being provided.

(10) Any employer or contractor who offers MAP services is responsible for maintaining a record of the MAP's training certification and annual validation and for making such records available for Agency review upon request.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New 3-30-08, Amended _____.

65G-7.005 Medication Administration Procedures.

Substantial rewording of Rule 65G-7.005, F.A.C. follows. See Florida Administrative Code for current text.

(1) Upon receipt of the Basic Medication Administration training certification and validation certification, MAPs are authorized to administer medications or to supervise the self-administration of medications via the following medication routes for which the MAP has been validated:

(a) Oral;

(b) Enteral, with the exception of prescribed enteral formulas;

(c) Transdermal;

(d) Otic;

(e) Ophthalmic;

(f) Rectal;

(g) Inhaled; and

(h) Topical.

(2) MAPs that have not completed the Prescribed Enteral Formula Administration Training and received the corresponding training certification and validation certification shall not administer Prescribed Enteral Formula.

(3) Licensed health care practitioners shall administer or supervise the self-administration of medications within their scope of practice.

(4) MAPs and licensed health care practitioners shall:

(a) Only provide administration of medication or supervision with self-administration of medications as prescribed or ordered by the client's health care practitioner and which are properly labeled and dispensed in

accordance with Chapters 465 and 499, F.S. If multiple clients are prescribed identical OTC medications, the facilities may utilize a single stock container to provide the medications to multiple clients;

(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 or supervising the self-administration of medication, become familiar with the client's medical history and medication background and locate the name and contact numbers of the client's prescribing practitioner for consultation regarding the prescribed medications;

(e) Perform appropriate hand sanitation measures before administering medication or supervising the self-administration of medication, with repeated sanitization as needed during medication administration;

(f) Assist only one client at a time with medication administration in a quiet location free from distraction;

(g) Only prepare medications for one client, at the time the medication is given;

(h) Following the administration of medication or supervision of self-administration of medication, return each client's medication to its portable or permanent medication storage location before assisting another client;

(i) Call the client's primary care provider within 24 hours to reconcile the client's medications with those ordered upon the client's discharge from any inpatient, emergency, or urgent care facility. This call 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 MAP must also ask for faxed or electronically supplied instructions;

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

(k) 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;

(l) 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;

(m) Verify that the correct medication is administered to the correct client, at the correct time, with the correct dosage, by the correct route, and for the correct reason, as prescribed by the health care practitioner;

(n) Observe complete ingestion of oral medication before leaving the client and before recording or documenting the administration of the medication on the MAR;

(o) Record the date, time, dosage, and name of each regularly scheduled medication or PRN medication on the MAR immediately following administration or supervision of self-administration and sign or initial the entries. For PRN medications, the MAP or licensed health care practitioner must also enter the reason for the medication on the back of the MAR (if using the APD MAR form adopted in Rule 65G-7.008, F.A.C.) or in a place provided for such an entry on a pharmacy-provided or electronic MAR;

(p) Following the first three doses of a new medication, including PRN medications, observe the client 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 MAR 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;

(q) Enter the response to the medication on the back of the MAR for PRN medications (state whether the medication alleviated the symptom for which it was given, i.e. "headache is better") or in the place provided for such an entry on a pharmacy provided or electronic MAR. This entry should indicate date and time of entry, and be initialed or signed by the MAP or licensed health care practitioner;

(r) Ensure that the prescription for a medication is promptly refilled so that a client does not miss a prescribed dosage of medication. If the MAP or licensed health care practitioner is not responsible for routine refills of a medication, he or she shall notify the individual responsible for refilling the client's prescriptions that the client needs a medication refill and document this notification;

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

1. The client'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 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.

(5) Licensed health care practitioners and MAPs who are validated to administer or supervise self-administration of whole (not crushed) oral medication may give the medication in any substance that facilitates swallowing and is tolerated by the client.

(6) A MAP who has been validated to administer or supervise self-administration of prescribed enteral formulas may administer prescribed enteral formulas through gastrostomy tubes, including percutaneous endoscopic gastrostomy ("PEG"), button-style gastrostomy, and jejunal ("JT").

(7) In the administration of medications, a MAP shall not:

(a) Assist with the administration or supervise the self-administration of any OTC medication or medication samples without a written order by the client's physician, PA, or APRN;

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

(c) Administer medications or supervise the self-administration of medications, including PRN and OTC medications, unless a health care practitioner has provided directions for the medication;

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

(e) Administer medications or supervise the self-administration of medication route for which the MAP has not been validated, with the exception of a rectal gel prescribed for seizures and administered in an emergency situation;

(f) Administer medications or supervise the self-administration of medication 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. However, a MAP may test blood sugar if the test is not associated with insulin administration;

(g) Administer or supervise self-administration of medications that are inserted vaginally, or administered via a tracheostomy;

(h) Perform irrigation of partial or full thickness wounds (such as vascular ulcers, diabetic ulcers, pressure ulcers, surgical wounds) or apply agents used in the debridement of necrotic tissues in wounds of any type;

(i) Supervise, monitor, prompt, assist or cue a client to correctly fill a pill organizer (also known as a "pill minder" and "pill box"); and

(j) Assist a client with 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 MAP.

(k) Administer medications or supervise the self-administration of medications from a pill organizer.

(8) A MAP who has been validated to administer or supervise self-administration of 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 client, 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.

(9) MAPs shall comply with s. 393.506, F.S., and this Chapter.

(10) MAPs shall not:

(a) Obtain or attempt to obtain a passing grade on either the training course exam or validation through fraud, deceit, false statements, or misrepresentation of material facts, whether such statements are made knowingly or negligently;

(b) Falsify any records regarding medication administration;

(c) Continue to provide services as a MAP if he or she fails to successfully pass required re-validation on his or her primary route(s);

(d) 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 MAP while not currently authorized to do so by the State of Florida;

(e) Provide services as a MAP after the Agency has determined the MAP shall not continue to provide medication administration assistance.

(11) If a MAP violates any provision of s. 393.506, F.S., or this Chapter, the Agency may:

(a) Prohibit the MAP from providing medication administration services to clients of the Agency;

(b) Request the MAP:

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.

(12) If a MAP or licensed health care practitioner violates any provision of s. 393.506, F.S., or this Chapter within an Agency-licensed residential facility, the Agency may take such actions as set forth in Chapter 65G-2, F.A.C. against the residential facility where the MAP or licensed health care practitioner is providing services as is necessary to ensure the health, safety, and welfare of the Agency's clients and third parties.

(1213) 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 s. 381.00315, F.S., a state of emergency which has been declared pursuant to s. 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.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New 3-30-08, Amended _____.

65G-7.006 Medication Errors.

Substantial rewording of Rule 65G-7.006, F.A.C. follows. See Florida Administrative Code for current text.

(1) A "medication error" is any of the following:

(a) Administration or supervision of self-administration of a wrong medication, including:

1. Administration or supervision of self-administration of medication for any symptom, illness, or reason other than the one for which the medication was prescribed;

2. Administration or supervision of self-administration of medication for which there is no current prescriber order;

(b) Administration or supervision of self-administration of a wrong dose, including:

1. Administration or supervision of self-administration of an incorrect dose of medication;

2. Administration or supervision of self-administration of more than one dose of the same medication in a scheduled time period;

(c) Administration or supervision of self-administration of a medication to the wrong client, which means the administration or supervision of self-administration of medication to a client that is prescribed or ordered for someone else;

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

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

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

(g) Administration or supervision of 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 supervise the self-administration of a medication, for any of the following reasons:

1. Client refused the medication;

2. MAP or licensed health care practitioner did not administer or supervise 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 not given;

(j) Administration or the supervision of self-administration of medication by a MAP not validated as required by Rule 65G-7.004, F.A.C.

(2) Immediately following an error as listed in subsection (1), the MAP, licensed health care practitioner, or facility administrator must take the following steps:

(a) Notify supervisory personnel;

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

(c) For all errors listed in subsection (1), with the exception of paragraphs e, f, g, h, and j, notify the client'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 client's home, facility, or pharmacy, and document the client's health care practitioner's response or lack of response; and

(d) Fully document all observations and contacts made regarding a medication error in a "Medication Error Report," APD Form 65G-7.006 A, effective December 2018, incorporated herein by reference, which may be obtained at _____. The MAP or licensed health care practitioner shall place a copy of the Report in the client's file. It is permissible to use an alternate Medication Error Report form generated by an electronic system, provided that the alternate electronic form collects all the information required and collected on the Agency form.

(3) If a medication error occurs in a facility, the MAP or licensed health care practitioner must:

(a) Submit the Medication Error Report to the facility administrator and to the Regional Office within 24 hours of discovering the error; and

(b) Maintain a copy of the report in the client's record and also with the MAR for review.

(4) If a medication error occurs in a client's home, the MAP or licensed health care practitioner who committed the error must:

(a) Submit a Medication Error Report to the Regional Office within 24 hours of discovering the error;

(b) Maintain a copy of the report in the client's record and with the MAR for review.

(5) If a discrepancy in the accounting of a controlled substance occurs following a medication count, the MAP or licensed health care practitioner must report the discrepancy within 24 hours following discovery of the error to:

(a) The Regional Office; and

(b) The MAP's or licensed health care practitioner's supervisor, if applicable.

(6) If an Agency MCM determines that the medication error justifies corrective action, including, but not limited to additional training, the Regional Office will notify the MAP, licensed health care practitioner, or his or her supervisor in writing of the necessary corrective action plan, including a specific and reasonable timeframe for completion of the corrective action plan. If the MAP or licensed health care practitioner fails to comply with the corrective action plan, the Agency may take action against:

(a) The MAP's validation, including and up to prohibiting the MAP from providing medication administration services; or

(b) The provider's residential facility license, and

(c) The provider's Medicaid Waiver Services Agreement.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New 3-30-08, Amended _____.

65G-7.007 Storage Requirements.

(1) ~~Medication assistance providers~~ MAPs and licensed health care practitioners must observe the following medication storage requirements:

(a) Store each medication at the temperature appropriate for that medication, including refrigeration if required;

(b) Destroy any prescription medication that has expired per the pharmacist's label or the label provided by the manufacturer on OTC medications, or is no longer prescribed and document the medication disposal on a "Medication Destruction Record," APD Form 65G-7.007 A, ~~65G7-06 (3/30/08)~~ effective December 2018, ~~(3/30/08)~~ incorporated herein by reference, which ~~A copy of the form~~ may be obtained at . The MAP or licensed health care practitioner must sign ~~by writing or calling the Agency for Persons with Disabilities, at 4030 Esplanade Way, Suite 380, Tallahassee, FL 32399-0950; main phone number (850)488-4257. Sign~~ the Record before a third-party witness;

(c) Maintain medication samples in their original containers labeled by the dispensing health care practitioner with the client's name, the practitioner's name, and the directions for administering the medication. The ~~medication assistance provider~~ MAP or licensed health care practitioner must initial and add to the label the date the medication is opened;

(d) Maintain OTC medications in their original stock containers. OTC medications in original stock containers are not required to have individual client's names provided on the container;

(e) Store the medications centrally in a locked container in a secured enclosure if the client requiring the medication assistance is residing or receiving services in a facility setting;

(f) Organize and maintain stored medications in a manner that ensures their safe retrieval and minimizes medication errors;

(g) 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;

(h) Return each medication to its portable or permanent storage unit immediately following medication administration assistance.

(2) A residential facility or supported living client who does not require medication administration assistance or supervised self-administration may store his or her medication in a secure, locked place within his or her room. However, a client's medications must be centrally stored and retrieved by the ~~medication assistance provider~~ MAP or licensed health care practitioner if:

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

(b) The client fails to securely maintain the medication in a locked place;

(c) The ~~medication assistance provider~~ MAP, licensed health care practitioner, facility administrator, or Agency determines that, based on the home's physical arrangements or the habits of other residents, the client's personal possession of medication poses a threat to the safety of others, or

(d) The client or the client's authorized representative requests in writing that the client's medication be centrally stored.

~~(3) If the client requiring medication assistance is residing or receiving services in a facility setting, the medications must be centrally stored in a locked container in a secured enclosure.~~

(3)~~(4)~~ Either a licensed health care practitioner or ~~medication assistance provider~~ MAP must securely maintain keys to the locked containers and storage enclosures containing ~~controlled~~ medications~~,~~ and provide written procedural provisions for accessibility to medications in cases of emergency.

~~(5) Stored medications must be organized and maintained in a manner that ensures their safe retrieval and minimizes medication errors.~~

~~(6) Medications requiring refrigeration must be stored in a refrigerator. The medications shall be stored in their original containers either within a locked storage container clearly labeled as containing medications or in a refrigerator located in a locked, secured medication storage room.~~

~~(7) Each medication must be returned to its portable or permanent storage unit immediately following medication administration assistance.~~

(4) If multiple clients are prescribed identical OTC medications, the facility may utilize a single stock container to provide the medications to multiple clients;

(5)~~(8)~~ Controlled medication storage requires the following additional safeguards:

(a) The controlled medications must be stored separately from other prescription and OTC medications in a locked container within a locked enclosure.

(b) For facilities operating in shifts, a ~~medication assistance provider~~ MAP or licensed health care practitioner must perform controlled medication counts for each incoming and outgoing personnel shift, as follows:

1. The medication count must be performed by a ~~medication assistance provider~~ MAP or licensed health care practitioner and witnessed by another ~~medication assistance provider~~ MAP or licensed health care practitioner,

2. Both providers must verify count accuracy by documenting the amount of medication present and comparing

that amount to both the previous count and number of doses administered between counts,

3. The providers must record the medication count on a "Controlled Medication Form~~,~~." The Agency provides two versions of the form, one with dates provided, and one where the providers may fill in the dates manually. The dated version of the Controlled Medication form, APD Form 65G-7.007 B1 ~~APD Form 65G7-07~~, effective December 2018, ~~(3/30/08)~~ incorporated herein~~. by reference. A copy of the form~~ may be obtained at _____. The undated version of the Controlled Medication form, APD Form 65G-7.007 B2, effective December 2018, incorporated herein. may be obtained at _____. ~~by writing or calling the Agency for Persons with Disabilities, at 4030 Esplanade Way, Suite 380, Tallahassee, FL 32399-0950; main phone number (850)488-4257.~~ The MAP or licensed health care practitioner must sign and date the form ~~must be signed and dated by the providers~~ verifying the count; and

4. Immediately document and report any medication discrepancies to the facility supervisor.

(c) For facilities with only one ~~medication assistance provider~~ MAP or licensed health care practitioner per shift, the ~~medication assistance provider~~ MAP or licensed health care practitioner must conduct, document, and sign a daily medication count on the Controlled Medication Form; and

(d) For facilities with no shifts, the ~~medication assistance provider~~ MAP or licensed health care practitioner who is responsible for medication administration must conduct, document, and sign a controlled medication count at least once each day on the Controlled Medication Form, using the same counting and documentation technique described in subparagraph (4)(c) ~~above~~.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New 3-30-08, Amended _____.

65G-7.008 Documentation and Record Keeping.

(1) The MAP and licensed health care practitioner shall maintain a~~A~~n up-to-date MAR ~~shall be maintained~~ for each client requiring assistance with medication administration, except when the client is off-site. The ~~medication assistance provider~~ MAP and licensed health care practitioner must document the administration of medication or supervision of self-administered medication immediately on the MAR~~,~~. The MAP and licensed health care practitioner may utilize the Agency's Medication Administration Record Form, APD Form 65G-7.008 A ~~using either APD Form 65G7-00~~, effective December 2018 ~~(3/30/08)~~, adopted and incorporated by reference herein, which may be obtained at _____, ~~at subsection 65G-7.001(12), F.A.C.,~~ or on an alternative MAR form that includes the following information:

(a) The client's name;

(b) Any client food or medication allergies;

(c) The name of each medication prescribed for the client;

(d) The medication strength (e.g. ~~i.e.~~, 5mg/ tsp);

(e) The prescribing health care practitioner for each medication;

(f) The date that the medication was ordered and any date the medication was changed (including D/C date);

(g) Prescribed dosage for each medication;

(h) Scheduled time of administration for each medication;

(i) Prescribed route of administration for each medication;

(j) Prescribed instructions for crushing, mixing or diluting of specific medications, if applicable;

(k) The dates each medication was administered;

(l) The initials and signature of the ~~medication assistance provider~~ MAP or licensed health care practitioner who administered or supervised the self-administration of medications ~~assisted with medication administration~~;

(m) A record of any medication dosage refused or missed, documented by the ~~medication assistance provider~~ MAP or licensed health care practitioner responsible for administering the scheduled dosage, by drawing a circle around the appropriate space on the MAR form and initialing it; and

(n) The reasons for not administering a medication, annotated and initialed by the ~~medication assistance provider~~ MAP or licensed health care practitioner in the comments section on the MAR form using the following system, or a comparable numbering and coding system containing the same information: 1 – home, 2 – work, 3 – ER/hospital, 4 – refused, 5 – medication not available (explain on back of MAR form), 6 – held by MD (explain on back of MAR), 7 – other (explain on back of MAR).

(2) If necessary, it is acceptable for more than one 'back' of the MAR to be attached to any MAR to allow for more entries and explanations.

(3) It is permissible for MAPs or licensed health care practitioners to use a MAR provided by a pharmacy or from an electronic system if that MAR collects and records the same information as the Agency MAR.

(4)~~(2)~~ Each client's record must contain the following medication documentation, recorded in a manner that

effectively communicates to the Agency Staff and other health care providers, and which must be readily available to the ~~medication assistance provider~~ MAP or licensed health care practitioner and for Agency review upon request:

(a) Completed MAR forms;

(b) 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;

(c) A record of drug counts for each controlled medication;

(d) Written determination by the client's physician that the client requires assistance with the administration of his or her medications, utilizing Authorization for Medication Administration, as adopted in Rule 65G-7.002, F.A.C.; and

(e) The current Informed Consent form adopted in Rule 65G-7.002, F.A.C., permitting a ~~medication assistance provider~~ MAP to assist with the administration of medication.

(5)~~(3)~~ The ~~validated~~ ~~medication assistance provider~~ MAP or his or her ~~the provider's~~ employer must maintain documentation that the ~~medication assistance provider~~ MAP has completed an approved medication administration course and is currently validated as competent to assist with the administration of medication.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New 3-30-08, Amended _____.

65G-7.009 Off-site Medication Administration.

(1) If a client who has his or her medications administered to him or her or who is supervised with self-administration of medication will be away from a licensed residential facility or supported living home and requires assistance with medications during that time ~~administration of medication~~ by persons other than the ~~medication assistance provider~~ MAP or licensed health care practitioner, the ~~medication assistance provider~~ MAP or licensed health care practitioner must comply with the following requirements to assure that the client has appropriate medications during his or her absence:

(a) Provide an adequate amount of medication for administration of all dosages the client will require ~~requires~~ while away;

(b) Perform a count of the medication amounts provided to the client for administration during the absence and a second count of the medication amounts received upon the client's return;

(c) Record both medication counts in an "Off-Site Medication Form," APD Form 65G-7.009 A ~~APD Form 65G7-08~~, effective December 2018, ~~(3/30/08),~~ incorporated herein by reference, which may be obtained at http://apd.myflorida.com/medication/forms. The MAP or licensed health care practitioner shall not use an alternative Off-Site Medication Form. The MAP or licensed health care practitioner must retain a copy of the original form and send a copy with the client and the responsible person. ~~A copy of the form may be obtained by writing or calling the Agency for Persons with Disabilities, at 4030 Esplanade Way, Suite 380, Tallahassee, FL 32399-0950; main phone number (850)488-4257.~~

(2) Medication may not be transferred from its original container to a ~~weekly~~ pill organizer or be otherwise co-mingled outside of its original container unless the client's primary care provider determines that the client is able to self-administer ~~that~~ medication without supervision; in that case, only the client, the client's family member or family member surrogate, a natural support, or a legal representative ~~guardian~~ may transfer the medications from the original container. The MAP may not supervise, monitor, prompt, assist or cue any client to correctly fill a pill organizer (also known as a "pill minder" or "pill box").

(3) The ~~medication assistance provider~~ MAP or licensed health care practitioner must provide the name and telephone number of a contact person and the name and telephone number of the client's prescribing practitioner to the person who will assist the client with medication administration while the client is off-site, for use in the event that there are questions or adverse reactions.

Rulemaking Authority 393.501, 393.506 F.S. Law Implemented 393.506 F.S. History–New 3-30-08, Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Lori Gephart
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Barbara Palmer
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