CHAPTER 65G-7 MEDICATION ADMINISTRATION

65G-7.001	Definitions
65G-7.002	Authorization for Medication Administration and Informed Consent
65G-7.003	Medication Administration 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

65G-7.001 Definitions.

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 drugs by a legally authorized person to an Agency client for his or her consumption.

(2) "Area Office" is the local office responsible for managing one of the Agency's fourteen service areas.

(3) "Authorized representative" means the client's parent if the client is a minor, the client's authorized guardian, courtappointed guardian advocate, health care surrogate, or a health care proxy appointed in accordance with chapter 765, F.S., or any other client advocate legally authorized to make decisions on behalf of a client.

(4) "Central Office" is the Agency's headquarters, situated at 4030 Esplanade Way, Suite 380, Tallahassee, FL 32399-0950; main phone number (850)488-4257.

(5) "Client's record" means a file maintained for each client that contains the client's name and date of birth, written authorization for routine medical/dental care from the client or guardian and medical summary, the name address and telephone of the client's physician and dentist, a record of the client's illnesses and accidents, the legal status of the client, current services and implementation plan, and client financial documentation

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

(7) "Corrective Action Plan," for purpose of this rule, means a written plan of action developed by the Agency for the purpose of correcting cited deficiencies in compliance with this rule chapter.

(8) "Enteral medication" means medication delivered by tube via the body's gastrointestinal system.

(9) "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.

(10) "Inhaled medication" means the delivery of medication droplets or moisture suspended in a gas, such as oxygen, by inhalation through the nose or mouth.

(11) "Medical Case Manager" means a registered nurse or ARNP employed by the Agency to provide nursing consultation and technical assistance to an Area office regarding the medical care of Agency clients.

(12) "Medication Administration Record" or "MAR" means the chart maintained for each client which records the medication information required by this rule chapter. Other information or documents pertinent to medication administration may be attached to the MAR. A copy of the Agency's form "Medication Administration Record," APD Form 65G7-00 (3/30/08), incorporated herein by reference, 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.

(13) "Medication Assistance Provider" means a direct service provider not otherwise licensed to administer medication who has successfully completed an agency-approved training course and has current validation to provide clients with medication administration or to assist clients with self-administration of medication.

(14) "Nebulizer" means an atomizer equipped to produce an extremely fine spray for deep penetration of the lungs.

(15) "Over-the-counter (OTC) medication" means a medication for general distribution and use without a prescription in the treatment of human illnesses, ailments, or injuries.

(16) "Ophthalmic medication" means a solution or ointment to be instilled into the eye or applied on or around the eyelid.

(17) "Oral medication" means any medication in tablet, capsule, or liquid form introduced into the gastrointestinal tract by

mouth.

(18) "Otic medication" means solutions or ointments to be placed in the outer ear canal or applied around the outer ear.

(19) "Parenteral" means injected into the body through some route other than the alimentary canal.

(20) "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., or the applicable laws of the state in which the service is furnished.

(21) "Prescribed medication" means simple or compound substances or mixtures of substances that are prescribed for the cure, mitigation, or prevention of disease or for health maintenance prescribed by a licensed practitioner authorized by law to prescribe such substances.

(22) "Prescription" means any order for drugs, medical supplies, equipment, appliances, devices, or treatments written or transmitted by any means of communication by a licensed practitioner legally authorized to issue such an order, or any order issued by the lawfully designated agent of such practitioner, intended to be filled, compounded, dispensed or furnished by a person authorized by the laws of the State to do so.

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

(24) "Rectal medication" means any prescribed medication, capsule, enema or suppository to be administered via the rectum.

(25) "Supported living services" 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.

(26) "Supervised self-administered medication" means direct, face-to-face observation of a client during the client's selfadministration of medication and includes instruction or other assistance necessary to ensure correct self-administration of the medication.

(27) "Topical medication" means a salve, lotion, ointment, cream, shampoo or solution applied locally to a body part.

(28) "Transdermal patch" means an adhesive patch containing a pre-measured amount of topical medication that is absorbed into the body via the epidermis (outer layer of skin) at a fixed rate.

(29) "Unlicensed" means, for purposes of this rule, not authorized, certified, or otherwise permitted by other Florida law to administer medication or to supervise self-administration of medication.

(30) "Validation" means an unlicensed direct service provider's demonstration of competency in administering or supervising self-administration of a medication to a client, certified by a licensed, registered nurse or licensed physician following the provider's successful completion of an Agency-approved medication administration training course.

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.

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

(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, physician assistant, or Advanced Registered Nurse Practitioner, licensed under Chapter 464, 458, or 459, F.S., to practice in the State of Florida, on an "Authorization for Medication Administration," APD Form 65G7-01, (3/30/08), incorporated herein by reference. 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) A client who is authorized, as provided above, to self-administer medication without supervision shall be encouraged to do so. The medication assistance provider shall assist the client by making the medication available and reminding the client to take medication at appropriate times.

(3) The medication assistance provider must maintain a current Authorization form, reviewed by the client's physician, physician assistant, or ARNP at least annually and upon any change to the client's medical condition or self-sufficiency which would affect the client's ability to self-administer medication or to tolerate particular administration routes.

(4) An unlicensed provider is not authorized to administer medication or assist a client with self-administration of medication unless he or she has successfully completed an Agency-approved medication administration training course and has obtained a current validation.

(5) In addition to an executed Authorization for Medication Administration and before providing a client with medication assistance, a provider must also obtain from the client or the client's authorized representative an "Informed Consent for Medication Administration" APD Form 65G7-02 (3/30/08) incorporated herein by reference. 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. The Informed Consent form must contain a description of the medication routes and procedures that the medication assistance provider is authorized to supervise or administer.

(6) The medication assistance provider may not also act as the client's health care surrogate or proxy, or sign the Medication Administration Informed Consent form referenced above. Providers or other facility staff may witness the execution of the form.

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

(8) The requirements of this rule chapter do not apply to the following:

(a) Health care practitioners whose professional licenses include administration of medication;

(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 under chapter 400, part III, hospices regulated under chapter 400, Part IV, or health care service pools 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 documented by an executed Authorization, APD Form 65G7-01 (3/30/08) incorporated herein by reference. 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.

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.

65G-7.003 Medication Administration Trainer Requirements.

(1) Medication administration training courses not offered through the Agency must be approved by the Agency in order to provide qualification for validation. To obtain Agency approval, a course provider must submit an application on a "Medication Administration Provider/Course Approval Form," APD Form 65G7-03 (3/30/08) incorporated herein by reference. 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. Course providers offering medication administration training at the time this rule is adopted shall have 180 days from the effective date of the rule to request and receive Agency approval for their course, during which time they may continue to offer the training.

(2) The application must include the following information: the total number of training course hours; a course syllabus; a detailed outline of the contents of the course; and the names, qualifications, and license numbers of all proposed instructors known at the time of the application.

(3) If the Agency denies an application for course approval, it will identify the reasons for the denial in writing. A course may be resubmitted to the Agency with modifications.

(4) Only licensed registered nurses or Advanced Registered Nurse Practitioners may conduct training courses for medication administration assistance certification.

(5) Medication administration training courses must provide training curriculum and step-by-step procedures covering, at a minimum, the following subjects:

(a) Safe storage, handling, and disposal of medications;

(b) Comprehensive understanding of and compliance with medication instructions on a prescription label, a health care practitioner's order, and proper completion of a MAR form;

(c) The medical indications and purposes for commonly used medications, their common side effects, and symptoms of adverse reactions;

(d) The proper administration of oral, transdermal, ophthalmic, otic, rectal, inhaled or topical medications;

(e) Safety and sanitation practices while administering medication;

(f) Medication administration documentation and record-keeping requirements;

(g) Medical errors and medical error reporting;

(h) Determinations of need for medication administration assistance and informed consent requirements;

(i) Procedural arrangements for clients who require medication offsite; and,

(j) Validation requirements.

(6) Medication administration courses may be administered either through web-based distance learning or in a traditional classroom setting, utilizing an Agency or Agency-approved medication administration training curriculum.

(7) A course provider applying for Agency approval of web-based distance learning must submit documentation indicating the following:

(a) The means by which the course will demonstrate interactivity between the student and course provider within a maximum of 24 hours, which interactivity promotes student involvement and demonstrates that the course measures learning and addresses comprehension of content at regular intervals;

(b) The means by which the course provider is able to monitor student enrollment, participation, and course completion;

(c) The means by which the course provider will be able to satisfactorily demonstrate that stated course hours are consistent with the actual hours spent by the student to complete the course;

(d) The means by which the provider will assure qualified instructors will be available to answer questions and provide students with necessary support during the course; and,

(e) A requirement that the student complete a statement at the end of the course indicating that he/she personally completed each module/session of instruction.

(8) Each medication administration course must consist of a minimum of four hours of instruction and classroom courses must be limited to no more than 20 participants for each class.

(9) Any change to an approved course curriculum or protocol requires new agency approval for that course.

(10) The Agency shall assign to approved courses a course number that the course provider must display in the course syllabus and all other materials used in connection with the course.

(11) The Agency may deny or withdraw course approval for any of the following acts or omissions:

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

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

(c) Failure to notify the Agency within six weeks of a change in the information required for course approval;

(d) Falsification of any records regarding the course conducted by the provider or persons attending the course;

(e) Failure to maintain any required records regarding the course conducted by the provider or persons who attended the course;

(f) Failure to maintain the course curriculum in the format and content approved by the Agency;

(g) Advertisement or administration of the course before the date it is approved by the Agency;

(h) Administration of course training by instructors not licensed as registered nurses or Advanced Registered Nurse Practitioners;

(i) Failure to maintain records of course administration and attendance.

(12) As a prerequisite to validation as a medication assistance provider, the applicant must achieve a score of at least 80% on an agency provided or agency-approved medication administration training course exam. Upon successful completion of the examination, the course provider shall issue the examinee a certificate containing the name of the provider, the course number, date(s) of course administration, name of the student and, for classroom-based courses, the name and signature of the course instructor.

(13) Medication assistance providers must maintain proof of certification and validation. Employers of medication administration assistance providers also must maintain a copy of the certificate and proof of current validation for each employee providing medication assistance.

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.

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

(1) An unlicensed provider applying for validation as a medication assistance provider must be assessed and validated at least annually, through demonstration, as competent to administer medication or to supervise the self-administration of medication. Successful completion of an Agency-approved medication administration course is a prerequisite to an assessment of competency validation.

(2) Only a registered nurse licensed pursuant to chapter 464, F.S., or a physician licensed pursuant to chapter 458 or 459, F.S.,

may validate the competency of an unlicensed direct service provider to provide medication administration assistance.

(3) The applicant for validation must complete an on-site assessment with 100% proficiency documented on a "Validation Certificate," APD Form 65G7-004 (3/30/08) incorporated herein by reference. 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. The form must contain the following information:

(a) The name and address of the applicant being validated and, if an employee, the name of the employing entity;

(b) The date of assessment and validation;

(c) A description of the medication routes and procedures that the applicant is authorized to supervise or administer;

(d) Any limitations on the applicant's validation to administer medication, such as limitations on validated routes of medication administration;

(e) The printed name and original signature of the validating nurse or physician as it appears on his or her license; and,

(f) The validating nurse or physician's license number and license expiration date.

(4) Successful assessment and validation requires that the applicant demonstrate in an actual onsite client setting his or her capability to correctly administer medication and supervise the self-administration of medications in a safe and sanitary manner as required by this rule chapter, including a demonstration of the following proficiencies:

(a) The ability to comprehend and follow medication instructions on a prescription label, physician's order, and properly complete a MAR form;

(b) The ability to administer medication by oral, transdermal, ophthalmic, otic, rectal, inhaled, or topical administration routes;

(c) 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 a Physician's Desk Reference or other professionally recognized medication resource, and maintaining this information for easy access and future reference;

(d) The ability to write legibly, convey accurate information, and comply with medication administration record-keeping requirements;

(e) Knowledge of the proper storage and handling of medications;

(f) Knowledge of proper disposal of expired or unused medications;

(g) Knowledge of special requirements relating to storage and disposal of controlled medications;

(h) Requirements for obtaining authorizations for assistance with medication administration, authorization for selfadministration of medication without supervision, and informed consent for medication assistance; and,

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

(5) When a client is prescribed a medication requiring an administration route for which the medication assistance provider has not been validated, the provider must obtain an assessment and validation for that specific administration route before administering the medication to the client.

(6) A medication assistance provider must be re-validated annually within the 60 days preceding the expiration of his or her current validation. An unlicensed provider may not under any circumstances administer or supervise the self-administration of medication before receiving validation or following expiration of an annual validation.

(7) Medication assistance providers who fail to acquire re-validation before the expiration of the current validation must retake the medication administration training course and obtain current validation before assisting with the administration or selfadministration of medication.

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

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.

65G-7.005 Medication Administration Procedures.

(1) Upon certification and validation as provided by this rule chapter, unlicensed providers are authorized to assist with the administration of prescribed medications via the following medication routes:

(a) Oral;

(b) Transdermal;

(c) Ophthalmic;

(d) Otic;

(e) Rectal;

(f) Inhaled; and,

(g) Topical.

(2) A validated medication assistance provider must comply with the following requirements:

(a) Before providing any medication assistance, 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;

(b) Perform appropriate hand sanitation measures before providing medication assistance, with repeated sanitization as needed during medication administration;

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

(d) Following medication administration or assistance with self-administration, return each client's medication to its portable or permanent medication storage location before assisting another client;

(e) Limit administration, or assistance with self-administration, to medications prescribed in writing by the client's health care practitioner and properly labeled and dispensed in accordance with chapters 465 and 499, F.S.;

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

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

(h) 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;

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

(j) Record the date, time, dosage, and name of each medication in the MAR immediately following administration and sign the entries;

(k) Observe the client directly for a minimum of 20 minutes following the first three doses of a new or PRN medication in order 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.

(3) A medication assistance provider may not assist with the administration of any OTC medication or medication samples without a written order by the client's primary care physician or Advanced Registered Nurse Practitioner.

(4) Medications may not be crushed, diluted, or mixed without written instructions from the prescribing health care practitioner in the MAR.

(5) The medication assistance provider is responsible for ensuring that the prescription for a medication is promptly refilled so that a client does not miss a prescribed dosage of medication. If the medication assistance provider is not responsible for routine refills of a medication, he or she shall notify the provider responsible for refilling the client's prescriptions that the client is in need of medication and document this notification.

(6) The medication assistance provider may not assist with PRN medications, including OTC medications, unless a health care practitioner has provided written directions for the medication. The provider must attach to the client's MAR a copy of the prescription or order legibly displaying the following information:

(a) The name of the medication;

(b) The prescription number, if applicable;

(c) The prescribed dosage; and,

(d) Specific directions for use, including the medical basis for the medication, the time intervals for administration, the maximum number of doses, the maximum number of days that the medication should be administered, and conditions under which the health care practitioner should be notified.

(7) A medication assistance provider may not perform the following acts of assistance:

(a) Prepare syringes for a client's use during the self-administration of medication via a subcutaneous, intra-dermal, intramuscular or intravenous route; (b) Administer, or supervise self-administration of, medications that are inserted vaginally, administered enterally, or administered via a tracheostomy;

(c) Mix or pour medications administered through intermittent positive pressure breathing machines or nebulizers, unless the medication assistance provider and client who self-administers medication with supervision have received one-on-one, step-by-step, training in the proper use and maintenance of such equipment from a certified equipment technician, respiratory therapist, or a registered nurse, with documentation in the client's file of the date of training, the name and qualifications of the persons providing the training, and a description of the breathing equipment that was the subject of the training;

(d) Administer medications via a subcutaneous, intra-dermal, intra-muscular or intravenous route;

(e) 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; and,

(f) Assist a client with medications for which the health care provider's prescription does not specify the medication schedule, medication amount, dosage, route of administration, purpose for the medication, or with medication which would require professional medical judgment by the medication assistance provider.

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.

65G-7.006 Medication Errors.

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

(a) Administration of a wrong medication;

(b) Administration of a wrong dose;

(c) Administration of medication via the wrong route;

(d) Administration of medication for any symptom, illness, or reason other than the one for which the medication was prescribed;

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

(f) Administration of a medication, or the provision of a self-administered medication, to the wrong client;

(g) Failure to immediately and accurately document administration on the MAR;

(h) Failure to fill newly prescribed medications within twenty-four hours of receipt of the prescription;

(i) Failure to promptly refill current medications, resulting in one or more missed doses of medication;

(j) Administration or assistance with self-administration of an expired or improperly labeled medication; and,

(k) Failure to conduct an accurate medication count for controlled medications.

(2) Immediately following a medication error, the medication assistance provider or facility administrator must take the following steps:

(a) Notify any supervisory personnel;

(b) In the case of administration of a wrong medication or a wrong dosage, observe the client closely for a minimum period of 20 minutes after the medication was administered or self-administered, 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) Notify the client's prescribing health care practitioner of the error, request that the practitioner prepare and fax a medication directive addressing the error to the client's home, facility, or pharmacy, and document the client's health care practitioner's response; and,

(d) Fully document all observations and contacts made regarding a medication error in a "Medication Error Report," APD Form 65G7-05 (3/30/08) incorporated herein by reference, and place a copy of the Report in the client's file. 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. An electronic copy of the form is available at http://apd.myflorida.com/medication/forms.

(3) If a medication error occurs in a facility, the medication assistance provider must submit copies of the Report to the facility administrator and to the Agency area office within 24 hours of discovering the error.

(4) If a medication error occurs in a client's home and the medication assistance provider committed the error, the provider must submit a Medication Error Report to the Agency area office within 24 hours of the discovering the error and maintain a copy of the report in the client's file or other location easily accessible for review.

(5) Following a medication count, the medication assistance provider must report a discrepancy in the accounting of controlled

substances by 5:00 p.m. of the next business day following discovery of the error to the Area office and, if applicable, to the facility supervisor.

(6) If the Agency Medical Case Manager determines that a medication assistance provider's medication error justifies corrective action, including additional training, the Area Office will notify the provider in writing of the necessary corrective action plan, including a specific and reasonable timeframe for completion of the corrective action plan. If the medication assistance provider fails to comply with the corrective action plan, the Agency will revoke the medication assistance provider's validation, subject to the provisions of chapter 120, F.S.

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.

65G-7.007 Storage Requirements.

(1) Medication assistance providers 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 or is no longer prescribed and document the medication disposal on a "Medication Destruction Record," APD Form 65G7-06 (3/30/08) incorporated herein by reference. 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. 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 must initial and add to the label the date the medication is opened;

(d) Maintain OTC medications in their original stock containers.

(2) A residential facility or supported living client who does not require medication assistance or supervised self-administration may store his or her medication in secure, locked place within his or her room. However, a client's medications must be centrally stored and retrieved by the medication assistance provider 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, 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 posses a threat to the safety of others, or

(d) The client or the client's authorized representative requests 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.

(4) Either a licensed health care practitioner or medication assistance provider 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.

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

(a) The 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 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 and witnessed by another medication assistance provider,

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," APD Form 65G7-07 (3/30/08) incorporated herein by reference. 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. 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 per shift, the medication assistance provider 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 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 above.

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.

65G-7.008 Documentation and Record Keeping.

(1) An 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 must document the administration of medication or supervision of self-administered medication immediately on the MAR, using either APD Form 65G7-00 (3/30/08), incorporated by reference 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 (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;

(1) The initials and signature of the medication assistance provider who assisted with medication administration;

(m) A record of any medication dosage refused or missed, documented by the medication assistance provider 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 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) Each client record must contain the following medication documentation readily available to the medication assistance provider 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;

(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; and,

(e) The original Informed Consent form permitting a medication assistance provider to assist with the administration of medication.

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

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.

65G-7.009 Off-site Medication Administration.

(1) If a client will be away from a licensed residential facility or supported living home and requires during that time administration of medication by persons other than the medication assistance provider, the medication assistance provider 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 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 65G7-08 (3/30/08), incorporated herein by reference. 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 otherwise co-mingled 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 a legal guardian may transfer the medications from the original container.

(3) The medication assistance provider 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 offsite.

Rulemaking Authority 393.501 FS. Law Implemented 393.506 FS. History-New 3-30-08.