

Nathan Deal, Governor

Frank W. Berry, Commissioner

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-656-4507 | www.dch.georgia.gov

PUBLIC NOTICE OF PROPOSED RULE CHANGES

Pursuant to the Georgia Administrative Procedures Act, Official Code of Georgia (O.C.G.A.) 50-13-1 et seq., the Georgia Department of Community Health is required to provide public notice of its intent to adopt, amend or repeal certain rules other than interpretive rules or general statements of policy. Accordingly, the Department hereby provides notice of its intent to amend the **Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, Chapter 111-8-100**. These changes are being proposed pursuant to the authority granted to the Department in O.C.G.A. §§ 31-2-5 and 31-2-7. An exact copy of the revised rules and a synopsis of the revisions are attached to this public notice.

NOTICE OF PUBLIC HEARING

An opportunity for public comment will be held on **March 13, 2018** at **10:00 a.m.**, at the Department of Community Health (2 Peachtree Street, N.W., Atlanta, Georgia 30303) in the 5th Floor Board Room. Oral comments may be limited to 10 minutes per person. Individuals who are disabled and need assistance to participate during this meeting should contact the Office of General Counsel at (404) 657-7195 at least three (3) business days prior to the meeting.

Citizens wishing to comment in writing on any of the proposed changes should do so on or before March 16, 2018. Comments may be faxed to (404) 656-0663, emailed to renee.robinson@dch.ga.gov or mailed to the following address:

Attention: Office of General Counsel Georgia Department of Community Health Post Office Box 1966 Atlanta, Georgia 30301

Comments from written and public testimony will be provided to the Board of Community Health prior to the April 12, 2018 Board meeting. The Board will vote on the proposed changes at the Board meeting to be held at 10:30 a.m. on April 12, 2018 at the Georgia Department of Community Health (2 Peachtree Street, N.W., Atlanta, Georgia 30303 in the 5th Floor Board Room).

NOTICE IS HEREBY GIVEN THIS 8th DAY OF February, 2018.

Frank W. Berry, Commissioner

Attachments

RULES OF GEORGIA DEPARTMENT OF COMMUNITY HEALTH HEALTHCARE FACILITY REGULATION DIVISION REVISE CHAPTER 111-8-100 RULES AND REGULATIONS FOR PROXY CAREGIVERS USED IN LICENSED HEALTHCARE FACILITIES

SYNOPSIS OF PROPOSED RULE CHANGES

STATEMENT OF PURPOSE: The Georgia Department of Community Health proposes to revise the Rules and Regulations for Proxy Caregivers Used in Licensed Facilities, Chapter 111-8-100. These changes are being proposed pursuant to the authority granted the Department of Community Health in O.C.G.A. § 31-6-21 and O.C.G.A. § 31-6-21.1.

MAIN FEATURE OF THE PROPOSED RULE: Revision of the rule to comply with the provisions of House Bill 486 which changes the definition of proxy caregiver and requires the Department to develop a training curriculum for medication administration.

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RULES OF DEPARTMENT OF COMMUNITY HEALTH

CHAPTER 111-8 HEALTHCARE FACILITY REGULATION

111-8-100 PROXY CAREGIVERS USED IN LICENSED HEALTHCARE FACILITIES

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111-8-100-.01 Legal Authority

These rules are adopted and published pursuant to the Official Code of Georgia Annotated (OCGA) §§ 31-7-2.1 and 43-26-12.

111-8-100-.02 Title and Purpose

These rules, known as the Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, set forth the requirements for designated proxy caregivers performing health maintenance activities in connection with certain licensed healthcare facilities subject to regulation by the department.

111-8-100-.03 Definitions

In these rules, unless the context otherwise requires, the terms set forth herein shall mean the following:

- (a) "Administrative action" means the initiation of a contested case as defined in the Georgia Administrative Procedures Act (APA), O.C.G.A. § 50-13-2(2) against a licensed facility for violation of licensing requirements.
- (b) "Client(s)" means a person or persons receiving services through the licensed facility. Clients include such terms as residents, consumers, patients and program participants.
- (c) "Competency-based training" means training which is tied to an identified set of skills and knowledge and requires demonstration and documentation of an acceptable level of performance of a task or achievement of an outcome.
- (d) "Complex wound care" means the specialized nursing care that is required for certain wounds. Typically, the following kinds of wounds require complex care: wounds in the lower extremity of diabetic patients, pressure ulcers, chronic venous ulcers, wounds following extensive necrotic processes caused by infections (Fournier's and other), and chronic wounds related to vasculitis and immunosuppressive therapy that have not healed using simple care.
- (e) "Department" means the Department of Community Health, its agents and employees.
- (f) "Health maintenance activities" means those are limited to those activities that, but for a disability, a person could reasonably be expected to do for himself or herself. Such activities are typically taught by a registered professional nurse, but may be taught by an attending physician, advanced practice registered nurse, physician assistant, or directly to a patient and are part of ongoing care. Health maintenance activities are those activities that do not include complex care such as administration of intravenous medications, central line maintenance, and complex wound care; do

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- not require complex observations or critical decisions; can be safely performed and have reasonably precise, unchanging directions; and have outcomes or results that are reasonably predictable. Health maintenance activities conducted pursuant to this these rulesparagraph shall not be considered the practice of nursing.
- (g) "Individual with a disability" or "disabled individual" means an individual who has a physical or mental impairment that substantially limits one or more major life activities and who meets the criteria for a disability under state or federal law. such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing and/or learning, and who meets the criteria for a disability under state or federal law.
- (h) "Inspection" means any examination by the department or its representatives of a licensed healthcare facility, including but not necessarily limited to the premises, and staff, persons in care, and documents pertinent to initial and continued licensing so that the department may determine whether a facility is operating in compliance with licensing requirements. The term "inspection" includes any survey, complaint investigation, monitoring visit, or other inquiry conducted for the purpose of making a compliance determination with respect to licensing requirements.
- (i) "Legally authorized representative" means the person legally authorized to act on behalf of the individual with a disability with respect to providing consent to medical treatment or procedures not prohibited by law which may be suggested, recommended, prescribed or directed by a duly licensed physician or as otherwise authorized by law. The representative is not authorized to act on behalf of the individual with a disability to provide consent until a medical determination has been made that the individual with a disability lacks decision-making capacity regarding medical treatment or the ability to communicate such decisions by any means.
- (j) "Licensed healthcare professional" means an individual who is licensed and authorized under Georgia law to perform certain healthcare practices. The term includes physicians, advance practice registered nurses, physician's assistants, registered nurses, pharmacists, physical, speech and occupational therapists who are functioning within their scopes of licensed practice. The term does not include licensed practical nurses, certified nursing assistants or medication aides.
- (k) "Licensed healthcare facility" or "licensed facility" means any agency, institution, entity or person subject to regulation by the department under Chapters 7, 13, 22, 23, 44 of Title 31; paragraph (8) of subsection (d) of Code Section 31-2-4; Chapter 5 of Title 26; and Article 7 of Chapter 6 of Title 49 of the Official Code of Georgia Annotated, except hospitals, residential mental health facilities, nursing homes, intermediate care facilities for the mentally retarded, Medicare-certified home health agencies and hospices.
- (I) "Licensed residential facility" means a licensed facility which serves as the home, either temporarily or permanently, of an individual with a disability. Such facilities are licensed as assisted living communities, personal care homes, community living arrangements, residential drug abuse treatment programs and traumatic brain injury

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facilities.

- (m) "Proxy caregiver" means an unlicensed person or a licensed health care facility thatwhe has been selected by a disabled individual or a person legally authorized to act on behalf of such individual to serve as such individual's proxy caregiver, provided that such person shall receive training and shall demonstrate the necessary knowledge and skills to perform documented health maintenance activities, including identified specialized procedures, for such individual, who has been determined qualified to have the necessary knowledge and skills acquired through training by a licensed healthcare professional to perform documented health maintenance activities, including specialized procedures, for an individual with a disability who has delegated to the designated proxy caregiver the performance of such health maintenance activities through execution of a written informed consent by the individual with a disability or a person legally authorized to act on behalf of such individual with a disability.
- (n) <u>"Training" means teaching proxy caregivers the necessary knowledge and skills to perform health maintenance activities for disabled individuals.</u>
- (no) "Written plan of care" means the specific set of written instructions which have been determined necessary, usually by a registered professional nurse, to implement the written orders of the attending physician or an advanced practice registered nurse or physician assistant working under a nurse protocol agreement or job description respectively. The written plan of care must specify the frequency of training and evaluation requirements for the proxy caregiver, including additional training when changes in the written plan of care necessitate added duties for which such proxy caregiver has not previously been trained.

111-8-100-.04 Use of Proxy Caregivers and Informed Consent

- (1) Proxy Caregiving Permitted. Licensed facilities, may allow proxy caregivers to perform health maintenance activities for individuals with disabilities who are being served by or through the licensed facility, as authorized in these rules, provided that the individual with a disability or legally authorized representative has executed a written informed consent.
- (2) Written Informed Consent. No licensed facility will permit a proxy caregiver to provide health maintenance activities by or through the licensed facility unless the individual with a disability, or the legally authorized representative has executed an informed consent. The written informed consent must contain the following information:
 - (a) a definition of health maintenance activities as set forth in the law;
 - (b) the actual health maintenance activities to be performed;

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- (c) an explanation that such health maintenance activities are to be provided pursuant to the written orders of an attending physician, advance practice registered nurse or physician's assistant working under protocol or job description as further detailed in the written plan of care;
- (d) the name(s) of the proxy caregiver(s) who are being authorized to provide health maintenance activities:
- (e) a disclosure that Georgia law now allows licensed healthcare professionals to train unlicensed proxy caregivers to provide the specific health maintenance activities listed on the written plan of care;
- (f) an acknowledgement that proxy caregivers are not licensed healthcare professionals and do not have the same education and training as licensed healthcare professionals. Therefore, there may be additional health risks associated with receiving this care from proxy caregivers who may not recognize an important change in the individual's medical condition requiring assessment and/or treatment:
- (g) an acknowledgment that the individual with a disability, or the legally authorized representative consents and is willing to take such risks;
- (h) that the informed consent is conditioned upon the proxy caregiver(s) being determined by an appropriately qualified licensed healthcare professional to have the knowledge and skills necessary to perform safely the specific health maintenance activities listed on the consent;
- (i) a statement that the informed consent for any proxy caregiver designated to deliver health maintenance activities may be withdrawn orally or in writing by the individual with a disability or the legally authorized representative by informing the proxy caregiver and any licensed facility through which the proxy caregiver may be operating; and
- (j) an authorization for such health maintenance activities to be provided which is signed and dated by the individual with a disability or the legally authorized representative.
- (3) Proxy Caregivers Functioning Independently in Licensed Residential Facilities. Where the licensed residential facility permits the individual with a disability or the legally authorized representative to hire a proxy caregiver directly to perform tasks that are appropriately classified as health maintenance activities, the licensed residential facility must do the following:
 - (a) Develop and enforce written policies and procedures which do not conflict with the requirements of the law and these rules, and which outline the following:
 - 1. The scope of the health maintenance activities that proxy caregivers are

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permitted to perform;

- 2. The notification procedures that will be utilized when either the proxy caregiver observes a change in the condition of the individual with a disability which may require evaluation/treatment by a licensed healthcare professional, or there is a change in the care being provided through the licensed residential facility that might impact the performance of health maintenance activities; and
- The safety and security precautions that will be employed in the licensed residential facility to protect clients being served from harm by proxy caregivers who are independent and not under the control of the facility.
- (b) Maintain a copy of the written informed consent which meets the requirements of rule 111-8-100-.04(2) and appears to be properly executed by the individual with a disability or the legally authorized representative
- (c) Maintain a copy of the written plan of care for the individual with a disability which has been developed by a licensed healthcare professional pursuant to written orders of an attending physician, or an advanced practice registered nurse or physician assistant working under a nurse protocol agreement or job description respectively.
- (d) Determine that the written plan of care provided specifies the health maintenance activities to be performed, the frequency of training and evaluation for the proxy caregiver and the kinds of changes in the written plan of care that would necessitate additional training for the proxy caregiver.
- (e) Maintain current documentation signed by a licensed healthcare professional which reflects that the proxy caregiver has been determined to have the knowledge and skills necessary to perform safely the required health maintenance activities for the individual client.
- (f) Verify that there is a back-up proxy caregiver service plan which has been put in place for the individual with a disability which addresses at a minimum the following:
 - The notification procedures and contact information that will be utilized when the proxy caregiver and/or licensed facility staff observe a change in the condition of the individual with a disability which may require evaluation/treatment by a licensed healthcare professional;
 - 2. The alternative resources to be used to provide needed health maintenance activities in the event that the proxy caregiver is not available for any reason; and
 - 3. The notification procedures and contact information that will be utilized if

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- staff members of the licensed facility become aware of a potentially unsafe situation involving the client and the proxy caregiver.
- (g) Ensure that the proxy caregiver is familiar with emergency evacuation procedures.
- (4) Licensed Facilities Delivering Services Through Proxy Caregivers. Where the licensed facility employs, contracts or refers proxy caregivers to deliver health maintenance activities to individuals with disabilities receiving services through the licensed facility, the licensed facility must do the following:
 - (a) Develop and enforce written policies and procedures, which do not conflict with the requirements of the law and these rules and which outline the following:
 - 1. The scope of the health maintenance activities that proxy caregivers are permitted to perform;
 - 2. The notification procedures that will be utilized when the proxy caregiver observes a change in the condition of the individual with a disability which may require evaluation/treatment by a licensed healthcare professional; and
 - 3. The safety and security precautions that will be employed by the licensed facility to protect clients being served by the licensed facility from harm by proxy caregivers.
 - (b) Disclose to individuals with disabilities who are potential clients of the licensed facility or the legally authorized representative the following:
 - The manner in which proxy caregivers are used to deliver health maintenance activities and the general professional qualifications of the staff providing supervision to the proxy caregivers;
 - 2. Whether there are additional charges for such proxy caregivers and the amount that would be charged;
 - 3. The manner in which the licensed facility ensures that clients are permitted to designate and change proxy caregivers;
 - 4. The qualifications of the licensed healthcare professionals who develop written plans of care for the clients and provide training; and
 - 5. The frequency of competency-based skills determinations and the extent of trainings provided to proxy caregivers.
 - (c) Ensure that the individual with a disability or the legally authorized representative has executed a written informed consent which meets the

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requirements of rule 111-8-100-.04(2).

- (d) Ensure that a written plan of care is developed for the individual with a disability by a licensed healthcare professional in accordance with the written orders of an attending physician, an advanced practice registered nurse or physician's assistant working under a nurse protocol agreement or job description respectively, and that such plan of care specifies the frequency of training and evaluation requirements for the proxy caregiver and when additional training will be required for new duties added to the written plan of care for which the proxy caregiver has not been previously trained. The licensed facility must either use the written plan of care form made available by the Department or another form containing all the required elements.
- (e) Ensure that the written plan of care is implemented by appropriately trained proxy caregivers who have been specifically designated by the individual with a disability or the legally authorized representative.
- (f) Maintain documentation of the specific training that was provided on the health maintenance activities that the proxy caregiver performs. The documentation must include a competency-based skills checklist completed by the licensed healthcare professional. The checklist must reflect that the proxy caregiver has personally demonstrated to the satisfaction of the licensed healthcare professional the necessary knowledge and skills to perform safely the specific health maintenance activities. There must be a separate skills checklist for each health maintenance activity that the proxy caregiver provides. For the medication administration training, the facility must use the curriculum established by DCH and any associated checklist.
- (g) Maintain supporting documentation reflecting that the employee or contractor serving as the proxy caregiver has the basic qualifications as represented, e.g. no findings of abuse, neglect or exploitation entered against the individual in the nurse aide registry, a satisfactory report of motor vehicle driving record where the proxy caregiver may be transporting clients and a satisfactory criminal records check where required by other rules applicable to the specific licensed facility.
- (h) Maintain written evidence of satisfactory performances on initial and annual skills competency determinations utilizing skills competency checklists which have either been made available by the department or developed and completed by appropriately licensed healthcare professionals. The competency-based skills checklists must reflect a testing of the knowledge and observation of the skills associated with the completion of all of the discrete tasks necessary to do the specific health maintenance activity in accordance with accepted standards of care.

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111-8-100-.05 Training and Other Requirements for Proxy Caregivers

- (1) Training Curricula. A licensed facility utilizing proxy caregivers must employ a written training curricula developed by appropriately licensed healthcare professionals which ensures that the proxy caregiver accurately demonstrates how to do the required health maintenance activities correctly and safely. At a minimum, the training curricula used for proxy caregivers must include the following:
 - (a) Learning objectives which relate specifically to the health maintenance activities to be performed;
 - (b) Content knowledge and skills that are required to accomplish the learning objectives;
 - (c) Learning activities that will be utilized to provide instruction on knowledge and skills required;
 - (d) The results of the Test of Functional Health Literacy (TOFHLA) used as an assessment tool to individualize necessary training for the specific skills if the caregiver does not have a high school diploma or a general equivalency degree (G.E.D);
 - (e) Satisfactory and independent completion of the required skills competency checklists relating to the specific health maintenance activities to be performed before an appropriately licensed healthcare professional;
 - (f) The use of skills competency checklist forms when made available by the department for the specific health maintenance activities to be performed or other skills checklist forms that include all of the competencies in the correct order as contained on the forms made available by the department and as required for the specific client; and
 - (g) Satisfactory evidence of routine evaluations of continued skills competencies by an appropriately licensed healthcare professional, at least annually if not assessed more frequently as specified on the written plan of care.
- (2) Licensed Facilities Providing Medication Assistance Administration. A licensed facility may use proxy caregivers to administer provide assistance with managing medications for to an individual with a disability unless the use of proxy caregivers is subsequently prohibited or modified by regulations applicable to a specific type of licensed facility adopted after the effective date of these rules. In the absence of more specific requirements, the licensed facility using proxy caregivers for medication assistance administration must meet the following conditions:
 - (a) The individual with a disability or the legally authorized representative has provided a written informed consent which meets the requirement of these rules;
 - (b) The medications and assistance administration being provided have been

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- determined by an appropriately licensed healthcare professional to be health maintenance activities that may be safely performed by properly trained proxy caregivers; and
- (c) The proxy caregiver has been trained in accordance with these rules and determined through completion of a skills competency checklist before an appropriately licensed healthcare professional to have the knowledge and skills necessary to perform the specific health maintenance activities in accordance with the written plan of care.
- (3) Medication Assistance Administration Curriculum. Licensed facilities that employ or contract with proxy caregivers to provide medication administration must maintain documentation reflecting that the facility has trained these proxy caregivers in accordance with the medication administration training curriculum established by DCH.

Where the licensed facility provides medication assistance through proxy caregivers, the licensed facility must maintain documentation reflecting that the proxy caregiver providing assistance with medications has received training with an established written curriculum developed by an appropriately licensed healthcare professional that includes all of the topics listed:

- (a) The licensed facility's medication policies and procedures;
- (b) How to read prescription labels including common abbreviations;
- (c) Providing the right medication to the right client at the right time in the right amount and the right way including how to measure various medications that the specific client is taking;
- (d) The importance of taking the medications as prescribed:
- (e) Recognition of side effects and adverse reactions for the specific medications;
- Understanding the common classifications of medications, typical side effects and adverse reactions and medications which must never be administered by proxy caregivers;
- (g) Actions to take when concerns regarding medications are identified;
- (h) Infection control procedures;
- (i) Proper medication storage and disposal;
- Proper documentation and record keeping that the proxy caregiver is required to complete using a Medication Assistance Record (MAR) and the role of reference documents such as package inserts and medication manuals; and
- (k) Information about medication errors, error-prone situations and strategies to

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prevent such medication errors and instruction on proper documentation and reporting of medication errors.

- (4) The training on medication <u>assistance administration</u> must be provided by an appropriately licensed healthcare professional, e.g. registered professional nurse, advance practice registered nurse, physician's assistant, pharmacist or physician and must be individualized and supplemented as appropriate to meet the unique needs of the individual with a disability being served.
- (5) Where a new medication is ordered, athe-licensed healthcare professional who completed the written plan of care must be contacted by phone to ensure that no additional training is required prior to the caregiver providing assistance with the new medication. The date, time and the outcome of the contact with phone call to the licensed healthcare professional must be documented in the individual's record by the caregiver making the call at the time that the call is made. Where additional training is required prior to the caregiver providing assistance, such training will be provided and documented by a licensed healthcare professional.
- (6) Proxy caregivers providing medication assistance must be proficient in reading and following detailed written instructions in English, recording understandable written entries in the client's records, communicating effectively with the client and have achieved at least a minimum score of 75 on the Test of Functional Health Literacy for Adults (TOFHLA).
- (7) Prohibited Assistance. The licensed facility providing medication management services must not train or permit proxy caregivers to provide the following assistance with medications:
 - (a) Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication, breaking a scored tablet, crushing a tablet or adding water or other liquid to laxatives and nutritional supplements when such substance preparations are being done in accordance with a specific written prescription;
 - (b) Preparing syringes for intravenous injection or the administration of medications intravenously;
 - (c) Administering any intravenous medications and the first dose of any subcutaneous or intramuscular injection;
 - (d) Interpreting a "PRN" (as needed) medication order when the order does not identify the resident behaviors or symptoms which would trigger the need for the medication and/or does not identify the appropriate dosing and is not specifically authorized on the written plan of care;
 - (e) Irrigating or debriding agents used in the treatment of skin conditions;
 - (f) Assisting in the administration of sample or over the counter medications

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- where there is no written doctor's order providing amount and dosing instructions; and
- (g) Assisting in the administration of any medication to a client without appropriate evidence of a written order signed by an appropriately licensed healthcare professional; and
- (h) Performing any health maintenance activities where the licensed health care professional has determined that either the care required no longer meets the definition of health maintenance activities or the proxy caregiver has not demonstrated the knowledge and skill necessary to perform the health maintenance activities safely.
- (8) Maintaining Records on Medication Assistance Administration. Where the licensed facility manages medications for an individual with a disability, the licensed facility must maintain a daily Medication Assistance Record (MAR) for each person who receives assistance. At a minimum, the MAR must include the name of the specific person receiving assistance, any known allergies, the name and telephone number of the individual's health care provider, the name, strength and specific directions for the medications being managed, and a chart for staff who provide assistance to record initials, time and date when medications are taken, refused or a medication error is identified (e.g. missed dosage). The staff providing the assistance must immediately update the MAR for each individual each time the medication is offered or taken.
 - (a) The licensed facility must make medication information concerning the descriptions of medication, dosing, side effects, adverse reactions and contraindications for each medication being administered to the individual with a disability immediately available for reference by proxy caregivers providing medication assistance. The licensed facility must utilize a properly indexed medication information notebook or folder which contains information about only the medications for which the caregivers are providing assistance.
 - (b) Proxy caregivers provided by the licensed facility who provide assistance with medications must document in the client's record any unusual reactions to the medications and provide such information to the individual with a disability, legally authorized representative, if any, and healthcare provider as appropriate.
- (9) Medication Assistance Competency Assessments. The licensed facility must maintain documentation showing that the proxy caregivers have been trained and determined to have the knowledge and skills necessary to provide the assistance with medications by the specified licensed healthcare professional.
 - (a) The specified licensed healthcare professional must sign and date the skills competency checklist for the staff they are evaluating.
 - (b) Skills competency checklists for proxy caregivers assisting with medications

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- must be promptly updated by a licensed healthcare professional whenever new medications are added for which such staff has not previously received training and at least annually.
- (c) The licensed facility must not allow any proxy caregiver to assist with administration of specific medications unless the proxy caregiver has been trained and determined competent by a registered professional nurse, or an authorized advance practice registered nurse, a physician's assistant or physician to assist with the administration of medications in that classification.
- (940) Competency Evaluations for Specialized Health Maintenance Activities. Where the health maintenance activity to be performed has multiple discrete tasks that must be performed in proper sequence to deliver safe care, the licensed healthcare professional must ensure that the skills competency checklist properly sequences all necessary tasks. The licensed healthcare professional must verify by direct observations and sign documentation that the proxy caregiver can complete all tasks required satisfactorily in proper sequence from memory without prompting or assistance of any kind. Competency to perform specialized health maintenance activities must be reevaluated whenever the health maintenance activities change, and on a regularly recurring schedule as determined appropriate by the licensed healthcare professional on the written plan of care. The schedule for such re-evaluations must take into consideration the nature of the health maintenance activities to be performed and the condition of the client. At a minimum, such reevaluations by the licensed healthcare professional must occur no less frequently than annually.

111-8-100-.06 Variances and Waivers

- (1) The Department may, in its discretion, grant variances and waivers of specific rules upon application or petition filed on forms provided by the Department. The Department may establish conditions which must be met by the licensed facility in order to operate under the variance or waiver granted.
 - (a) Variance. A variance may be granted by the Department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety, and care of the individuals with disabilities exist and will be met in lieu of the exact requirements of the rule or regulations in question.
 - (b) Waiver. The Department may dispense entirely with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, care, and rights of the individuals being served; and

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- (c) Experimental Variance or Waiver. The Department may grant variances and waivers to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant or petitioner that the intended protections afforded by the rule or regulation which is the subject of the request are met and that the innovative approach has the potential to improve service delivery without compromising health, safety, individuals' rights, or other relevant standards.
- (2) The decision of the Department regarding either granting or denying the application of the governing body of the licensed facility for a waiver or variance is not subject to further administrative review. The governing body may file a petition for judicial review in the appropriate superior court.
- (3) Where the Department has denied the application for a waiver or variance in writing, the Department will not consider a subsequent application for the same waiver or variance as a new application unless the applicant includes new evidence of a substantial change in the circumstances which formed the basis for the initial request.

111-8-100-.07 Enforcement

A licensed facility which permits proxy caregivers to deliver health maintenance activities is subject to inspection by the Department to determine compliance with the requirements contained in the Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, Chapter 111-8-100 or other licensure regulations applicable to the specific licensed facility. A licensed facility which is determined not to be in compliance with these rules or other rules applicable to the licensed facility, is subject to civil and administrative actions brought by the Department to enforce licensing requirements as provided by law and rules. Such actions will be initiated in compliance with the Georgia Administrative Procedures Act, O.C.G.A. § 50-13-1et seq., O.C.G.A. § 31-2-11 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

111-8-100-.08 Severability

In the event that any rule, sentence, clause or phrase of any of the rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions thereof shall remain in full force and effect as if such rule or portions thereof so determined, declared or adjudicated invalid or unconstitutional were not originally part of these rules.

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