DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH
Statutory Authority: 29 Delaware Code, Section 7903(10) (29 Del.C. §7903(10))
16 DE Admin. Code 4402, 4406, 4410 and 4469

FINAL
Health Systems Protections

ORDER

Delaware Health and Social Services ("Department") / Division of Public Health initiated proceedings to provide information of public interest with respect to adding provisions to require certain persons to receive dementia specific training. The Department's proceedings were initiated pursuant to 29 Delaware Code Section 101 and its authority as prescribed by 29 Delaware Code Section 7903(10).

The Department published its notice of public comment pursuant to 29 Delaware Code Section 10115 in the April 2011 Delaware Register of Regulations, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by April 30, 2011 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSED CHANGES

The proposal amends policies regarding Health Systems Protections to require certain persons to receive dementia specific training as required by the amendment to 29 Del.C. §7903 which added a paragraph (10) directing the DHSS Secretary to adopt regulations which require dementia specific training each year for persons who are certified, licensed, or registered by the State, and/or who are partially or fully funded by the State, to provide direct healthcare services to persons diagnosed as having Alzheimer's disease or other forms of dementia.

The proposed changes affect the following policy sections:
4402 Regulations for Adult Day Care Facilities;
4406 Home Health Agencies -Aide Only (Licensure);
4410 Skilled Home Health Agencies (Licensure);
4469 Personal Assistance Services Agencies.

Statutory Authority
29 Del.C. §7903(10), Powers, duties and functions of the Secretary

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE

The Governor's Advisory Council for Exceptional Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) offered the following observations and recommendations summarized below. The Division of Long Term Care Residents Protection (DLTCRP) has considered each comment and responds as follows.

First, the law requires the training to be provided "each year". The proposed §13.17, which is applicable to adult day care facilities, does not specifically require that the training be provided on an annual basis. Section 13.14.3 contemplates annual training but §13.17 is a "stand-alone" provision which omits any frequency of training standard.

Agency Response: Thank you for your suggestion. The words “each year” are added to the final regulations identified in the comment. The amended regulations are indicated by [Bracketed Bold Text].

Second, proposed §5.8.12 is ostensibly misplaced, incomplete, and lacking an annual training reference. Each preceding section (§§5.8.1 through 5.8.11) is a complete sentence. Section 5.8.12 is a clause. There is no reference to the frequency of training. These deficits could be easily resolved by incorporating the text of proposed §5.8.12 into a bullet under §5.8.6.

Agency Response: We agree with this comment. It was our intention to propose what was published as §5.8.12 as a bullet under §5.8.6 and that is what our records indicate we submitted. We are unsure where the numbering change occurred but will submit as final, the text of what was published as §5.8.12 as a bullet under §5.8.6.

Carol Lovett offered the following observations and recommendations.
Thank you for all the your work incorporating HB 159 into the regulations
I am particularly impressed by the recitation of the several domains for training and I am hopeful that administrators will realize that training will take more than 1 to 2 hours
Agency Response: Thank you for your support.

I recall that at one time we discussed including Hospice Organizations under the scope of HB 159. It is great that the aides will be trained but I understand from aides that if senior staff is not also trained it becomes difficult for them to use what they have learned.

I think there are nurses, LPNs, social workers, clergy etc that work in hospice organizations. It has been the experience of family caregivers with who I have spoken that they also need to be trained. In fact many caregivers have provide dementia training them selves to these folks when they come into their homes.

In 3230 Rest and residential Homes is there staff other than Aides and does the dementia training apply to other staff. I am not familiar with this venue so I don't know

Also with the Home Health Agencies and Skilled home Health Agencies are staff other than the Aides required to complete an orientation and continuing education which includes the dementia training.

I think both of these agencies employ LPNs and nurses and the skilled agencies have speech therapists, physical therapists, social workers etc.

It was not clear when I read the regulation if all staff was included

Agency Response: Thank you for your suggestion. In interpreting HB 159, DHSS identified regulations where we are most likely to have persons providing "direct healthcare services to persons diagnosed as having Alzheimer's disease or other forms of dementia." (HB 159). DHSS staff did not realize there was an intention to include Hospice under HB 159.

In reviewing regulations where this requirement would fit, we did not include the training requirement in the Hospice regulations. However, as we learn from the implementation of this requirement, we will consider adding it to these additional regulations. Regarding the questions about what staff exist in different settings and which staff are required to receive the dementia training, the answer varies by provider and setting. Also, DHSS does not have the authority to regulate people in the professions you list. As such, the regulations use the exact language from 29 Del.C. §7903(10) (HB 159) to make sure that any staff at the facilities or in the agencies who fall under the law's requirement are required to receive the training.

FINDINGS OF FACT

The Department finds that the proposed changes as set forth in the April 2011 Register of Regulations should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Department of Public Health regulations the with respect to adding provisions to require certain persons to receive dementia specific training is adopted and shall be final effective August 1, 2011.

July 17, 2011, Rita M. Landgraf, Secretary, DHSS

Please Note: Only those sections of the regulations that are being amended are reproduced below. The complete regulation can be viewed in the Administrative Code.

4402 Regulations for Adult Day Care Facilities

(Break in Continuity of Sections)

13.0 Personnel/administrative

13.1 Adult day care providers must comply with the special employment practices relating to health care and child care facilities (19 Del.C. §708 and 11 Del.C. §8563) and adult abuse registry check (11 Del.C. §8564) and the regulations promulgated by the Department of Labor regarding same.

13.2 No employee shall be less than 18 years of age and no person shall be employed who has been convicted of a crime where the victim was a person regardless of whether the crime was a felony or a misdemeanor.

13.3 The facility shall have written personnel policies and procedures that adequately support sound care and services to participants.

13.4 Personnel records of each employee shall be kept current and available upon request by the Department’s representatives and shall contain sufficient information to support placement in the positions to which assigned.

13.5 Minimum requirements for pre-employment and annual tuberculosis (TB) testing are those currently recommended by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.
13.5.1 No person, including volunteers, found to have active tuberculosis in an infectious stage shall be permitted to give care or service to participants.

13.5.2 Any person having a positive skin test but a negative X-ray must complete a statement annually attesting that they have experienced no symptoms which may indicate active TB infection.

13.5.3 A report of all test results and all attestation statements shall be on file at the facility of employment.

13.6 All new employees shall be required to have a pre-employment physical examination. A copy of the pre-employment physical examination shall be maintained in individual personnel files.

13.7 Any individual who cannot adequately perform her/his duties or who may jeopardize the health or safety of the participants shall be relieved of his duties and removed from the center until such time as the condition is resolved. This includes infections of a temporary nature.

13.8 The adult day care provider shall provide for systematic performance review to communicate expectations and responsibilities, recognize achievement, and identify areas for skill development and work performance improvement. Performance reviews shall be completed annually and shall be maintained in the employee personnel record.

13.9 The director/administrator shall be responsible for complying with the regulations herein contained. In the absence of the director, a qualified substitute shall be authorized, in writing, to be in charge.

13.10 The director’s/administrator’s responsibilities shall include, but not be limited to, the following areas:

13.10.1 The development of the content of the program offered to the participants;

13.10.2 Programmatic functions, including orientation, training, and scheduling of all staff whether or not the director personally performs these functions; and

13.10.3 Assignment of a sufficient number of qualified staff to meet the participant’s needs for:

13.10.3.1 Adequate nutrition;
13.10.3.2 Health supervision and maintenance;
13.10.3.3 Personal care;
13.10.3.4 Socialization;
13.10.3.5 Recreation;
13.10.3.6 Activities and stimulation; and,
13.10.3.7 Supervision, protection, and safety.

13.11 The director shall have a Bachelor’s Degree in health or social services or a related field, with one (1) year supervisory experience (full-time or equivalent) in a social or health service setting; have comparable technical and human service training with demonstrated competence and experience managing in a health or human service setting; or, be a registered nurse with two (2) years of supervisory experience (full-time or equivalent) in a social or healthcare setting.

13.12 Volunteers

13.12.1 All volunteers shall be under the supervision of the director/administrator or designated staff person.

13.12.2 The duties of volunteers shall be clearly defined.

13.12.3 The adult day care facility shall maintain a record of volunteer hours/activities and provide appropriate supervision of volunteers.

13.13 Aides/Assistants/Technicians

13.13.1 All aides must meet the following minimum criteria:

13.13.1.1 Completion of an orientation/training program which meets the requirements contained within these regulations; AND,

13.13.1.2 Certification as a nurse aide (CNA); or,
13.13.1.3 Possession of one year of experience in a health care setting; or,
13.13.1.4 Enrollment in a nursing program and completion of a medical surgical clinical practicum.

13.13.2 All aides must pass a competency evaluation test prior to providing unsupervised care to participants in the program.

13.13.3 It is the responsibility of the adult day care program to ensure that aides are proficient to carry out the care assigned in a safe, effective, and efficient manner.

13.14 Staff Training and Development

13.14.1 Prior to assuming job responsibilities, all personnel shall receive training in:

13.14.1.1 Their individual responsibilities in the event of fire, including the location and operation of any fire extinguisher and fire alarm box;
13.14.1.2 Their individual responsibilities in the event of illness or injuries, including the location and use of the first aid emergency supplies;
13.14.1.3 Their individual responsibilities in the event of any emergency;
13.14.1.4 Infection control, body mechanics and first aid; and
13.14.1.5 Special needs of the elderly, persons with cognitive disabilities or persons with other disabilities, including the specific needs of the participants being served.

13.14.2 Ongoing staff development is required to maintain and improve the skills of the adult day care team and should include:

13.14.2.1 The needs of the elderly and persons with disabilities.
13.14.2.2 Assisting participants to achieve maximum self-reliance through re-learning and modifying activities of daily living.
13.14.2.3 Physical restraint and the use of less restrictive alternatives.
13.14.2.4 Maintaining an environment that encourages morale building and self-help.
13.14.2.5 Review of participant care policies and procedures.
13.14.2.6 Prevention and control of infection.
13.14.2.7 Confidentiality of participant information.
13.14.2.8 Rights of participants.

13.14.3 Personnel who are primarily responsible for the direct care of the participants shall attend at least twelve (12) hours annually of staff development activities which shall consist of in-service training programs, workshops, or conferences related to adult day care or specific needs of participants.

13.15 Aide Orientation and Training

13.15.1 An orientation/training program should be based on an instruction plan that includes learning objectives, clinical content and minimum acceptable performance standards.

13.15.2 The orientation program must include at least forty (40) hours of instruction and supervised practicum.

13.15.3 An orientation/training program must include the following:

13.15.3.1 The aide’s role as a member of the adult day care team.
13.15.3.2 Personal care services.
13.15.3.3 Principles of good nutrition.
13.15.3.4 Process of growth, development, and aging.
13.15.3.5 Principles of infection control.
13.15.3.6 Observation, reporting, and documentation of participant status.
13.15.3.7 Maintaining a clean, safe, and healthy environment.
13.15.3.8 Maintaining a least restrictive environment.
13.15.3.9 Verbal/nonverbal communication skills.
13.15.3.10 Principles of body mechanics.

13.16 The adult day care program must maintain sufficient documentation to demonstrate that all requirements of this section have been met.

13.17 An Adult Day Care facility that provides direct healthcare services to persons diagnosed as having Alzheimer’s disease or other forms of dementia shall provide dementia specific training [each year] to those healthcare providers who must participate in continuing education programs. The mandatory training must include: communicating with persons diagnosed as having Alzheimer’s disease or other forms of dementia; the psychological, social, and physical needs of those persons; and safety measures which need to be taken with those persons. This paragraph shall not apply to persons certified to practice medicine under the Medical Practice Act, Chapter 17 of Title 24 of the Delaware Code.

4406 Home Health Agencies--Aide Only (Licensure)

(Break in Continuity of Sections)

5.0 Administration/Personnel

5.1 Director

5.1.1 There shall be a full-time agency director.

5.1.2 The director shall have the overall authority and responsibility for the daily operation and management of the agency.
5.1.3 The authority, duties and responsibilities of the director shall be defined in writing and shall include but not be limited to:

5.1.3.1 Interpretation and execution of the policies adopted by the governing body;
5.1.3.2 Program planning, budgeting, management and program evaluation;
5.1.3.3 Maintenance of the agency's compliance with licensure regulations and standards;
5.1.3.4 Preparation and submission of required reports;
5.1.3.5 Distribution of a written plan for the delegation of administrative responsibilities and functions in the absence of the director;
5.1.3.6 Documentation of complaints relating to the conduct or actions by employees/contractors and action taken secondary to the complaints;
5.1.3.7 Conducting or supervising the resolution of complaints received from patients in the delivery of care or services by the agency; and
5.1.3.8 Reviewing policies and procedures at least annually and reporting, in writing, to the governing body on the review.

5.1.4 The director shall designate, in writing, a similarly qualified person to act in the absence of the director.

5.2 Supervision of Services

5.2.1 The director shall appoint a full-time employee as the clinical director.
5.2.2 The clinical director shall be responsible for implementing, coordinating and assuring quality of patient care services.
5.2.3 The clinical director shall:

5.2.3.1 Be available at all times during operating hours of the home health agency;
5.2.3.2 Participate in all activities related to the services provided, including the qualifications of personnel and contractors as related to their assigned duties; and
5.2.3.3 Provide general supervision and direction of the services offered by the home health agency.

5.2.4 In the absence of the clinical director, an equally qualified designee must be appointed.

5.3 Contract Services

5.3.1 The home health agency maintains responsibility for all services provided to the patient.
5.3.2 Services provided by the home health agency through arrangements with a contractor agency shall be set forth in a written contract which clearly specifies:

5.3.2.1 That the patient's contract for care is with the home health agency;
5.3.2.2 The services to be provided by the contractor;
5.3.2.3 The necessity to conform to all home health agency policies;
5.3.2.4 The procedure for recording services delivered and scheduling of visits;
5.3.2.5 The procedure for annual assurance of competence of all individuals utilized under contract;
5.3.2.6 The procedure for supervision of services of the contracted individuals;
5.3.2.7 That all payments by the patient for services rendered shall be made directly to the agency or its billing representative and no payments shall be made to or in the name of contractors of the agency;
5.3.2.8 That patients are accepted only by the home health agency. Patients may not be admitted for home health aide services by a contracted individual without prior review of the case and acceptance of the patient by the home health agency in accordance with agency policies; and
5.3.2.9 That the written contractual arrangement must contain a renewal clause or be renewed annually.

5.3.3 The agency must ensure that personnel and services contracted meet the requirements specified in these regulations for home health agency personnel and services.

5.4 Written Policies

5.4.1 Policy manuals shall be prepared which outline the procedures and practices to be followed by employees/contractors of the agency.
5.4.2 The home health agency shall establish written policies regarding:

5.4.2.1 The rights and responsibilities of patients;
5.4.2.2 The handling and documentation of incidents, accidents and medical emergencies;
5.4.2.2.1 Reports of these events shall be kept on file at the agency.
5.4.2.3 Control of the exposure of patients and staff to persons with communicable diseases;
5.4.2.4 Reporting of all reportable communicable diseases to the Department;
5.4.2.5 The patient's (and family or representative, if any) right to have concerns addressed without fear of reprisal. This policy must include the mechanism for informing the patient of her/his right to report concerns/complaints to the Department at a telephone number established for that purpose.

5.4.2.6 The procedure to be followed in the event that the home health agency is not able to provide services scheduled for any particular day or time. This policy shall include at a minimum:

5.4.2.6.1 The procedure for contacting the patient prior to the missed visit;
5.4.2.6.2 The procedure for attempts to find a substitute home health aide; and
5.4.2.6.3 Documentation of the missed visit, patient contact and attempts to find a substitute home health aide.

5.4.2.7 Infection control.

5.4.2.8 Employment/Personnel which shall include:

5.4.2.8.1 Qualifications, responsibilities and requirements for each job classification;
5.4.2.8.2 Pre-employment requirements;
5.4.2.8.3 Position descriptions;
5.4.2.8.4 Orientation for all employees and contractors;
5.4.2.8.5 Inservice education;
5.4.2.8.6 Annual performance review and competency testing; and
5.4.2.8.7 The process of appointment to the professional staff whereby it can satisfactorily be determined that the individual is appropriately licensed and qualified for the privileges and responsibilities to be given.

5.4.2.9 Referrals received, admission of patients to agency services, delivery of those services and discharge of patients.

5.4.2.10 The use and removal of records and the conditions for release of information in accordance with statutory provisions pertaining to confidentiality.

5.4.3 The home health agency shall review its written policies at least annually and revise them as necessary.

5.4.4 Policies shall be made available to representatives of the Department upon request.

5.5 Personnel Records

5.5.1 Records of each home health aide shall be kept current and available upon request by authorized representatives of the Department.

5.5.2 For individuals utilized via contract with another agency, the home health agency shall obtain, upon request, any records as required by the Department.

5.5.3 For all individuals, the agency shall maintain individual personnel records which shall contain at least:

5.5.3.1 Written verification of compliance with pre-employment requirements;
5.5.3.2 Documentation of competence;
5.5.3.3 Evidence of current professional licensure, registration or certification as appropriate;
5.5.3.4 Educational preparation and work history;
5.5.3.5 Written performance evaluations (annually); and
5.5.3.6 A written and signed job description.

5.6 Health History

5.6.1 All new employees/contractors shall be required to have a physical examination prior to providing care:

5.6.1.1 The physical examination must have been completed within 3 months prior to employment/referral and
5.6.1.2 A copy of the physical examination shall be maintained in individual files.

5.6.2 Minimum requirements for tuberculosis (TB) testing are those currently recommended by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services:

5.6.2.1 A baseline testing must be completed upon hire and, thereafter, as determined by a TB risk assessment.
5.6.2.2 No person found to have active TB in an infectious stage shall be permitted to give care or service to patients.
5.6.2.3 Any person having a positive skin test but a negative chest X-ray must complete a statement annually attesting that they have experienced no symptoms which may indicate active TB infection.
5.6.2.4 A report of all TB test results and all attestation statements shall be on file at the home health agency.
5.6.3 Any individual who cannot adequately perform the duties required or who may jeopardize the health or safety of the consumers shall be relieved of their duties and removed from the agency until such time as the condition is resolved. This includes infections of a temporary nature.

5.7 Staff Development

5.7.1 Staff development must be supervised by a registered nurse with at least one year of home health and administrative/supervisory experience.

5.7.2 All employees/contractors are required to complete an orientation program.

5.7.3 An orientation/training program should be based on an instruction plan that includes learning objectives, clinical content and minimum acceptable performance standards and shall include but not be limited to:

5.7.3.1 Organizational structure of the agency;
5.7.3.2 Agency patient care policies and procedures;
5.7.3.3 Philosophy of patient care;
5.7.3.4 Description of patient population and geographic location served;
5.7.3.5 Patient rights;
5.7.3.6 Agency personnel and administrative policies;
5.7.3.7 Job description;
5.7.3.8 Disaster Preparedness; and
5.7.3.9 Applicable state regulations governing the delivery of home health care services.

5.7.4 All newly hired/contracted aides shall be required to complete or show evidence of having completed seventy-five (75) hours of training which shall include instruction and supervised practicum and which addresses:

5.7.4.1 Personal care services;
5.7.4.2 Principles of good nutrition;
5.7.4.3 Process of growth, development and aging;
5.7.4.4 Principles of infection control;
5.7.4.5 Observation, reporting and documentation of patient status;
5.7.4.6 Maintaining a clean, safe and healthy environment;
5.7.4.7 Maintaining a least restrictive environment;
5.7.4.8 Verbal/non-verbal communication skills;
5.7.4.9 Reading and recording temperature, pulse and respiration;
5.7.4.10 Safe transfer techniques and ambulation;
5.7.4.11 Normal range of motion and positioning;
5.7.4.12 Introduction to common assistive technology;
5.7.4.13 Principles of body mechanics; and
5.7.4.14 The needs of the elderly and persons with disabilities.

5.7.5 Aides who experience a break in service for greater than two (2) calendar years will be expected to repeat the seventy-five (75) hour training requirement.

5.7.6 Ongoing staff development is required to maintain and improve the skills of the home health aide. Aides shall attend at least twelve (12) hours annually of staff development activities which shall consist of in-service training programs, workshops or conferences related to home health care or specific needs of patients and which shall include but not be limited to:

5.7.6.1 Instruction in how to assist patients to achieve maximum self-reliance through re-learning and modifying activities of daily living;
5.7.6.2 Principles of good nutrition;
5.7.6.3 Meal planning, food purchasing and preparation of meals, including special diets;
5.7.6.4 Information on the emotional and physical problems accompanying illness, disability or aging;
5.7.6.5 Principles and practices in maintaining a clean, healthy, pleasant and safe environment that encourages morale building and self-help;
5.7.6.6 Items requiring referral to the clinical director, including changes in the patient's condition or family situation;
5.7.6.7 Observation, reporting and documentation of patient status;
5.7.6.8 Policies and objectives of the agency;
5.7.6.9 Confidentiality of patient information;
5.7.6.10 Patient rights;
5.7.6.11 Principles of infection control;
5.7.6.12 Verbal/non-verbal communication skills; and
5.7.6.13 Principles of body mechanics.
5.7.6.14 Dementia specific training that includes: communicating with persons diagnosed as having Alzheimer’s disease or other forms of dementia; the psychological, social, and physical needs of those persons; and safety measures which need to be taken with those persons.

5.7.7 Documentation of orientation and continuing education must be in each individual’s personnel record and must include the date(s) and hour(s), content, and name and title of the person providing the orientation/education.

5.7.8 It is the responsibility of the home health agency to ensure that employees/contractors are proficient to carry out the care assigned in a safe, effective, and efficient manner.

5.7.9 All newly hired employees and contractors must pass a competency evaluation test prior to providing care to patients and annually thereafter.

5.7.10 The time allotted for training shall be sufficient to foster safe and skillful services to the patient.

5.7.11 Attendance records must be kept for all orientation and continuing education programs.

12 DE Reg. 1209 (03/01/09)

4410 Skilled Home Health Agencies (Licensure)

(Break in Continuity of Sections)

5.0 Administration/Personnel

5.1 Director

5.1.1 There shall be a full-time agency director.

5.1.2 The director shall have the overall authority and responsibility for the daily operation and management of the agency.

5.1.3 The authority, duties and responsibilities of the director shall be defined in writing and shall include but not be limited to:

5.1.3.1 Interpretation and execution of the policies adopted by the governing body;
5.1.3.2 Program planning, budgeting, management and program evaluation;
5.1.3.3 Maintenance of the agency’s compliance with licensure regulations and standards;
5.1.3.4 Preparation and submission of required reports;
5.1.3.5 Distribution of a written plan for the delegation of administrative responsibilities and functions in the absence of the director;
5.1.3.6 Documentation of complaints relating to the conduct or actions by employees/contractors and action taken secondary to the complaints; and
5.1.3.7 Conducting or supervising the resolution of complaints received from patients in the delivery of care or services by the agency.
5.1.3.8 Reviewing policies and procedures at least annually and reporting, in writing, to the governing body and the Professional Advisory Group on the review.

5.1.4 The director shall designate, in writing, a similarly qualified person to act in the absence of the director.

5.2 Professional Advisory Group

5.2.1 The home health agency must have an advisory group of professionals to include:

5.2.1.1 At least one physician;
5.2.1.2 One registered nurse (preferably with home health or public health experience); and
5.2.1.3 Representatives from other professional disciplines.

5.2.2 One member of the advisory group must be neither an owner nor an employee of the home health agency.

5.2.3 The advisory group meets as often as necessary, but at least semi-annually.

5.2.4 The advisory group maintains dated minutes of the meetings.

5.2.5 The advisory group is responsible for the annual review of the home health agency policies governing scope of services offered, admission and discharge policies, medical supervision and plans of treatment, emergency care, patient records and program evaluations. Based upon this review, the advisory group will
make recommendations for additions, revisions, or deletions to policies and programs to the governing body.

5.3 Supervision of Clinical Services

5.3.1 The director shall appoint a full-time employee as the clinical director.

5.3.2 The clinical director shall be responsible for implementing, coordinating and assuring quality of patient care services.

5.3.3 The clinical director shall:

5.3.3.1 Be a registered nurse with at least one year of home health and administrative/supervisory experience;

5.3.3.2 Be available at all times during operating hours of the home health agency;

5.3.3.3 Participate in all activities related to the services provided, including the qualifications of personnel and contractors as related to their assigned duties; and

5.3.3.4 Provide general supervision and direction of the services offered by the home health agency.

5.3.4 In the absence of the clinical director, an equally qualified designee must be appointed.

5.4 Contract Services

5.4.1 The home health agency maintains responsibility for all services provided to the patient.

5.4.2 Services provided by the home health agency through arrangements with a contractor agency or individual shall be set forth in a written contract which clearly specifies:

5.4.2.1 That the patient's contract for care is with the home health agency;

5.4.2.2 The services to be provided by the contractor;

5.4.2.3 The necessity to conform to all home health agency policies;

5.4.2.4 The procedure for submitting clinical and progress notes, scheduling visits, periodic patient evaluation, and determining charges and reimbursement;

5.4.2.5 The procedure for annual assurance of clinical competence of all individuals utilized under contract;

5.4.2.6 The procedure for supervision of services of the contracted individuals;

5.4.2.7 That all payments by the patient for services rendered shall be made directly to the agency or its billing representative and no payments shall be made to or in the name of contractors of the agency;

5.4.2.8 That patients are accepted only by the home health agency. Patients may not be admitted for services by a contracted individual without prior review of the case and acceptance of the patient by the home health agency in accordance with agency policies; and

5.4.2.9 That the written contractual arrangement must contain a renewal clause or be renewed annually.

5.4.3 The agency must ensure that personnel and services contracted meet the requirements specified in these regulations for home health agency personnel and services.

5.5 Written Policies

5.5.1 Policy manuals shall be prepared and followed which outline the procedures and practices of the agency.

5.5.2 The home health agency shall establish written policies regarding:

5.5.2.1 The rights and responsibilities of patients;

5.5.2.2 The handling and documentation of incidents, accidents and medical emergencies;

5.5.2.2.1 Reports of these events shall be kept on file at the agency.

5.5.2.3 Control of the exposure of patients and staff to persons with communicable diseases;

5.5.2.4 Reporting of all reportable communicable diseases to the Department;

5.5.2.5 The patient's (and family or representative, if any) right to have concerns addressed without fear of reprisal. This policy must include the mechanism for informing the patient of her/his right to report concerns/complaints to the Department at a telephone number established for that purpose.

5.5.2.6 The procedure to be followed in the event that the home health agency is not able to provide services scheduled for any particular day or time. This policy shall include at a minimum:

5.5.2.6.1 The procedure for contacting the patient prior to the missed visit;

5.5.2.6.2 The procedure for attempts to find a substitute caregiver; and

5.5.2.6.3 Documentation of the missed visit, patient contact, and attempts to find a substitute caregiver.

5.5.2.7 Infection control.

5.5.2.8 Employment/Personnel which shall include:
5.5.2.8.1 Qualifications, responsibilities and requirements for each job classification;
5.5.2.8.2 Pre-employment requirements;
5.5.2.8.3 Position descriptions;
5.5.2.8.4 Orientation policy and procedure for all employees and contractors;
5.5.2.8.5 Inservice education policy;
5.5.2.8.6 Annual performance review and competency testing; and
5.5.2.8.7 The process of appointment to the professional staff whereby it can satisfactorily be
determined that the individual is appropriately licensed and qualified for the privileges and
responsibilities to be given.
5.5.2.9 Referrals received, admission of patients to agency services, delivery of those services and
discharge of patients.
5.5.2.10 The use and removal of records and the conditions for release of information in accordance with
statutory provisions pertaining to confidentiality.
5.5.3 The home health agency shall review its written policies at least annually, and revise them as necessary.
5.5.4 Policies shall be made available to representatives of the Department upon request.

5.6 Personnel Records
5.6.1 Records of each employee/contractor shall be kept current and available upon request by authorized
representatives of the Department.
5.6.2 For individuals utilized via contract with another agency, the home health agency shall obtain, upon
request, any records as required by the Department.
5.6.3 For all individuals, the agency shall maintain individual personnel records which shall contain at least:
5.6.3.1 Written verification of compliance with pre-employment requirements;
5.6.3.2 Documentation of clinical competence;
5.6.3.3 Evidence of current professional licensure, registration or certification as appropriate;
5.6.3.4 Educational preparation and work history;
5.6.3.5 Written performance evaluations (annually); and
5.6.3.6 A written and signed job description.

5.7 Health History
5.7.1 All new employees/contractors shall be required to have a physical examination prior to providing care:
5.7.1.1 The physical examination must have been completed within 3 months prior to employment/referral
and
5.7.1.2 A copy of the physical examination shall be maintained in individual files.
5.7.2 Minimum requirements for tuberculosis (TB) testing are those currently recommended by the Centers for
Disease Control and Prevention of the U.S. Department of Health and Human Services:
5.7.2.1 A baseline testing must be completed upon hire and, thereafter, as determined by a TB risk
assessment.
5.7.2.2 No person found to have active TB in an infectious stage shall be permitted to give care or service
to patients.
5.7.2.3 Any person having a positive skin test but a negative chest X-ray must complete a statement
annually attesting that they have experienced no symptoms which may indicate active TB
infection.
5.7.2.4 A report of all TB test results and all attestation statements shall be on file at the home health
agency.
5.7.3 Any individual who cannot adequately perform the duties required or who may jeopardize the health or
safety of the consumers shall be relieved of their duties and removed from the agency until such time as
the condition is resolved. This includes infections of a temporary nature.

5.8 Staff Development
5.8.1 Staff development must be supervised by a registered nurse with at least one year of home health and
administrative-supervisory experience.
5.8.2 All employees/contractors are required to complete an orientation program.
5.8.3 An orientation/training program should be based on an instruction plan that includes learning objectives,
clinical content and minimum acceptable performance standards. and shall include but not be limited to:
5.8.3.1 Organizational structure of the agency;
5.8.3.2 Agency patient care policies and procedures;
5.8.3.3 Philosophy of patient care;
5.8.3.4 Description of patient population and geographic location served;
5.8.3.5 Patient rights;
5.8.3.6 Agency personnel and administrative policies;
5.8.3.7 Job description;
5.8.3.8 Disaster Preparedness; and
5.8.3.9 Applicable state regulations governing the delivery of home health care services.

5.8.4 All newly hired/contracted aides shall be required to complete or show evidence of having completed seventy-five (75) hours of training which shall include instruction and supervised practicum and which addresses:

5.8.4.1 Personal care services;
5.8.4.2 Principles of good nutrition;
5.8.4.3 Process of growth, development and aging;
5.8.4.4 Principles of infection control;
5.8.4.5 Observation, reporting and documentation of patient status;
5.8.4.6 Maintaining a clean, safe and healthy environment;
5.8.4.7 Maintaining a least restrictive environment;
5.8.4.8 Verbal/non-verbal communication skills;
5.8.4.9 Reading and recording temperature, pulse and respiration;
5.8.4.10 Safe transfer techniques and ambulation;
5.8.4.11 Normal range of motion and positioning;
5.8.4.12 Principles of body mechanics; and
5.8.4.13 The needs of the elderly and persons with disabilities.

5.8.5 Aides who experience a break in service for greater than two (2) calendar years will be expected to repeat the seventy-five (75) hour training requirement.

5.8.6 Ongoing staff development is required to maintain and improve the skills of the caregiver. Aides shall attend at least twelve (12) hours annually of staff development activities which shall consist of in-service training programs, workshops, or conferences related to home health care or specific needs of patients and which shall include but not be limited to:

- Instruction in how to assist patients to achieve maximum self-reliance through re-learning and modifying activities of daily living;
- Principles of good nutrition;
- Meal planning, food purchasing and preparation of meals, including special diets;
- Information on the emotional and physical problems accompanying illness, disability or aging;
- Principles and practices in maintaining a clean, healthy, pleasant and safe environment that encourages morale building and self-help;
- Items requiring referral to the home health agency, including changes in the patient's condition or family situation;
- Observation, reporting, and documentation of patient status;
- Policies and objectives of the agency;
- Confidentiality of patient information;
- Patient rights;
- Principles of infection control;
- Verbal/non-verbal communication skills; and
- Principles of body mechanics.

5.8.7 Documentation of orientation and continuing education must include the date(s) and hour(s), content, and name and title of the person providing the orientation/education.

5.8.8 It is the responsibility of the home health agency to ensure that employees/contractors are proficient to carry out the care assigned in a safe, effective and efficient manner.

5.8.9 All newly hired employees and contractors must pass a competency evaluation test prior to providing care to patients and annually thereafter.

5.8.10 The time allotted for training shall be sufficient to foster safe and skillful services to the patient.

5.8.11 Attendance records must be kept for all orientation and continuing education programs.
Dementia specific training that includes: communicating with persons diagnosed as having Alzheimer’s disease or other forms of dementia; the psychological, social, and physical needs of those persons; and safety measures which need to be taken with those persons.

12 DE Reg. 1217 (03/01/09)

4469 Personal Assistance Services Agencies

(Break in Continuity of Sections)

4.0 Administration

4.1 Agency Director

4.1.1 Every Agency shall have a full-time agency director.

4.1.2 The director shall appoint an individual to act in the director's absence.

4.1.3 The director shall have full authority and responsibility to plan, staff, direct and implement the programs and manage the affairs of the agency.

4.2 Purchase of Contracted Services

4.2.1 The personal assistance services agency maintains responsibility for all services provided to the consumer.

4.2.2 The personal assistance services agency shall establish a written contractual arrangement with a contractor for the provision of all services which are not provided directly by employees of the agency.

4.3 Written Policies

4.3.1 The personal assistance services agency shall have written policies regarding qualifications, responsibilities and requirements for employment/referral for each job classification.

4.3.2 The written policies shall include but not be limited to:

4.3.2.1 Pre-employment/referral requirements;

4.3.2.2 Position descriptions;

4.3.2.3 Orientation policy and procedure for all direct care workers;

4.3.2.4 Annual performance review and competency testing policy and procedure; and

4.3.2.5 Program review and evaluation of its program.

4.3.3 Policies shall be reviewed and dated annually and revised as necessary.

4.4 Direct Care Worker Records

4.4.1 Records of each direct care worker shall be kept current and available upon request by authorized representatives of the Department.

4.4.2 For all direct care workers, the agency shall maintain individual records which shall contain at least:

4.4.2.1 Written verification of compliance with pre-employment/referral requirements;

4.4.2.2 Documentation of competence;

4.4.2.3 Educational preparation and work history;

4.4.2.4 Written performance evaluations or consumer satisfaction surveys (annually); and

4.4.2.5 A letter of appointment specifying conditions of employment/referral.

4.4.2.6 Health History

4.4.2.6.1 Minimum requirements for pre-employment/referral and annual tuberculosis (TB) testing are those currently recommended by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

4.4.2.6.2 No person, including volunteers, found to have active tuberculosis in an infectious stage shall be permitted to give care or service to consumers.

4.4.2.6.3 Any person having a positive skin test but a negative X-ray must complete a statement annually attesting that they have experienced no symptoms which may indicate active TB infection.

4.4.2.6.4 A report of all test results and all attestation statements shall be on file at the agency.

4.4.2.6.5 All new direct care workers shall be required to have a pre-employment/referral physical examination, a copy of which shall be maintained in individual files.

4.4.2.6.6 Any individual who cannot adequately perform the duties required or who may jeopardize the health or safety of the consumers shall be relieved of their duties and removed from the
agency until such time as the condition is resolved. This includes infections of a temporary nature.

4.5 Orientation and Testing

4.5.1 All direct care workers are required to complete an orientation program given by the Agency before providing services to a consumer.

4.5.2 The orientation program shall include but not be limited to:

4.5.2.1 Organizational structure of the agency;
4.5.2.2 Agency consumer care policies and procedures;
4.5.2.3 Philosophy of consumer care;
4.5.2.4 Description of consumer population and geographic location served;
4.5.2.5 Consumer rights;
4.5.2.6 Agency personnel and administrative policies;
4.5.2.7 Principles of good nutrition;
4.5.2.8 Process of growth, development and aging;
4.5.2.9 Principles of infection control;
4.5.2.10 Observation, reporting and documentation of consumer status;
4.5.2.11 Maintaining a least restrictive environment;
4.5.2.12 Verbal/non-verbal communication skills;
4.5.2.13 Principles of body mechanics;
4.5.2.14 The needs of the elderly and persons with disabilities;
4.5.2.15 Activities of daily living;
4.5.2.16 Introduction to common assistive technology;
4.5.2.17 Meal planning, food purchasing and preparation of meals, including special diets;
4.5.2.18 Information on the emotional and physical problems accompanying illness, disability or aging;
4.5.2.19 Principles and practices in maintaining a clean, healthy, pleasant and safe environment that encourages morale building and self-help;
4.5.2.20 Items requiring referral to the personal assistance services agency, including changes in the consumer's condition or family situation;
4.5.2.21 Confidentiality of consumer information;
4.5.2.22 Service Plan specific description; and
4.5.2.23 Applicable state regulations governing the delivery of personal assistance services to consumers.

4.5.3 All newly hired/contracted direct care workers must pass a competency test prior to providing care to consumers and annually thereafter.

4.5.3.1 The competency test must include questions addressing the competencies listed in Section 4.5.2.
4.5.3.2 It is the responsibility of the personal assistance services agency to ensure that direct care workers are proficient to carry out the care assigned in a safe, effective and efficient manner.

4.5.4 A Personal Assistance Services Agency that provides direct healthcare services to persons diagnosed as having Alzheimer’s disease or other forms of dementia shall provide dementia specific training to those healthcare providers who must participate in continuing education programs. The mandatory training must include: communicating with persons diagnosed as having Alzheimer’s disease or other forms of dementia; the psychological, social, and physical needs of those persons; and safety measures which need to be taken with those persons. This paragraph shall not apply to persons certified to practice medicine under the Medical Practice Act, Chapter 17 of Title 24 of the Delaware Code.

15 DE Reg. 220 (08/01/11) (Final)