

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, §122(3)x (16 Del.C. §122(3)x)
16 DE Admin. Code 4469

FINAL

ORDER

4469 Personal Assistance Services Agencies

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services (“DHSS”) initiated proceedings to adopt the State of Delaware Regulations Governing Personal Assistance Service Agencies. The DHSS proceedings to adopt regulations were initiated pursuant to 29 Del.C. Ch. 101 and authority as prescribed by 16 Del.C. §122(3)o.

On November 1, 2015 (Volume 19, Issue 5), DHSS published in the Delaware *Register of Regulations* its notice of proposed regulations, pursuant to 29 Del.C. §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by December 17, 2015, or be presented at a public hearing on December 2, 2015, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying “Summary of Evidence.”

SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Personal Assistance Service Agencies were published in the *Delaware State News*, the *News Journal* and the Delaware *Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (November 1, 2015 through December 17, 2015).

Entities offering written comments include:

- State Council for Persons with Disabilities, Daniese McMullin-Powell, Chairperson
- Governor’s Advisory Council for Exceptional Citizens, Robert D. Overmiller, Chairperson

As the comments from both agencies were similar in scope and nature, they are addressed concurrently in this summary of evidence.

Public comments and the DHSS (Agency) responses are as follows:

Comment:

In §1.0, definition of “Personal Assistance Service Agency (PASA)”, the second sentence reads as follows: “The PASA shall only provide services in the county in which the PASA is located and/or the county(ies) which are immediately adjacent.” This new limitation may be ill-conceived. A PASA “located” in Kent County could serve the entire State. However, an Agency “located” in New Castle County (NCC) could not serve clients in Sussex and an Agency “located” in Sussex could not serve clients in NCC. The rationale for this change is not provided. The term “located” is not defined. It is not based on statute. See 16 Del.C. §122(3)o. Delaware is a small state and the limitation may unnecessarily restrict residents’ choice of providers.

Incidentally, inclusion of this limitation in a definition violates subsection 4.3 of the Delaware Administrative Code Style Manual since it creates a substantive standard in a definition.

Agency Response: The Agency appreciates and acknowledges these comments. The purpose of this revision was not meant to restrict the choice of providers, but to ensure the provision of safe and quality care. This requirement has been part of the protocol for all skilled home health agencies for many years.

The rationale behind this requirement is that the skilled home health agencies need to be in close enough proximity to their patients and employees/contractors to provide adequate supervision. The agencies must have the ability to adequately supervise and monitor all services to assure that the quality and scope of services provided to all patients promotes the highest practicable functional capacity for each patient to meet their individual needs. Supervision of services requires that a qualified person be physically present to directly supervise the provision of services. Most of the patients receiving services from these agencies are part of a very vulnerable population. Inadequate supervision of the employees/contractors providing care in the patient’s private residence has the potential to lead to more abuse/crimes/theft against these vulnerable people.

To comply with subsection 4.3 of the Delaware Administrative Code Style Manual, the following technical changes will be made:

1. The definition of “Personal Assistance Services” will be revised to the following:
“Personal Assistance Services Agency” is an agency that employs or contracts with direct care workers to provide personal assistance services to consumers of the agency primarily in his/her place of residence.
2. The requirement that the PASA shall only provide services in the county in which the agency is located and/or the county(ies) which are immediately adjacent will be added to “2.0 Licensing Requirements and Procedures” as follows:
2.1.7 The agency shall only provide services in the county in which the agency is located and/or the county(ies) which are immediately adjacent.

The public comment period was open from November 1, 2015 through December 17, 2015. In addition, a public hearing was held December 2, 2015. Based on comments received, only non-substantive changes have been made to the proposed regulations. The regulations have been reviewed by the Delaware Attorney General’s office and approved by the Cabinet Secretary of DHSS.

FINDINGS OF FACT:

Changes made to the regulations based on the comments received are detailed in the summary of evidence. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Personal Assistance Service Agencies is adopted and shall become effective March 11, 2016, after publication of the final regulation in the Delaware Register of Regulations.

Rita M. Landgraf, Secretary
 February 16, 2016

4469 Personal Assistance Services Agencies

1.0 Definitions

- 1.1 The following words and terms, when used in this regulation, should have the following meaning unless the context clearly indicates otherwise:

“Activities of Daily Living” means the tasks for self-care which are performed either independently, with supervision, or with assistance. Activities of daily living include but are not limited to ambulating, transferring, grooming, bathing, dressing, eating and toileting.

“Agency” means a personal assistance services agency licensed by the Department of Health and Social Services.

“Change of Ownership (CHOW)” see **“Modification of Ownership and Control (MOC)”**.

“Companion” means a person who provides social interaction for an individual primarily in her/his place of residence. A companion may provide such services as cooking, housekeeping, errands, etc.

“Consumer” means the individual (client, customer, or other designation used) requesting and/or receiving personal assistance services as defined in this chapter, primarily in his/her residence.

“Consumer Record” means a written account of all services provided to a consumer by the personal assistance services agency, as well as other pertinent information necessary to provide care.

“Contractor” means an individual (subcontractor, independent contractor or other designation used) that does not meet the definition of employee, who holds a valid business license and provides services for the agency.

“Department” means the Delaware Department of Health and Social Services.

“Direct Care Worker” means those individuals (aide, assistant, caregiver, technician or other designation used) employed by or under contract to a personal assistance services agency to provide personal care services, companion services, homemaker services, transportation services and those services as permitted in 24 Del.C. Section 1921(a)(19) to consumers. The direct care worker provides these services to an individual primarily in their place of residence.

“Director” means a job-descriptive term used to identify the individual appointed by the governing body to act on its behalf in the overall management of the personal assistance services agency. Job titles may include administrator, superintendent, director, executive director, president, vice-president, or executive vice-president.

“Governing Body or Other Legal Authority” means the individual, partnership, agency, group, or corporation designated to assume full legal responsibility for the policy determination, management, operation and financial liability of the personal assistance services agency.

"Healthcare Facility" means any facility licensed under 16 Del.C. Ch. 10 or 11.

"Homemaker" means a person who performs household chores for an individual primarily in her/his place of residence. Household chores may include but are not necessarily limited to housekeeping, meal preparation and shopping.

"Home Visit" is a visit to the consumer's residence by an agency director, or designee, for the purpose of initial consumer need evaluation and update and revision of the service plan.

"Immediate Jeopardy" means a crisis situation in which the health and safety of consumers is at risk. It is a deficient practice which indicates an inability to furnish safe care and services.

"Legal Entity" means a business organizational structure that is recognized as such by 6 Del.C. or 8 Del.C.

"License" means a license issued by the Department.

"Licensee" means the individual, corporation, or legal entity with whom rests the ultimate responsibility for maintaining approved standards for the personal assistance services agency.

"Majority Interest" means the largest percentage of ownership interest.

"Minority Interest" means any percentage of ownership less than the majority interest.

"Modification of Ownership and Control (MOC)" means the sale, purchase, transfer or re-organization of ownership rights.

"Office" means the physical location in which the business of the personal assistance services agency is conducted and in which the records of personnel, contractors and consumers of the agency are stored. The office shall be located in the State of Delaware.

"Owner" means an individual or legal entity with ownership rights of the agency.

"Ownership" means the state or fact of exclusive possession and control of the agency.

"Ownership Interest" means the percentage of ownership an individual or legal entity possesses.

"Personal Assistance Services" means the provision of services for compensation that do not require the judgment and skills of a licensed nurse or other professional. The services are limited to individual assistance with/or supervision of activities of daily living, companion services, transportation services, homemaker services, reporting changes in consumer's condition and completing reports. These services do not require physician's orders.

"Personal Assistance Services Agency" is an agency that employs or contracts with direct care workers to provide personal assistance services to consumers of the agency primarily in his/her place of residence. ~~[The personal assistance services agency shall only provide services in the county in which the agency is located and/or the county(ies) which are immediately adjacent.]~~

"Plan of Correction" means a personal assistance services agency's written response to findings of regulatory non-compliance. Plans must adhere to the format specified by the licensing agency, must include acceptable timeframes in which deficiencies will be corrected and must be approved by the licensing agency.

"Representative" means a person acting on behalf of the consumer, as permitted by Delaware law.

"Residence" means the domicile of the consumer either personally owned by that consumer or considered the place of residence of that consumer ~~and that is not licensed, operated for profit, or operating as a healthcare facility.~~

"Safety Supervision" means the services provided by a direct care worker to help prevent wandering and other occurrences sometimes associated with dementia or diminished capacity.

"Service Plan" means a written plan that specifies scope, frequency and duration of services.

2.0 Licensing Requirements and Procedures

2.1 General Requirements

- 2.1.1 No person shall establish, conduct, or maintain in this State any personal assistance services agency without first obtaining a license from the Department.
- 2.1.2 A separate license shall be required for each office maintained by a personal assistance services agency.
- 2.1.3 The personal assistance services agency shall advise the Department in writing at least thirty (30) calendar days prior to any change in office location.
- 2.1.4 Any agency that undergoes a change of ownership is required to re-apply as a new agency.
- 2.1.5 A license is not transferable from person to person or from entity to entity.
- 2.1.6 The license shall be posted in a conspicuous place on the licensed premises.
- [2.1.7 The agency shall only provide services in the county in which the agency is located and/or the county(ies) which are immediately adjacent.]**

2.2 Application Process

- 2.2.1 All persons or entities applying for a license shall submit a written statement of intent to the Department describing the services to be offered by the agency and requesting a licensure application from the Department.
 - 2.2.1.1 The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department.
 - 2.2.1.2 No person or entity shall hold themselves out to the public as being a personal assistance services agency until a license has been issued.
- 2.2.2 In addition to a completed application for licensure, applicants shall submit to the Department the following information:
 - 2.2.2.1 The names, addresses and types of facilities owned or managed by the applicant;
 - 2.2.2.2 A copy of the Applicant's policies and procedures manual as outlined in ~~Regulation~~ Section 4.3;
 - 2.2.2.3 Identity of:
 - 2.2.2.3.1 Each officer and director of the corporation if the entity is organized as a corporation;
 - 2.2.2.3.2 Each general partner or managing member if the entity is organized as an unincorporated entity;
 - 2.2.2.3.3 The governing body;
 - 2.2.2.3.4 Proof of not-for-profit status if claiming tax-exempt status; and,
 - 2.2.2.3.5 Any officers/directors, partners, or managing members, or members of a governing body who have a financial interest of five percent (5%) or more in a licensee's operation or related businesses;
 - 2.2.2.4 Disclosure of any officer, director, partner, employee, direct care worker, managing member, or member of the governing body with a felony criminal record;
 - 2.2.2.5 Name of the individual (director/administrator/etc.) who is responsible for the management of the personal assistance services agency;
 - 2.2.2.6 A list of management personnel, including credentials;
 - 2.2.2.7 A copy of the test to be given to each direct care worker, as required by ~~Regulation~~ Section 4.5;
 - 2.2.2.8 Proof of insurance and bonding as required in ~~Regulation~~ Section 7.0.
 - 2.2.2.9 Any other information required by the Department.

2.3 Issuance of Licenses

2.3.1 Probationary license

- 2.3.1.1 A probationary license shall be granted for a period of ninety (90) calendar days to every agency that completes the application process consistent with these regulations.
- 2.3.1.2 All personal assistance services agencies shall have an on-site survey during the first ninety (90) days of operation. A personal assistance services agency, at the time of an initial on-site survey, must meet the definition of a personal assistance services agency as contained within these regulations and must be in operation and caring for consumers. Personal assistance services agencies that, at the time of an on-site survey, do not meet the definition of a personal assistance services agency or that are not in substantial compliance with these regulations will not be granted a license.
- 2.3.1.3 A probationary license will permit an agency to hire or contract with direct care workers and establish a consumer caseload.
- 2.3.1.4 A probationary license may not be renewed.

2.3.2 Provisional license

- 2.3.2.1 A provisional license may be granted, for a period of less than one year, to all personal assistance services agencies that:
 - 2.3.2.1.1 are not in substantial compliance with these regulations; or
 - 2.3.2.1.2 fail to renew a license within the timeframe prescribed by these regulations.
- 2.3.2.2 The Department shall designate the conditions and the time period under which a provisional license is issued.
- 2.3.2.3 A provisional license issued to an agency that is not in substantial compliance with these regulations may not be renewed unless a Plan of Correction has been approved by the Department and implemented by the personal assistance services agency.
- 2.3.2.4 A license will not be granted after the provisional licensure period to any agency that is not in substantial compliance with these regulations.

2.3.2.5 A license will be granted to the personal assistance services agency after the provisional licensure period if:

2.3.2.5.1 The agency has regained substantial compliance with these regulations and

2.3.2.5.2 The agency fulfilled the expectations of the plan of correction that was created to address the deficient practices that gave rise to the license action.

2.3.3 License

2.3.3.1 A license shall be granted, for a period of one year (12 months) to all personal assistance services agencies which are and remain in substantial compliance with these regulations.

2.3.3.2 A license shall be effective for a twelve-month period following date of issue and shall expire one year following the issue date, unless it is: modified to a provisional license, suspended, revoked, or surrendered prior to the expiration date.

2.3.3.3 Existing personal assistance services agencies must apply for licensure at least thirty (30) calendar days prior to the expiration date of the license.

2.3.3.4 A license may not be issued to a personal assistance services agency; ~~that is not in substantial compliance with these regulations or whose deficient practices present an immediate threat to the health and safety of its consumers.~~

2.3.3.4.1 Which does not meet the definition of a personal assistance services agency as contained within these regulations;

2.3.3.4.2 Which is not in substantial compliance with these regulations; or

2.3.3.4.3 Whose deficient practices present an immediate threat to the health and safety of its consumers.

2.4 Disciplinary proceedings

2.4.1 The Department may impose any of the following sanctions (subsection 2.4.2 of this section) singly or in combination when it finds a licensee or former licensee is guilty of any offense described herein:

2.4.1.1 Violated any of these regulations;

2.4.1.2 Failed to submit a reasonable timetable for correction of deficiencies;

2.4.1.3 Exhibited a pattern of cyclical deficiencies which extends over a period of two or more years;

2.4.1.4 Failed to correct deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department;

2.4.1.5 Engaged in any conduct or practices detrimental to the welfare of the consumers;

2.4.1.6 Exhibited incompetence, negligence, or misconduct in operating the personal assistance services agency or in providing services to individuals;

2.4.1.7 Mistreated or abused individuals cared for by the personal assistance services agency; or

2.4.1.8 Refused to allow the Department access to the agency or records for the purpose of conducting inspections/surveys/investigations as deemed necessary by the Department.

2.4.2 Disciplinary sanctions include:

2.4.2.1 Permanently revoke a license.

2.4.2.2 Suspend a license.

2.4.2.3 Issue a letter of reprimand.

2.4.2.4 Place a licensee on provisional status and require the licensee to:

2.4.2.4.1 Report regularly to the Department upon the matters which are the basis of the provisional status.

2.4.2.4.2 Limit practice to those areas prescribed by the Department.

2.4.2.4.3 Suspend new intakes and admissions.

2.4.2.5 Refuse a license.

2.4.2.6 Refuse to renew a license.

2.4.2.7 The Department may request the Superior Court to impose a civil penalty of not more than \$5,000 for a violation of these regulations. Each day a violation continues constitutes a separate violation.

2.4.2.7.1 In lieu of seeking a civil penalty, the Department, in its discretion, may impose an administrative penalty of not more than \$5,000 for a violation of these regulations. Each day a violation continues constitutes a separate violation.

2.4.2.7.2 In determining the amount of any civil or administrative penalty imposed, the Court or the Department shall consider the following factors:

- 2.4.2.7.2.1 The seriousness of the violation, including the nature, circumstances, extent and gravity of the violation and the threat or potential threat to the health or safety of a consumer(s);
- 2.4.2.7.2.2 The history of violations committed by the person or the person's affiliate(s), agents, employee(s), or controlling person(s);
- 2.4.2.7.3 The efforts made by the agency to correct the violation(s);
- 2.4.2.7.4 Any misrepresentation made to the Department; and
- 2.4.2.7.5 Any other matter that affects the health, safety or welfare of a consumer(s).
- 2.4.2.8 Or otherwise discipline.
- 2.4.3 Imposition of Disciplinary Action
 - 2.4.3.1 Before any disciplinary action under this chapter is taken (except as authorized by 2.4.4):
 - 2.4.3.1.1 The Department shall give twenty (20) calendar days written notice to the holder of the license, setting forth the reasons for the determination.
 - 2.4.3.1.2 The disciplinary action shall become final twenty (20) calendar days after the mailing of the notice unless the licensee, within such twenty (20) calendar-day period, shall give written notice of the Agency's desire for a hearing.
 - 2.4.3.1.3 If the licensee gives such notice, the Agency shall be given a hearing before the Secretary of the Department or her/his designee and may present such evidence as may be proper.
 - 2.4.3.1.4 The Secretary of the Department or her/his designee shall make a determination based upon the evidence presented.
 - 2.4.3.1.5 A written copy of the determination and the reasons upon which it is based shall be sent to the Agency.
 - 2.4.3.1.6 The decision shall become final twenty (20) days after the mailing of the determination letter unless the licensee, within the twenty (20) day period, appeals the decision to the appropriate court of the State.
- 2.4.4 Order to immediately suspend a license
 - 2.4.4.1 In the event the Department identifies activities which the Department determines present an immediate or imminent danger to the public health, welfare and safety requiring emergency action, the Department may issue an order temporarily suspending the licensee's license, pending a final hearing on the complaint. No order temporarily suspending a license shall be issued by the Department, with less than 24 hours prior written or oral notice to the licensee or the licensee's attorney so that the licensee may be heard in opposition to the proposed suspension. An order of temporary suspension under this section shall remain in effect for a period not longer than 60 days from the date of the issuance of said order, unless the suspended licensee requests a continuance of the date for the final hearing before the Department. If a continuance is requested, the order of temporary suspension shall remain in effect until the Department has rendered a decision after the final hearing.
 - 2.4.4.2 The licensee, whose license has been temporarily suspended, shall be notified forthwith in writing. Notification shall consist of a copy of the deficiency report and the order of temporary suspension pending a hearing and shall be personally served upon the licensee or sent by certified mail, return receipt requested, to the licensee's last known address.
 - 2.4.4.3 A licensee whose license has been temporarily suspended pursuant to this section may request an expedited hearing. The Department shall schedule the hearing on an expedited basis provided that the Department receives the licensee's request for an expedited hearing within 5 calendar days from the date on which the licensee received notification of the Department's decision to temporarily suspend the licensee's license.
 - 2.4.4.4 As soon as possible, but in no event later than 60 days after the issuance of the order of temporary suspension, the Department shall convene for a hearing on the reasons for suspension. In the event that a licensee, in a timely manner, requests an expedited hearing, the Department shall convene within 15 days of the receipt by the Department of such a request and shall render a decision within 30 days.
 - 2.4.4.5 In no event shall an order of temporary suspension remain in effect for longer than 60 days unless the suspended licensee requests an extension of the order of temporary suspension pending a final decision of the Department. Upon a final decision of the Department, the order of temporary suspension shall be vacated in favor of the disciplinary action ordered by the Department.
- 2.4.5 Termination of license

- 2.4.5.1 Termination of a license to provide services as a personal assistance services agency occurs secondary to:
 - 2.4.5.1.1 Revocation of a license or the voluntary surrender of a license in avoidance of revocation action.
 - 2.4.5.1.2 Termination of rights to provide services extends to:
 - 2.4.5.1.2.1 Agency;
 - 2.4.5.1.2.2 Owner(s);
 - 2.4.5.1.2.3 Officers/Directors, partners, managing members, or members of a governing body who have a financial interest of five percent (5%) or more in the personal assistance services agency; and
 - 2.4.5.1.2.4 Corporation officers.
- 2.5 Modification of Ownership and Control (MOC)
 - 2.5.1 Any proposed MOC must be reported to the Department a minimum of thirty (30) calendar days prior to the change.
 - 2.5.2 A MOC voids the current license in possession of the agency.
 - 2.5.3 A MOC may include but is not limited to:
 - 2.5.3.1 Transfer of full ownership rights to a new owner;
 - 2.5.3.2 Transfer of the majority interest to a new owner.
 - 2.5.3.3 Transfer of ownership interests that result in the owner with the majority interest becoming a minority interest owner.
 - 2.5.3.4 Transfer or re-organization that results in an additional majority interest that is equal in ownership rights.
 - 2.5.3.5 Transfer resulting in a measurable impact upon the operational control of the agency.
- 2.6 Fees
 - 2.6.1 Fees shall be in accordance with 16 **Del.C.** §122 (3)x.
- 2.7 Inspection
 - 2.7.1 A representative of the Department shall periodically inspect every personal assistance services agency for which a license has been issued under this chapter. Inspections by authorized representatives of the Department may occur at any time and may be scheduled or unannounced.
- 2.8 Notice to Consumers
 - 2.8.1 The personal assistance services agency shall notify each consumer or the consumer's authorized representative, and any third-party payers at least thirty (30) calendar days before the voluntary surrender of its license or as directed under an order of denial, revocation, or suspension of license issued by the Department.
- 2.9 Exclusions from Licensure

The following persons, associations or organizations are not required to obtain a Personal Assistance Services Agency license:

 - 2.9.1 Those individuals who contract directly with a consumer to provide services for that consumer, where the consumer pays the individual for services rendered and neither the consumer nor the individual pays an agency on a periodic basis.
 - 2.9.2 Those agencies that provide only durable medical equipment and supplies for in-home use.
 - 2.9.3 Those agencies that provide staff to licensed personal assistance services agencies, such as temporary employment/staffing agencies.
 - 2.9.3.1 Temporary employment/staffing agencies may not provide services under direct agreements with consumers.
 - 2.9.3.2 Temporary employment/staffing agencies must be contractually bound to perform services under the contracting providers' direction and supervision.
 - 2.9.3.3 Temporary staff working for a licensed provider must meet the requirements of these regulations.
 - 2.9.4 Any visiting nurse service or personal assistance services conducted by and for those who rely upon spiritual means through prayer alone for healing in accordance with the tenets and practices of a registered church or religious denomination.
 - 2.9.5 An agency which solely provides services as defined in 16 **Del.C.** Ch. 94, the Community Based Attendant Services Act.
 - 2.9.6 A Home Health Agency which solely provides services defined in 16 **Del.C.** §122~~(e)~~(3)g.

3.0 General Requirements

- 3.1 The personal assistance services agency shall neither knowingly admit, nor continue to care for, consumers whose needs cannot be met by a personal assistance services agency.
- 3.2 The personal assistance services agency shall establish written policies regarding the rights and responsibilities of consumers.
- 3.3 The personal assistance services agency shall establish policies and procedures that address the handling and documentation of incidents, accidents and medical emergencies.
- 3.4 Reports of incidents, accidents and medical emergencies shall be kept on file at the agency for a minimum of six years.
- 3.5 The personal assistance services agency shall establish policies which control the exposure of consumers and staff to persons with communicable diseases.
- 3.6 A procedure including the consumers and families right to report concerns/complaints to the Department at a telephone number established for that purpose, shall be established to enable consumers and their families or representatives, if any, to have their concerns addressed without fear of reprisal.
- 3.7 The personal assistance services agency shall advise the Department in writing within fifteen (15) calendar days following any change in the designation of the director/administrator or other management personnel within the agency.
- 3.8 The personal assistance services agency may contract for services to be provided to its consumers by direct care workers. Individuals providing services under contract must meet the same requirements as the direct care workers employed by the agency.
- 3.9 The director or a designee of any agency shall be available to consumers at all times during the operating hours of the personal assistance services agency.
- 3.10 The agency shall have policies and an operational system which assure uninterrupted implementation of the service plan. In furtherance of this requirement, the agency shall, at a minimum: 1) maintain a sufficient pool of qualified direct care workers to fulfill service plans and provide scheduled services; and 2) develop and maintain a back-up system to provide substitute direct care workers if regularly scheduled direct care workers are unavailable.
- 3.11 The personal assistance services agency shall permit photocopying of any records or other information by authorized representatives of the Department, as necessary to determine or verify compliance with these regulations.
- 3.12 Prior to the provision of personal care services in a healthcare facility, the personal assistance services agency must:
 - 3.12.1 Disclose the personal assistance services agency's and the direct care worker's status with respect to attendant tax, worker's compensation and liability insurance obligations, insurance coverage or the lack thereof to each healthcare facility in which services are provided.
 - 3.12.2 Obtain written permission from each healthcare facility in which personal care services will be provided.
- 3.13 The personal assistance services agency must not use the word "healthcare", or any other language which implies or indicates the provision of healthcare services, in its title or in its advertising.

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.
 - 4.1.4 The director must ensure that the personal assistance services agency adheres to its policies and procedures.
- 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 Personnel and Direct Care Worker Records
 - 4.4.1 Records of all personnel, including each direct care worker shall be kept current and available upon request by authorized representatives of the Department.
 - 4.4.2 For all personnel, including 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.~~ All new personnel, including direct care workers shall be required to have a physical examination prior to providing care:
 - 4.4.2.6.5.1 The physical examination must have been completed within three (3) months prior to employment/referral; and
 - 4.4.2.6.5.2 A copy of the physical examination shall be maintained in the individual's file.
 - 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 subsection 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.
- ~~4.5.44.5.3.2.1A 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 all direct care workers. 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)

5.0 Consumer Care Management

5.1 Admission/Intake

- 5.1.1 The personal assistance services agency shall have written policies governing intake procedures of consumers to agency services, referral of direct care workers and case closures.
- 5.1.2 The intake policies shall be discussed with each consumer or the consumer's representative.
- 5.1.3 The personal assistance services agency shall disclose to all consumers the personal assistance services agency's and the direct care worker's status with respect to attendant tax, worker's compensation and liability insurance obligations, insurance coverage or the lack thereof. Disclosure of this information shall be on a form developed by the Department.
- 5.1.4 There shall be a written agreement between the consumer and the personal assistance services agency. The agreement shall:
 - 5.1.4.1 Specify the services to be provided by the agency, including but not limited to: scheduled days, scheduled hours, transportation agreements as appropriate, emergency procedures and procedures for termination of services.
 - 5.1.4.2 Specify financial agreement which shall minimally include:
 - 5.1.4.2.1 A description of services purchased and the associated cost;
 - 5.1.4.2.2 An acceptable method of payment(s) for these services; and
 - 5.1.4.2.3 An outline of the billing procedures.
 - 5.1.4.3 Be signed by the consumer or their representative and the representative of the personal assistance services agency.
 - 5.1.4.4 Be given to the consumer or representative and a copy shall be kept at the agency in the consumer record.
 - 5.1.4.5 Be reviewed and updated as necessary to reflect any change in the terms.

5.2 Home Visits

- 5.2.1 An initial home visit of the consumer shall be performed by the agency director, or designee.
- 5.2.2 The initial home visit must be performed in the consumer's residence prior to or at the time that personal assistance services are initially requested by the consumer. The purpose of the home visit is to determine whether the agency has the ability to provide the necessary services in a safe manner.
- 5.2.3 The initial home visit shall include, at a minimum, an itemized written description of the consumer's:
 - 5.2.3.1 Physical condition, including ability to perform activities of daily living and sensory limitations;
 - 5.2.3.2 Social situation, including living arrangements and the availability of family and community support; and
 - 5.2.3.3 Mental status, including any cognitive impairment and known psychiatric, emotional and behavioral problems.
- 5.2.4 Follow-up home visits shall occur at regular intervals based upon the consumer's condition and needs, but no less often than every ninety (90) calendar days.
- 5.2.5 A follow-up home visit, performed by the agency director or designee, shall be conducted when the needs of the consumer change which indicate a revision to the service plan is needed.
- 5.2.6 The results of the initial home visit and follow-up home visits shall become a permanent part of the consumer's record.

5.3 Service Plan

- 5.3.1 The personal assistance services agency shall provide services in accordance with a written service plan developed under the supervision of the agency director.
- 5.3.2 A service plan shall be developed at intake based upon the initial home visit of the consumer.
- 5.3.3 The service plan shall be developed in consultation with the consumer or the consumer's representative.
- 5.3.4 The service plan shall be reviewed no less often than every ninety (90) calendar days and revised as necessary.

5.4 Scope of Services

- 5.4.1 Competent consumers who do not reside in a medical facility or a facility regulated pursuant to 16 **Del.C.** Ch. 11 may delegate personal care services to direct care workers provided:
 - 5.4.1.1 The nature of the service/task is not excluded by **Del.C. law** or other state or federal regulation.
 - 5.4.1.2 The services/tasks are those competent consumers could normally perform themselves but for functional limitation.
 - 5.4.1.3 The delegation decision is entirely voluntary.
- 5.4.2 For consumers who are not able to delegate services/tasks due to impaired cognitive function, services/tasks shall be limited by the following:
 - 5.4.2.1 Skin Care
 - 5.4.2.1.1 Skin care which is preventive rather than therapeutic may be provided and may include: application of non-medicated or non-prescribed lotions or creams, massaging of non-reddened areas and application of preventive spray on unbroken skin areas that may be susceptible to development of pressure sores. Also permitted is the application of band aids to minor skin breaks.
 - 5.4.2.1.2 Skin care which may not be provided includes sterile invasive procedures involving a wound or anatomical site and application of prescription medications.
 - 5.4.2.2 ~~Fingernail~~ Nail Care
 - 5.4.2.2.1 Fingernail care includes: soaking of nails, pushing back cuticles, and trimming/filing/polishing of nails.
 - 5.4.2.2.2 Fingernail care may not be provided in the presence of medical conditions that may involve peripheral circulatory problems or loss of sensation. Toenail care may not be provided.
 - 5.4.2.3 Mouth Care
 - 5.4.2.3.1 Mouth care includes denture care and basic oral hygiene.
 - 5.4.2.3.2 Mouth care may not be provided when the consumer is unconscious or when oral suctioning is required.
 - 5.4.2.4 Shaving
 - 5.4.2.4.1 Shaving may be performed only with the consumer's personal electric razor.
 - 5.4.2.4.2 Shaving may not be performed on an area where there is the presence of an injury or infection.

5.4.2.5 Feeding

- 5.4.2.5.1 Feeding includes assistance with eating by mouth, using common or adaptive feeding utensils.
- 5.4.2.5.2 Feeding may not be provided when oral suctioning is also needed or when there is a high risk of choking that could result in the need for emergency measures such as cardiopulmonary resuscitation. Tube and syringe feeding are not permitted.

5.4.2.6 Adult Transfers

- 5.4.2.6.1 Assistance with transfer may be provided when the consumer has sufficient balance and strength to assist with the transfer to some extent.
- 5.4.2.6.2 Assistance with transfer is not permitted if the consumer is unable to assist with the transfer.

5.4.2.7 Bladder Care

- 5.4.2.7.1 Bladder care includes assistance to and from the bathroom; assistance with bedpans, urinals or commodes; and changing of pads or diapers used for the care of incontinence.
- 5.4.2.7.2 Bladder care does not include insertion or removal of a foley or suprapubic catheter; care of a foley or suprapubic catheter; and care for an ostomy.

5.4.2.8 Bowel Care

- 5.4.2.8.1 Bowel care includes assistance to and from the bathroom; assistance with bedpans or commodes; and changing of pads or diapers used for the care of incontinence.
- 5.4.2.8.2 Bowel care does not include digital stimulation; enemas; and care for an ostomy.

5.5 Records and Reports

- 5.5.1 There shall be a separate record maintained at the personal assistance services agency for each consumer which shall contain:

5.5.1.1 Intake data including:

- 5.5.1.1.1 Consumer's name;
- 5.5.1.1.2 Consumer's birth date;
- 5.5.1.1.3 Consumer's home address;
- 5.5.1.1.4 Consumer's identification for purposes of third party billing, if applicable.
- 5.5.1.1.5 Consumer's date of intake;
- 5.5.1.1.6 Consumer's primary physician's name, address and telephone number; and
- 5.5.1.1.7 Names, addresses and telephone numbers of family members, friends, or other designated people to be contacted in the event of illness or an emergency.

- 5.5.1.2 Request for Services or Consumer Intake Form;

- 5.5.1.3 Records of Home visits (initial and follow-up);

- 5.5.1.4 Individual service plan (initial and reviews);

- 5.5.1.5 Direct care worker activity logs documenting services provided on a daily basis;

- 5.5.1.6 A copy of the written agreement between the consumer and the personal assistance services agency including any updates made to the original reflecting changes in services or arrangements;

- 5.5.1.7 Written acknowledgment that the consumer or the consumer's representative has been fully informed of the consumer's rights;

- 5.5.1.8 Consumer satisfaction survey results.

- 5.5.1.9 Signed disclosure form required by ~~Regulation~~ subsection 5.1.3; and

- 5.5.1.10 Case closure documents.

- 5.5.2 Direct care worker activity logs shall contain the following information:

- 5.5.2.1 Date(s) on which service(s) are provided;

- 5.5.2.2 Hour(s) of service(s) provided;

- 5.5.2.3 Type(s) of services provided; and

- 5.5.2.4 Observations/problems/comments, as necessary.

- 5.5.3 Activity logs shall be signed and dated by the direct care worker on the day that the service is rendered.

- 5.5.4 Copies of all activity logs shall be maintained at the residence of the consumer.

- 5.5.5 Original activity log notes must be incorporated into the consumer's record located at the Agency no less often than every 90 days.

- 5.5.6 All agency records shall be available at all times for review by authorized representatives of the Department and to legally authorized persons; otherwise consumer records shall be held confidential. The

consent of the consumer or his representative if the consumer is incapable of making decisions shall be obtained before any personal information is released from his records as authorized by these regulations or Delaware law.

- 5.5.7 The personal assistance services agency records shall be retained in a retrievable form until destroyed.
 - 5.5.7.1 Records of adults (18 years of age and older) shall be retained for a minimum of six (6) years after the last date of service before being destroyed.
 - 5.5.7.2 Records of minors (less than 18 years of age) shall be retained for a minimum of six (6) years after the consumer reaches eighteen (18) years of age.
 - 5.5.7.3 All records must be disposed of by shredding, burning, or other similar protective measure in order to preserve the consumers' rights of confidentiality.
 - 5.5.7.4 Documentation of record destruction must be maintained by the personal assistance services agency.
- 5.5.8 Records shall be protected from loss, damage and unauthorized use.
- 5.5.9 All notes and reports in the consumer's record shall be legibly written in ink (or typewritten), dated and signed by the recording person with his full name and title.
- 5.5.10 The personal assistance services agency must develop acceptable policies for authentication of any computerized records.
- 5.5.11 The agency must have written policies regarding the use and removal of records and the conditions for release of information.
- 5.5.12 Report of Major Adverse Incidents
 - 5.5.12.1 The personal assistance services agency must report all major adverse incidents occurring in the presence of a direct care worker involving a consumer to the Department within forty-eight (48) hours in addition to other reporting requirements required by law.
 - 5.5.12.2 A major adverse incident includes but is not limited to:
 - 5.5.12.2.1 Suspected abuse, neglect, mistreatment, financial exploitation, solicitation or harassment;
 - 5.5.12.2.2 An accident that causes injury to a consumer; and
 - 5.5.12.2.3 The unexpected death of a consumer.
 - 5.5.12.3 Major adverse incidents must be investigated by the Agency.
 - 5.5.12.3.1 A complete report will be forwarded to the Department within thirty (30) calendar days of occurrence or of the date that the Agency first became aware of the incident.
- 5.5.13 The personal assistance services agency must ensure all consumer records are accurate and complete.

5.6 Case Closure

- 5.6.1 The consumer or the consumer's representative shall be informed of and participate in planning for case closure.
- 5.6.2 The personal assistance services agency shall develop a written plan of case closure which includes a summary of services provided and outlines the services needed by the consumer upon case closure.
- 5.6.3 When an Agency decides to close a case against that consumer's wishes, a minimum of two (2) weeks notice will be provided to permit the consumer to obtain an alternate service provider. Exceptions to the two (2) week notice provision would include:
 - 5.6.3.1 The closure of a case when service goals have been met;
 - 5.6.3.2 The closure of a case when service needs undergo a change which necessitates transfer to a higher level of care;
 - 5.6.3.3 The closure of a case when there is documented non-compliance with the service plan or the admission agreement (including, but not limited to, non-payment of justified charges); or
 - 5.6.3.4 The closure of a case when activities or circumstances in the home jeopardize the welfare and safety of the personal assistance services agency direct care worker.

6.0 Consumer Rights

- 6.1 The personal assistance services agency shall establish and implement policies and procedures regarding the rights of consumers.
- 6.2 The personal assistance services agency must provide the consumer with a written notice of the consumer's rights during the initial home visit or before initiation of services.
- 6.3 Each consumer shall have the right to:
 - 6.3.1 Be treated with courtesy, consideration, respect and dignity;

- 6.3.2 Be encouraged and supported in maintaining one's independence to the extent that conditions and circumstances permit and to be involved in a program of services designed to promote personal independence;
- 6.3.3 Self-determination and choice, including the opportunity to participate in developing one's service plan;
- 6.3.4 Privacy and confidentiality;
- 6.3.5 Be protected from abuse, neglect, mistreatment, financial exploitation, solicitation and harassment;
- 6.3.6 Voice grievances without discrimination or reprisal;
- 6.3.7 Be fully informed, as evidenced by the consumer's written acknowledgment of these rights, of all regulations regarding consumer conduct and responsibilities;
- 6.3.8 Be fully informed, at the time of admission into the program, of services and activities available and related charges, including the disclosure required by Regulation subsection 5.1.3; and
- 6.3.9 Be served by individuals who are competent to perform their duties.

7.0 Insurance and Bonding

- 7.1 The personal assistance services agency shall have appropriate insurance coverage in force to compensate consumers for injuries and losses resulting from services provided by the agency.
- 7.2 The following types and minimum amounts of coverage shall be in force at all times:
 - 7.2.1 General liability insurance covering personal property damages, bodily injury, libel and slander:
 - 7.2.1.1 \$1 million comprehensive general liability per occurrence; and
 - 7.2.1.2 \$500,000 single limit coverage.

8.0 Severability

- 8.1 In the event any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effect.

11 DE Reg. 196 (08/01/07)

19 DE Reg. 852 (03/01/16) (Final)