

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH CARE QUALITY

Statutory Authority: 16 Delaware Code, Section 1119C (16 Del.C. §1119C)
16 DE Admin. Code 3345

PROPOSED

PUBLIC NOTICE

3345 Personal Assistance Services Agencies

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code) and under the authority of Title 16 of the Delaware Code, Chapter 11, Section 1119C, Delaware Health and Social Services (DHSS)/Division of Health Care Quality (DHCQ) is proposing regulations governing Personal Assistance Services Agencies.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed regulatory amendments must submit same by email to Corinna.Getchell@Delaware.gov or by fax to 302-292-3931 by 4:30 p.m. on January 3, 2022. Please identify in the subject line: Regulations Governing Personal Assistance Services Agencies.

The action concerning the determination of whether to adopt the proposed regulations will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services /Division of Health Care Quality is proposing regulations governing Personal Assistance Services Agencies.

Statutory Authority

16 Del.C. §1119C

Background

Rapid and widespread transmission of COVID-19 significantly impacted many vulnerable individuals receiving healthcare services throughout the community. Emergency regulations to require an infection prevention and control program were published in the July 2021 *Register* at 25 DE Reg. 21 (07/01/21) and extended in the November 2021 *Register* at 25 DE Reg. 457 (11/01/21).

Summary of Proposal

Summary of Proposed Changes

The Division of Health Care Quality plans to publish the "proposed" amendments to the regulations governing Personal Assistance Services Agencies and hold them out for public comment per Delaware law. Rapid and widespread transmission of COVID-19 significantly impacted many vulnerable individuals receiving healthcare services throughout the community. While the availability of COVID-19 vaccines has helped to mitigate some of the risk, health and safety protocols must continue. To protect our most vulnerable citizens from COVID-19, Personal Assistance Services Agencies must expand infection prevention and control program requirements. A comprehensive infection control and prevention program based upon guidance from the Centers for Disease Control and Prevention and other nationally recognized sources is imperative for facilities to prevent or significantly decrease transmission of COVID-19 and other infections within facilities. In addition, staff at Personal Assistance Services Agencies must either provide evidence of COVID-19 vaccination or undergo regular testing to prevent the transmission of COVID-19. While the state's requirements will offer employees the choice between getting vaccinated or getting tested, employers should encourage vaccination and federal guidance permits employers to require vaccinations.

Public Notice

In accordance with the state public notice requirements of Title 29, Chapter 101 of the Delaware Code, Delaware Health and Social Services/Division of Health Care Quality gives public notice and provides an open comment period for thirty (30) days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments must be received by 4:30 p.m. on January 3, 2022.

Fiscal Impact

3345 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. Assistance with transfers is not permitted if the consumer is unable to physically assist with the transfer (i.e. use of transfer boards, mechanical lifts are not permitted).

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

“Appropriate Capacity” means an individual’s ability to comprehend both the nature and consequences of one’s acts.

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

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

“Complaint” means a consumer issue that can be immediately addressed by staff who are present at the time of the complaint.

“Consumer” means a person, person’s spouse, parent, legal guardian, or legal custodian of a person under 18, or any legal guardian, legal custodian or surrogate of a person who is an adult, requesting and receiving personal assistance services as defined in this chapter, primarily in the consumer’s 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)(15) 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. The director shall have at least an associates degree plus two (2) years healthcare supervisory experience. A Director in place at the time of the final publication of these regulations will be exempt from this requirement.

“Full-Time” means the established hours of the personal assistance services agency.

“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.

“Grievance” means a written or verbal report of a concern that is made to the agency by a consumer. A grievance cannot be immediately resolved by staff present at the time of the report.

“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 the individual’s 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 Title 6 or Title 8 of the Delaware Code.

“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.

“Medication Administration” means the process whereby a single dose of a prescription or non-prescription medication is given to a consumer by a direct care worker. The responsible caregiver must provide prepackaged medication. The responsible caregiver must provide the direct care worker with written instructions regarding the administration procedure.

“Medication Reminder” means a verbal prompt to the consumer to take their medication. A medication reminder does not include the administration of or any physical contact with the medication.

“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, medication reminders and completing reports. Medication administration is permitted if all of the requirements under subsection 5.4.3 of these regulations are met. These services do not require physician's orders.

“Personal Assistance Services Agency” means any business entity or subdivision thereof, whether public or private, proprietary or not-for-profit, which refers direct care workers to provide personal assistance services to individuals primarily in their home or private residence.

“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.

“Prepackaged Medication” means medication labeled with the consumer name, medication name, medication dosage, and the date and time the medication is to be administered. Each medication must be packaged separately and labeled.

“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.

“Responsible Caregiver” means an individual eighteen (18) years old or older who is the primary caretaker for an adult consumer.

“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.

“Serious Injury” means physical injury that creates a substantial risk of death, or that causes serious disfigurement, serious impairment of health or serious loss or impairment of the function of any bodily organ.

“Service Area” means the county in the state of Delaware in which the agency office is located and the county or counties in the state of Delaware which are immediately adjacent.

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

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

23 DE Reg. 1033 (06/01/20)

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 service area.
 - 2.1.7.1 The agency may provide personal assistance services to a consumer during time-limited travel outside the service area.

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 subsection 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 subsection 4.5;
 - 2.2.2.8 Proof of insurance and bonding as required in Section 7.0.
 - 2.2.2.9 Any other information required by the Department.

2.3 Issuance of Licenses

2.3.1 Initial license

- 2.3.1.1 An initial 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 An initial license will permit an agency to hire or contract with direct care workers and establish a consumer caseload.
- 2.3.1.4 An initial 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 Annual License

- 2.3.3.1 An annual 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 An annual 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;
 - 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;
 - 2.4.2.7.2.2 The history of violations committed by the person or the person's affiliates, agents, employees, or controlling persons;
- 2.4.2.7.3 The efforts made by the agency to correct the violations;
- 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.
- 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 subsection 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 the Secretary's designee and may present such evidence as may be proper.
 - 2.4.3.1.4 The Secretary of the Department or the Secretary's 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 Owners;

- 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.

- 2.5.3.2 Transfer of the majority interest.

- 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

- 2.9.1 The following persons, associations or organizations are not required to obtain a personal assistance services agency license:

- 2.9.1.1 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.

- 2.9.1.2 Those agencies that provide only durable medical equipment and supplies for in-home use.

- 2.9.1.3 Those agencies that provide staff to licensed personal assistance services agencies, such as temporary employment/staffing agencies.

- 2.9.1.3.1 Temporary employment/staffing agencies may not provide services under direct agreements with consumers.

- 2.9.1.3.2 Temporary employment/staffing agencies must be contractually bound to perform services under the contracting providers' direction and supervision.

2.9.1.3.3 Temporary staff working for a licensed provider must meet the requirements of these regulations.

2.9.1.4 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.

2.9.1.5 An agency which solely provides services as defined in 16 Del.C. Ch. 94, the Community Based Attendant Services Act.

2.9.1.6 A home health agency which solely provides services defined in 16 Del.C. §122(3)o.

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

23 DE Reg. 1033 (06/01/20)

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.

3.14 The agency shall be in compliance with federal, state and local laws and codes.

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

23 DE Reg. 1033 (06/01/20)

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 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 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;
- 4.5.2.23 Applicable state regulations governing the delivery of personal assistance services to consumers.
- 4.5.2.24 Dementia-specific training must include: communications 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.
- 4.5.3 All 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.
- 4.5.4 A personal assistance services agency that provides services to persons diagnosed as having Alzheimer's disease or other forms of dementia shall provide annual dementia-specific training to 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.
- 4.6 A direct care worker that has successfully completed a Department approved administration of medications training program may administer medication to a consumer if all other requirements specified in these regulations are met.

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

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

23 DE Reg. 1033 (06/01/20)

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: hours per day or week and days per week, 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 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 and consumer evaluation 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 the provision of services. 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 At a minimum, the following must be evaluated and included in an itemized written description of the consumer prior to providing personal assistance services:

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 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 Personal assistance services 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 Nail Care
 - 5.4.2.2.1 Fingernail care includes: soaking of nails and 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.
- 5.4.3 Medication Administration Authorized by a Responsible Caregiver
 - 5.4.3.1 A responsible caregiver with appropriate capacity may authorize a direct care worker to administer prescription or non-prescription medications to an adult consumer if all of the following are met:
 - 5.4.3.1.1 The responsible caregiver and personal assistance services agency enter into an agreement regarding the administration of medication. The agreement must include confirmation by the responsible caregiver that both the medication to be administered and the process for administering the medication are safe and appropriate.
 - 5.4.3.1.2 The responsible caregiver provides prepackaged medication to be given by the direct care worker by date and time and provides direct care worker with written instructions regarding the administration procedure.
 - 5.4.3.1.2.1 Each medication must be packaged separately and labeled with the consumer name, medication name, medication dosage and date and time to be administered. The responsible caregiver may decide which medication is to be given to the adult consumer by the direct care worker.
 - 5.4.3.1.3 Medications may not be administered via the following routes:
 - 5.4.3.1.3.1 Injection;
 - 5.4.3.1.3.2 Intravenous therapy;
 - 5.4.3.1.3.3 Through the rectum or vagina;
 - 5.4.3.1.3.4 Through a catheter; or

5.4.3.1.3.5 Through a feeding tube, including nasogastric, gastrostomy, or jejunostomy tube.

5.4.3.1.4 Medications listed as Schedule II or Schedule IV under Subchapter 11 of Chapter 47 of Title 16 of Delaware Code may not be administered by a direct care worker.

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 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 Dates on which services are provided;

5.5.2.2 Hours of services provided;

5.5.2.3 Types of services provided; and

5.5.2.4 Observations/problems/comments, as necessary.

5.5.2.5 If medication administration services are provided to the consumer:

5.5.2.5.1 The direct care worker who administers medication to the consumer must document in writing the medication name, dosage, date and time administered; and

5.5.2.5.2 Provide this documentation to the agency.

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 electronically available or 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 two (2) weeks.

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 typed, 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 serious injury to a consumer;
 - 5.5.12.2.3 The unexpected death of a consumer;
 - 5.5.12.2.4 Medication diversion; and
 - 5.5.12.2.5 Medication error or omission.
 - 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.

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

23 DE Reg. 1033 (06/01/20)

6.0 Consumer Rights

- 6.1 The personal assistance services agency shall establish and implement policies and procedures regarding the rights and responsibilities of consumers.
- 6.2 The personal assistance services agency must provide the consumer with a written notice of the consumer's rights and responsibilities 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 subsection 5.1.3; and
- 6.3.9 Be served by individuals who are competent to perform their duties.
- 6.4 The agency must establish a process for prompt resolution of consumer/representative grievances, which must include:
 - 6.4.1 The procedure for the submission of a written or verbal grievance;
 - 6.4.2 The timeframes for review of the grievance and the provision of a response; and
 - 6.4.3 A written notice of the decision to the consumer/representative that contains the name of the agency contact person, the steps taken on behalf of the consumer to investigate the grievance, the results of the grievance process, and the date of completion.

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

23 DE Reg. 1033 (06/01/20)

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 Disaster Preparedness

- 8.1 Each personal assistance services agency shall prepare and maintain a comprehensive emergency management plan that is consistent with the national standards (i.e. FEMA, ASPR, TRACIE) and consistent with the local and state plans.
- 8.2 The plan shall:
 - 8.2.1 Provide for continuing personal assistance services during an emergency that interrupts consumer care or services in the consumer's home; and
 - 8.2.2 Describe how the personal assistance services agency establishes and maintains an effective response to emergencies and disasters, including:
 - 8.2.2.1 Notification of staff when emergency response measures are initiated;
 - 8.2.2.2 Provision for communication with and between staff members, local emergency management agencies, the state emergency management agency and consumers;
 - 8.2.2.3 Provision for a backup system;
 - 8.2.2.4 Identification of resources necessary to continue essential care and services; and
 - 8.2.2.5 Prioritization of consumer care needs and services.
- 8.3 All agency staff must be oriented to the disaster preparedness plan(s).
 - 8.3.1 Records of staff attendance must be maintained for six (6) years.
- 8.4 A copy of the disaster preparedness plan or plans shall be available to all staff.
- 8.5 Each personal assistance services agency shall inform consumers and consumers' representative, upon admission, of the agency's procedures during and immediately following an emergency.

23 DE Reg. 1033 (06/01/20)

9.0 Infection Prevention and Control Program

- 9.1 The agency shall establish and implement an infection prevention and control program which shall be based upon Centers for Disease Control and Prevention and other nationally recognized infection prevention and control guidelines.
 - 9.1.1 The infection prevention and control program must cover all services provided by the agency, including provision of the appropriate personal protective equipment for all customers and staff.

- 9.2 The individual designated to lead the agency's infection prevention and control program must develop and implement a comprehensive plan that includes actions to prevent, identify, and manage infections and communicable diseases. The plan must include mechanisms that result in immediate action to take preventive or corrective measures that improve the agency's infection control outcomes.
- 9.3 All agency staff shall receive orientation at the time of employment and annual in-service education regarding the infection prevention and control program.
- 9.4 Specific Requirements for COVID-19
- 9.4.1 Before their start date, all new staff, vendors and volunteers must be tested for COVID-19 in accordance with Division of Public Health guidance.
- 9.4.2 All staff, vendors and volunteers must be tested for COVID-19 in a manner consistent with Division of Public Health guidance.
- 9.4.3 The agency must follow recommendations of the Centers for Disease Control and Prevention and the Division of Public Health regarding the provision of care or services to consumers by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.
- 9.5 The agency shall amend their policies and procedures to include:
- 9.5.1 Work exclusion and return to work protocols for staff tested positive for COVID-19;
- 9.5.2 Staff refusals to participate in COVID-19 testing;
- 9.5.3 Staff refusals to authorize release of testing results or vaccination status to the agency;
- 9.5.4 Procedures to obtain staff authorizations for release of laboratory test results to the agency to inform infection control and prevention strategies; and
- 9.5.5 Plans to address staffing shortages and agency demands should a COVID-19 outbreak occur.

9.0 10.0 Severability

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)

23 DE Reg. 1033 (06/01/20)

25 DE Reg. 601 (12/01/21) (Prop.)