

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 122(1), (3)a and 11(8)
(16 Del.C. §122(1), (3)a and 11(8))

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 Services Agencies. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Delaware Code**, Section 122(1), (3)a and 11(8).

On March 1, 2007 (Volume 10, Issue 9), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Delaware Code** Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by March 31, 2007, or be presented at a public hearing on March 27, 2007, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

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

Findings of Fact:

Based on comments received, non-substantive changes were made to the proposed regulations. 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 Services Agencies are adopted and shall become effective August 10, 2007, after publication of the final regulation in the *Delaware Register of Regulations*.

Vincent P. Meconi, Secretary, 7/16/07

Summary of Evidence

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Personal Assistance Services Agencies (PASA) were published in the Delaware State News, the News Journal and the *Delaware Register of Regulations*. Verbal and written comments were received on the proposed regulations during the public comment period (March 1, 2007 through March 31, 2007). Entities offering written comments included:

- State Council for Persons with Disabilities (SCPD)
- Comfort Keepers (non-medical in-home care)
- Community CHEER (Georgetown, DE)
- Griswold Special Care, Inc. (Exec. VP)
- Griswold Special Care, Inc. (Dir. DE Offices)
- Delaware Association for Home and Community Care (DAHCC)
- Companion Hearts, LLC
- Senior Social Services, Inc.

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

- **Section 1.0 (Definitions):** There were multiple comments regarding the definition of the word “Contractor” within the regulations. Some asked that the words, “ . . . who holds a valid business license” and the reference in the definition whereby the contractor is providing services “for the agency” (PASA) be removed, while others asked that these words remain in the definition.

Agency Response: It is the Agency’s position that the contractor is providing services on behalf of the PASA and a contractor of the PASA is required to have a Delaware business license.

- **Section 1.0 (Definitions):** There was a comment that the words, “ . . . to provide care.” be removed from the definition of “Consumer Record” because PASA’s do not provide direct care, their contracted direct care workers do.

Agency Response: The Agency respectfully disagrees with this and as such the definition of “Consumer Record” will remain unchanged.

- **Section 1.0 (Definitions):** It was asked that the definition of “Direct Care Worker” include one year practical experience in a hospital or satisfactorily complete a personal care course which includes training requirements within the regulations. The personal care course should be at a minimum 75 hours, like that required for home health aide certification.

Agency Response: The Agency recognizes that to require such training for in-home personal assistance, would drive up costs for the consumer of the services and in some cases make such services unaffordable for those in need. The definition and qualifications of a direct care worker reflected in these regulations strikes an appropriate balance between consumer protection and affordable consumer-driven, personal assistance services.

- **Section 1.0 (Definitions):** There was a comment regarding the definition of “Home Visit” in that using the word “evaluation” in the definition could imply an assessment other than self-reporting (consumer) information.

Agency Response: In the regulation definition of 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 services plan” the Agency contends that the word evaluation is appropriately used.

- **Section 1.0 (Definitions):** There was a comment that the regulation use the definition of “Personal Assistance Services Agency” as provided in the statute

Agency Response: After careful review, the Agency has determined that the regulatory definition is appropriate.

- **Section 1.0 (Definitions):** There was a comment that, “Supervision of Services” be included under the definition section and include qualifications to the competency of the individual.

Agency Response: The Agency contends that to require this would be over-reaching and inappropriate for this social model of in-home personal assistance service.

- **Section 1.0 (Definitions):** There was a comment asking that the Agency adopt clarifying definitions between “Companion” and “Homemaker” that would make distinctions between these categories of services.

Agency Response: The Agency has defined each term (Companion & Homemaker) separately in the regulations and contends that there is a distinction between each type of service within those definitions. There is a fine line between these services, in that each defined service can actually encompass the other. For example, a companion may also provide homemaker type services and a homemaker may also provide companion type services. The Agency contends that each definition is sufficiently distinct and clear in the regulations.

- **Section 1.0 (Definitions):** There was a comment that transportation services are not listed in the definition section of the regulations. Additionally it was suggested that it be added to the definition of personal assistance services.

Agency Response: Transportation services are included in the definition section of the regulations under the definition of Direct Care Worker and as a result of this comment the words “transportation services” will be added to the definition of Personal Assistance Services.

- **Section 2.1.2 (Licensing Requirements and Procedures) There was a request that a PASA only require one license for multiple offices in Delaware.**

Agency Response: The Agency contends that this requirement is consistent with other regulated in-home care services.

- **Section 2.2.2.9 (Application Process): There was a comment that this section gives the Agency ability to ask for unlimited information.**

Agency Response: As the regulatory authority, the Agency reserves the right to collect information regarding a PASA that it deems pertinent for the safe and effective delivery of personal assistance services.

- **Section 2.4 (Disciplinary Proceedings): There was a comment that due process protections were not clear under this section.**

Agency Response: Under subsection 2.4.3, the Agency clearly and adequately provides due process protection for any disciplinary sanction imposed. Additionally, in subsection 2.4.2.7 Superior Court due process protections would apply.

- **Section 2.3.2.3 (Provisional License): It was requested that a timeframe be indicated for when a plan of correction must be submitted to the agency after a provisional license has been issued due to substantial noncompliance with the regulations.**

Agency Response: The Agency reserves the right to set this timeframe on a case-by-case basis. In cases where the noncompliance is administrative in nature (no risk to consumer) the time to submit a corrective action plan could be different than if the noncompliance issue has the potential to put consumers at risk.

- **Section 2.7.1: (Inspection): It was requested that a minimum timeframe be established for inspection of PASA by the Agency.**

Agency Response: The Agency intentionally left this open by using the term “periodically” so as not to create a predictable pattern of inspections. It is the Agency’s experience that this is the most effective way to evaluate real-time performance and compliance efforts.

- **Sections 3.3 & 3.4 (General Requirements): It was requested that the Agency clarify the difference between incident, accident and medical emergency.**

Agency Response: After careful review, the Agency contends that the words used have explicit meaning. Any questions as to the PASA responsibility to develop policies and procedures on handling and documenting, and reporting such instances should be directed to the Office of Health Facilities Licensing and Certification.

- **Section 3.8 (General Requirements): There was a request to strike or clarify this paragraph.**

Agency Response: After careful review of this paragraph, the Agency contends that it is sufficiently and legally clear. The PASA may contract with direct care workers versus hire them as employees of the PASA. The Agency is charged with protecting the health of the consumer, and these regulations must apply to every direct care worker regardless of their employment status. If the PASA contracts with direct care workers, the direct care contractors must meet the same requirements as direct care workers employed by the PASA.

- **Section 3.10 (General Requirements): It was suggested that this paragraph requires a PASA to have a backup plan no matter what.**

Agency Response: After careful review of this paragraph the Agency contends that it is reasonable to require a PASA to have a plan for uninterrupted services and a backup plan for substitute direct care workers. The Agency contends that this is a reasonable expectation for PASA providing direct care services.

- **Section 4.2.1 (Purchase of Contract Services): There was a request to strike this section and a comment that a PASA should not be held responsible for all services provided by their direct care**

workers or direct care contractors.

Agency Response: The Agency contends that the PASA is responsible for services delivered to the consumer.

- **Sections 4.2.2. & 4.4.2.5 (Purchase of Contracted Services & Direct Care Worker Records): There was a request a disclosure form be developed by the Department that clearly advised contracted workers of their personal financial responsibility and liability risks associated with contractor status.**

Agency Response: The Agency has no authority to require the PASA to develop and provide its direct care contractors with this type of information.

- **Section 4.4.2.4 (Direct Care Worker Records): There was a request to require the PASA to maintain consumer satisfaction surveys as well as written performance evaluations in the direct care worker record. There was also a request that in addition to a consumer satisfaction survey that consumer references be included in the record.**

Agency Response: The Agency contends that requiring a consumer satisfaction survey, consumer references and a written performance evaluation on each direct care worker would be ideal, but from a regulatory perspective may be considered overly onerous. The Agency is trying to strike a balance between consumer protection and consumer-driven, economically feasible personal assistance.

- **Section 4.3.2.4 (Written Policies): There was a request to reword this section to “annual performance or reference review.”**

Agency Response: After careful review, the Agency is satisfied that the language used “Annual performance review” is sufficiently clear.

- **Section 4.3.2.5 (Written Policies): There was a comment that this statement is not clear.**

Agency Response: The Agency contends that this section is clear and it requires the PASA to have a policy that addresses program review and evaluation of its program.

- **Section 4.4.2.5 (Direct Care Worker Records): There was a comment that requiring “A letter of appointment specifying conditions of employment/referral” may cause confusion when interpreting the definition of an independent contractor. It is not necessary and a request was made to strike it.**

Agency Response: The Agency contends that such a letter is needed.

- **Section 4.4.2.6.5 (Direct Care Worker Records): There was a request that health screening language such as “freedom of communicable disease” clearance by a health care professional rather than requiring a physical.**

Agency Response: The Agency contends that a physical captures these requirements and ensures direct care worker is physically able to perform functions of the job.

- **Section 4.5 (Orientation and Testing): It was requested that this section be combined with competency section and that the competency test be less stringent.**

Agency Response: After careful review of the regulations it was determined that these content areas are already combined under section 4.5. The Agency contends that the required items under competency testing are not too stringent.

- **Section 4.5 (Orientation and Testing): It was suggested that this section address shopping-related financial documentation since shopping and running errands are included among personal assistance services.**

Agency Response: The Agency contends that this section is sufficiently detailed and that the consumer (or their designee) is the right person to determine this level of process detail.

- **Section 4.5 and 4.3.2.4 (Orientation and Testing; Written Policies) There was a suggestion that qualifications be included for the individual that will provide the clinical components of orientation and annual competency of those workers who provide personal care.**

Agency Response: The Agency contends that these regulations cover consumer driven personal assistance services and strike an adequate balance between consumer protection and economical consumer choice. In this case, placing clinical requirements on a social model PASA will cause unnecessary costs to the consumer.

- **Section 4.5.3 (Orientation and Testing):** It was suggested that the phrase “competency evaluation test” be shortened to read, “competency test.” It was also requested that the requirement for annual competency testing be changed to on an as needed basis determined by the PASA.

Agency Response: After review, the Agency agrees with the first part of this suggestion and will remove the word “evaluation.” The Agency contends that the annual competency test required by this section is necessary and will not change that requirement.

- **Section 4.5.3.2 (Orientation and Testing):** There was a suggestion to delete the words, “are proficient” and “care assigned” in this section and replace them with the words “have demonstrated competency” because the current language refers to employee status.

Agency Response: The Agency carefully reviewed this section and contends that the wording in this section is necessary and adequate.

- **Section 5.0 (Consumer Care Management):** There was a suggestion that this section be renamed to, “Consumer Files.”

Agency Response: The Agency contends that the title of this section accurately reflects the content of the section.

- **Section 5.1.3 (Consumer Care Management):** It was suggested that the PASA have input to the form referred to in this section.

Agency Response: As the regulatory authority, the Agency reserves the right to develop the disclosure form required in this section.

- **Sections 5.1.3 and 7.0 (Consumer Care Management; Insurance and Bonding):** There was a comment referring to “tension” between these sections. Section 5.1.3 would authorize a PASA to forego liability insurance while section 7.0 would require it.

Agency Response: Section 5.1.3 does not authorize a PASA to forego liability insurance. The Agency requires the PASA to have liability insurance in section 7.0.

- **Section 5.1.4.1 (Consumer Care Management):** It was suggested that this section reflect that the services are requested by the consumer, not provided by the PASA, as services are provided by the direct care worker. It was also suggested that the word “scheduled” not be used in this section because it is not preferred when dealing with contractors.

Agency Response: The Agency carefully reviewed this section and contends it is properly worded.

- **Sections 5.1.4 & 5.4 (Written Agreement & Service Plan):** It was suggested that the written agreement between consumer and PASA and the service plan be combined into one document to be signed by the consumer.

Agency Response: The Agency carefully reviewed these sections and contends that for clarity purposes on the part of the consumer, these documents remain separate.

- **Section 5.2 (Home Visits):** It was suggest that the PASA does not provide personal assistance services, the direct care worker does, thus this section should include language that information obtained during these visits is self-reported by the consumer, rather than observed by the PASA.

Agency Response: The Agency carefully reviewed this section and contends it reflects intended PASA requirements regarding home visits.

- **Section 5.2 (Home Visits):** It was suggested that during the initial home visit to determine whether the PASA has the ability to provide services, that this should be an assessment done by someone

clinically competent. A Registered Nurse should be the qualification required to perform the initial assessment.

Agency Response: Under the umbrella of a consumer-driven, social personal assistance model, the Agency contends that the requirements in this section are appropriate.

- **Section 5.2.4 (Follow-up Home Visits): It was suggested that the follow-up home visits required in this section be done through telephone checks.**

Agency Response: The Agency contends that follow-up home visits every 90 days is appropriate to ensure safe and effective in-home personal assistance services.

- **Section 5.2.4 (Follow-up Home Visits): It was suggested the wording in this section be changed from “follow-up home visits” to “home supervisory visits.” This will clearly state the responsibility of the agency performing the follow-up home visits to confirm the service plan is being carried out.**

Agency Response: As a consumer-driven, social personal assistance service model, the Agency contends this section is appropriately worded.

- **Sections 5.2.4 & 5.5.2 (Home Visits and Activity Logs): It was suggested that there should be a provision in the regulation for the client to opt out of follow-up home visits or activity logs.**

Agency Response: Under the umbrella of consumer protection, the Agency contends that both follow-up visits and activities logs are appropriate and required to ensure effective and safe in-home care.

- **Section 5.3 (Service Plan): It was suggested that this section say the service plan includes the scope, frequency, and duration of service.**

Agency Response: The definition of Service Plan appropriately includes this wording.

- **Sections 5.4 (Scope of Services): There was a request that sections 5.4.1 through 5.4.2 that deal with delegation of personal assistance services from competent consumers to the direct care worker be deleted because it is confusing.**

Agency Response: As a social consumer driven care model, the Agency believes within the parameters of Delaware statute, these sections properly authorize assistance for activities of daily living that the consumer could otherwise provide for himself or herself.

- **Section 5.4.2.6.2 (Scope of Services): There was a request that this section that deals with assistance in transferring a consumer be amended by adding the words, “...unless there is more than one person present to assist or a mechanical lift available.”**

Agency Response: Under the umbrella of consumer protection and safety, the Agency believes this section is appropriately worded.

- **Section 5.5.2 (Records and Reports): It was suggested that the regulatory agency require consumer’s signature be included on the activity logs.**

Agency Response: The Agency does not require this of other regulated home delivered service, thus will not require it of a PASA. However, the Agency does require the consumer to be involved with development of the service plan.

- **Section 5.5.5 (Activity Logs): There was a suggestion that the requirement for activity logs be consumer directed and if required that they be included in the PASA record on a quarterly basis versus monthly.**

Agency Response: The Agency contends that activity logs are required and will make an amendment to the regulation that reflects that activity logs be included in the PASA files every 90 days versus on a monthly basis.

- **Section 5.5.12.1 (Report of Major Adverse Incidents): There was a request that the Agency further clarify what constitutes an injury to a client.**

Agency Response: The Agency contends that the wording in section 5.5.12.2.2, “An accident that causes injury to a consumer” is sufficiently clear and to list out what type of injuries apply, would be inappropriate. If there

is a question whether a report is required, the PASA can contact staff at the Office of Health Facilities Licensing and Certification for clarification. Additionally, the Agency will clarify PASA responsibilities by adding the words, "occurring in the presence of a direct care worker" between the words, "incidents" and "involving" in this section.

- **Section 5.5.12.3.1 (Report of Major Adverse Incidents) There was a suggestion that adverse incident reports not be forwarded to the Department and instead they be sent to the PASA file to be reviewed by the regulatory agency during regularly scheduled surveys. Under this section, there was also a concern that 30 days was too long to report an adverse incident.**

Agency Response: The Agency disagrees with this and the requirement to forward an adverse incident report to the Agency within 30 days is required. A PASA is required to submit an adverse incident full investigation report within 30 days, however under section 5.5.12.1, a PASA is required to report to the Agency an adverse incident within 48 hours.

- **Section 5.6 (Case Closure): There was suggestions that this section or parts there of is not necessary and be deleted as it is indicative of a medical model regulation. In lieu of case closure requirements, it was suggested a note to the PASA consumer file state why the case ended and when.**

Agency Response: The Agency contends that this is a continuity care issue and reserves the right to require a PASA to follow case closure requirements as specified in the PASA regulations.

- **Section 5.6.3 (Case Closure) There was a request that the PASA give 30 days notice prior to "discharge" rather than 2 weeks. It may be difficult for a consumer to obtain an alternate PASA services plan within 2 weeks.**

Agency Response: The Agency selected this timeframe based on stakeholder desires (consumer & PASA) and came up with 2 weeks as an acceptable compromise. The regulation states a minimum of 2 weeks; this does not preclude a consumer from negotiating a longer timeframe with an outgoing PASA.

- **Section 5.6.3.2 (Case Closure): There was a comment that this section allows a PASA to unilaterally discontinue services if a consumer requires a higher level of care.**

Agency Response: The Agency contends that this section requires the consumer be involved with planning of any case closure (Section 5.6.1). It also requires that the PASA develop a written plan to include a summary of services provided and services needed by the consumer upon case closure (Section 5.6.2). Part of that planning, as documented in this section is the transfer of the consumer to a higher level of care.

- **Section 5.6.3.3 (Case Closure): There was a comment that exceptions to the 2 week notice for case closure when service goals are met and documented non-compliance with the service plan/admission agreement or non-payment is highly objectionable. A recommendation was made to dispense with all exceptions (Sections 5.6.3.1-5.6.3.4) and to adopt a 30 day notice period before termination of services.**

Agency Response: The Agency contends that the minimum 2 weeks notice period required is reasonable for in-home consumer-driven, social personal assistance services. It also contends that exceptions to the 2 week notice period for service goals being met; consumer needs dictating a higher level of care; non-compliance/non-payment; and, circumstances in home that jeopardize the welfare and safety of the direct care worker are reasonable for this social model of in home personal assistance.

- **Section 7.0 (Insurance and Bonding): It was suggested that consideration be given to requiring that the insurance policy include a provision requiring notice to the regulatory Agency upon termination of the policy.**

Agency Response: The Agency contends that such a requirement would be over-reaching and legally questionable.

- **Section 7.3 (Insurance & Bonding): There was a comment that requiring a performance bond for a PASA utilizing contractors is unfair and an unnecessary cost.**

Agency Response: After careful review of this requirement, the Agency has decided that the insurance requirements in this section 7.0 are adequate, thus it will not require the performance bond and will delete this requirement from the regulations.

- **There was a question regarding the relationship of a PASA, its direct care workers and direct care worker contractors, and the consumer.**

Agency Response: The Agency makes no distinction between the PASA employed direct care worker and the PASA contracted direct care worker. The relationship with the consumer will be outlined in a service agreement signed by the PASA and consumer. Additionally, the Agency will develop an appropriate and understandable disclosure form to help the consumer make an informed decision about their in-home personal assistance services.

- **Although areas of training were listed, there was a concern expressed that no minimum amount of training hours are required of direct care workers and there is no standard competency examination established for direct care workers.**

Agency Response: The Agency considered both of these requirements when developing the regulations. In an effort to balance affordable in-home personal assistance services with appropriate consumer protection the Agency contends that the requirements of the PASA regulations are adequate.

- **There were comments requesting the regulations specify minimum qualifications of owners and direct care workers. Require nursing supervision/oversight and all direct care workers to be a Certified Nursing Assistant (CNA).**

Agency Response: In keeping with the social model of care, for the Agency to require such qualifications would unnecessarily drive up costs and make such personal assistance care unaffordable to those in need of such in-home services.

- **There was a concern expressed that the Agency has the authority, but lacks resources to enforce the regulations.**

Agency Response: The Agency pledges that it will do everything in its power to ensure consumers are protected and to facilitate the PASA in providing effective and safe personal assistance services.

- **There was a general question regarding how to report a PASA entity not following the law or regulations.**

Agency Response: The Agency recommends reporting this to the Office of Health Facilities Licensing and Certification (302-995-8521).

- **Listed below are four technical corrections made to the regulations that were announced at the public hearing.**

Section 2.2.2.2: Changed reference to Regulation 4.2 to 4.3.

Section 2.4.3.1.2: Replaced the words, "suspension or revocation" with the words "disciplinary action"

Section 5.4.2.9: Deleted this section in its entirety because it conflicts with Title 24, Section 1921

Section 5.2.5: Replaced the words, "plan for services" with the words, "service plan"

The DHSS recognizes that there is a growing need for a consumer-driven economical model of in-home personal assistance services to meet the needs of some of Delaware's population. Those consumers who can self-direct their care, who do not require placement in an institution, and who choose to remain at home but do not need the in-home care of a health professional can best be served by this model of care. These regulations assure a balance between affordable consumer-driven services and consumer protection.

In addition to non-substantive amendments mentioned above, minor grammatical corrections were made to further clarify the proposed regulations.

The public comment period was open from March 1-31, 2007.

Verifying documents are attached to the Hearing Officer's record. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

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.

“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.

"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.

2.2 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 ~~[4.2~~ 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 4.5;

2.2.2.8 Proof of insurance and bonding as required in Regulation 7.

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.

2.4 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 ~~[suspension or revocation]~~ 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(o).

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.

4.0 Administration

4.1 Agency Director

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

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

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

4.2 Purchase of Contracted Services

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

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

4.3 Written Policies

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

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

4.3.2.1 Pre-employment/referral requirements;

4.3.2.2 Position descriptions;

4.3.2.3 Orientation policy and procedure for all direct care workers;

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

4.3.2.5 Program review and evaluation of its program.

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

4.4 Direct Care Worker Records

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

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

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

4.4.2.2 Documentation of competence;

4.4.2.3 Educational preparation and work history;

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

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

4.4.2.6 Health History

4.4.2.6.1 Minimum requirements for pre-employment/referral and annual tuberculosis (TB) testing are those currently recommended by the Centers for Disease Control and Prevention of

the U.S. Department of Health and Human Services.

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

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

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

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

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

4.5 Orientation and Testing

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

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

4.5.2.1 Organizational structure of the agency;

4.5.2.2 Agency consumer care policies and procedures;

4.5.2.3 Philosophy of consumer care;

4.5.2.4 Description of consumer population and geographic location served;

4.5.2.5 Consumer rights;

4.5.2.6 Agency personnel and administrative policies;

4.5.2.7 Principles of good nutrition;

4.5.2.8 Process of growth, development and aging;

4.5.2.9 Principles of infection control;

4.5.2.10 Observation, reporting and documentation of consumer status;

4.5.2.11 Maintaining a least restrictive environment;

4.5.2.12 Verbal/non-verbal communication skills;

4.5.2.13 Principles of body mechanics;

4.5.2.14 The needs of the elderly and persons with disabilities;

4.5.2.15 Activities of daily living;

4.5.2.16 Introduction to common assistive technology;

4.5.2.17 Meal planning, food purchasing and preparation of meals, including

special diets;

4.5.2.18 Information on the emotional and physical problems accompanying illness, disability or aging;

4.5.2.19 Principles and practices in maintaining a clean, healthy, pleasant and safe environment that encourages morale building and self-help;

4.5.2.20 Items requiring referral to the personal assistance services agency, including changes in the consumer's condition or family situation;

4.5.2.21 Confidentiality of consumer information;

4.5.2.22 Service Plan specific description; and

4.5.2.23 Applicable state regulations governing the delivery of personal assistance services to consumers.

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

4.5.3.1 The competency test must include questions addressing the competencies listed in Section 4.5.2.

4.5.3.2 It is the responsibility of the personal assistance services agency to ensure that direct care workers are proficient to carry out the care assigned in a safe, effective and efficient manner.

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 ~~[plan for services 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. 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 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.

5.4.2.9 Medication Assistance

5.4.2.9.1 A direct care worker, who has taken a Board approved

~~medication training program, may assist the consumer in self administration of medication other than by injection, provided that the medication is in the original container with a proper label and directions.~~

~~5.4.2.9.2 The direct care worker may hold the container for the consumer, assist with the opening of the container, and assist the consumer in taking the medication.]~~

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 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 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 **[monthly every 90 days]**.

5.5.6 All agency records shall be available 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.

5.6 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 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.

~~7.3 Performance bond of \$50,000 for those agencies utilizing only contractors as direct care workers.~~

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.