

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH CARE QUALITY

Statutory Authority: 16 Delaware Code, Section 122(3)o (16 Del.C. §122(3)o)
16 DE Admin. Code 3350

PROPOSED

PUBLIC NOTICE

3350 Skilled Home Health Agencies (Licensure)

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 1, Section 122(3)o, Delaware Health and Social Services (DHSS)/ Division of Health Care Quality (DHCQ) is proposing regulations governing Skilled Home Health 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 Nancy.Lizzi@Delaware.gov or by fax to 302-292-3931 by 4:30 p.m. on May 1, 2023. Please identify in the subject line: Regulations Governing Skilled Home Health 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 Skilled Home Health Agencies.

Statutory Authority

16 Del.C. §122(3)o

Background

As more services are being provided in the home and community setting, it is necessary to ensure adequate oversight of the home care agency's workers providing in-home services. The COVID-19 pandemic has greatly impacted the workforce providing these in-home services. A number of flexibilities were implemented during the course of the pandemic and were found to have addressed staffing issues and allowed agencies to expand to provide services to more individuals in their homes while still ensuring safe and effective care.

Summary of Proposal

Summary of Proposed Changes

The Division of Health Care Quality plans to publish the "proposed" amendments to the regulations governing skilled home health agencies and hold them out for public comment per Delaware law. The amendments:

- Extend the allowable timeframe for a pre-employment physical due to resource issues.
- Include options for agencies to utilize telehealth mechanisms.

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 May 1, 2023.

Fiscal Impact

Not applicable

3350 Skilled Home Health Agencies (Licensure)

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 ambulating, transferring, grooming, bathing, dressing, eating and toileting.

“Agency” means a home health agency licensed by the Department.

“Allowable provider” means a person currently licensed as an advanced practice nurse pursuant to 24 **Del.C.** Ch. 17, or a person currently licensed as a physician’s assistant pursuant to 24 **Del.C.** Ch. 19.

“Audiologist” means an individual who is licensed to practice audiology pursuant to 24 **Del.C.** Ch. 37 and who offers the services to the public under any title or description of services incorporating the words "audiologist", "hearing clinician", "hearing therapist", "aural rehabilitator" or any other similar title or description of service.

“Audiology aide” means an individual who is certified by the Council of Accreditation of Occupational Hearing Conservationists pursuant to 24 **Del.C.** Ch. 37 and who performs services only under the direct supervision of an audiologist licensed in this State.

“Audiology services” means those services defined pursuant to 24 **Del.C.** Ch. 37.

“Bylaws” means a set of rules adopted by a home health agency for governing the agency’s operation.

“Caregivers” means those individuals employed by or under contract to a home health agency to provide personal care services or health care services to patients.

“Change of ownership (CHOW)” see “Modification of ownership and control (MOC)”.

“Clinical Director” means a registered nurse who is sufficiently qualified to provide general supervision and direction of the services offered by the home health agency and who has at least one year of home health care experience and at least one year of administrative or supervisory health care experience. The "Clinical Director" and "Director" may be the same individual if that individual is dually qualified.

“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.

“Complaint” means a formal or informal written or verbal notification of patient issues that can be immediately addressed by staff who are present at the time of the complaint.

“Contractor” means an entity or individual 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.

“Dietitian” means an individual who engages in the provision of nutrition services pursuant to 24 **Del.C.** Ch. 38. The terms nutritionist and dietitian are used interchangeably.

“Director” means the individual appointed by the governing body to act on its behalf in the overall management of the home health agency. The director shall:

- (1) Have a baccalaureate degree with five years health care experience and at least one year supervisory experience (full-time or equivalent) in home health care, or
- (2) Be a registered nurse with five years health care experience and at least one year of supervisory experience (full-time or equivalent) in home health care.

“Full-time” means the established business hours of the home health 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 home health agency.

“Grievance” means a formal or informal written or verbal complaint that is made to the agency by a patient, or the patient’s representative. A grievance cannot be immediately resolved by staff present at the time of the complaint.

“Health care experience” means the direct participation of an individual in the maintenance or improvement of health via the prevention, diagnosis, treatment, recovery, or cure of disease, illness, injury, and other physical and mental impairments in patients.

“Health care facility” means any facility that is licensed under 16 **Del.C.** Ch. 10 or 11.

“Home health agency” or **“HHA”** means any business entity or sub-division thereof, whether public or private, proprietary or not-for-profit, which provides, to an individual primarily in their place of residence, two (2) or more home care services, one of which must be either licensed nursing services or home health aide services.

“Home health aide” means a non-licensed person who provides personal care services, companion services, homemaker services and who may perform tasks delegated by a licensed nurse as permitted by 24 **Del.C.** Ch. 19. A home health aide (A) has at least one year of practical experience in a Department licensed or approved hospital, nursing home, or home care setting; or (B) has satisfactorily completed an appropriate home care course which includes the training requirements contained within these regulations; or (C) is a student nurse pursuing a degree in nursing who has completed the clinical practicum portion of their training.

“Home health aide care plan” means a written plan developed by the nurse or professional therapist that specifies the tasks that are to be performed by the aide primarily in the patient’s residence. The written plan specifies scope, frequency and duration of services.

“Home health aide services” means services, provided to an individual primarily in their place of residence, that are limited to personal care services, companion services, homemaker services, medication reminders and tasks delegated by a licensed nurse as permitted by 24 Del.C. Ch. 19.

“Home health care experience” means the provision of services by a home health agency to meet the needs of patients being cared for in their residence for an illness or injury.

“Home health care services” means services, provided to an individual primarily in her/his place of residence, that include but are not limited to: (A) licensed nursing services; (B) physical therapy services; (C) speech therapy services; (D) audiology services; (E) occupational therapy services; (F) nutritional services; (G) social services; or (H) home health aide services.

“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.

“Immediate jeopardy” means a crisis situation in which the health and safety of patients 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.

“Licensed clinical social worker” means an individual licensed pursuant to 24 Del.C. Ch. 39.

“Licensed nursing services” means those services defined pursuant to 24 Del.C. Ch. 19.

“Licensee” means the individual, corporation or legal entity with whom rests the ultimate responsibility for maintaining approved standards for the home health agency.

“Located” means the physical address of the agency’s business office.

“Majority interest” means the largest percentage of ownership interest.

“Medication reminder” means a verbal prompt to the patient to take their medication. A medication reminder does not include the administration or any physical touching of 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.

“Nurse” means an individual who is currently licensed to practice nursing pursuant to 24 Del.C. Ch. 19.

“Nutritional services” means those services defined pursuant to 24 Del.C. Ch. 38.

“Occupational therapist” means an individual who is currently licensed to practice occupational therapy pursuant to 24 Del.C. Ch. 20 and who offers the services to the public under any title incorporating the words "occupational therapy," "occupational therapist" or any similar title or description of occupational therapy services.

“Occupational therapist assistant” means an individual licensed to assist in the practice of occupational therapy pursuant to 24 Del.C. Ch. 20, under the supervision of an occupational therapist.

“Occupational therapy services” means those services defined pursuant to 24 Del.C. Ch. 20.

“Office” means the physical location in which the business of the home health agency is conducted and in which the records of personnel, contractors and patients 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.

“Patient” means the individual receiving home health agency services as defined in this chapter.

“Patient record” means a written account of all services provided to a patient by the home health agency, as well as other pertinent information necessary to provide care.

“Personal care services” means the provision of services 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 patient’s condition and completing reports.

“Physical therapist” means an individual who is currently licensed to practice physical therapy pursuant to 24 Del.C. Ch. 26.

“Physical therapist assistant” means an individual who assists licensed physical therapists pursuant to 24 Del.C. Ch. 26.

“Physical therapy services” means those services defined pursuant to 24 Del.C. Ch. 26.

“Physician” means an individual currently licensed as such by 24 Del.C. Ch. 17.

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

“Plan of correction” means a home health 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.

“Professional” means a person currently licensed in the State as an advance practice nurse, registered nurse, physician, physician assistant, physical therapist, occupational therapist, speech therapist, dentist, dietitian, social worker, respiratory care practitioner or psychologist.

“Professional therapy” means those services provided by a licensed professional in one of the following areas: physical therapy, occupational therapy, speech therapy, audiology or nutrition.

“Qualified professional” means an occupational therapist, a physical therapist, or a speech/language pathologist.

“Representative” means a person acting on behalf of the patient under Delaware law.

“Residence” means the domicile of the patient either personally owned by that patient or considered the place of residence of that patient where the home health care services will be provided.

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

“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.

“Skilled services” means those services provided directly by a licensed professional for the purpose of promoting, maintaining, or restoring the health of an individual or to minimize the effects of injury, illness or disability. Skilled services must be ordered by a physician or an allowable provider.

“Social services” means activity designed to promote social well-being. The services provided by the social worker depend on the needs of the patient. The social worker acts as an advocate to secure the patient's rights, directly counsels the patient and the patient's family, and refers the patient to other social agencies, community resources or facilities that can meet the patient's immediate and long-term needs.

“Social worker” means an individual who has met the requirements of a graduate curriculum, leading to a master's degree, in a school of social work that is accredited by the council on Social Work Education.

“Social work assistant” means an individual with a baccalaureate degree in social work, psychology, sociology or other related field and has had at least one (1) year of social work experience in a health care setting or has an associate degree in psychology, sociology or other related field and has had at least two (2) years of social work experience in a health care setting. This individual works under the supervision of a social worker.

“Speech/language pathologist” means an individual who is currently licensed pursuant to 24 Del.C. Ch. 37 and who offers the services to the public under any title or description of services incorporating the words "speech/language pathologist," "speech pathologist," "language pathologist," "speech and/or language therapist," "speech and/or language correctionist," "speech and/or language clinician," "voice therapist," "communicologist," "aphasiologist" or any other similar title or description of service.

“Speech pathology aide” means an individual who meets minimum qualifications pursuant to 24 Del.C. Ch. 37, which permit a speech pathology aide to assist speech/language pathologists in their professional endeavors, but only while under the direct supervision of a licensed speech/language pathologist.

“Speech therapy services” means those services defined pursuant to 24 Del.C. Ch. 37.

“Supervision of services” means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity.

“Telehealth Mechanism” means the use of information exchange from 1 site to another via an electronic interactive telecommunication system. Telehealth is provided with specialized equipment at each site including real-time streaming via the use of video streaming and audio equipment. The telecommunications must permit real-time encryption of the interactive audio and video exchanges with the home health agency. The consumer must consent to the use of telehealth.

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

18 DE Reg. 133 (08/01/14)

19 DE Reg. 849 (03/01/16)

2.0 Licensing Requirements and Procedures

2.1 General Requirements

- 2.1.1 No person shall establish, conduct or maintain in this State any home health agency without first obtaining a license from the Department.
- 2.1.2 A separate license shall be required for each office maintained by a home health agency.
- 2.1.3 The home health 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 modification of ownership and control 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. The agency may provide services to a patient during the patient's 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 home health agency until a license has been issued by the Department.
- 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 agencies owned or managed by the applicant;
 - 2.2.2.2 A copy of the applicant's policies and procedures manual as requested by the Department;
 - 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 Any officers/directors, partners, 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, managing member or member of the governing body with a felony criminal record;
 - 2.2.2.5 Name of the individual (director) who is responsible for the management of the home health agency;
 - 2.2.2.6 A list of management personnel, including credentials;
 - 2.2.2.7 A plan for providing continuing education and training for agency personnel or contractors during the first year of operation; and
 - 2.2.2.8 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 and whose policies and procedures demonstrate compliance with the rules and regulations pertaining to skilled home health agency licensure.
- 2.3.1.2 All home health agencies shall have an on-site survey during the first ninety (90) calendar days of operation.
- 2.3.1.3 A home health agency, at the time of an initial on-site survey, must meet the definition of a home health agency as contained within these regulations and must be in operation and caring for patients. Agencies that, at the time of an on-site survey, do not meet the definition of a home

health agency or that are not in substantial compliance with these regulations will not be granted a license.

2.3.1.4 An initial license will permit an agency to hire or contract with personnel and establish a patient caseload.

2.3.1.5 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 home health agencies that:

2.3.2.1.1 Are not in substantial compliance with these rules and 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 may not be renewed unless a plan of correction for coming into substantial compliance with these rules and regulations has been approved by the Department and implemented by the home health 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 rules and regulations.

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 home health agencies which are in substantial compliance with these rules and regulations at the time of application.

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, suspended or revoked, or surrendered prior to the expiration date.

2.3.3.3 Existing home health agencies must apply for renewal of 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 home health agency:

2.3.3.4.1 Which does not meet the definition of a home health 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 patients.

2.4 Disciplinary proceedings

2.4.1 The Department may impose sanctions (subsection 2.4.2 of this regulation) singly or in combination when it finds a licensee or former licensee has:

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 patients;

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

2.4.1.7 Mistreated or abused individuals cared for by the home health agency;

2.4.1.8 Violated any statutes relating to Medical Assistance or Medicare reimbursement for those agencies who participate in those programs; or

2.4.1.9 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 may 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; and
- 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 \$10,000 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 \$10,000 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 any patient;
 - 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);
 - 2.4.2.7.2.3 The efforts made by the agency to correct the violation(s);
 - 2.4.2.7.2.4 Any misrepresentation made to the Department; and
 - 2.4.2.7.2.5 Any other matter that affects the health, safety or welfare of a patient(s).
- 2.4.2.8 Otherwise discipline.
- 2.4.3 Imposition of Disciplinary Action
 - 2.4.3.1 Before any disciplinary action 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 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) calendar days after the mailing of the determination letter unless the licensee, within the twenty (20) calendar 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 jeopardy 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 calendar 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 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 written 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 calendar 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 calendar days of the receipt by the Department of such a request and shall render a decision within 30 calendar days.

2.4.4.5 In no event shall an order of temporary suspension remain in effect for longer than 60 calendar 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 may 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 home health 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.

2.4.5.2 Termination of rights to provide services extends to:

2.4.5.2.1 Agency;

2.4.5.2.2 Owner(s);

2.4.5.2.3 Officers/Directors, partners, managing members or members of a governing body who have a financial interest of five percent (5%) or more in the home health agency; and

2.4.5.2.4 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; or

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)o.

2.7 Inspection. A representative of the Department shall periodically inspect every home health 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 Patients. The home health agency shall notify each patient or the patient's authorized representative, the patient's attending physician or allowable provider (as appropriate), 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 home health agency license:

2.9.1 Those individuals who contract directly with a patient to provide services for that patient, where the patient pays the individual for services rendered and neither the patient 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 home health agencies, such as temporary employment/staffing agencies, provided that:

2.9.3.1 Temporary employment/staffing agencies may not provide services under direct agreements with patients.

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 home health 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 Personal Assistance Services Agency which solely provides services defined in 16 **Del.C.** §122(3)x.

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

19 DE Reg. 849 (03/01/16)

25 DE Reg. 527 (11/01/21)

3.0 General Requirements

- 3.1 All records maintained by the home health agency shall at all times be open to inspection by the authorized representatives of the Department.
- 3.2 No policies shall be adopted by the home health agency which are in conflict with these regulations.
- 3.3 Reports of incidents, accidents and medical emergencies shall be kept on file at the agency for a minimum of six years.
- 3.4 The home health agency shall advise the Department in writing within thirty (30) calendar days following any change in the designation of the director or clinical director within the agency.
- 3.5 The home health agency may contract for services to be provided to its patients. Individuals providing services under contract must meet the same requirements as those persons employed directly by the agency.
- 3.6 The director or clinical director shall be available at all times during the operating hours of the home health agency.
- 3.7 The home health agency shall advise the Department in writing at least thirty (30) calendar days prior to any change in office location.
- 3.8 The home health agency must permit photocopying of any records or other information by, or on behalf of authorized representatives of the Department, as necessary to determine or verify compliance with these regulations.
- 3.9 The agency shall have policies and an operational system which assure uninterrupted implementation of the plan of care. In furtherance of this requirement, the agency shall, at a minimum: 1) maintain a sufficient pool of qualified employees/contractors to fulfill plans of care and provide scheduled services; and 2) develop and maintain a back-up system to provide substitute employees/contractors if regularly scheduled employees/contractors are unavailable.
- 3.10 The agency shall be in compliance with federal, state and local laws and codes.
- 3.11 Prior to the provision of services in a health care facility, the home health agency must obtain written permission from each health care facility in which services will be provided.

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

19 DE Reg. 849 (03/01/16)

25 DE Reg. 527 (11/01/21)

4.0 Governing Body

- 4.1 Each home health agency shall have an organized governing body (governing authority, owner or person(s) designated by the owner).
- 4.2 The governing body shall be ultimately responsible for:
 - 4.2.1 The management and control of the agency;
 - 4.2.2 The assurance of quality care and services;
 - 4.2.3 Compliance with all federal, state and local laws and regulations;
 - 4.2.4 Adoption of written policies and procedures which describe the functions and services of the agency;
 - 4.2.5 Providing a sufficient number of appropriately qualified personnel;
 - 4.2.6 Providing physical resources and equipment, supplies and services for the provision of safe, effective and efficient delivery of care services;
 - 4.2.7 Developing an organizational structure establishing lines of authority and responsibility;
 - 4.2.8 Appointing a qualified director;
 - 4.2.9 Appointing members of the clinical staff, ensuring their competence and delineating their clinical privileges;

- 4.2.10 Conducting meetings, when the governing body is more than one person, at least annually and maintaining written minutes of the meeting(s);
- 4.2.11 Annual review and evaluation of the agency policies and services; and
- 4.2.12 Other relevant health and safety requirements.
- 4.3 There shall be a description of each type of service offered.
- 4.4 There shall be written policies and procedures pertaining to each service offered.
- 4.5 There shall be a description of the system for the maintenance of patient records.
- 4.6 Bylaws shall be reviewed annually by the governing body and so dated. Revisions shall be completed as necessary.

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

5.0 Administration/Personnel

5.1 Director

- 5.1.1 There shall be a full-time agency director.
- 5.1.2 The director shall have the overall authority and responsibility for the daily operation and management of the agency.
- 5.1.3 The authority, duties and responsibilities of the director shall be defined in writing and shall include but not be limited to:
 - 5.1.3.1 Interpretation and execution of the policies adopted by the governing body;
 - 5.1.3.2 Program planning, budgeting, management and program evaluation;
 - 5.1.3.3 Maintenance of the agency's compliance with licensure regulations and standards;
 - 5.1.3.4 Preparation and submission of required reports;
 - 5.1.3.5 Distribution of a written plan for the delegation of administrative responsibilities and functions in the absence of the director;
 - 5.1.3.6 Documentation of complaints and grievances relating to the conduct or actions by employees/contractors and action taken secondary to the complaints or grievances; and
 - 5.1.3.7 Conducting or supervising the resolution of complaints and grievances received from patients in the delivery of care or services by the agency.
 - 5.1.3.8 Reviewing policies and procedures at least annually and reporting, in writing, to the governing body on the review.
- 5.1.4 The director shall designate, in writing, a similarly qualified person to act in the absence of the director.

5.2 Supervision of Clinical Services

- 5.2.1 The director shall appoint a full-time employee as the clinical director.
- 5.2.2 The clinical director shall be responsible for implementing, coordinating and assuring quality of patient care services.
- 5.2.3 The clinical director shall:
 - 5.2.3.1 Be a registered nurse with at least one year of home health and administrative/supervisory experience;
 - 5.2.3.2 Be available at all times during operating hours of the home health agency;
 - 5.2.3.3 Participate in all activities related to the services provided, including the qualifications of personnel and contractors as related to their assigned duties; and
 - 5.2.3.4 Provide general supervision and direction of the services offered by the home health agency.
- 5.2.4 In the absence of the clinical director, an equally qualified designee must be appointed.

5.3 Contract Services

- 5.3.1 The home health agency maintains responsibility for all services provided to the patient.
- 5.3.2 Services provided by the home health agency through arrangements with a contractor agency or individual shall be set forth in a written contract which clearly specifies:
 - 5.3.2.1 That the patient's contract for care is with the home health agency;
 - 5.3.2.2 The services to be provided by the contractor;
 - 5.3.2.3 The necessity to conform to all home health agency policies;
 - 5.3.2.4 The procedure for submitting clinical and progress notes, scheduling visits, periodic patient evaluation, and determining charges and reimbursement;

- 5.3.2.5 The procedure for annual assurance of clinical competence of all individuals utilized under contract;
- 5.3.2.6 The procedure for supervision of services of the contracted individuals;
- 5.3.2.7 That all payments by the patient for services rendered shall be made directly to the agency or its billing representative and no payments shall be made to or in the name of contractors of the agency;
- 5.3.2.8 That patients are accepted only by the home health agency. Patients may not be admitted for services by a contracted individual without prior review of the case and acceptance of the patient by the home health agency in accordance with agency policies; and
- 5.3.2.9 That the written contractual arrangement must contain a renewal clause or be renewed annually.
- 5.3.3 The agency must ensure that personnel and services contracted meet the requirements specified in these regulations for home health agency personnel and services.

5.4 Written Policies

- 5.4.1 Policy manuals shall be prepared and followed which outline the procedures and practices of the agency.
- 5.4.2 The home health agency shall establish written policies regarding:
 - 5.4.2.1 The rights and responsibilities of patients;
 - 5.4.2.2 The handling and documentation of incidents, accidents and medical emergencies;
 - 5.4.2.2.1 Reports of these events shall be kept on file at the agency.
 - 5.4.2.3 Control of the exposure of patients and staff to persons with communicable diseases;
 - 5.4.2.4 Reporting of all reportable communicable diseases to the Department;
 - 5.4.2.5 The patient's (and family or representative, if any) right to have concerns addressed without fear of reprisal. This policy must include the mechanism for informing the patient of her/his right to report concerns/complaints to the Department at a telephone number established for that purpose.
 - 5.4.2.6 The procedure to be followed in the event that the home health agency is not able to provide services scheduled for any particular day or time. This policy shall include at a minimum:
 - 5.4.2.6.1 The procedure for contacting the patient prior to the missed visit;
 - 5.4.2.6.2 The procedure for attempts to find a substitute caregiver; and
 - 5.4.2.6.3 Documentation of the missed visit and patient contact.
 - 5.4.2.7 Infection control.
 - 5.4.2.8 Employment/Personnel which shall include:
 - 5.4.2.8.1 Qualifications, responsibilities and requirements for each job classification;
 - 5.4.2.8.2 Pre-employment requirements;
 - 5.4.2.8.3 Position descriptions;
 - 5.4.2.8.4 Orientation policy and procedure for all employees and contractors;
 - 5.4.2.8.5 Inservice education policy;
 - 5.4.2.8.6 Annual performance review and competency testing; and
 - 5.4.2.8.7 The process of appointment to the professional staff whereby it can satisfactorily be determined that the individual is appropriately licensed and qualified for the privileges and responsibilities to be given.
 - 5.4.2.9 Referrals received, admission of patients to agency services, delivery of those services and discharge of patients.
 - 5.4.2.10 The use and removal of records and the conditions for release of information in accordance with statutory provisions pertaining to confidentiality.
- 5.4.3 The home health agency shall review its written policies at least annually, and revise them as necessary.
- 5.4.4 Policies shall be made available to representatives of the Department upon request.

5.5 Personnel Records

- 5.5.1 Records of each employee/contractor shall be kept current and available upon request by authorized representatives of the Department.
- 5.5.2 For individuals utilized via contract with another agency, the home health agency shall obtain, upon request, any records as required by the Department.
- 5.5.3 For all individuals, the agency shall maintain individual personnel records which shall contain at least:
 - 5.5.3.1 Written verification of compliance with pre-employment requirements;
 - 5.5.3.2 Documentation of clinical competence;

- 5.5.3.3 Evidence of current professional licensure, registration or certification as appropriate;
- 5.5.3.4 Educational preparation and work history;
- 5.5.3.5 Written performance evaluations (annually); and
- 5.5.3.6 A written and signed job description.

5.6 Health History

- 5.6.1 All new employees/contractors shall be required to have a physical examination prior to providing care:
 - 5.6.1.1 The physical examination must have been completed within 3 12 months prior to employment/referral and
 - 5.6.1.2 A copy of the physical examination shall be maintained in individual files.
- 5.6.2 Minimum requirements for tuberculosis (TB) testing are those currently recommended by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services:
 - 5.6.2.1 A baseline testing must be completed upon hire and, thereafter, as determined by a TB risk assessment.
 - 5.6.2.2 No person found to have active TB in an infectious stage shall be permitted to give care or service to patients.
 - 5.6.2.3 Any person having a positive skin test but a negative chest X-ray must complete a statement annually attesting that they have experienced no symptoms which may indicate active TB infection.
 - 5.6.2.4 A report of all TB test results and all attestation statements shall be on file at the home health agency.
- 5.6.3 Any individual who cannot adequately perform the duties required or who may jeopardize the health or safety of the patient or patients shall be relieved of their duties and removed from the agency until such time as the condition is resolved. This includes infections of a temporary nature.

5.7 Staff Development

- 5.7.1 Staff development must be supervised by a registered nurse with at least one year of home health and administrative/supervisory experience.
- 5.7.2 All employees/contractors are required to complete an orientation program.
- 5.7.3 An orientation/training program should be based on an instruction plan that includes learning objectives, clinical content and minimum acceptable performance standards. and shall include but not be limited to:
 - 5.7.3.1 Organizational structure of the agency;
 - 5.7.3.2 Agency patient care policies and procedures;
 - 5.7.3.3 Philosophy of patient care;
 - 5.7.3.4 Description of patient population and geographic location served;
 - 5.7.3.5 Patient rights;
 - 5.7.3.6 Agency personnel and administrative policies;
 - 5.7.3.7 Job description;
 - 5.7.3.8 Disaster Preparedness; and
 - 5.7.3.9 Applicable state regulations governing the delivery of home health care services.
- 5.7.4 All newly hired/contracted aides shall be required to complete or show evidence of having completed a minimum of seventy-five (75) hours of training which shall include instruction and supervised practicum and which addresses:
 - 5.7.4.1 Personal care services;
 - 5.7.4.2 Principles of good nutrition;
 - 5.7.4.3 Process of growth, development and aging;
 - 5.7.4.4 Principles of infection control;
 - 5.7.4.5 Observation, reporting and documentation of patient status;
 - 5.7.4.6 Maintaining a clean, safe and healthy environment;
 - 5.7.4.7 Maintaining a least restrictive environment;
 - 5.7.4.8 Verbal/non-verbal communication skills;
 - 5.7.4.9 Reading and recording temperature, pulse and respiration;
 - 5.7.4.10 Safe transfer techniques and ambulation;
 - 5.7.4.11 Normal range of motion and positioning;
 - 5.7.4.12 Principles of body mechanics; and

- 5.7.4.13 The needs of the elderly and persons with disabilities.
- 5.7.5 Aides who experience a break in service for greater than two (2) calendar years will be required to:
- 5.7.5.1 Repeat the minimum of 75 hour training requirement; or
- 5.7.5.2 Successfully demonstrate competence in each of the required training areas.
- 5.7.6 Ongoing staff development is required to maintain and improve the skills of the caregiver. Aides shall attend at least twelve (12) hours annually of staff development activities which shall consist of in-service training programs, workshops, or conferences related to home health care or specific needs of patients and which shall include but not be limited to:
- Instruction in how to assist patients to achieve maximum self-reliance through re-learning and modifying activities of daily living;
 - Principles of good nutrition;
 - Meal planning, food purchasing and preparation of meals, including special diets;
 - Information on the emotional and physical problems accompanying illness, disability or aging;
 - Principles and practices in maintaining a clean, healthy, pleasant and safe environment that encourages morale building and self-help;
 - Items requiring referral to the home health agency, including changes in the patient's condition or family situation;
 - Observation, reporting, and documentation of patient status;
 - Policies and objectives of the agency;
 - Confidentiality of patient information;
 - Patient rights;
 - Principles of infection control;
 - Verbal/non-verbal communication skills; and
 - Principles of body mechanics.
- 5.7.7 Documentation of orientation and continuing education must include the dates and hours, content, and name and title of the person providing the orientation/education.
- 5.7.8 It is the responsibility of the home health agency to ensure that employees/contractors are proficient to carry out the care assigned in a safe, effective and efficient manner.
- 5.7.9 All employees and contractors must pass a competency evaluation test prior to providing care to patients and annually thereafter.
- 5.7.10 The time allotted for training shall be sufficient to foster safe and skillful services to the patient.
- 5.7.11 Attendance records must be kept for all orientation and continuing education programs.
- 5.7.12 All employees/contractors providing direct patient care must complete annual dementia-specific training that includes: communicating with persons diagnosed as having Alzheimer's disease or other forms of dementia; the psychological, social, and physical needs of those persons; and safety measures which need to be taken with those persons.

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

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

19 DE Reg. 641 (01/01/16)

19 DE Reg. 849 (03/01/16)

25 DE Reg. 527 (11/01/21)

6.0 Patient Care Management

6.1 Admission

- 6.1.1 The admission policies shall be discussed with each patient entering the program or their representative, if applicable.
- 6.1.2 The home health agency shall only admit those individuals whose needs can be met by the agency.
- 6.1.3 There shall be a written agreement between the patient and the home health agency. The agreement shall:
- 6.1.3.1 Specify the services to be provided by the agency, including but not limited to: frequency of visits including hours per day or week and days per week, transportation agreements as appropriate, emergency procedures and conditions for discharge and appeal.
- 6.1.3.2 Specify the procedure to be followed when the agency is not able to keep a scheduled patient visit.
- 6.1.3.3 Specify financial arrangements which shall minimally include:
- 6.1.3.3.1 A description of services purchased and the associated cost;
- 6.1.3.3.2 An acceptable method of payment(s) for these services;

- 6.1.3.3.3 An outline of the billing procedures; and
- 6.1.3.3.4 That all payments by the patient for services rendered shall be made directly to the agency or its billing representative and no payments shall be made to or in the name of individual employees/contractors of the agency.
- 6.1.3.4 Be signed by the patient, if (s)he is able, or representative, if any, and the representative of the home health agency.
- 6.1.3.5 Be given to the patient or representative, if any, and a copy shall be kept at the agency in the patient record.
- 6.1.3.6 Be reviewed and updated as necessary to reflect any change in the services or the financial arrangements.

6.2 Assessment

- 6.2.1 An initial assessment of the patient must be performed by a registered nurse or qualified professional and must be completed:
 - 6.2.1.1 Within forty-eight (48) hours of referral if patient is currently in their residence; or
 - 6.2.1.2 Within forty-eight (48) hours of discharge from a health care facility; or
 - 6.2.1.3 On the physician or allowable provider ordered start of care date.
- 6.2.2 Prior to the provision of services, at a minimum, the initial assessment must include evidence of the following:
 - 6.2.2.1 Physical condition, including ability to perform activities of daily living and sensory limitations;
 - 6.2.2.2 Social situation, including living arrangements and the availability of family and community support;
 - 6.2.2.3 Mental status, including any cognitive impairment and known psychiatric, emotional, and behavioral problems; and
 - 6.2.2.4 Current medication regimen.
 - 6.2.2.5 A visit to the patient's residence to determine whether the agency has the ability to provide the necessary services in a safe manner.
- 6.2.3 Reassessments must include, at a minimum, a description of the patient's:
 - 6.2.3.1 Physical condition, including ability to perform activities of daily living and sensory limitations;
 - 6.2.3.2 Social situation, including living arrangements and the availability of family and community support;
 - 6.2.3.3 Mental status, including any cognitive impairment and known psychiatric, emotional, and behavioral problems; and
 - 6.2.3.4 Current medication regimen.
- 6.2.4 Patient reassessments and monitoring must occur at regular intervals based upon the patient's condition and needs, but no less often than every sixty (60) calendar days. A registered nurse, or a qualified professional of the appropriate discipline, must participate in the reassessment and monitoring of the patient.
 - 6.2.4.1 Every other patient reassessment must be completed in person.
 - 6.2.4.2 Patient reassessments not completed in person must be completed by a telehealth mechanism.
- 6.2.5 A reassessment shall be conducted when the needs of the patient change which indicate a revision to the plan of care is needed.
- 6.2.6 The initial assessment and reassessments shall become a permanent part of the patient's record.

6.3 Plan of Care

- 6.3.1 The home health agency must provide services in accordance with an individualized written plan of care:
 - 6.3.1.1 The individualized written plan of care for patients receiving skilled services must be established by the physician or allowable provider and developed in consultation with a registered nurse or qualified professional of the appropriate discipline and the patient/patient representative (if the patient/patient representative chooses).
 - 6.3.1.2 The written plan of care for patients receiving aide only services must be established and developed by the registered nurse or qualified professional of the appropriate discipline and the patient/patient representative (if the patient/patient representative chooses).
- 6.3.2 A plan of care is developed on admission based upon the initial assessment of the patient.
- 6.3.3 The plan of care shall include reference to at least the following:
 - 6.3.3.1 Pertinent diagnoses;

- 6.3.3.2 Prognosis, including short-term and long-term objectives of treatment;
- 6.3.3.3 Types of services (such as nursing, other therapeutic, or support services), frequency and duration of services to be provided, medications, diet, treatments, procedures, equipment and transportation required;
- 6.3.3.4 Functional limitations of the patient;
- 6.3.3.5 Activities permitted; and
- 6.3.3.6 Safety measures required to protect the patient from injury;
- 6.3.4 The plan of care must be reviewed as often as the severity of the patient's condition requires, but at least every sixty (60) calendar days.
 - 6.3.4.1 The plan of care for patients receiving skilled services must be reviewed by the physician or allowable provider and with a registered nurse or qualified professional of the appropriate discipline.
 - 6.3.4.2 The plan of care for patients receiving aide only services must be reviewed by the registered nurse or qualified professional of the appropriate discipline.
- 6.3.5 The home health agency must have policies and procedures describing the method to obtain and incorporate the physician or allowable provider's orders into the plan of care.
- 6.3.6 The home health agency shall promptly alert the attending physician or allowable provider to any changes in the patient's condition that suggest a need to alter the plan of care.
- 6.3.7 The home health agency shall consider benefits versus risks of treatment as well as patient choice and independence in the development and subsequent revisions of the plan of care.
- 6.4 Home Health Aide Care Plan
 - 6.4.1 The home health agency must develop a written home health aide care plan for each patient receiving home health aide services.
 - 6.4.2 A copy of the home health aide care plan is kept at the patient's residence.
 - 6.4.3 The written home health aide care plan must be established by a registered nurse or qualified professional of the appropriate discipline.
 - 6.4.4 A home health aide care plan is developed on admission based upon the initial assessment of the patient.
 - 6.4.5 The home health aide care plan must be reviewed by a registered nurse or other qualified professional of the appropriate discipline as often as the severity of the patient's condition requires, but at least every sixty (60) calendar days.
- 6.5 Medication and Treatment Management
 - 6.5.1 Medication shall not be administered to a patient unless prescribed by a licensed practitioner with independent prescriptive authority as provided by **Delaware Code**.
 - 6.5.2 All medication administered to patients by the home health agency shall be ordered in writing, dated and signed by the prescribing licensed practitioner.
 - 6.5.3 All prescription medications shall be properly labeled.
 - 6.5.4 Appropriately licensed individuals must immediately record, sign, and date verbal orders for medications and treatments. The signature of the licensed practitioner ordering the medications or treatments must be obtained as soon as possible.
 - 6.5.5 Medications and treatments may be self-administered or, when administered by the home health agency, shall be administered in accordance with all State and Federal laws, including the State of Delaware Board of Professional Regulation's requirements. Those patients who, upon admission, are incapable of self-administration or who become incapable of self-administration shall have their medications/treatments administered according to the requirements of the Board of Professional Regulation, when the medications/treatments are administered by the home health agency.
 - 6.5.6 The home health agency shall maintain a record of all medication and treatments administered to a patient indicating date, time of day, type of medication/treatment, dose, route of self-administration/administration, by whom given and any reactions noted.
- 6.6 Patient Services
 - 6.6.1 Nursing
 - 6.6.1.1 Services are provided by registered and licensed practical nurses.
 - 6.6.1.2 The home health agency must maintain verification of current licensure as required by the Delaware Board of Nursing.
 - 6.6.1.3 Services must be provided in accordance with the written plan of care and acceptable standards of practice.

- 6.6.1.4 Services are provided under the supervision and direction of the clinical director.
- 6.6.2 Professional Therapy
 - 6.6.2.1 Services are provided by, or under the supervision of, the appropriate professional therapist (physical therapy, occupational therapy, speech therapy, audiology, nutrition).
 - 6.6.2.2 The home health agency must maintain verification of current licensure/registration as required by the Delaware Division of Professional Regulation.
 - 6.6.2.3 Services must be provided in accordance with the written plan of care and acceptable standards of practice.
 - 6.6.2.4 Services are provided under the supervision and direction of the clinical director.
- 6.6.3 Social Services
 - 6.6.3.1 Social services, when provided, are given by a qualified social worker and in accordance with the written plan of care.
- 6.6.4 Home Health Aide
 - 6.6.4.1 Services are provided under the supervision and direction of the clinical director or the appropriate qualified professional.
 - 6.6.4.2 On-site professional supervisory visits are required for all patients receiving home health aide services.
 - 6.6.4.2.1 When patients are receiving home health aide services as well as another skilled service, a registered nurse (or another professional therapist if the patient is not receiving nursing services) must make an on-site supervisory visit to the patient's residence no less frequently than every two (2) weeks.
 - 6.6.4.2.2 When home health aide services are being provided in the absence of a skilled service, a registered nurse must make an on-site supervisory visit to the patient's residence (while the home health aide is providing care) no less frequently than every sixty (60) calendar days.
 - 6.6.4.2.3 Every other supervisory visit must be completed in person.
 - 6.6.4.2.4 Supervisory visits not completed in person must be completed by a telehealth mechanism.
 - 6.6.4.3 Services must be provided in accordance with a written home health aide care plan.
- 6.6.5 A home health agency is responsible for coordination of services to assure that the services effectively complement one another and support the objective(s) outlined in the plan of care.
- 6.6.6 Competent patients 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 home health aides provided:
 - 6.6.6.1 The nature of the service/task is not excluded by law or other state or federal regulation;
 - 6.6.6.2 The services/tasks are those competent patients could normally perform themselves but for functional limitation; and
 - 6.6.6.3 The delegation decision is entirely voluntary.
- 6.6.7 Services provided to patients who are not able to delegate services/tasks due to impaired cognitive function shall be those delegated by the registered nurse as permitted by law.
- 6.7 Records and Reports
 - 6.7.1 There shall be a separate record maintained at the home health agency for each patient which shall contain:
 - 6.7.1.1 Admission record including:
 - 6.7.1.1.1 Name;
 - 6.7.1.1.2 Birth date;
 - 6.7.1.1.3 Home address;
 - 6.7.1.1.4 Telephone number;
 - 6.7.1.1.5 Identification number(s) (i.e. Social Security, Medicaid, Medicare);
 - 6.7.1.1.6 Date of admission;
 - 6.7.1.1.7 Physician or allowable provider's name, address and telephone number; and
 - 6.7.1.1.8 Names, addresses and telephone numbers of family members, friends or other designated people to be contacted in the event of illness or an emergency.
 - 6.7.1.2 Referral Form and Request for Services Form.
 - 6.7.1.3 Assessment (initial and reassessments).
 - 6.7.1.4 Individual plan of care (initial, reviews and revisions).
 - 6.7.1.5 Home health aide care plan.

- 6.7.1.6 Progress notes, chronological and timely.
- 6.7.1.7 Advance health-care directive form that complies with 16 **Del.C.** Ch. 25, a statement that a copy of the advance health-care directive form has been requested, or a statement that none has been signed.
- 6.7.1.8 A copy of the written agreement between the patient and the home health agency including any updates made to the original reflecting changes in services or arrangements.
- 6.7.1.9 Written acknowledgment that the patient or the patient's representative has been fully informed of the patient's rights.
- 6.7.1.10 Medication orders.
- 6.7.1.11 Nutrition orders.
- 6.7.1.12 Treatment orders.
- 6.7.1.13 Activity orders.
- 6.7.1.14 Copies of any summary reports requested by the physician or allowable provider.
- 6.7.1.15 A discharge summary.
- 6.7.2 Aide notes must contain the following information:
 - 6.7.2.1 Date(s) on which service(s) are provided;
 - 6.7.2.2 Hour(s) of service(s) provided;
 - 6.7.2.3 Type(s) of service(s) provided; and
 - 6.7.2.4 Observations/problems/comments.
- 6.7.3 All notes written in the patient's record must be signed and dated or authenticated by the employee/contractor on the day that the service is rendered.
- 6.7.4 All notes and reports in the patient's record shall be electronic or legibly written in ink, dated and signed by the recording person with her/his full name and title.
- 6.7.5 All notes must be incorporated into the patient's record no less often than every ~~two (2) weeks~~ 30 days.
- 6.7.6 All patients' records shall be maintained in accordance with professional standards.
- 6.7.7 All patient records shall be available for review by authorized representatives of the Department and to legally authorized persons; otherwise patient records shall be held confidential. The consent of the patient or her/his representative, if the patient is incapable of making decisions, shall be obtained before any personal information is released from her/his records as authorized by these regulations or Delaware law.
- 6.7.8 Computerized patient records must be printed by the agency as requested by authorized representatives of the Department.
- 6.7.9 The home health agency records shall be retained in a retrievable form until destroyed.
 - 6.7.9.1 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.
 - 6.7.9.2 Records of minors (less than 18 years of age) shall be retained for a minimum of six (6) years after the patient reaches eighteen (18) years of age.
 - 6.7.9.3 All records must be disposed of by shredding, burning, or other similar protective measure in order to preserve the patients' rights of confidentiality.
 - 6.7.9.4 Documentation of record destruction must be maintained by the home health agency.
 - 6.7.9.5 At least thirty (30) calendar days before the home health agency discontinues operations, it must inform the Department where patient records will be maintained.
- 6.7.10 Records shall be protected from loss, damage and unauthorized use.
- 6.7.11 The home health agency must develop acceptable policies for authentication of any computerized records.
- 6.7.12 Report of Major Adverse Incidents
 - 6.7.12.1 The home health agency must report all major adverse incidents, occurring in the presence of a home health employee/contractor, involving a patient to the Department within forty-eight (48) hours in addition to other reporting requirements required by law.
 - 6.7.12.2 A major adverse incident includes but is not limited to:
 - 6.7.12.2.1 Suspected abuse, neglect, mistreatment, financial exploitation, solicitation or harassment;
 - 6.7.12.2.2 An accident that causes serious injury to a patient;
 - 6.7.12.2.3 A medication error with the potential to result in adverse health outcomes for the patient; or
 - 6.7.12.2.4 The unexpected death of a patient.
 - 6.7.12.3 Major adverse incidents must be investigated by the agency.

6.7.12.4 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.

6.8 Discharge

- 6.8.1 The patient, or her/his representative if any, shall be informed of and participate in discharge planning.
- 6.8.2 The home health agency shall develop a written plan of discharge which includes a summary of services provided and outlines the services needed by the patient upon discharge.
 - 6.8.2.1 The plans for the patient's discharge and any revisions must be communicated to all physicians and allowable providers participating in the patient's care and the patient's primary physician or allowable provider or other health care professionals who will be responsible for providing care and services to the patient after discharge (if any).
- 6.8.3 When discharging a patient who does not wish to be discharged, a minimum of two (2) weeks notice will be provided to permit the patient to obtain an alternate service provider. Exceptions to the two (2) week notice provision would include:
 - 6.8.3.1 The discharge of patients when care goals have been met.
 - 6.8.3.2 The discharge of patients when care needs undergo a change which necessitates transfer to a higher level of care and for whom a new discharge plan needs to be developed.
 - 6.8.3.3 The discharge of patients when there is documented non-compliance with the plan of care or the admission agreement (including, but not limited to, non-payment of justified charges).
 - 6.8.3.4 The discharge of patients when activities or circumstances in the home jeopardize the welfare and safety of the home health agency caregiver.

6.9 Infection Prevention and Control

- 6.9.1 The agency shall establish 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.
 - 6.9.1.1 The infection prevention and control program must include all services offered by the agency, including the appropriate personal protective equipment for all patients and staff.
- 6.9.2 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 of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the Skilled Home Health Agency's infection control outcomes.
- 6.9.3 All agency staff shall receive orientation at the time of employment and annual in-service education regarding the infection prevention and control program.
- 6.9.4 Specific Requirements for COVID-19
 - 6.9.4.1 Before their start date, all new staff, vendors, and volunteers must be tested for COVID-19 in accordance with Division of Public Health guidance.
 - 6.9.4.2 All staff, vendors, and volunteers must be tested for COVID-19 in a manner consistent with Division of Public Health guidance.
 - 6.9.4.3 The skilled home health 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 patients by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.
- 6.9.5 The skilled home health agency shall amend their policies and procedures to include:
 - 6.9.5.1 Work exclusion and return to work protocols for staff tested positive for COVID-19;
 - 6.9.5.2 Staff refusals to participate in COVID-19 testing;
 - 6.9.5.3 Staff refusals to authorize release of testing results or vaccination status to the skilled home health agency;
 - 6.9.5.4 Procedures to obtain staff authorizations for release of laboratory test results to the skilled home health agency to inform infection control and prevention strategies; and
 - 6.9.5.5 Plans to address staffing shortages and the skilled home health agency demands should a COVID-19 outbreak occur.

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

19 DE Reg. 849 (03/01/16)

25 DE Reg. 527 (11/01/21)

25 DE Reg. 773 (02/01/22)

7.0 Patient Rights

- 7.1 The home health agency must provide the patient with a written notice of the patient's rights during the initial assessment visit or before initiation of care.
- 7.2 Each patient shall have the right to:
 - 7.2.1 Be treated with courtesy, consideration, respect and dignity;
 - 7.2.2 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;
 - 7.2.3 Self-determination and choice, including the opportunity to participate in developing one's plan of care;
 - 7.2.4 Privacy and confidentiality;
 - 7.2.5 Be protected from abuse, neglect, mistreatment, financial exploitation, solicitation and harassment;
 - 7.2.6 Voice grievances without discrimination or reprisal;
 - 7.2.7 Be fully informed, as evidenced by the patient's written acknowledgment of these rights, and of all rules and regulations regarding patient conduct and responsibilities;
 - 7.2.8 Be fully informed, at the time of admission into the program, of services and activities available and related charges;
 - 7.2.9 Be served by individuals who are properly trained and competent to perform their duties; and
 - 7.2.10 Refuse care and to be informed of possible health consequences of the refusal.
- 7.3 The agency must establish a process for the prompt resolution of grievances, which must include:
 - 7.3.1 The procedure for the submission of a written or verbal grievance;
 - 7.3.2 The timeframes for review of the grievance and the provision of a response; and
 - 7.3.3 A written notice of the decision to the patient/representative that contains the name of the agency contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

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

25 DE Reg. 527 (11/01/21)

8.0 Quality Improvement

- 8.1 Each home health agency shall develop and implement a documented ongoing quality improvement program. The program shall include at a minimum:
 - 8.1.1 An internal monitoring process that tracks performance measures;
 - 8.1.2 A review of the program's goals and objectives at least annually;
 - 8.1.3 A review of the grievance/complaint process;
 - 8.1.4 A review of all unexpected patient deaths;
 - 8.1.5 A review of all medication errors;
 - 8.1.6 A review of actions taken to address identified issues; and
 - 8.1.7 A process to monitor the satisfaction of the patients or their representatives with the program.

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

25 DE Reg. 527 (11/01/21)

9.0 Insurance

The home health agency shall have appropriate insurance coverage in force to compensate patients for injuries and losses resulting from services provided by the agency.

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

10.0 Disaster Preparedness

- 10.1 Each home health 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.
- 10.2 The plan shall:
 - 10.2.1 Provide for continuing home health services during an emergency that interrupts patient care or services in the patient's home;
 - 10.2.2 Describe how the home health agency establishes and maintains an effective response to emergencies and disasters, including:

- 10.2.2.1 Notification of staff when emergency response measures are initiated;
 - 10.2.2.2 Provision for communication with and between staff members, local emergency management agencies, the State emergency management agency and patients;
 - 10.2.2.3 Provision for a backup system;
 - 10.2.2.4 Identification of resources necessary to continue essential care and services; and
 - 10.2.2.5 Prioritization of patient care needs and services.
- 10.3 All agency staff must be oriented to the disaster preparedness plan(s).
- 10.3.1 Records of staff attendance must be maintained.
- 10.4 A copy of the disaster preparedness plan(s) shall be available to all staff.
- 10.5 Each home health agency shall inform patients and patients' caregivers, upon admission, of the agency's procedures during and immediately following an emergency.

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

25 DE Reg. 527 (11/01/21)

11.0 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.

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

18 DE Reg. 133 (08/01/14)

25 DE Reg. 527 (11/01/21)

25 DE Reg. 773 (02/01/22)

26 DE Reg. 814 (04/01/23) (Prop.)