

# 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 4410

**FINAL**

**ORDER**

### **4410 Skilled Home Health Agencies (Licensure)**

IN THE MATTER OF:

ADOPTION OF THE STATE OF DELAWARE  
REGULATIONS GOVERNING SKILLED HOME  
HEALTH AGENCIES

|  
|  
|  
|  
|

#### **Nature of The Proceedings**

The Delaware Department of Health and Social Services ("DHSS") initiated proceedings to adopt revised Regulations Governing Skilled Home Health 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 (3)o.

On August 1, 2021 (Volume 25, Issue 2), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 *Del.C.* § 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by September 1, 2021, after which time the DHSS would review information, factual evidence and public comment to the proposed regulations.

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

#### **Summary of Proposal**

Effective November 1, 2021, DHSS/Division of Health Care Quality (DHCQ) is publishing the final regulations governing Skilled Home Health Agencies.

#### **Background**

As more services are being provided in the home and community setting, it is necessary to ensure skilled home health services are provided in accordance with recognized standards of practice.

#### **Statutory Authority**

16 Del.C. §122(3)(o)

#### **Purpose**

The Division of Health Care Quality published proposed amendments to regulations governing skilled home health agencies and held them out for public comment according to required procedures. The proposed amendments will update home health agency regulations to be consistent with nationally recognized standards of practice and to clarify regulatory requirements to ensure patients receive safe and quality care for a skilled home health agency.

Prior to this proposed change, a physician had to establish a written plan of care for each patient receiving skilled home health agency services. This requirement created an extreme hardship for home care providers and the vulnerable patients needing skilled home health services. The proposed amendment will permit allowable providers to order skilled home health services, allow individuals more access to skilled home health services.

Lastly, rapid and widespread transmission of COVID-19 significantly impacted many vulnerable individuals receiving healthcare services throughout the community. In an effort to prevent or significantly decrease transmission of COVID-19 and other infections, a requirement was added for the skilled home health agency to have a comprehensive infection control and prevention program based upon guidance from the Centers for Disease Controls and Prevention and other nationally recognized sources.

#### **Fiscal Impact**

N/A

#### **Findings of Fact:**

There were no changes made to the regulations based on the comments received and detailed in the "Summary of Evidence". The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Skilled Home Health Agencies is adopted and shall become effective November 11, 2021, after publication of the final regulation in the *Delaware Register of Regulations*.

10/13/2021

Date

Molly Magarik, Secretary, DHSS?

## SUMMARY OF EVIDENCE

### STATE OF DELAWARE REGULATIONS GOVERNING SKILLED HOME HEALTH AGENCIES

In accordance with Delaware Law, public notice regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Skilled Home Health Agencies was published in the *Delaware Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (August 1, 2021 through September 1, 2021).

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

#### **Jean Mullen, Executive Director, Delaware Association of Home and Community Care**

**Comment:** Thank you for initially meeting with the DAHCC Board to work with us on revisions for both Home Health Skilled Agency and Home Health Aide Only regulations.

As you know, considerable time (approximately 2 years) has passed since our revision meetings with you. Since that time, experience has created new perspectives on our work. As a result of both time lapsed and a new normal, the Board is submitting the attached comments for additional revisions along with rationale for the same.

Please find the attached four pages outlining our suggestions for both 4406 and 4410 revisions.

We are available to provide further explanation where needed, and or to meet with you for discussion.

1.0 Definitions

1.0 Definitions

"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 and administrative/supervisory health care experience. The "Clinical Director" and "Director" may be the same individual if that individual is dually qualified.

Recommend removing "home health care".

Rationale: Based on the definition of "home health care experience" added to the definitions, continuing to restrict this role only to registered nurses who have home health care agency experience will compromise agencies' ability to hire otherwise qualified nurses for this role in an increasingly limited labor market and in the face of a significant nursing shortage. A nurse with administrative/supervisory experience in a segment of the health care industry other than home health care should qualify to oversee skilled agency services with proper training and onboarding to the position.

**Response:** Thank you for your comments. The Clinical Director is responsible for providing general supervision and direction of all services offered by the home health agency; therefore, it is imperative that the Clinical Director have home health care experience. The regulatory definition will stand as written.

**Comment:** 1.0 Definitions

"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 have a Baccalaureate Degree in health or a related field. The "Director" and "Clinical Director" may be the same individual if that individual is dually qualified. 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.

Recommend replacing 5 years with 2 years health care experience and removing the word "home" from the one-year supervisory experience.

Rationale: Adding 5 years experience in health care and one year supervisory experience in home health care will severely limit the pool of qualified candidates among new and existing agencies and as a result, will impede any ability to operate an aide only agency in Delaware. In addition, there must be two people on staff that meet these qualifications, with one designated as the alternate. It is not clear with a Clinical Director also on staff, why the director could not qualify with translatable experience from another industry. Also, with a registered nurse also required to have 5 years experience, this

in essence results in an extremely narrowed labor pool and inability of home care providers in Delaware to bring in qualified people to the industry. Also, should there be a vacancy, the ability to replace will compromise the agency's ability to continue operating - resulting in closures and reduced access to care.

**Response:** Thank you for your comments. Revisions to the definition of "Director" were not proposed. The "Director" is responsible for the overall management of the home health agency, therefore, they must have the knowledge and experience to perform these duties. This regulatory definition will remain as written.

**Comment:**

"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.

Recommend removing "immediately" and "who are present at the time"

Recommend adding "and resolved with the patient or patient representative"

Vs.

"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.

Recommend replacing the definition above with the definition below to provide clarification for the difference in complaint vs. grievance. This definition was taken from the following link:

<https://www.reliasmedia.com/articles/57864-when-does-a-complaint-become-a-grievance>

"The factor that distinguishes a complaint from a grievance is the formality of the process. In a grievance situation, the patient (or the patient's representative) is specifically requesting that his or her complaint undergo a formal (and therefore well-defined) review process. This request may follow a complaint that was not resolved to the patient's satisfaction, or the request for a formal review may be the first step a patient takes when he is dissatisfied."

**Response:** Thank you for your comments. The difference between a complaint and a grievance is the timeframe in which the issue can be resolved. Furthermore, a grievance does require investigation of the issue to ensure that a fair and just resolution can be established. The regulatory definition will remain as written.

**Comment: 2.0 Licensing Requirements and Procedures, 2.3 Issuance of Licenses**

Section 2.3.1.5 A ~~probationary~~ An initial license may not be renewed.

Recommend adding language that an initial license may be renewed at the discretion of the state in the event circumstances unrelated to the agency prevent the state from conducting the initial survey within the first 90 days.

**Response:** Thank you for your comments. There is a process for initial licensure surveys. Renewing an initial license is not consistent with other state regulations. The regulation will remain as written.

**Comment: 4.0 Governing Body:**

4.6 Bylaws shall be reviewed annually by the governing body and so dated. Revisions shall be completed as necessary.

Recommend removal. This should be left to the agency's governing body to determine.

**Response:** Thank you for your comments. Reviewing the bylaws annually is a minimum standard to ensure the delivery of safe quality care. Agencies can choose to review the bylaws more frequently. The regulations will remain as written.

**Comment: 5.0 Administration/Personnel, 5.1 Director**

5.1.3.2 Program planning, budgeting, management and program evaluation;

Recommend removal of **program evaluation as responsibility of director** and replacing with "implementing a quality improvement program as defined in Section 8.0 of these regulations."

Rationale: CMS removed the program evaluation requirement along with the PAC.

**Response:** Thank you for your comments. The "Director" is responsible for the overall management of the home health agency which includes the program evaluation and the quality improvement program. Both aspects are necessary to ensure the delivery of safe, quality care to vulnerable patients. The regulation will remain as written.

**Comment: 6.0 Patient Care Management, 6.1 Admission**

6.1.3.1 Specify the services to be provided by the agency, including but not limited to: frequency of visits Including ~~scheduled days and hours (or visits) per day or week and number of days per week~~, transportation agreements as appropriate, emergency procedures and conditions for discharge and appeal.

Recommend adding "(or visits)" and "number of" for clarification as inserted above.

**Response:** Thank you for your comments. The Centers for Medicare and Medicaid Services requires that the frequency and duration of visits be included in the individualized plan of care, which is consistent with the proposed language. The regulation will remain as written.

**Comment: 6.8 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).

Aide Only Services: Recommend this apply to patients who are receiving skilled services only where the plan of care is established by physician or other allowed provider. Based on the proposed language of 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.

suggests that a physician's review and order is not required for establishment of plan of care for aide only services, and therefore, this requirement should not apply to this level of service.

**Response:** Thank you for your comments. Any physicians and allowable providers that are participating in the patient's care should receive communications about revisions to the discharge plan. In addition, revisions to the discharge plan must be communicated to the patient's primary physician or allowable provider and any other health care professionals that will be responsible for providing care and services to the patient after discharge. Healthcare professionals that are not participating in the patient's care or not responsible for providing care after discharge would not be required to receive communications about the discharge plan. This regulation will stand as written.

### **Terri Hancharick, Chairperson, State Council for Persons with Disabilities**

**Comment:** The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/Division Health Care Quality's (DHCQ) proposal to amend its regulation regarding Skilled Home Health Agencies (Licensure). Consistent with the *Summary of Proposal*, the intent is to update the requirements to be consistent with nationally recognized standards of practice and clarify the regulatory requirements to ensure patients receive safe and quality care from a skilled home health agency. The proposed regulation was published as 25 DE Reg. 138 in the August 1, 2021 issue of the Register of Regulations. SCPD has the following observations.

First, the regulation adds the requirement that the "Clinical Director" has at least one year of home health care experience and at least one year of administrative or supervisory health care experience. SCPD believes this may improve quality, but questions whether one year of experience is sufficient for a job of this magnitude.

**Response:** Thank you for your comments. The Division of Health Care Quality agrees that it is imperative that the Clinical Director have home health care experience. However, given the current healthcare staffing crisis having a requirement that is too stringent may leave the skilled home health agencies unable to fill the "Clinical Director" position. The regulatory definition will stand as written.

**Comment:** Second, "Medication Reminder" is an addition that defines a reminder as a verbal prompt and which specifically excludes administration or "any physical touching of the medication." The definition of "health aide services" is modified to include medication reminders. SCPD strongly recommends that DHQC further broaden the health aide services definition to include assistance with medication short of actual administration to competent individuals with disabilities who lack the physical ability to open a medication box or a bottle but who can otherwise self-administer. Currently, under restrictive Nurse Practices regulations, nurses cannot delegate medication administration to anyone, licensed or not. Therefore, home health aides, who are supervised by nurses, cannot assist in administration. However, 24 Del. Code 1921(a)(15) allows competent individuals not in Chapter 11 facilities to direct unlicensed individuals to assist in administration; 25 Del Code 1921 (a)(16) authorizes lay administration under Section 1932 (child care workers, etc.) and 24 Del Code Section 1921(a)(17) allows caregivers to instruct and supervise personal care services employees to administer medications.

This can result in the unfortunate and potentially dangerous situation where licensed home health aides who are supervised by medical personnel cannot even touch medication and lay people can administer it. This may be an ADA violation because individuals with disabilities cannot utilize home health aides to provide assistance in administration as an accommodation. Also, the restriction defies common sense as a person who is under the supervision of a nurse cannot assist, and a person "off the street" can.

**Response:** Thank you for your comments. The current regulations contain provisions at 6.6.6 to address 24 Del. Code 1921(a)(15). The regulations at 6.6.6 address circumstances where a competent patient who does 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: the nature of the service/task is not excluded by law or other state or federal regulation, the services/tasks are those competent patients could normally perform themselves but for functional limitation; and the delegation decision is entirely voluntary. The regulation will stand as written.

**Comment:** Third, "Service Area" is defined to include the county in which the agency office is located and the one immediately adjacent. The term is further used in Section 2.1.7 restricting service to this area with the exception of allowing "time limited travel outside of the service area." The ability of nurses and HHAs to travel with patients more broadly than the county where the office is located and the contiguous county is absolutely necessary in order to allow access to specialty health services, day programs, educational opportunities for children and family recreation and travel. Nursing or HHA services for these activities can be covered under Medicaid and waiver programs. SCPD recommends, at a minimum, that DHCQ further elaborate that these activities are contemplated by this exception to the "service area" restriction so there is no misunderstanding as to what "time limited" means.

**Response:** Thank you for your comments. Skilled home health agencies have used this exception for instances such as traveling with the patient to a specialist appointment in another state or to travel with children to destinations arranged through the Make-A-Wish Foundation. Due to the various circumstances this exception could address, compiling a list of all activities and destinations that would fall under this exception would be presumptuous and extremely cumbersome. The regulation will stand as written.

**Comment:** Fourth, "Serious Injury" is a new definition which is restricted to physical injuries that create a substantial risk of death or which cause serious disfigurement, injury or impairment of function of any bodily organ. In Section 6.7.12,

home health agencies are only obligated to report and investigate "major adverse events." These are defined to include suspected abuse and neglect, unexpected death, a medication error with the potential to cause harm, and an accident that causes "serious injury." The proposed language adds the qualifier "serious" to injury. This addition greatly diminishes the types of injuries that must be reported to the Department.

Although the section does require reporting of suspected abuse or neglect, the restriction of accident reporting to "serious" injury may lead to under-reporting of such abuse and neglect. Accidents that are not life-threatening or potentially disfiguring nevertheless can be indicia of abuse or neglect that was not otherwise reported by a home health aide. SCPD strongly recommends that DHCQ modify this language to require reporting of any injury that requires outside medical attention or treatment.

**Response:** Thank you for your comments. Without the addition of "serious," the definition of injury is open to interpretation. Adding the word "serious" and clarifying the definition was necessary to ensure the Division of Health Care Quality received such reports. Lastly, this definition is consistent with other Division of Health Care Quality regulations. The definition will stand as written.

**Comment:** Fifth, in Section 6.2.2.5, the proposed regulation adds a home visit to the Assessment for the purpose of "determine[ing] whether the agency has the ability to provide necessary services in a safe manner." "Safe manner" and "safe" are not defined. While it is important for the agency to assess the home, the risk with this language is that it gives unlimited discretion to the agency to decide what "safety" is. SCPD may wish to ask DHCQ to provide parameters for this assessment, in order to avoid agencies discriminating based on perceptions of risk that may not be appropriate or that could be alleviated. For example, an agency may not allow a HHA to serve people in a particular neighborhood based on generalized opinions about safety.

**Response:** Thank you for your comments. Prior to the provision of services, each home health agency must complete an initial assessment to ensure that they are able to deliver safe, quality care in the patient's home. This assessment does not include an assessment of the "neighborhood". The regulation will stand as written.

**Comment:** Sixth, Section 6.7.5 expands the time frame for notes to be incorporated in the patient record from one week to two. SCPD requests the justification for this change since it could interfere with abuse and neglect investigations and adequate supervision of client care.

**Response:** Thank you for your comments. This regulation was revised to be consistent with the Home Health Agency - Aide Only regulations. Additionally, as more home health agencies move toward electronic records, this is becoming a moot point. Lastly, the agency must allow the Department access to all agency records for the purposes of conducting inspections/surveys /investigations. Therefore, the Department could request notes prior to the two-week timeframe if necessary. The regulation will stand as written.

**Comment:** Seventh, Section 6.8 discusses Discharge. Section 6.8.2.1 adds the requirement that plans for discharge must be communicated to all health care providers participating in the patient's care. SCPD believes this requirement should also include the case manager if the patient has one. In addition, the regulation does not provide any parameters for involuntary discharge, nor does it provide for any meaningful obligation to assist the patient in finding alternative care. We are all aware of situations where agencies leave clients at risk of hospitalization or institutionalization by failing to assist in providing adequate planning for follow up care. We are all aware of situations where patients are dumped without good reason. SCPD recommends additional provisions strengthening the rights of consumers of these services so that they are not compromised by inadequate discharge planning and unfair discharges.

**Response:** Thank you for your comments. Case management is often provided by the patient's insurer, which are generally notified if services are needed after discharge or in the event of a discharge. Insurance and billing issues are not regulated by the Division of Health Care Quality.

The regulations at 6.8.3 address discharging a patient who does not wish to be discharged. In these cases, the home health agency is required to give the patient two week notice to permit the patient to obtain an alternate service provider. Exceptions to the two (2) week notice provision include the following situations:

- The discharge of patients when care goals have been met.
- 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.
- 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).
- The discharge of patients when activities or circumstances in the home jeopardize the welfare and safety of the home health agency caregiver.

The regulation will remain as written.

**Comment:** Eighth, Section 7.3 establishes the requirement that agencies have a grievance process for complaints without any details regarding these processes. SCPD requests more specificity regarding these procedures and additional language that redacted grievance data be publicly available and shared with the licensing agency.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations or recommendations on the proposed regulation.

**Response:** Thank you for your comments. Each agency must develop their own process to handle grievances which must be in compliance with the regulations included in 7.3. Since each agency must develop their own policy and

procedure, each agency will have a different policy and procedure. Grievances often contain protected information and cannot be made publicly available due to the sensitive nature of the information. The regulation will remain as written.

**Tay Kopanos, DNP, NP, VP of Government Affairs, American Association of Nurse Practitioners**

**Comment:** The American Association of Nurse Practitioners (AANP), with a membership of over 118,000 nurse practitioners (NPs), represents the interests of the more than 325,000 NPs in the United States. This includes the over 1,358 NPs practicing in Delaware, 280 of whom are AANP members. AANP welcomes the opportunity to provide comment on the Delaware Department of Health and Social Services, Office of Health Facilities Licensing and Certification, Division of Health Care Quality, proposed regulations governing Skilled Home Health Agencies (Licensure). The proposed amendment would permit allowable providers, including a person currently licensed as an advanced practice nurse pursuant to 24 Del. C. Ch. 17, to order skilled home health services, and allow individuals more access to skilled home health services.

NPs are advanced practice registered nurses who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages and walks of life. Daily practice includes: assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests; making diagnoses; initiating and managing treatment including prescribing medication and non-pharmacologic treatments; coordinating care; counseling; and educating patients and their families and communities. NPs practice in nearly every health care setting including clinics, hospitals, Veterans Health Administration and Indian Health Services facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), skilled nursing facilities (SNFs) and nursing facilities (NFs), schools, colleges and universities, retail clinics, public health departments, nurse managed clinics, homeless clinics, and home health. NPs hold prescriptive authority in all 50 states and the District of Columbia.

AANP appreciates that the Delaware Department of Health and Social Services, Office of Health Facilities Licensing and Certification Division of Health Care Quality made it a priority to update their home health agency regulations. As noted by the agency, the previous requirement that a physician establish a written plan of care for each patient receiving skilled home health agency services created an extreme hardship for home care providers and the vulnerable patients needing skilled home health services. These proposed changes will update the Delaware requirements to be consistent with nationally recognized standards of practice and clarify the regulatory requirements to ensure patients have access to safe and quality care from a skilled home health agency.

We agree that updating the home health regulations pursuant to the recent changes made by section 3708 of the CARES Act will better align the Department of Health and Social Services regulations with 42 CFR 440.70 and provide Delaware patients with critical increased access to home health care services.

We support the proposed changes to 16 DE Admin. Code 4410, as they would ensure Delaware Home Health regulations are consistent with nationally recognized standards of practice and federal regulations.

This new authority streamlines the home health care process and reduces the risk of costly complications resulting from delays in care.

We thank you for the opportunity to comment on these proposed changes to the Delaware Department of Health and Social Services, Office of Health Facilities Licensing and Certification, Division of Health Care Quality Regulations Governing Skilled Home Health Agencies. We again express our appreciation for making increased access to home health services a priority. These proposed regulations will increase the ability of NPs and other clinicians to deliver high-quality, cost-effective health care and will improve access to these services for residents of Delaware.

**Response:** Thank you very much for your comments.

**Dr. Susan Conaty-Buck, DNP, FNP-C, FAANP Chair, DNCP Advocacy Committee, Delaware Coalition of Nurse Practitioners**

**Comment:** This email is from the members of the Delaware Coalition of Nurse Practitioners, the state membership organization representing the 1,358 Nurse Practitioners providing care to patients in Delaware. We are writing in support of Delaware Department of Health and Social Services, Office of Health Facilities Licensing and Certification, Division of Health Care Quality's proposed regulatory amendments permitting allowable providers, including a person currently licensed as an advanced practice nurse pursuant to 24 Del. C. Ch. 17, to order skilled home health services, thus allowing Delawareans greater access to skilled home health services.

Nurse Practitioners are advanced practice registered nurses who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages in a variety of settings. This work includes patient assessment, ordering and evaluating diagnostic testing, providing an evidence-based plan of care and following up to ensure the patient response to care meets expectations. Nurse Practitioners are qualified to order care for home health patients without the collaboration of another healthcare professional.

Prior to the recommended amendment, home health regulations in 16 DE Admin. Code 4410 required a physician to provide a plan of care for any patient requiring skilled home health agency services. This dangerously delayed care for some of Delaware's most vulnerable patients. Updating Delaware's home health regulations to concur with Section 3708 of the CARES Act ensures qualified allowable providers (including NPs) are able to provide care that will better align Department of Health and Social Services regulations with 42 CFR 440.70. This makes Delaware's requirements

consistent with nationally recognized standards of practice and clarifies the regulatory requirements needed to ensure patients in Delaware have access to safe, effective care from a skilled home health agency.

Thank you for offering these proposed changes to the regulations governing Skilled Home Health Agencies which demonstrate the state's prioritization of the health of its citizens. Increasing the ability of qualified NPs to deliver prompt, high-quality, cost-effective health care to patients in all settings improves Delaware's health and wellness.

**Response:** Thank you very much for your comment.

## 4410 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 ~~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,” “audiologist,” “hearing clinician,” “clinician,” “hearing therapist,” “therapist,” “aural rehabilitator” or any other similar title or description of service.

**“Audiology Aide ~~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 ~~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 ~~ownership~~ (CHOW)”** see “Modification of Ownership ~~ownership~~ and Control ~~control~~ (MOC)”.

**“Clinical Director”** means a registered nurse who is sufficiently qualified to provide general supervision and direction of the ~~skilled~~ 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~~ baccalaureate degree with five years ~~healthcare~~ 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.

**"Healthcare Facility Health care facility"** means any facility that is licensed under 16 Del.C. Ch. 10 or 11.

**"Home Health Agency (HHA) 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 her/his ~~her~~ 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 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 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 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 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. ~~The HHA must provide at least one of these services directly and in its entirety by employees of the HHA. The other therapeutic services and any additional services may be provided either directly or under arrangement.~~

**"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 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 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 clinical social worker"** means an individual licensed pursuant to 24 Del.C. Ch. 39.

**"Licensed Independent Practitioner"** means an advanced practice nurse or physician's assistant licensed pursuant to 24 Del.C. Ch. 17 and 24 Del.C. Ch. 19.

**"Licensed Nursing Services 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 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 interest"** means any percentage of ownership less than the majority interest.

**"Modification of Ownership ownership and Control 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 services"** means those services defined pursuant to 24 Del.C. Ch. 38.



**Occupational Therapist 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 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 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 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 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 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 therapist** means an individual who is currently licensed to practice physical therapy pursuant to 24 Del.C. Ch. 26.

**Physical Therapist Assistant therapist assistant** means an individual who assists licensed physical therapists pursuant to 24 Del.C. Ch. 26.

**Physical Therapy Services 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 care** means a written plan that specifies scope, frequency and duration of services.

**Plan of Correction 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 a 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 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 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 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~~ 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~~ 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~~ 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~~ therapy services** means those services defined pursuant to 24 Del.C. Ch. 37.

**~~Supervision of Services~~ 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.

**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 county in which the agency is located and/or the county(ies) which are immediately adjacent 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 ~~Probationary~~ Initial license

2.3.1.1 ~~A probationary~~ 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 ~~A probationary~~ An initial license will permit an agency to hire or contract with personnel and establish a patient caseload.

2.3.1.5 ~~A probationary~~ 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 ~~A~~ 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 ~~A~~ 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 ~~section~~ 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 ~~a patient(s)~~ 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 ~~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; 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)~~ §122(3).

2.7 ~~Inspection~~ Inspection. ~~2.7.1~~ 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 ~~Patients~~ Patients. ~~2.8.1~~ 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~~ 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)**

## 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 ~~fifteen (15)~~ 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 ~~healthcare~~ health care facility, the home health agency must obtain written permission from each ~~healthcare~~ health care facility in which services will be provided.

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

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

#### **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 ~~and the Professional Advisory Group~~ on the review.
  - 5.1.4 The director shall designate, in writing, a similarly qualified person to act in the absence of the director.

## 5.2 Professional Advisory Group

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

~~5.2.1.1 At least one physician;~~

~~5.2.1.2 One registered nurse (preferably with home health or public health experience); and~~

~~5.2.1.3 Representatives from other professional disciplines.~~

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

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

~~5.2.4 The advisory group maintains dated minutes of the meetings.~~

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

## 5.35.2 Supervision of Clinical Services

~~5.3.15.2.1~~ The director shall appoint a full-time employee as the clinical director.

~~5.3.25.2.2~~ The clinical director shall be responsible for implementing, coordinating and assuring quality of patient care services.

~~5.3.35.2.3~~ The clinical director shall:

~~5.3.3.15.2.3.1~~ Be a registered nurse with at least one year of home health and administrative/supervisory experience;

~~5.3.3.25.2.3.2~~ Be available at all times during operating hours of the home health agency;

~~5.3.3.35.2.3.3~~ Participate in all activities related to the services provided, including the qualifications of personnel and contractors as related to their assigned duties; and

~~5.3.3.45.2.3.4~~ Provide general supervision and direction of the services offered by the home health agency.

~~5.3.45.2.4~~ In the absence of the clinical director, an equally qualified designee must be appointed.

## 5.45.3 Contract Services

~~5.4.15.3.1~~ The home health agency maintains responsibility for all services provided to the patient.

~~5.4.25.3.2~~ 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:

~~5.4.2.15.3.2.1~~ That the patient's contract for care is with the home health agency;

~~5.4.2.25.3.2.2~~ The services to be provided by the contractor;

~~5.4.2.35.3.2.3~~ The necessity to conform to all home health agency policies;

~~5.4.2.45.3.2.4~~ The procedure for submitting clinical and progress notes, scheduling visits, periodic patient evaluation, and determining charges and reimbursement;

~~5.4.2.55.3.2.5~~ The procedure for annual assurance of clinical competence of all individuals utilized under contract;

~~5.4.2.65.3.2.6~~ The procedure for supervision of services of the contracted individuals;

~~5.4.2.75.3.2.7~~ 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;

~~5.4.2.85.3.2.8~~ 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

~~5.4.2.95.3.2.9~~ That the written contractual arrangement must contain a renewal clause or be renewed annually.

~~5.4.35.3.3~~ The agency must ensure that personnel and services contracted meet the requirements specified in these regulations for home health agency personnel and services.

## 5.55.4 Written Policies

~~5.5.15.4.1~~ Policy manuals shall be prepared and followed which outline the procedures and practices of the agency.

~~5.5.25.4.2~~ The home health agency shall establish written policies regarding:

~~5.5.2.15.4.2.1~~ The rights and responsibilities of patients;

~~5.5.2.25.4.2.2~~ The handling and documentation of incidents, accidents and medical emergencies;

~~5.5.2.2.15.4.2.2.1~~ Reports of these events shall be kept on file at the agency.



- ~~5.5.2.35.4.2.3~~ Control of the exposure of patients and staff to persons with communicable diseases;
- ~~5.5.2.45.4.2.4~~ Reporting of all reportable communicable diseases to the Department;
- ~~5.5.2.55.4.2.5~~ 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.
- ~~5.5.2.65.4.2.6~~ 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:
  - ~~5.5.2.6.15.4.2.6.1~~ The procedure for contacting the patient prior to the missed visit;
  - ~~5.5.2.6.25.4.2.6.2~~ The procedure for attempts to find a substitute caregiver; and
  - ~~5.5.2.6.35.4.2.6.3~~ Documentation of the missed visit, visit and patient contact, ~~and attempts to find a substitute caregiver.~~
- ~~5.5.2.75.4.2.7~~ Infection control.
- ~~5.5.2.85.4.2.8~~ Employment/Personnel which shall include:
  - ~~5.5.2.8.15.4.2.8.1~~ Qualifications, responsibilities and requirements for each job classification;
  - ~~5.5.2.8.25.4.2.8.2~~ Pre-employment requirements;
  - ~~5.5.2.8.35.4.2.8.3~~ Position descriptions;
  - ~~5.5.2.8.45.4.2.8.4~~ Orientation policy and procedure for all employees and contractors;
  - ~~5.5.2.8.55.4.2.8.5~~ Inservice education policy;
  - ~~5.5.2.8.65.4.2.8.6~~ Annual performance review and competency testing; and
  - ~~5.5.2.8.75.4.2.8.7~~ 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.
- ~~5.5.2.95.4.2.9~~ Referrals received, admission of patients to agency services, delivery of those services and discharge of patients.
- ~~5.5.2.105.4.2.10~~The use and removal of records and the conditions for release of information in accordance with statutory provisions pertaining to confidentiality.

~~5.5.35.4.3~~ The home health agency shall review its written policies at least annually, and revise them as necessary.

~~5.5.45.4.4~~ Policies shall be made available to representatives of the Department upon request.

#### ~~5.65.5~~ Personnel Records

~~5.6.15.5.1~~ Records of each employee/contractor shall be kept current and available upon request by authorized representatives of the Department.

~~5.6.25.5.2~~ For individuals utilized via contract with another agency, the home health agency shall obtain, upon request, any records as required by the Department.

~~5.6.35.5.3~~ For all individuals, the agency shall maintain individual personnel records which shall contain at least:

- ~~5.6.3.15.5.3.1~~ Written verification of compliance with pre-employment requirements;
- ~~5.6.3.25.5.3.2~~ Documentation of clinical competence;
- ~~5.6.3.35.5.3.3~~ Evidence of current professional licensure, registration or certification as appropriate;
- ~~5.6.3.45.5.3.4~~ Educational preparation and work history;
- ~~5.6.3.55.5.3.5~~ Written performance evaluations (annually); and
- ~~5.6.3.65.5.3.6~~ A written and signed job description.

#### ~~5.75.6~~ Health History

~~5.7.15.6.1~~ All new employees/contractors shall be required to have a physical examination prior to providing care:

~~5.7.1.15.6.1.1~~ The physical examination must have been completed within 3 months prior to employment/referral and

~~5.7.1.25.6.1.2~~ A copy of the physical examination shall be maintained in individual files.

~~5.7.25.6.2~~ 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:

~~5.7.2.15.6.2.1~~ A baseline testing must be completed upon hire and, thereafter, as determined by a TB risk assessment.

~~5.7.2.25.6.2.2~~ No person found to have active TB in an infectious stage shall be permitted to give care or service to patients.

5.7.2.35.6.2.3 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.

5.7.2.45.6.2.4 A report of all TB test results and all attestation statements shall be on file at the home health agency.

5.7.35.6.3 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.

#### 5.85.7 Staff Development

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

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

5.8.35.7.3 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:

5.8.3.15.7.3.1 Organizational structure of the agency;

5.8.3.25.7.3.2 Agency patient care policies and procedures;

5.8.3.35.7.3.3 Philosophy of patient care;

5.8.3.45.7.3.4 Description of patient population and geographic location served;

5.8.3.55.7.3.5 Patient rights;

5.8.3.65.7.3.6 Agency personnel and administrative policies;

5.8.3.75.7.3.7 Job description;

5.8.3.85.7.3.8 Disaster Preparedness; and

5.8.3.95.7.3.9 Applicable state regulations governing the delivery of home health care services.

5.8.45.7.4 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:

5.8.4.15.7.4.1 Personal care services;

5.8.4.25.7.4.2 Principles of good nutrition;

5.8.4.35.7.4.3 Process of growth, development and aging;

5.8.4.45.7.4.4 Principles of infection control;

5.8.4.55.7.4.5 Observation, reporting and documentation of patient status;

5.8.4.65.7.4.6 Maintaining a clean, safe and healthy environment;

5.8.4.75.7.4.7 Maintaining a least restrictive environment;

5.8.4.85.7.4.8 Verbal/non-verbal communication skills;

5.8.4.95.7.4.9 Reading and recording temperature, pulse and respiration;

5.8.4.105.7.4.10 Safe transfer techniques and ambulation;

5.8.4.115.7.4.11 Normal range of motion and positioning;

5.8.4.125.7.4.12 Principles of body mechanics; and

5.8.4.135.7.4.13 The needs of the elderly and persons with disabilities.

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

5.8.65.7.6 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.

~~5.8-75.7.7~~ 5.8-75.7.7 Documentation of orientation and continuing education must include the ~~date(s)~~ dates and ~~hour(s)~~ hours, content, and name and title of the person providing the orientation/education.

~~5.8-85.7.8~~ 5.8-85.7.8 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.

~~5.8-95.7.9~~ 5.8-95.7.9 All employees and contractors must pass a competency evaluation test prior to providing care to patients and annually thereafter.

~~5.8-105.7.10~~ 5.8-105.7.10 The time allotted for training shall be sufficient to foster safe and skillful services to the patient.

~~5.8-115.7.11~~ 5.8-115.7.11 Attendance records must be kept for all orientation and continuing education programs.

~~5.8-125.7.12~~ 5.8-125.7.12 ~~Dementia specific~~ 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)**

## **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 ~~scheduled days and 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 other appropriate licensed health care professional for therapy services)~~ 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 ~~The initial assessment must be performed in the patient's residence prior to or at the time that home health services are initially provided to the patient. The assessment must determine whether the agency has the ability to provide the necessary services in a safe manner.~~
- 6.2.3 ~~6.2.2~~ The assessment shall include, at a minimum, a description of the patient's: Prior to the provision of services, at a minimum, the initial assessment must include evidence of the following:
  - 6.2.3.1 6.2.2.1 Physical condition, including ability to perform activities of daily living and sensory limitations;
  - 6.2.3.2 6.2.2.2 Social situation, including living arrangements and the availability of family and community support;
  - 6.2.3.3 6.2.2.3 Mental status, including any cognitive impairment and known psychiatric, emotional, and behavioral problems; and
  - 6.2.3.4 6.2.2.4 Current drug 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.
- 6.2.5 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 a an individualized written plan of care established by the physician and developed in consultation with a registered nurse or qualified professional of the appropriate discipline. 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 ~~All pertinent~~ 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 by the attending physician and 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.~~

- 6.3.4.1 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 ~~licensed independent practitioner's~~ 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.

6.6.4.3 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's 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 (~~or typewritten~~), 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 weekly every two (2) weeks.
- 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.

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

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

## **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)**

## **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)**

**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 ~~standards adopted by national accreditation organizations~~ 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 ~~in the employee file.~~
- 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)**

**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) (Final)**