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** 4406

FINAL

ORDER

4406 Home Health Agencies--Aide Only (Licensure)

BEFORE THE DEPARTMENT OF HEALTH AND SOCIAL SERVICES

IN THE MATTER OF:	|
	|
ADOPTION OF THE STATE OF DELAWARE	|
REGULATIONS GOVERNING HOME	|
HEALTH AGENCIES - AIDE ONLY	|

Nature of The Proceedings

The Delaware Department of Health and Social Services ("DHSS") initiated proceedings to adopt revised Regulations Governing Home Health Agencies - Aide Only. 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 EVIDENCE
STATE OF DELAWARE REGULATIONS GOVERNING
HOME HEALTH AGENCIES - AIDE ONLY

In accordance with Delaware Law, public notice regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Home Health Agencies - Aide Only 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

"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 and".

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 language in the skilled home health agency regulations. The regulation will remain as written.

Terri Hancharick, Chairperson, State Council for Persons with Disabilities

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 Home Health Agencies -Aide Only (Licensure). Consistent with the Summary of Proposal, the intent is to update the regulatory language to clearly define the scope of practice required of a home health agency - aide only. In addition, the amendments intend to provide a level of protection for the patients that seek services from home health agencies - aide only, by ensuring the delivery of safe and adequate care. The proposed regulation was published as 25 DE Reg. 137 in the August 1, 2021 issue of the Register of Regulations. SCPD has the following observations.

First, the definition of "Clinical Director" requires at least one year of home health care experience and at least one year of administrative or supervisory health care experience. SCPD endorses the requirement, 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 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 6.4.1 to address 24 Del. Code 1921(a)(15). The regulations at 6.4.1 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. 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 6.5.10, 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 DHQC 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 6.5.4 states the time frame for notes to be incorporated in the patient record is every 2 weeks. SCPD requests the justification for this time period since it could interfere with abuse and neglect investigations, and adequate supervision of client care as opposed to a shorter time period (e.g., every week).

Response: Thank you for your comments. This regulation was not revised. 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 6.6 discusses Discharge. There is no requirement that plans for discharge must be communicated to all health care providers participating the patient's care or the case manager. SCPD recommends such requirements. 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. Home health agency - aide only services do not require a physician or health care provider order and are usually not involved in the plan of care for the provision of home health agency - aide only services. 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 6.6.3 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 can not be made publicly available due to the sensitive nature of the information. The regulation will remain as written.

Summary of Proposal

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

Background

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

Statutory Authority

16 **Del.C.** §122(3)(o)

Purpose

The purpose of this proposed amendment is to update the requirements to be consistent with recognized standards of practice and to ensure patients receive safe and quality care from home health agencies - aide only.

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 Home Health Agencies - Aide Only are adopted and shall become effective November 11, 2021, after publication of the final regulations in the Delaware Register of Regulations.

10/13/2021
Date

Molly K. Magarik, Secretary, DHSS

~~4406~~ 3351 Home Health Agencies--Aide Only (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.

"**Bylaws**" means a set of rules adopted by a home health agency for governing the agency's operation.

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

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

"**Companion Services"** means provision of 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 agency that holds a valid business license and provides staffing services to the home health agency.

"**Department**" means the Delaware Department of Health and Social Services.

"**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.

"**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~~ Health Care Facility**" means any facility licensed under 16 **Del.C.** Ch.10 or 11.

"**Home Health Agency (HHA)**" means any business entity or sub-division thereof, whether public or private, proprietary or not-for-profit, which provides home health aide services, to an individual primarily in their place of residence.

"**Home Health Aide**" means a non-licensed person employed by the agency who provides personal care services, companion services, homemaker services, transportation 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 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 Aide Care Plan**" means a written plan developed by the nurse 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 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.

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

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

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

"**License**" means a license issued by the Department.

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

"**Located**" means the physical address of the agency's business office.

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

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

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

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

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

"**Office**" means the physical location in which the business of the home health agency is conducted and in which the records of personnel, contractors and patients of the agency are stored. The office shall be located in the State of Delaware.

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

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

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

"**Patient**" means the individual receiving home health agency services as defined in this chapter.

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

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

"**Plan of Care**" see "Home Health Aide Care Plan".

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

"**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 aide services will be provided.

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

"**Service Area**" means the county in the state of Delaware in which the agency office is located and may include the county or counties in the state of Delaware which are immediately adjacent.

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

12 DE Reg. 1209 (03/01/09)
19 DE Reg. 847 (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 home health agency – aide only 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 home health aides 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, issued to an agency that is not in substantial compliance with these regulations, 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 pursuant to 2.3.3 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) 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 patients;

2.4.1.7 Mistreated or abused patients 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; or

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, at 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);

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 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)o.

2.7 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 Notice to Patients

2.8.1 The home health agency shall notify each patient or the patient's authorized representative, the patient's attending physician (as appropriate), and any third-party payers at least thirty (30) calendar days before the voluntary surrender of its license, or as directed under an order of denial, revocation, or suspension of license issued by the Department.

2.9 Exclusions from Licensure

The following persons, associations or organizations are not required to obtain a home health agency license:

2.9.1 Those individuals who contract directly with a patient to provide services for that patient, where the patient pays the individual for services rendered and neither the patient nor the individual pays an agency on a periodic basis.

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

2.9.3 Those agencies that provide staff to licensed home health agencies, such as temporary employment/ staffing agencies.

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. 1209 (03/01/09)
19 DE Reg. 847 (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 with a staffing agency for services to be provided to its patients when the home health agency is not able to meet staffing needs. 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. 1209 (03/01/09)
19 DE Reg. 847 (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. 1209 (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;

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; and

5.1.3.8 Reviewing policies and procedures at least annually and reporting, in writing, to the governing body on the review.

5.1.4 The director shall designate, in writing, a similarly qualified person to act in the absence of the director.

5.2 Supervision of Services

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

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

5.2.3 The clinical director shall:

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

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

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

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

5.3 Contract Services

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

5.3.2 Services provided by the home health agency through arrangements with a contractor agency shall be set forth in a written contract which clearly specifies:

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

5.3.2.2 The services to be provided by the contractor;

5.3.2.3 The necessity to conform to all home health agency policies;

5.3.2.4 The procedure for recording services delivered and scheduling of visits;

5.3.2.5 The procedure for annual assurance of competence of all individuals utilized under contract;

5.3.2.6 The procedure for supervision of services of the contracted individuals;

5.3.2.7 That all payments by the patient for services rendered shall be made directly to the agency or its billing representative and no payments shall be made to or in the name of contractors of the agency;

5.3.2.8 That patients are accepted only by the home health agency. Patients may not be admitted for home health aide services by a contracted individual without prior review of the case and acceptance of the patient by the home health agency in accordance with agency policies; and

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

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

5.4 Written Policies

5.4.1 Policy manuals shall be prepared which outline the procedures and practices to be followed by employees/ contractors of the agency.

5.4.2 The home health agency shall establish written policies regarding:

5.4.2.1 The rights and responsibilities of patients;

5.4.2.2 The handling and documentation of incidents, accidents and medical emergencies;

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

5.4.2.3 Control of the exposure of patients and staff to persons with communicable diseases;

5.4.2.4 Reporting of all reportable communicable diseases to the Department;

5.4.2.5 The patient's (and family or representative, if any) right to have concerns addressed without fear of reprisal. This policy must include the mechanism for informing the patient of her/his right to report concerns/complaints to the Department at a telephone number established for that purpose.

5.4.2.6 The procedure to be followed in the event that the home health agency is not able to provide services scheduled for any particular day or time. This policy shall include at a minimum:

5.4.2.6.1 The procedure for contacting the patient prior to the missed visit;

5.4.2.6.2 The procedure for attempts to find a substitute home health aide; and

5.4.2.6.3 Documentation of the missed ~~visit,~~ visit and patient contact ~~and attempts to find a substitute home health aide~~.

5.4.2.7 Infection control.

5.4.2.8 Employment/Personnel which shall include:

5.4.2.8.1 Qualifications, responsibilities and requirements for each job classification;

5.4.2.8.2 Pre-employment requirements;

5.4.2.8.3 Position descriptions;

5.4.2.8.4 Orientation for all employees and contractors;

5.4.2.8.5 Inservice education;

5.4.2.8.6 Annual performance review and competency testing; and

5.4.2.8.7 The process of appointment to the professional staff whereby it can satisfactorily be determined that the individual is appropriately licensed and qualified for the privileges and responsibilities to be given.

5.4.2.9 Referrals received, admission of patients to agency services, delivery of those services and discharge of patients.

5.4.2.10 The use and removal of records and the conditions for release of information in accordance with statutory provisions pertaining to confidentiality.

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

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

5.5 Personnel Records

5.5.1 Records of each home health aide shall be kept current and available upon request by authorized representatives of the Department.

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

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

5.5.3.1 Written verification of compliance with pre-employment requirements;

5.5.3.2 Documentation of competence;

5.5.3.3 Evidence of current professional licensure, registration or certification as appropriate;

5.5.3.4 Educational preparation and work history;

5.5.3.5 Written performance evaluations (annually); and

5.5.3.6 A written and signed job description.

5.6 Health History

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

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

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

5.6.2 Minimum requirements for tuberculosis (TB) testing are those currently recommended by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services:

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

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

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

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

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

5.7 Staff Development

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

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

5.7.3 An orientation/training program should be based on an instruction plan that includes learning objectives, clinical content and minimum acceptable performance standards and shall include but not be limited to:

5.7.3.1 Organizational structure of the agency;

5.7.3.2 Agency patient care policies and procedures;

5.7.3.3 Philosophy of patient care;

5.7.3.4 Description of patient population and geographic location served;

5.7.3.5 Patient rights;

5.7.3.6 Agency personnel and administrative policies;

5.7.3.7 Job description;

5.7.3.8 Disaster Preparedness; and

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

5.7.4 All newly hired/contracted aides shall be required to complete or show evidence of having completed a minimum of seventy-five (75) hours of training which shall include instruction and supervised practicum and which addresses:

5.7.4.1 Personal care services;

5.7.4.2 Principles of good nutrition;

5.7.4.3 Process of growth, development and aging;

5.7.4.4 Principles of infection control;

5.7.4.5 Observation, reporting and documentation of patient status;

5.7.4.6 Maintaining a clean, safe and healthy environment;

5.7.4.7 Maintaining a least restrictive environment;

5.7.4.8 Verbal/non-verbal communication skills;

5.7.4.9 Reading and recording temperature, pulse and respiration;

5.7.4.10 Safe transfer techniques and ambulation;

5.7.4.11 Normal range of motion and positioning;

5.7.4.12 Introduction to common assistive technology;

5.7.4.13 Principles of body mechanics; and

5.7.4.14 The needs of the elderly and persons with disabilities.

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

5.7.5.1 Repeat the minimum 75-hour training requirement; or

5.7.5.2 Successfully demonstrate competence in each of the required training areas.

5.7.6 Ongoing staff development is required to maintain and improve the skills of the home health aide. 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:

5.7.6.1 Instruction in how to assist patients to achieve maximum self-reliance through re-learning and modifying activities of daily living;

5.7.6.2 Principles of good nutrition;

5.7.6.3 Meal planning, food purchasing and preparation of meals, including special diets;

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

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

5.7.6.6 Items requiring referral to the clinical director, including changes in the patient's condition or family situation;

5.7.6.7 Observation, reporting and documentation of patient status;

5.7.6.8 Policies and objectives of the agency;

5.7.6.9 Confidentiality of patient information;

5.7.6.10 Patient rights;

5.7.6.11 Principles of infection control;

5.7.6.12 Verbal/non-verbal communication skills; and

5.7.6.13 Principles of body mechanics.

5.7.6.14 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.

5.7.7 Documentation of orientation and continuing education must be in each individual's personnel record and must include the date(s) and hour(s), content, and name and title of the person providing the orientation/ education.

5.7.8 It is the responsibility of the home health agency to ensure that employees/contractors are proficient to carry out the care assigned in a safe, effective, and efficient manner.

5.7.9 All employees and contractors must pass a competency evaluation test prior to providing care to patients and annually thereafter.

5.7.10 The time allotted for training shall be sufficient to foster safe and skillful services to the patient.

5.7.11 Attendance records must be kept for all orientation and continuing education programs.

12 DE Reg. 1209 (03/01/09)
15 DE Reg. 220 (08/01/11)
19 DE Reg. 847 (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 her/his 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 a representative, if any, and the representative of the home health agency.

6.1.3.5 Be given to the patient and 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 All assessments of the patient must be performed by a registered nurse.

~~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 occur at regular intervals based upon the patient's condition and needs, but no less often than every sixty (60) calendar days.

6.2.5 A reassessment shall be conducted when the needs of the patient change which indicate a revision to the home health aide care plan is needed.

6.2.6 The initial assessment and reassessments shall become a permanent part of the patient's record.

6.3 Home Health Aide Care Plan

6.3.1 The home health agency must provide services in accordance with a written plan of care established by the registered nurse.

6.3.2 A plan of care is developed on admission based upon the initial assessment of the patient.

6.3.3 The patient plan of care shall include reference to at least the following:

6.3.3.1 Types of aide services, scope of services, frequency and duration of services to be provided, including any diet, procedures and transportation required;

6.3.3.2 Functional limitations of the patient;

6.3.3.3 Activities permitted; and

6.3.3.4 Safety measures required to protect the patient from injury.

6.3.4 The plan of care must be reviewed by the registered nurse at least every sixty (60) calendar days.

6.3.5 The home health agency shall consider benefits versus risks of care as well as patient choice and independence in the development and subsequent revisions of the plan of care.

6.3.6 A copy of the plan of care is kept at the patient's residence; the original is kept in the patient's record at the agency.

6.4 Scope of Services

6.4.1 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:

6.4.1.1 The nature of the service/task is not excluded by law or other state or federal regulation;

6.4.1.2 The services/tasks are those competent patients could normally perform themselves but for functional limitation; and

6.4.1.3 The delegation decision is entirely voluntary.

6.4.2 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.

6.4.3 Services are provided under the supervision and direction of the registered nurse.

6.4.3.1 On-site professional supervisory visits are required for all patients receiving home health aide services.

6.4.3.1.1 The 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.

6.4.3.1.2 A report of the supervisory visit should be kept with the patient's record.

6.5 Records and Reports

6.5.1 There shall be a separate record maintained at the home health agency for each patient, in accordance with accepted standards, which shall contain:

6.5.1.1 Admission record including patient's:

6.5.1.1.1 Name;

6.5.1.1.2 Birth date;

6.5.1.1.3 Home address;

6.5.1.1.4 Telephone number; and

6.5.1.1.5 Date of admission.

6.5.1.2 Assessment (initial and reassessments) including but not limited to:

- Age;
- Height;
- Weight;
- Sex;
- Hearing;
- Vision;
- Speech;
- Functional limitations;
- Nursing diagnosis; and
- History.

6.5.1.3 Home health aide care plan.

6.5.1.4 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.

6.5.1.5 Written acknowledgment that the patient or the patient's representative has been fully informed of the patient's rights.

6.5.1.6 Aide notes which must contain the following information:

6.5.1.6.1 Date(s) on which service(s) are provided;

6.5.1.6.2 Hour(s) of service(s) provided;

6.5.1.6.3 Type(s) of service(s) provided; and

6.5.1.6.4 Observations/problems/comments.

6.5.1.7 A discharge statement.

6.5.1.8 Names, addresses and telephone numbers of family members, friends or other designated people to be contacted in the event of illness or an emergency.

6.5.2 All notes written in the patient's record must be signed and dated or authenticated on the day that the service is rendered.

6.5.3 All notes and reports in the patient's record shall be <u>electronic or</u> legibly written in ink ~~(or typewritten)~~, dated and signed by the recording person with her/his full name and title.

6.5.4 Original notes must be incorporated into the patient's record located at the agency no less often than every 2 weeks.

6.5.5 All patient records shall be available at all times for review by authorized representatives of the Department and to legally authorized persons; otherwise patient records shall be held confidential. The written 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.

6.5.6 Computerized patient records must be printed by the agency as requested by authorized representatives of the Department.

6.5.7 The agency must develop acceptable policies for authentication of any computerized records.

6.5.8 The home health agency records shall be retained in a retrievable form until destroyed.

6.5.8.1 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.

6.5.8.2 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.

6.5.8.3 All records must be disposed of by shredding, burning, or other similar protective measure in order to preserve the patients' rights of confidentiality.

6.5.8.4 Documentation of record destruction must be maintained by the home health agency.

6.5.8.5 At least thirty (30) calendar days before the agency discontinues operations, it must inform the Department where patient records will be maintained.

6.5.9 Records shall be protected from loss, damage, and unauthorized use.

6.5.10 Report of Major Adverse Incidents

6.5.10.1 The home health agency must report all major adverse incidents, occurring in the presence of a home health home health aide, involving a patient to the Department within forty-eight (48) hours in addition to other reporting requirements required by law.

6.5.10.2 A major adverse incident includes but is not limited to:

6.5.10.2.1 Suspected abuse, neglect, mistreatment, financial exploitation, solicitation or harassment;

6.5.10.2.2 An accident that causes serious injury to a patient; and

6.5.10.2.3 The unexpected death of a patient.

6.5.10.3 Major adverse incidents must be investigated by the agency.

6.5.10.4 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.

6.6 Discharge

6.6.1 The patient or her/his representative if any, shall be informed of and participate in discharge planning.

6.6.2 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.

6.6.3 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:

6.6.3.1 The discharge of patients when care goals have been met.

6.6.3.2 The discharge of patients when care needs undergo a change which necessitates transfer to a higher level of care.

6.6.3.3 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).

6.6.3.4 The discharge of patients when activities or circumstances in the home jeopardize the welfare and safety of the home health aide.

12 DE Reg. 1209 (03/01/09)
19 DE Reg. 847 (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. 1209 (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 actions taken to address identified issues; and

8.1.6 A process to monitor the satisfaction of the patients or their representatives with the program.

12 DE Reg. 1209 (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. 1209 (03/01/09)
19 DE Reg. 847 (03/01/16)

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; and

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)~~ plan.

~~10.3.1~~ Records of staff attendance must be maintained ~~in the employee file~~.

10.4 A copy of the disaster preparedness ~~plan(s)~~ plan shall be available to all staff.

10.5 Each home health agency shall inform patients and patients' representative, upon admission, of the agency's procedures during and immediately following an emergency.

12 DE Reg. 1209 (03/01/09)

11.0 Infection Control

11.1 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.

11.1.1 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.

11.2 The individual designated to lead the Agency's infection prevention and control program must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases. The plan must include mechanisms that result in immediate action to take preventive or corrective measures that improve the Agency's infection control outcomes.

11.3 All Agency staff shall receive orientation at the time of employment and annual in-service education regarding the infection prevention and control program.

~~11.0~~12.0 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. 1209 (03/01/09)
19 DE Reg. 847 (03/01/16)
25 DE Reg. 521 (11/01/21) (Final)