

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF LONG TERM CARE RESIDENTS PROTECTION

Statutory Authority: 29 Delaware Code, Section 7903(10) (29 **Del.C.** §7903(10))
16 **DE Admin. Code** 3201

FINAL

ORDER

3201 Skilled and Intermediate Care Nursing Facilities

NATURE OF THE PROCEEDINGS

Delaware Health and Social Services ("Department"), Division of Long Term Care Residents Protection, initiated proceedings to amend the regulations regarding the Skilled and Intermediate Care Nursing Facilities. The Department's proceedings to amend its regulations were initiated pursuant to 29 Delaware Code, Section 10114, with authority prescribed by 29 Delaware Code, Section 7971.

The Department published its notice of proposed regulatory change pursuant to 29 Delaware Code, Section 10115 in the May 2011 Delaware Register of Regulations, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by June 1, 2011 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSED CHANGE

The proposal amends existing Regulation 3201 – Skilled and Intermediate Nursing Care Facilities. The proposed change will amend the regulation relative to the tuberculin testing for employees and newly admitted residents.

Statutory Authority

16 **Del.C.** Chapter 11, Nursing Facilities and Similar Facilities

Background

DLTCRP identified the need to update various components of the existing regulation governing the tuberculin testing for employees and newly admitted residents to mirror, and adapt with changes to, the Centers for Disease Control requirements.

Summary of Proposed Amendment

This regulatory proposal amends the existing regulations as outlined below:

- Clarify the type of residents whose test results must be on file.
- Clarifies the type of testing required for employees.
- Requires an evaluation of any person having a positive skin test but a negative x-ray

Summary of Comments Received with Agency Response and Explanation of Changes

The Governor's Advisory Council for Exceptional Citizens and the State Council for Persons with Disabilities offered the comments and recommendations summarized below. DLTCRP has considered each comment and responds as follows:

Both entities endorsed the proposed revisions to the regulations.

Response: No response is required.

FINDINGS OF FACT:

The Department finds that the proposed changes set forth in the May 2011 Register of Regulations should be adopted.

THEREFORE, IT IS ORDERED, that the proposed changes to Regulation 3201 Skilled and Intermediate Care Nursing Facilities is adopted and shall be final effective August 1, 2011.

Rita Landgraf, Secretary, DHSS

3201 Skilled and Intermediate Care Nursing Facilities

1.0 Scope

- 1.1 A Nursing facility (NF) is a residential institution, as defined in 16 **Del.C.** §1102(4), which provides services to residents which include resident beds, continuous nursing services, and health and treatment services for individuals who do not currently require continuous hospital care. Care is given in accordance with a physician's orders and requires the competence of a registered nurse (RN).
- 1.2 Nursing facilities shall be subject to all applicable local, state and federal code requirements. The provisions of 42 **CFR** Ch. IV Part 483, Subpart B, requirements for Long Term Care Facilities, and any amendments or modifications thereto, are hereby adopted as the regulatory requirements for skilled and intermediate care nursing facilities in Delaware. Subpart B of Part 483 is hereby referred to, and made part of this Regulation, as if fully set out herein. All applicable code requirements of the State Fire Prevention Commission are hereby adopted and incorporated by reference.

13 DE Reg. 1322 (04/01/10)

2.0 Definitions

- 2.1 Activities of Daily Living (ADLs) - Normal daily activities including but not limited to ambulating, transferring, range of motion, grooming, bathing, dressing, eating and toileting.
- 2.2 Advance Directive - Written instructions such as a living will or durable power of attorney for health care, in accordance with 16 **Del.C.** Ch. 25, relating to the provision of health care should the individual become incapacitated.
- 2.3 Associated Entity - The partially or wholly owned subsidiary, parent company or partner of the applicant for licensure or any other entity identified on the corporation formation documents.
- 2.4 Department/DHSS - Department of Health and Social Services
- 2.5 Division - Division of Long Term Care Residents Protection
- 2.6 Extensive Remodeling - Renovations or alterations within the facility that modify the square footage of any room intended for resident use.
- 2.7 Food Service Manager -
 - 2.7.1 For facilities subject to 16 **Del.C.** §1164, an individual who meets the statutory requirements for a food service manager. A facility may seek a waiver of the statutory requirements if an insufficient pool of applicants exists. The facility must demonstrate the inability to hire a person who meets the requirements after a recruitment process of at least 90 days duration that included advertising in at least two newspapers of general circulation and one trade journal, offering a competitive salary. If those conditions are met, the Division may waive the education requirement for an applicant who meets the requirements of a "person in charge" as defined in the current Delaware Food Code.
 - 2.7.2 For facilities not subject to 16 **Del.C.** §1164, an individual who, at a minimum, meets the requirements of a "person in charge" as defined in the current Delaware Food Code.
- 2.8 Full-time - Forty hours per week or the standard workweek established by the facility.
- 2.9 Incident - An occurrence or event, a record of which must be maintained in facility files, which includes all reportable incidents and the additional occurrences or events listed in Section 9.7 of these regulations.
- 2.10 Nursing Home Administrator - A licensee of the Delaware Board of Examiners of Nursing Home Administrators who manages the facility on a full-time basis, and is responsible for the delivery quality care to its residents and for the implementation of the policies and procedures of the facility.
- 2.11 Nursing Services - Those curative, restorative, preventive or palliative health care services provided by certified nursing assistants, licensed practical nurses and registered nurses to assist a resident to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being as determined by the resident's assessment and individual care plan.
- 2.12 Pediatric resident - A person residing in a nursing facility who is under 18 years of age and for who there is a care plan including medical care, treatment and other related services in accordance with the Regulations for Nursing Homes Admitting Pediatric Residents.
- 2.13 Physician - A medical doctor or doctor of osteopathy licensed to practice medicine in the State of Delaware.
- 2.14 Rehabilitation - The actions and services such as physical therapy, occupational therapy, speech therapy and psychosocial services provided or required to restore an ill or injured person to self- sufficiency at his or her highest attainable level.
- 2.15 Reportable Incident - An occurrence or event which must be reported immediately to the Division and for which there is reasonable cause to believe that a resident has been abused, neglected, mistreated or subjected to financial exploitation/misappropriation of their property as those terms are defined in 16 Delaware Code, §1131

and/or 42 CFR 483.13(c). Reportable incident also includes an occurrence or event listed in Section 9.8 of these regulations.

- 2.16 Resident - A person admitted to a nursing facility because of illness or impairment, under a physician's care, for whom there is planned continuing health care directed toward improvement in health or for whom palliative medical and nursing measures are required.
- 2.17 Restraint - A physical or chemical means of restricting or controlling a resident. Specifically, a mechanical device, material or equipment attached or adjacent to a resident's body that the resident cannot remove easily, and which restricts freedom of movement or normal access to the resident's body.
- 2.18 Satisfactory Compliance History - A sworn affidavit, as required by 16 **Del.C.** §1104(d), attesting to a licensure applicant's provision of quality care in a nursing facility, during the five years preceding the initial application, as determined by the absence of the following:
 - 2.18.1 Termination or denial of participation in the Medicare or Medicaid program
 - 2.18.2 State licensure revocation
 - 2.18.3 Financial insolvency
 - 2.18.4 Outstanding civil actions for debt
 - 2.18.5 Outstanding civil money penalty
- 2.19 Social worker - For facilities subject to 16 **Del.C.** §1165, with at least 100 beds, an individual with a bachelor's degree in social work, or a bachelor's degree in a human services field including, but not limited to, sociology, special education, rehabilitation counseling, and psychology; and one year of supervised social work experience in a health care setting working directly with individuals. For facilities with fewer than 100 beds, the facility may designate the director of admissions or a nurse to assume the duties of the social worker.
- 2.20 Supervision - The oversight and direction of personnel necessary to ensure the safety, comfort and well-being of residents.

13 DE Reg. 1322 (04/01/10)

3.0 General Requirements

- 3.1 The term "nursing home" or "nursing facility" shall not be used as part of the name of any facility in this State unless it has been so licensed by the Division.
- 3.2 Each nursing facility shall develop written policies pertaining to the services provided.
- 3.3 A nursing facility shall not adopt any policy which conflicts with applicable statutes or regulations.
- 3.4 Inspections and monitoring by the Division shall be carried out in accordance with 16 **Del.C.** §1107.
- 3.5 Upon receipt of a report of any violation(s) of these regulations, the facility shall submit a written plan of action to correct cited deficiencies within 10 working days or such other time period as may be specified. The plan of action shall address corrective actions and include all measures and completion dates to prevent their recurrence as follows:
 - 3.5.1 How the corrective action will be accomplished for a resident(s) affected by the deficient practice;
 - 3.5.2 How the facility will identify other residents having the potential to be affected by the same deficient practice;
 - 3.5.3 What measures or systemic changes will be put in place to ensure that the deficient practice will not recur;
 - 3.5.4 What program will be put into place to monitor the continued effectiveness of the corrective actions.
- 3.6 The Division shall be notified, in writing, upon any changes in the administrator, assistant administrator or director of nursing positions.
- 3.7 The nursing facility shall comply with 42 CFR 483.10, 483.12, 483.13, 483.15 and/or 16 **Del.C.** §1121 regarding the rights of residents. Those rights shall be made available in writing to residents, guardians, representatives or next of kin.
- 3.8 Each facility shall provide, in writing, the refund and prepayment policy at the time of admission, and in the case of residents admitted while awaiting approval of third-party payment, an exact statement of responsibility in the event of retroactive denial. The facility shall notify residents, in writing, at least 30 days prior to a rate increase.
- 3.9 A facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract to provide for facility payment from the resident's income or resources. However, in doing so, the facility shall not require a third party to incur personal financial liability for the nursing facility expenses.

4.0 Licensing Requirements and Procedures

- 4.1 Licenses and renewals shall be issued to a nursing facility which meets the requirements of 16 **Del.C.** §1104. For initial licensure, the nursing facility shall also demonstrate during a physical inspection of the premises that the facility complies with all applicable regulations.
- 4.2 A new applicant for licensure shall substantiate a satisfactory compliance history as defined in these regulations.
- 4.3 The Division may consider sanctions or other information which, in combination, may impact licensure eligibility. Accordingly, the applicant shall disclose the following:
 - 4.3.1 The imposition of temporary management by the Centers for Medicare and Medicaid Services (CMS) or any state jurisdiction against the applicant or associated entity during the preceding five years
 - 4.3.2 The imposition of immediate jeopardy by CMS against the applicant or associated entity during the preceding five years
 - 4.3.3 A substandard survey by CMS or any state jurisdiction against the applicant or associated entity during the preceding five years
 - 4.3.4 The imposition of a civil money penalty by any state jurisdiction against the applicant or associated entity during the preceding five years
 - 4.3.5 A ban on admissions by any state jurisdiction against the applicant or associated entity during the preceding five years
 - 4.3.6 A list of all facilities managed, owned or controlled by the applicant or associated entity in any jurisdiction during the preceding five years
 - 4.3.7 Information as required by 16 **Del.C.** §1104(e)
- 4.4 Financial information disclosed to the Division as required by 16 **Del.C.** §1104(e) shall not be subject to Freedom of Information Act requests except as follows:
 - 4.4.1 Any information known to the Division regarding a civil action for debt owed by a facility
 - 4.4.2 Any information known to the Division regarding current facility bankruptcy proceedings
 - 4.4.3 The name of any facility currently under intensive Division review for potential financial incapability
- 4.5 Each license shall be renewed on the anniversary date of initial licensure. Each license holder shall file an application for renewal at least 30 days prior to the expiration of the current license and pay the applicable fee as established in 16 **Del.C.** §1106(a).
- 4.6 A new license shall be required in the event of a change in the nursing home management company, building owner or controlling person as defined in 16 **Del.C.** §1102(1).
- 4.7 Each license shall specify the number of licensed beds. A facility seeking to change the number of licensed beds shall apply to the Division for a modified license authorizing the revised number of beds.
- 4.8 Separate licenses are required for facilities maintained in separate locations, even though operated under the same management. A separate license is not required for separate buildings maintained by the same management on the same grounds.
- 4.9 When a facility plans to construct or extensively remodel a licensed facility or convert a building to a licensed facility, it shall submit one copy of properly prepared plans and specifications for the entire facility to the Division. An approval, in writing, shall be obtained before such work is begun. After the work is completed, in accordance with the plans and specifications, a modified license to operate shall be issued. All completed construction, extensive remodeling or conversions shall remain in accordance with the plans and specifications, as approved by the Division.

5.0 Personnel/Administrative

- 5.1 The administrator(s) shall be responsible for complying with all applicable laws and regulations.
- 5.2 Each nursing facility shall have a full-time administrator. When an administrator will be temporarily absent for a period of two weeks or more, a management employee shall be designated to be in charge. The Division shall be notified in writing upon such designation.
- 5.3 The nursing facility shall designate a physician to serve as the medical director who shall be responsible for implementation of resident care policies and the coordination of medical care in the facility.
- 5.4 Nursing facilities shall provide professional nursing, nursing services direct care and other services as follows:
 - 5.4.1 Nursing facilities subject to 16 **Del.C.** §1161 to §1165 shall provide professional nursing, nursing services direct care and other services in accordance with statutory requirements.
 - 5.4.2 Nursing facilities not subject to 16 **Del.C.** §1161 to §1165 shall provide professional nursing, nursing services direct care and other services as follows:

- 5.4.2.1 The facility shall provide a sufficient number of nursing services direct care staff to provide a minimum of 2.25 hours of direct care and treatment per resident per day.
 - 5.4.2.2 In addition to the requirement above, the nursing facility shall have a full-time director of nursing who is a registered nurse. The director of nursing shall have overall responsibility for the coordination, supervision and provision of nursing services.
 - 5.4.2.3 At a minimum, a registered nurse or licensed practical nurse shall be on duty at all times during the first and second shifts.
 - 5.4.2.4 At a minimum, in the absence of a nurse on the third shift, a registered nurse or licensed practical nurse shall be on call.
 - 5.4.2.5 Facilities not subject to 16 Del.C. §1164 may increase the level of care and services for a current resident whose condition requires such an increase in the level of care and services as an alternative to discharge to another facility. Such increased care and services shall be provided by a qualified caregiver(s) whose scope of practice includes the provision of such care and services, and shall be available during any shift when the resident's needs require such care and services.
 - 5.4.2.6 All other nursing services direct caregivers shall be certified nursing assistants.
 - 5.4.2.7 The facility shall employ an activities director who shall ensure the provision of activities as described in these regulations.
- 5.5 The facility shall have written personnel policies and procedures. Personnel records shall be kept current and available for each employee, and include the following:
- 5.5.1 Results of tuberculosis screening
 - 5.5.2 Documentation of annual influenza vaccination or refusal.
 - 5.5.3 Results of criminal background check
 - 5.5.4 Results of mandatory drug testing
 - 5.5.5 Result of Adult Abuse Registry check
 - 5.5.6 Titles and hours of in-service training
 - 5.5.7 If applicable, license number and expiration date
 - 5.5.8 If applicable, certification expiration date

13 DE Reg. 1322 (04/01/10)

6.0 Services To Residents

- 6.1 General Services. Any nursing facility not providing skilled services shall implement each resident's physician's orders obtained on the day of admission and renewed or revised every 60 days thereafter.
- 6.2 Medical Services
- 6.2.1 All persons admitted to a nursing facility shall be under the care of a physician licensed to practice in Delaware.
 - 6.2.2 All nursing facilities shall arrange for one or more licensed physicians to be called in an emergency. Names, telephone and fax numbers of these physicians shall be posted at all nurses' stations.
 - 6.2.3 For a resident admitted or readmitted from the hospital with orders for nine or more medications (excluding over-the-counter medications), the attending physician or designee or medical director shall conduct a comprehensive medication review and reconciliation of past and present medications within 5 days.
 - 6.2.4 All written or verbal physician orders shall be signed by the attending physician or prescriber within 10 days.
 - 6.2.5 After the initial physician visit, an advanced practice nurse or physician's assistant, affiliated with the physician, may alternate with the physician, making every other required visit.
 - 6.2.6 A progress note shall be written and signed by the physician or designee (an advanced practice nurse or physician's assistant) after examining the resident at each visit
- 6.3 Nursing Administration
- 6.3.1 The facility's director of nursing shall:
 - 6.3.1.1 Develop and/or maintain nursing policy and procedure manuals
 - 6.3.1.2 Assign duties to and supervise all levels of nursing services direct caregivers
 - 6.3.1.3 Coordinate nursing services with medical, therapy, dietary, pharmaceutical, recreational, and other ancillary services
 - 6.3.1.4 Coordinate orientation programs for new nursing services direct caregivers (including temporary staff) and in-service education, as appropriate, for such staff. Written records of the content of each in-service program and the attendance records shall be maintained for two years

- 6.3.1.5 Participate in the selection of prospective residents by evaluating the nursing services required and the facility's ability to competently provide those required services or ensure that such an evaluation is conducted by a designated registered nurse
- 6.3.2 Treatments and medications ordered by a physician shall be administered using professionally accepted techniques in accordance with 24 **Del.C.** Chapter 19.
- 6.3.3 Within 14 days of admission, the facility shall make a comprehensive assessment of each resident's needs. This assessment shall include, at a minimum, the following information:
 - 6.3.3.1 Identification, background and demographic information
 - 6.3.3.2 Customary routine
 - 6.3.3.3 Cognitive patterns
 - 6.3.3.4 Communication
 - 6.3.3.5 Vision
 - 6.3.3.6 Mood and behavior patterns
 - 6.3.3.7 Psychosocial well-being
 - 6.3.3.8 Physical functioning and structural problems
 - 6.3.3.9 Continence
 - 6.3.3.10 Disease diagnoses and health conditions
 - 6.3.3.11 Dental and nutritional status
 - 6.3.3.12 Skin condition
 - 6.3.3.13 Activity pursuits
 - 6.3.3.14 Medications
 - 6.3.3.15 Special treatments and procedures
 - 6.3.3.16 Discharge potential
- 6.3.4 The resident assessment shall include a screening instrument for mental illness, mental retardation, and developmental disabilities to assess if an individual has an active treatment need for one of these conditions.
- 6.3.5 Based on the physician's admission orders and the admission information for each resident, an interim individual nursing care plan shall be developed within 24 hours of admission pending the completion of a comprehensive resident assessment.
- 6.3.6 A comprehensive care plan shall be developed to address medical, nursing, nutritional and psychosocial needs within 7 days of completion of the comprehensive assessment. Care plan development shall include the interdisciplinary team that includes the attending physician, an RN/LPN and other appropriate staff as determined by the resident's needs. With the resident's consent, the resident, the resident's family or the resident's legal representative may attend care plan meetings.
- 6.3.7 The assessment and care plan for each resident shall be reviewed/revised as needed when a significant change in physical or mental condition occurs, and at least quarterly. A complete comprehensive assessment shall be conducted and a comprehensive care plan shall be developed at least yearly from the date of the last full assessment.
- 6.3.8 The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.
 - 6.3.8.1 The resident's comprehensive assessment shall document the medical symptom(s) potentially requiring the use of restraints.
 - 6.3.8.2 The facility shall follow a comprehensive, systematic process of evaluation and care planning to ameliorate medical and psychosocial indicators prior to restraint use.
 - 6.3.8.3 The resident's care plan shall document the facility's use of interventions, such as modifying the resident's environment to increase safety, and use of assistive devices to enhance monitoring in order to avoid the use of restraints.
 - 6.3.8.4 Should such interventions and assistive devices fail to provide for the resident's safety, a physician's written order permitting the use of restraints shall be required and shall specify the type of restraint ordered.
 - 6.3.8.5 The facility shall be accountable for the safe and effective implementation of the physician's order permitting the use of restraints.
 - 6.3.8.6 When the use of restraints has been implemented, the facility shall initiate a systematic process, on an ongoing basis, documented in the care plan, in an effort to employ the least restrictive restraint.

6.3.8.7 In an emergency, when the resident's unanticipated violent or aggressive behavior places him/her or others in imminent danger, restraints may be used as a last resort to protect the safety of the resident or others, and such use shall not extend beyond the immediate episode.

6.3.9 The facility shall ensure that each nursing and ancillary staff member providing care to a resident under 18 years of age meets the standards as defined in regulations for nursing facilities admitting pediatric residents.

6.3.10 The facility shall ensure that all licensed or certified direct care staff receive CPR certification and shall ensure that at least one staff person with current CPR certification is present in the facility during all shifts.

6.4 Social Services

6.4.1 The facility shall identify each resident's need for social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident; and shall assist each resident to obtain all required services to meet the individual resident's needs. These social services shall include, but not be limited to:

6.4.1.1 Making arrangements for obtaining needed adaptive equipment, clothing and personal items

6.4.1.2 Making referrals and obtaining services from outside entities

6.4.1.3 Assisting residents with financial and legal matters, according to facility policy

6.4.1.4 Discharge planning services

6.4.1.5 Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions

6.4.1.6 Meeting the needs of residents who are grieving

6.5 Food Service

6.5.1 Meals. Therapeutic diets, mechanical alterations and changes in either must be prescribed by an attending physician within 72 hours of implementation. All meals and snacks shall be served in accordance with the therapeutic diet, if prescribed.

6.5.2 Menus

6.5.2.1 Menus shall be planned in advance and a copy of the current week's menu shall be posted in the kitchen and in a public area. Portion sizes shall be listed on a menu in the food service area.

6.5.2.2 Menus showing food actually served each day shall be kept on file for at least 3 months. When changes in the menu are necessary, substitutions of similar nutritive value shall be provided.

6.5.2.3 A 3-day supply of food shall be kept on the premises at all times.

6.5.2.4 A copy of a recent dietary manual shall be available for planning therapeutic menus and as a resource for staff.

6.5.3 Nutritional Assessment

6.5.3.1 The immediate nutritional needs of each resident shall be addressed upon admission.

6.5.3.2 A comprehensive nutritional assessment which includes an evaluation of each resident's caloric, protein, and fluid requirements shall be completed within 14 days of admission in consultation with a dietitian.

6.5.3.3 The facility shall have an ongoing evaluation and assessment program to meet the nutritional needs of all residents.

6.5.3.4 The facility shall obtain and document each resident's weight at least monthly.

6.6 Housekeeping and Laundry Services

6.6.1 The facility shall maintain a safe, clean, and orderly environment, free from offensive odors, for the interior and exterior of the facility.

6.6.2 A full-time employee shall be designated responsible for housekeeping services and for supervision and training of personnel.

6.9.3 The facility shall have written policies and procedures and schedules for cleaning all areas of the facility.

6.9.4 The facility shall maintain a supply, in the amount of 3 sets per resident, of towels, washcloths, sheets and pillowcases changed weekly or whenever soiled.

6.9.5 The facility's handling, storage, processing and transporting of linens shall comply with facility infection control policies and procedures.

6.9.6 The facility shall contract with a licensed pest control vendor to ensure that the entire facility is free of live insects and other vermin.

6.7 Pharmacy Services

6.7.1 Each nursing facility shall have a consultant pharmacist who shall be responsible for the general supervision of the nursing facility's pharmaceutical services.

- 6.7.2 For a resident admitted or readmitted from the hospital with orders for nine or more medications (excluding over-the-counter medications), the facility shall complete an on-site or off-site pharmacy review within 10 days of admission or readmission.

6.8 Medications

6.8.1 Medication Administration

- 6.8.1.1 All medications (prescription and over-the-counter) shall be administered to residents in accordance with orders which are signed and dated by the ordering physician or prescriber. Each medication shall have a documented supporting diagnosis. Verbal or telephone orders shall be written by the nurse receiving the order and then signed by the ordering physician or prescriber within 10 days.
- 6.8.1.2 Standing orders may be established for over-the-counter medications that have been approved by the resident's attending physician.
- 6.8.1.3 Standing orders shall be initiated by licensed nurses, but shall not be used for more than 72 hours without approval by the physician.
- 6.8.1.4 When any standing order is initiated, it shall be written as a complete order on the MAR for the specified time period and charted when administered.
- 6.8.1.5 Medications shall be given only to the individual resident for whom the prescription or order was issued, and shall be given in accordance with the prescriber's instructions.
- 6.8.1.6 An individual resident may self-administer medications upon the written order of the physician, following determination by the interdisciplinary team that this practice is safe. The facility shall establish policies and procedures pertaining to the security of self-administered medication.
- 6.8.1.7 The facility's policies and procedures shall not prohibit or restrict a resident from receiving medications from the pharmacy of the resident's choice. However, the resident and/or his representative shall be informed of any ramifications of ordering medications from other than the facility's pharmacy, such as cost differences, responsibility for delivery of medication to the facility and length of ordering time.
- 6.8.1.8 Only licensed nurses shall administer medications and then record the administration on the resident's Medication Administration Record (MAR) immediately after administration to that resident.
- 6.8.1.9 The facility shall ensure that licensed nurses administering medications count controlled substances at the beginning and end of each shift. The on-coming medication nurse shall conduct, verify, and document the controlled substance count in the presence of the off-going medication nurse.
- 6.8.1.10 Any medications removed but not administered to the resident shall not be returned to the original container. In circumstances such as refusal of drugs by the resident, the drugs shall be discarded and the refusal recorded on the resident's Medication Administration Record (MAR). If the medication is a controlled substance, the signature of the administering nurse is required on the record of the controlled substance count.
- 6.8.1.11 Each nursing home shall have available a current edition of at least one drug reference text for the nursing staff.
- 6.8.1.12 Medication shall be released to residents on discharge or transfer only by the written authorization of the resident's physician. A resident who leaves the nursing facility on a short leave may be issued a quantity of medication to meet his/her needs, with the approval of the resident's physician.
- 6.8.1.13 The barrel, plunger, needle and contents of disposable hypodermic syringes shall be properly discarded in accordance with OSHA regulations immediately after use.
- 6.8.1.14 The administrator or designee shall notify the Office of Controlled Substances in the Division of Professional Regulation and the Division of Long Term Care Residents Protection of any unexplained loss of controlled substances, syringes, needles, or prescription pads within 8 hours of discovery of such loss or theft.

6.8.2 Medication Storage and Stocks

- 6.8.2.1 Stock supplies of drugs available without a prescription (over-the-counter drugs such as antacids, aspirin, laxatives) may be kept in the facility. These over-the-counter drugs shall be labeled "house stock".
- 6.8.2.2 All medications shall be stored in a locked cabinet. The key to the cabinet shall be kept in the control of the licensed nurse responsible for the administration of medications.

- 6.8.2.3 Prescription medications for emergency or interim use may be stocked by the facility subject to Board of Pharmacy regulations.

6.8.3 Medication Labeling

- 6.8.3.1 Medications shall be labeled in accordance with 24 Del.C. §2522 and the regulations of the Board of Pharmacy.
- 6.8.3.2 Medications dispensed using a unit dose system shall be pharmacy-prepared or manufacturer-prepared in individually packaged and sealed doses that are identifiable and properly labeled. The label shall include, at a minimum, the brand and/or generic name of the medication, strength, and lot number and expiration date.

6.9 Communicable Diseases

6.9.1 General Requirements

- 6.9.1.1 The facility shall follow Division of Public Health regulations for the Control of Communicable and Other Disease Conditions and Centers for Disease Control guidelines for communicable diseases.
- 6.9.1.2 The facility shall establish written policies and procedures implementing the Division of Public Health regulations and Centers for Disease Control guidelines for communicable diseases.
- 6.9.1.3 The nursing facility shall ensure that the necessary precautions stated in the policies and procedures are followed.
- 6.9.1.4 A resident, when suspected or diagnosed as having a communicable disease, shall be placed on the appropriate precautions as recommended for that disease by the Centers for Disease Control. Residents infected or colonized with the same organism may share a room based on current standard of practice.
- 6.9.1.5 The admission of a resident with or the occurrence of a disease or condition on the Division of Public Health List of Notifiable Diseases/Conditions within a nursing facility shall be reported to the resident's physician and the facility's medical director. The facility shall also report such an admission or occurrence to the Division of Public Health's Health Information and Epidemiology office.

6.9.2 Specific Requirements for Tuberculosis

- 6.9.2.1 A resident diagnosed with active tuberculosis in an infectious stage shall not continue to reside in a nursing facility unless that facility has a room with negative pressure ventilation and staff trained to care for residents requiring respiratory isolation.
- 6.9.2.2 A resident of any facility unable to provide care as described above who is diagnosed with active tuberculosis in an infectious stage shall be transferred to an acute care hospital, and the facility shall notify the Division of Public Health's Health Information and Epidemiology office immediately.
- 6.9.2.3 The facility shall have on file the results of tuberculin testing performed on all newly ~~admitted~~ placed residents.
- 6.9.2.4 Minimum requirements for pre-employment ~~and annual~~ tuberculosis (TB) testing ~~are those currently recommended by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.~~ require all employees to have a base line two step tuberculin skin test (TST) or single Interferon Gamma Release Assay (IGRA or TB blood test) such as QuantiFeron. Any required subsequent testing according to risk category shall be in accordance with the recommendations of the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. Should the category of risk change, which is determined by the Division of Public Health, the facility shall comply with the recommendations of the Center for Disease Control for the appropriate risk category.
 - 6.9.2.4.1 No person, including volunteers, found to have active tuberculosis in an infectious stage shall be permitted to give care or service to residents.
 - 6.9.2.4.2 Any person having a positive skin test but a negative X-ray ~~must complete a statement annually attesting that they have experienced no symptoms which may indicate active TB infection.~~ shall receive an annual evaluation for signs and symptoms of active TB if they can not provide documentation of completion of treatment for LTBI (latent TB infection).
 - 6.9.2.4.3 Persons with a prior BCG vaccination are required to be tested as set forth in 6.9.2.4.

6.9.3 Immunizations

- 6.9.3.1 All facilities shall have on file evidence of annual vaccination against influenza for all residents, as recommended by the Immunization Practice Advisory Committee of the Centers for Disease Control, unless medically contraindicated.

- 6.9.3.2 All facilities shall have on file evidence of vaccination against pneumococcal pneumonia for all residents older than 65 and as recommended by the Immunization Practice Advisory Committee of the Centers for Disease Control unless medically contraindicated.
- 6.9.3.3 A resident who refuses to be vaccinated against influenza or pneumococcal pneumonia shall be informed by the facility of the health risks involved. The reason for the refusal(s) shall be documented in the resident's medical record annually.

6.9.4 Employee Health

- 6.9.4.1 All employees shall receive education and training on standard precautions, use of personal protective equipment, the importance of hand hygiene, the facility's infection control policies and reporting of exposures to blood or other potentially infectious materials.
- 6.9.4.2 Personal protective equipment, as required by Centers for Disease Control guidelines, shall be made available by the facility for employee use.
- 6.9.4.3 If an accidental exposure to blood or other potentially infectious materials occurs (specifically to eye, mouth, other mucous membrane or non-intact skin), appropriate first aid treatment shall be given immediately and follow-up testing and counseling initiated. A copy of the exposure incident and follow-up treatment shall be maintained in the employee's personnel file.
- 6.9.4.4 Facilities shall establish procedures in accordance with Division of Public Health requirements and Centers for Disease Control guidelines for exclusion from work and authorization to return to work for staff with communicable diseases.

6.10 Infection Control

6.10.1 Infection Control Committee

- 6.10.1.1 The nursing facility shall establish an infection control committee (or a subcommittee of an overall quality control program) of professional staff whose responsibility shall be to manage the infection control program in the facility. One member of the committee shall be designated the infection control coordinator.
- 6.10.1.2 The infection control committee shall consist of members of the medical and nursing staffs, administration, dietetic department, pharmacy, housekeeping, maintenance, and therapy services.
- 6.10.1.3 The infection control committee shall establish written policies and procedures that describe the role and scope of each department/service in infection prevention and control activities.
- 6.10.1.4 The committee is responsible for the development and coordination of policies and procedures to accomplish the following:
 - 6.10.1.4.1 Prevent the spread of infections and communicable diseases
 - 6.10.1.4.2 Promote early detection of outbreaks of infection
 - 6.10.1.4.3 Ensure a sanitary environment for residents, staff and visitors
 - 6.10.1.4.4 Establish guidelines for the implementation of isolation/precautionary measures
 - 6.10.1.4.5 Monitor the rate of nosocomial infection
- 6.10.1.5 The infection control coordinator shall maintain records of all nosocomial infections and corrective actions related to those infections to enable the committee to analyze clusters or significant increases in the rate of infection and to make recommendations for the prevention and control of additional cases.
- 6.10.1.6 The infection control committee shall establish the infection control training of staff and volunteers, and disseminate current information on health practices.

6.10.2 Infectious Waste

- 6.10.2.1 The facility shall establish and implement policies and procedures for the collection, storage, handling and disposition of all pathological and infectious wastes within the facility as well as for those to be removed from the facility including the following:
 - 6.10.2.1.1 Needles, syringes and other solid, sharp, or rigid items shall be placed in a puncture resistant container prior to disposal by an infectious waste hauler approved by the Department of Natural Resources and Environmental Control (DNREC).
 - 6.10.2.1.2 Non-rigid items, such as blood tubing and disposable equipment and supplies, shall be placed in double, heavy duty, impervious plastic bags prior to disposal by an infectious waste hauler approved by DNREC.

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7.0 Plant, Equipment and Physical Environment

- 7.1 All new construction, extensive remodeling or conversions to a nursing facility shall comply with the standards and guidelines set forth under the "Nursing Facilities" section of the current edition of Guidelines for Design and Construction of Health Care Facilities, a publication of the American Institute of Architects Committee on Architecture for Health with assistance of the U.S. Department of Health and Human Services.
- 7.2 The facility shall be handicapped accessible and meet applicable American National Standards Institute (A.N.S.I.) standards.
- 7.3 Facility Systems Requirements
 - 7.3.1 Water Supply and Sewage Disposal
 - 7.3.1.1 The facility water supply and sewage disposal system shall comply with Division of Public Health and Department of Natural Resources and Environmental Control standards, respectively.
 - 7.3.1.2 The water system shall supply hot and cold water under sufficient pressure to satisfy facility needs at peak demand.
 - 7.3.1.3 Hot water accessible to residents shall not exceed 110° F.
 - 7.3.2 Heating, Ventilation, Air Conditioning. The HVAC system for all areas used by residents shall be safe and easily controlled.
 - 7.3.3 Facility lighting shall meet current standards of the Guidelines for Design and Construction of Health Care Facilities.
 - 7.3.4 The facility shall be equipped with a resident call system which meets the current standards of the Guidelines for Design and Construction of Health Care Facilities. An intermediate care facility serving only developmentally disabled residents shall be exempt from this regulation.
- 7.4 Physical Environment Requirements
 - 7.4.1 Safety Requirements
 - 7.4.1.1 Stairs shall have stair treads and handrails.
 - 7.4.1.2 Hallways shall have handrails on both sides of corridors. An intermediate care facility serving only developmentally disabled residents shall be exempt from this regulation.
 - 7.4.1.3 Non-skid flooring materials shall be used and maintained in good condition.
 - 7.4.2 Bedrooms
 - 7.4.2.1 Each resident shall be provided with a reading light. At least one bedroom light shall be controlled by a switch at the bedroom entrance.
 - 7.4.2.2 The facility shall provide at least one room with private toilet and hand washing sink for residents who require isolation.
 - 7.4.3 Bathrooms
 - 7.4.3.1 Bathroom walls and floors shall be impervious to water. Bathrooms shall have at least one window or mechanical ventilation exhausted to the outside.
 - 7.4.3.2 A minimum of one bathtub or shower shall be provided for every 20 residents not otherwise served by bathing facilities within residents' rooms. Each nursing unit shall have at least one bathtub.
 - 7.4.3.3 Each tub or shower in a central bathing facility shall be in an individual room or enclosure with space for the private use of the tub or shower, for drying and dressing, and for a wheelchair and attendant. Showers shall be at least four feet square without curbs. Toilets in central bathing facilities shall have provisions for privacy.
 - 7.4.3.4 Each resident's room shall have direct access to a hand washing sink and a toilet.
 - 7.4.3.5 A wall-mounted hand grip shall be provided at each resident toilet, bath tub and shower.
 - 7.4.3.6 Separate bathroom and hand washing sinks shall be provided for the staff.
 - 7.4.4 Resident Common Areas
 - 7.4.4.1 Areas for resident recreational and social activities shall provide at least 30 square feet per bed for the first 100 beds and 27 square feet per bed for beds in excess of 100.
 - 7.4.4.2 The dining areas shall accommodate all residents.
 - 7.4.4.3 Facilities for resident hair care and grooming shall be separate from resident rooms.
 - 7.4.4.4 Equipment and materials for resident hair care and grooming shall comply with facility infection control policies and procedures.
- 7.5 Kitchen and Food Storage Areas. Facilities shall comply with the Delaware Food Code.
- 7.6 Sanitation and Laundry
 - 7.6.1 The facility shall provide for the safe storage of cleaning materials, pesticides and other potentially toxic materials.

- 7.6.2 Each facility shall have a janitor's closet containing a service sink.
- 7.6.3 For on-site laundry processing, the facility shall:
 - 7.6.3.1 Provide a room under negative air pressure for receiving, sorting, and washing soiled linen.
 - 7.6.3.1.1 If hot water is used for destroying micro-organisms, washers must be supplied with water heated to a minimum of 160° F.
 - 7.6.3.1.2 If low temperature laundry cycles are used, a total available chlorine residual of 50-150 ppm must be present and monitored during the wash cycle.
 - 7.6.3.2 Provide a room under positive air pressure for drying and folding clean linen, equipped with a hand washing sink.
- 7.6.4 For off-site laundry processing, the facility shall:
 - 7.6.4.1 Contract with a commercial laundry.
 - 7.6.4.2 Provide a soiled linen holding room (or a designated area in the soiled utility room) under negative air pressure for the storage of soiled linen.
 - 7.6.4.3 Provide a clean linen storage area.
- 7.6.5 The facility shall have a soiled utility room under negative pressure for storage of infectious waste and for disposal of body fluids. The room shall have a work counter, hand washing sink, and clinical sink or other bed pan cleaning device.
- 7.7 Equipment and Supplies
 - 7.7.1 The facility shall supply sufficient equipment and supplies for nursing care to meet the needs of each resident. The facility shall obtain specific items when indicated for individual residents and approved by the attending physician or director of nursing.
 - 7.7.2 The facility shall provide each resident with:
 - 7.7.2.1 A hospital bed of appropriate size with a mattress covered with non-porous material. Modifications or attachments to the bed shall conform to manufacturer's specifications.
 - 7.7.2.2 A bedside stand with a drawer and storage space for a bedpan, urinal, emesis basin and washbasin.
 - 7.7.2.3 A minimum of two drawers in a dresser or chest of drawers.
 - 7.7.2.4 A closet or wardrobe.
 - 7.7.2.5 A chair suitable for resident relaxation.
 - 7.7.2.6 An over-bed table.
 - 7.7.3 The facility shall provide cubicle curtains around each bed in bedrooms occupied by more than one resident.
 - 7.7.4 The facility shall provide sufficient storage space on each nursing unit for nursing supplies and equipment.
 - 7.7.5 The facility shall provide safe storage for residents' valuables.
 - 7.7.6 The facility shall maintain a functioning scale, calibrated quarterly, capable of accurately weighing each resident.

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8.0 Emergency Preparedness

- 8.1 Nursing facilities shall comply with the rules and regulations adopted and enforced by the State Fire Prevention Commission or the municipality with jurisdiction.
- 8.2 Regular fire drills shall be held at least quarterly on each shift. Written records shall be kept of attendance at such drills.
- 8.3 Each facility shall develop and maintain all-hazard emergency plans for evacuation and sheltering in place.
- 8.4 The staff on all shifts shall be trained on emergency and evacuation plans. Evacuation routes shall be posted in a conspicuous place at each nursing station.
- 8.5 In the event of a facility evacuation, the evacuation plan shall, at a minimum, provide for the transfer or availability of resident medications and records.
- 8.6 Each facility shall submit with their annual license renewal an updated Division of Public Health Residential Health Care Facilities Emergency Planning Checklist, electronically if possible.

9.0 Records and Reports

- 9.1 There shall be a separate clinical record maintained on each resident as a chronological history of the resident's stay in the nursing facility. Each resident's record shall contain current and accurate information including the following:
- 9.1.1 Admission record which shall include the resident's name, birth date, home address prior to entering the facility, identification numbers (including Social Security), date of admission, physician's name, address and telephone number, admitting diagnoses, name, address and telephone number of resident's representative, the facility's medical record number, and advance directive(s) if applicable.
 - 9.1.2 History and physical examination prepared by a physician within 14 days of the resident's admission to the nursing facility. If the resident has been admitted to the facility from a hospital, the resident's summary and history prepared at the hospital and the resident's physical examination performed at the hospital, if performed within 14 days prior to admission to the facility, may be substituted. A record of subsequent annual medical evaluations performed by a physician must be contained in each resident's file.
 - 9.1.3 A record of post-admission diagnoses.
 - 9.1.4 Physician's orders which include a complete list of medications, dosages, frequency and route of administration, indication for usage, treatments, diets, restrictions on level of permitted activity if any, and use of restraints if applicable.
 - 9.1.5 Physician's progress notes.
 - 9.1.6 Nursing notes, which shall be recorded by each person providing professional nursing services to the resident, indicating date, time, scope of service provided and signature of the provider of the service. Nursing notes shall include care issues, nursing observations, resident change of status and other significant events.
 - 9.1.7 Medication administration record (MAR) including medications, dosages, frequency, route of administration, and initials of the nurse administering each dose. The record shall include the signature of each nurse whose initials appear on the MAR.
 - 9.1.8 Inventory of resident's personal effects upon admission.
 - 9.1.9 Results of laboratory tests, x-ray reports and results of other tests ordered by the physician.
 - 9.1.10 Discharge record which includes date and time, discharge location, and condition of resident.
 - 9.1.11 Special service notes, e.g., social services, activities, specialty consultations, physical therapy, dental, podiatry.
 - 9.1.12 Interagency transfer form, if applicable.
 - 9.1.13 Copies of power(s) of attorney and guardianship, if applicable.
 - 9.1.14 Nutrition progress notes and record of resident weights.
 - 9.1.15 CNA flow sheets.
- 9.2 Confidentiality of resident records shall be maintained in accordance with the federal Health Insurance Portability and Accountability Act (HIPAA) and 16 **Del.C.** §1121(6).
- 9.3 Records shall be retained for 6 years after discharge. For a minor, records shall be retained for three years after age of majority.
- 9.4 Electronic Record keeping
- 9.4.1 Where facilities maintain residents' records in electronic format by computer or other devices, electronic signatures shall be acceptable.
 - 9.4.2 The facility shall have a written attestation policy.
 - 9.4.3 The computer network and all devices used to maintain resident medical records shall have safeguards to prevent unauthorized access and alteration of records.
 - 9.4.4 All data entry devices shall require user authentication to access the computer network.
 - 9.4.5 The computer program shall control each person's extent of access to residents' records based on that individual's personal identifier.
 - 9.4.6 The computer's internal clock shall record the date and time of each entry.
 - 9.4.7 An entry, once recorded, shall not be deleted. Alterations or corrections shall supplement the original record.
 - 9.4.8 All entries shall have the date and time of the entry and the individual's personal identifier logged in a file which is accessible to designated administrative staff only.
 - 9.4.9 The computer system shall back up all data to ensure record retention.
 - 9.4.10 The facility shall provide independent computer access to electronic records to satisfy the requirements of the survey and certification process.

- 9.5 Incident reports, with adequate documentation, shall be completed for each incident. Adequate documentation shall consist of the name of the resident(s) involved; the date, time and place of the incident; a description of the incident; a list of other parties involved, including witnesses; the nature of any injuries; resident outcome; and follow-up action, including notification of the resident's representative or family, attending physician and licensing or law enforcement authorities, when appropriate.
- 9.6 All incident reports whether or not required to be reported shall be retained in facility files for three years. Reportable incidents shall be communicated immediately, which shall be within eight hours of the occurrence of the incident, to the Division of Long Term Care Residents Protection. The method of reporting shall be as directed by the Division.
- 9.7 Incident reports which shall be retained in facility files are as follows:
 - 9.7.1 All reportable incidents as detailed below.
 - 9.7.2 Falls without injury and falls with minor injuries that do not require transfer to an acute care facility or neurological reassessment of the resident.
 - 9.7.3 Errors or omissions in treatment or medication.
 - 9.7.4 Injuries of unknown source.
 - 9.7.5 Lost items which are not subject to financial exploitation.
 - 9.7.6 Skin tears.
 - 9.7.7 Bruises of unknown origin.
- 9.8 Reportable incidents are as follows:
 - 9.8.1 Abuse as defined in 16 **Del.C.** §1131.
 - 9.8.1.1 Physical abuse with injury if resident to resident and physical abuse with or without injury if staff to resident or any other person to resident.
 - 9.8.1.2 Any sexual act between staff and a resident and any non-consensual sexual act between residents or between a resident and any other person such as a visitor.
 - 9.8.1.3 Emotional abuse whether staff to resident, resident to resident or any other person to resident.
 - 9.8.2 Neglect, mistreatment or financial exploitation as defined in 16 **Del.C.** §1131.
 - 9.8.3 Resident elopement under the following circumstances:
 - 9.8.3.1 A resident's whereabouts on or off the premises are unknown to staff and the resident suffers harm.
 - 9.8.3.2 A cognitively impaired resident's whereabouts are unknown to staff and the resident leaves the facility premises.
 - 9.8.3.3 A resident cannot be found inside or outside a facility and the police are summoned.
 - 9.8.4 Significant injuries.
 - 9.8.4.1 Injury from an incident of unknown source in which the initial investigation or evaluation supports the conclusion that the injury is suspicious. Circumstances which may cause an injury to be suspicious are: the extent of the injury, the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma), the number of injuries observed at one particular point in time, or the incidence of injuries over time.
 - 9.8.4.2 Injury which results in transfer to an acute care facility for treatment or evaluation or which requires periodic neurological reassessment of the resident's clinical status by professional staff for up to 24 hours.
 - 9.8.4.3 Areas of contusions or bruises caused by staff to a dependent resident during ambulation, transport, transfer or bathing.
 - 9.8.4.4 Significant error or omission in medication/treatment, including drug diversion, which causes the resident discomfort, jeopardizes the resident's health and safety or requires periodic monitoring for up to 48 hours.
 - 9.8.4.5 A burn greater than first degree.
 - 9.8.4.6 Any serious unusual and/or life-threatening injury.
 - 9.8.5 Entrapment which causes the resident injury or immobility of body or limb or which requires assistance from another person for the resident to secure release.
 - 9.8.6 Suicide or attempted suicide.
 - 9.8.7 Poisoning.
 - 9.8.8 Fire within a facility.
 - 9.8.9 Utility interruption lasting more than eight hours in one or more major service including electricity, water supply, plumbing, heating or air conditioning, fire alarm, sprinkler system or telephones.

9.8.10 Structural damage or unsafe structural conditions.

9.8.11 Water damage which impacts resident health, safety or comfort.

- 9.9 The facility shall maintain written policies and procedures, in accordance with 16 Del.C. Ch. 25, regarding health care decisions including advance directives. The facility shall provide written information to all residents explaining such policies and procedures.

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10.0 Facility Closure

10.1 In the event of the closing of a facility, the facility shall:

10.1.1 Notify the Division of Long Term Care Residents Protection, the Ombudsman, the Division of Public Health and, if applicable, the Division of Medicaid and Medical Assistance and the Centers for Medicare and Medicaid Services at least 90 days before the planned closure.

10.1.2 Notify each resident directly and his/her attending physician and, if applicable, his/her responsible party by telephone and in writing at least 90 days before the planned closure.

10.1.3 Give the resident or the resident's responsible person an opportunity to designate a preference for relocation to a specific facility or for other arrangements.

10.1.4 Arrange for relocation to other facilities in accordance with the resident's preference, if possible.

10.1.5 Ensure that all resident records, medications, and personal belongings are transferred with the resident and, if to another facility, accompanied by the interagency transfer form.

10.1.6 Provide an accounting of resident trust fund accounts which shall be transferred to each resident's possession or to the facility to which the resident relocates. A record of the accounting of the funds shall be maintained by the closing facility for audit purposes.

10.1.7 Advise any applicant for admission to a facility which has a planned closure date in writing of the planned closure date prior to admission.

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11.0 Waivers and Severability

11.1 Waivers may be granted by the Division of Long Term Care Residents Protection for good cause.

11.2 Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.

12 DE Reg. 960 (01/01/09)

13 DE Reg. 1322 (04/01/10)

14 DE Reg. 1189 (05/01/11)

15 DE Reg. 79 (07/01/11) (Final)